APP #	TITLE	BUDGET REQ	SCORE	1	2	3	Previous CIRM Funding	Matching/ In Kind	Geographic Region
INFR4-13579	The [institution] Alpha Stem Cell Clinic	**$7,997,246**	**1**	15	0	0	N	$0	Bay Area
INFR4-13581	[institution] Alpha Stem Cell Clinic (ASCC)	**$7,994,347**	**1**	13	0	0	Y	$0	Bay Area
INFR4-13586	A comprehensive stem cell and gene therapy clinic to advance new therapies for a diverse patient population in California	**$7,957,966**	**1**	9	6	0	N	$6,000,000	Los Angeles Metro
INFR4-13587	The [institution] Alpha Clinic: A roadmap for equitable and inclusive access to regenerative medicine therapies for all Californians	**$8,000,000**	**1**	15	0	0	Y	$4,420,201	Los Angeles Metro
INFR4-13596	Alpha Stem Cell Clinic for Northern and Central California	**$7,999,997**	**1**	11	3	0	Y	$0	Central Valley
INFR4-13685	Expansion of the Alpha Stem Cell and Gene Therapy Clinic at [institution]	**$8,000,000**	**1**	15	0	0	Y	$0	Los Angeles Metro
INFR4-13878	Alpha Clinic Network Expansion for Cell and Gene Therapies	**$7,999,983**	**1**	14	0	0	N	$0	Los Angeles Metro
INFR4-13952	A hub and spoke community model to equitably deliver regenerative medicine therapies to diverse populations across four California counties	**$8,000,000**	**1**	9	4	0	Y	$0	Orange
INFR4-13597	[institution] CIRM Alpha Stem Cell Clinic	**$8,000,000**	**2**	6	8	0	Y	$8,000,000	San Diego/Imperial

Application #	INFR4-13579
Title (as written by the applicant)	The [Institution] Alpha Stem Cell Clinic
Summary (as written by the applicant)	Cell, gene and regenerative medicine therapies (CGRMT) have proven to be transformative approved therapies in a small number of indications. Promising pre-clinical and early phase clinical trials suggest these will be transformative for a much larger number of indications in the future. The mechanism of action of cell, gene and regenerative therapies is biologically different from other modes, which is one reason they have such potential. Our CGRMT programs are encompassed in two collaborative Centers. Both have demonstrated track records of supporting a broad array of CGRMT clinical trials and post-registration studies. The execution of CGRMT clinical trials originating outside of our system, demonstrates the infrastructure capacity to support ASCC network studies. Further, our program supports trials focused on ultra-rare, rare, and common diseases as well as diseases that impact patient populations who have been historically underserved (e.g., sickle cell disease). We support six platforms: 1) Blood Cell Engineering and Transplantation; 2) Engineering the immune System; 3) Genome Editing; 4) IPS derived Regenerative Medicines; 5) In Vivo Gene Therapy; and 6) CAR-T Therapies. Further, we identify four classes of clinical trials in which we have special expertise and that will add value to the ASCC network: 1) Initiating the first-in-human genetically engineered immune cell clinical trial to treat autoimmune disease; 2) A direct gene correction trial using genome editing; 3) Alternative methods of CAR-T delivery to treat intractable brain cancers; 4) Conducting a multi-site, real-world study to correlate patient outcomes with disease assessment in patients receiving commercial CAR-T therapy. We share the mission and vision of expanding cell and gene therapies into historically underserved populations. These populations can reflect a demographic inequality or the patient's disease itself is rare and deemed not significant for private sector investment. Based on this vision, we will hire a dedicated Access Facilitator (AF). The AF will lead efforts to both understand the gaps in enrollment on clinical trials and implement solutions. Our pilot should add significant value to the ASCC network. In addition, our center provides an array of educational programs to support the development and maturation of the field including fellowship training, certificate programs, and specialized workshops. These activities are tailored to diversify the workforce in the field. In sum, our lead offerings, core competencies, and educational activities will contribute to expanding the effectiveness of the ASCC in achieving its mission while increasing the value of the overall Network.
Funds Requested	$7,997,246
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG." Patient advocate members unanimously affirmed that "The review was carried out in a fair manner and was free from undue bias."

Scoring Data

Final Score: 1
Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	1
Count	15
Votes for Tier 1	15
Votes for Tier 2	0
Votes for Tier 3	0

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- A score of "3" means that the application is sufficiently flawed that it does not warrant funding

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	**Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?**
Yes: 15	• The proposed clinic is embedded in the center for cell and gene therapy (CGT) which has a demonstrated track record in conducting innovative clinical trials, with particular strength in pediatric trials for rare diseases and CAR-T cell therapy for brain cancer. • Breadth of therapeutic areas and deep faculty expertise are impressive, and clinical operations appear to be efficient. True leading edge innovation is fostered in this institution. • The proposed clinic is embedded in cell and gene therapies. The two lead offerings exemplify that CGT focus. • The proposed clinic would provide particular expertise for pediatric trials and more broadly cancer trials not currently being addressed by the existing Alpha Clinics. • Well established. The addition of CAR-T toxicity specific to non-hematologic malignancies and novel CAR-T is important. • Strengths of this application include: 1) The leadership team is very strong and has decades of experience with cell and gene therapies. 2) Excellent infrastructure to support clinical trials in the cell and gene therapy space. 3) History of developing and supporting clinical trials in the cell and gene therapy space. • Strong investigator initiated clinical trials that progress to licensure and become companies. • Strong track record in prior CIRM grants that have successfully met milestones.
No: 0	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 15	• Overall, the proposed activities are well planned and designed and will complement the capabilities and core activities of the Alpha Clinic network. • The application describes a carefully planned administrative structure for the proposed clinic that encompasses the entire spectrum of clinical trial conduct from design, GMP facilities for cell and gene therapy, IND submission, patient recruitment and consenting, and clinical data collection including toxicity monitoring. • Well-established training programs. • Training program looks very solid. • Well designed. I think the comments regarding ethics with a focus on justice and equity have not been included as specific foci in other proposals.

	• Strong infrastructure, and breadth of interests which should be important "lead offerings". • Applaud development of GMP Training certification. • The institution has a track record of successful collaboration and partnerships with other members of the Alpha Clinic network. • Long track record of partnership with industry. • Real world experience shows itself in their application. • Strong data sharing plan.
No: 0	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 15	• Based on the extensive description in the application, and the proven track record in clinical trials of the CGT, I believe the proposed plan is feasible. As to implementation within the timeline, this should be feasible barring unforeseen contingencies such as changes in key personnel. • The proposed team is impressively qualified and there is an appropriate institutional commitment to provision of necessary resources. The director, regulatory affairs head and cell therapy personnel have demonstrated relevant expertise. • Yes. The overall proposal was constructed, accessible and informative. I appreciated the combined presentation: I believe it demonstrated the internal collaboration and shared responsibility. • Proposal and proposed timeline are reasonable. • Organization is well established. • The timeline is reasonable. The scope of the proposal is feasible. • Strong sense of interaction with and potential collaboration with other Alpha Clinics. • No sense of any cardiovascular experience despite prior institute involvement in cardiac trials. • The proposed 1% effort by some key persons seems so low as to be impractical.
No: 0	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 15	• The proposal includes several tools and solutions that will enable the proposed Alpha Clinic to effectively serve the needs of underserved and disproportionately affected communities. • Yes---excellent, broad interests and commitment to DEI programs overall and a big commitment to understand unmet needs in the community. • I believe this is one of the strengths of the application. The proposed clinic will have a dedicated FTE for an "Access Facilitator" that explicitly addresses targeting under-represented minorities (Latinx, Hmong, Vietnamese are cited) for clinical trial recruitment. • There is an access facilitator on board. • The application cites ongoing experience with trial of gene therapy for an inherited disease as demonstrating commitment and establishing trust in a key community. • Simplified consent is provided in 40 languages. • Reasonable within proposal and articulated in the presentation. • Addressed DEI elements of application.
No: 0	*none*

Application #	INFR4-13581
Title (as written by the applicant)	[Institution] Alpha Stem Cell Clinic (ASCC)
Summary (as written by the applicant)	The sponsor organization is a leading biomedical research and health science education center in California that supports a broad array of research, teaching, and patient care activities. This Alpha Stem Cell Clinic (ASCC) was established in 2017 with a mission to accelerate cell and gene therapies for diseases that are difficult to treat and to ensure access to clinical trials of the new therapies. In its renewal proposal, this ASCC continues its focus on two areas of particular expertise. The first of these is rare hereditary disorders such as sickle cell disease and disorders of the immune system. The ASCC has formed a partnership with scientists at a collaborating institution to use gene editing technology to cure these disorders by repairing the defective gene in stem cells and then returning the corrected stem cells to persons affected by the disorders. If successful in these early clinical trials, we envision the use of this method of gene therapy more broadly, such as in rare disorders of the nervous system, of the blood, and cancer. The second area of expertise is in bringing the immune response under control when the lung is severely injured after infection or trauma. A team of doctors is conducting a clinical trial using a type of stem cell in persons who become gravely ill with pneumonia caused by COVID infection. If this clinical trial is successful, other ASCC network sites will be recruited to conduct a larger, definitive clinical study of this treatment in persons with life-threatening lung infection or lung trauma. This ASCC is also committed to training the next generation of physicians and scientists who will discover and apply new cell and gene therapies in regenerative medicine. This training program, which was started in 2018 and will be extended in the new proposal, already has been instrumental in supporting 3 junior faculty positions for physician scientists in the ASCC clinical scholar training program. The training program also will make use of broader opportunities for learning in the expanded network of ASCC sites in the current proposal. Finally, a core mission is to ensure equitable access to participating in cell and gene therapy clinical trials. As illustrated by our lead clinical trials, we have focused on finding improved therapies for persons from under-served and under-represented groups in the communities we serve. We also propose to establish new partnerships with community-based organizations and community health care centers to improve awareness about these clinical trials of cell and gene therapies, and to improve access to participation. In the end, the effectiveness and impact of these exciting new therapies on human disease will be measured according to how readily and easily the citizens of California are able to get the new therapy.
Funds Requested	$7,994,347
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.” Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”

Scoring Data

Final Score: 1

Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	1
Count	13
Votes for Tier 1	13
Votes for Tier 2	0
Votes for Tier 3	0

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- A score of "3" means that the application is sufficiently flawed that it does not warrant funding

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	**Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?**

Yes: 13	• The applicant has functioned as part of the Alpha Clinic (AC) network since 2017, and in the present application describes expansion of ongoing clinical trials as well as several novel trials that would expand access to underrepresented populations.
	• An expansion of trials to pediatric hereditary diseases and autoimmune disorders represent new disease areas. New technical capabilities include early treatment for certain hereditary disorders. A collaboration with a leading genomics institute on novel CRISPR technologies is likely to enhance clinical trials of stem cell and gene therapy.
	• Strengths include:
	  ◦ Strong productive research—evident success to date.
	  ◦ Established partnerships: building on existing infrastructure; external collaborations within the AC network and other networks/groups, as simple examples.
	  ◦ Established mechanisms for clinical research approval.
	  ◦ GMP facility size and partnerships in development.
	• Strong application addressing all CIRM requirements.
	• Outstanding physician-scientist investigator group.
	• Good breadth of therapeutic areas--including both adults and pediatrics.
	• Gene editing studies are advanced.
	• Partnership with pre-existing infrastructure for translation.
	• Inclusion of a site and elsewhere in Central Valley is potentially important.
	• Is there significant development of stem cell programs for neurological diseases?
	• Potential weakness: the time commitment of the PD (30%) is appropriate for the project. The time commitment of other physician/clinician/scientist personnel described within the grant is somewhat surprising (2-5%). This includes the director of the fellowship training program, and the lead of one of the proposed clinical trials.

No: 0	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 13	• The application shows careful design and planning of the proposed AC. This is evident in description of key staff recruited, clear definition and tracking of trial performance metrics, and attention to streamlining approval processes including decreasing redundancy of committee approvals and multiple IRBs. • Major lead offerings is a strength with expertise/partnerships within CRISPR-related clinical research, and core competency in inherited blood disorders.

	• The centerpiece of the training program is the AC-funded Clinical Scholars training program, a clinical fellowship for junior faculty in the stem cell and gene therapy fields.. Between 2018-2022 there have been 5 graduates of which 3 are on faculty now, one in industry and one still in training. The program includes coursework, ethics training, community engagement, seminars and workshops on all aspects of trial design and implementation. Notably 80% of time is protected for research. • Fellowship training program appears to be an example of particular strength within this section, with an excellent description of the program foundations. Ethics training program appears to be an excellent addition too. Community facing activities are to be commended. • Well developed component of the proposal. There are clear examples of established research projects with high impact which are highlighted as part of this proposal. • Other areas described within the proposal appear to complement/expand opportunities. • The described GMP compliant manufacturing facility appears to be a particular strength, including partnerships with industry. • There are excellent examples of other networks/partnerships through the application which should also accelerate research. • Yes for core, excellent training and lead offerings; strong network both via CIRM-supported institutions and national CTSA hub network (Trial Innovation Network). • Very well-developed application. • Robust innovative DEI offering. • Major concern within the fellowship program is that individuals could get 'lost' within the demands of local faculty and their research: there is a need for a strong fellowship training program director with time commitment commensurate to ensure success of the next generation of researchers as proposed. • Issue with low percentages assigned to key staff. • The training of manufacturing staff plan was weak. • One trial mentioned as a lead offering is already 80% complete and admittedly deals with COVID not other forms of lung injury. This type of stem cell in COVID has not been positive elsewhere and no mention of the ability to respond to that or pivot was indicated even with questioning. It is not a strength.
No: 0	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 13	• Given the track record in the prior funding period and the careful planning reflected in the application, the proposed renewed AC is both feasible and likely to be implemented within the proposed timeline. • The study activation goals and significant infrastructure implemented since 2017 are positive. • Work to date demonstrates at minimum established teams within the major areas proposed as clinical research within the proposal. • Track record of applicants, particularly PD, are a strength. There is demonstrated value add of collaborations. • The work on the lung injury clinical trial is from an international leader with established collaborations/prior work with national networks. • The applicants have also described well the collaborations/leveraging from other network sites. Have no concerns about the key personnel and team structure, leadership, and communications plan. • Strong leadership and experienced staff. • Yes, well staffed. • As a minor negative point, it is unclear that the pathobiology and phenotype of COVID lung injury is the same as non-COVID lung injury and that the results of the current 2a will be able to be generalized. But, that's the beauty of science, and why Phase 2b to Phase 3 trials will follow any promising 2a results.
No: 0	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 13	• A number of initiatives to enhance outreach and participation in trials are described in the application: a community engagement program which includes "structural" consultation to

	identify priority needs; an electronic health record-based method to identify gaps in treatment. ● The application includes well developed examples of diseases which the application will facilitate developing targeted therapies/have direct applications. The application includes an example of clinical trial enrollment which demonstrates inclusivity of diverse patients/communities. ● Community engagement and service/support are all excellent. ● COVID patients were treated with stem cells of whom there was a large proportion of Hispanic persons. ● The inclusion of central valley collaborations to expand access of cellular therapy to socioeconomically disadvantaged groups is laudable but remains perhaps aspirational—the success of this aspect should be part of ongoing evaluations of the impact of funding. ● As a minor weakness, the demonstrated inclusion of diverse racial communities within the 2a trial of stem cells in COVID associated lung injury assumes that risk of non-COVID lung injury will also impact similar distribution of patients (by race, SES, etc.). ● The enrollment of DEI patients in one or two trials especially in a pandemic where minorities were disproportionately affected and showing up at hospitals is not a good indication of the success of efforts going forward.
No: 0	*none*

Application #	INFR4-13586
Title (as written by the applicant)	A comprehensive stem cell and gene therapy clinic to advance new therapies for a diverse patient population in California
Summary (as written by the applicant)	The Alpha Clinic (AC) is modeled after our established Regenerative Medicine (RM) Clinic, with newly added enhancements to include lead clinical research and lead administrative coordinators and regulatory official to enhance efficiency and make patient contact and onboarding of new clinical trials easy to navigate. As an AC, we intend to reach all Californians in need by marketing and education via physician and patient directed websites of active clinical trials, communication with specialty groups for specific conditions, contact and collaboration with our Network partners and community outreach via social media. We will host a regenerative medicine one day symposium and partake in patient directed forums. Our AC is particularly strong in neurological and cardiovascular diseases, with multiple trials underway and/or planned in each area. The pipeline is rich not only in these areas but also in musculoskeletal and autoimmune diseases. Our lead offerings are geared to advance the field of regenerative medicine and to collaborate with our Network partners. These include biomanufacturing facilities to produce a range of regenerative medicine products for clinical trials. Our computational biomedicine group will bring informatics, artificial intelligence, and machine learning to the Network for patient identification, data management and outcomes prediction. We have an advanced imaging core for research in pre-clinical and patient trials and an advanced proteomics core to study protein patterns in disease and identify biomarker proteins. We plan to develop a Master's degree program in regenerative medicine available by application across the Network. Our IRB can provide study monitoring for Network sites as well as assistance with key IRB functions such as single IRB reliance for a multitude of sites. We will train a comprehensive cohort in regenerative medicine with a view to careers in regenerative medicine. This includes residents, fellows and junior faculty, nursing staff, postdoctoral scientists, research pharmacy staff as well as offering advanced degrees in regenerative medicine. We also will reach out to high school students. Our regenerative medicine clinic provides key services for clinical trials with testing modalities on site and experienced personnel. Our expanded capabilities include: the Biobank, electronic medical records, extensive IT support, robust telecommunications and telemedicine services, investigational drug pharmacy, research buildings and laboratories, marketing program, nursing institute, biostatistics core, clinical trials agreement office, office of diversity and inclusion and highly experienced research coordinators and research managers. We will have regular operations committee meetings to ensure efficient progress at all levels and regular meetings with our Network partners to discuss possible patient referral, key topics to advance the field and collaboration on clinical trials and other important projects. We will enforce the highest standards to ensure diversity, equity and inclusion in all our proceedings, as well as robust knowledge sharing.
Funds Requested	$7,957,966
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG." Patient advocate members unanimously affirmed that "The review was carried out in a fair manner and was free from undue bias."

Scoring Data

Final Score: 1

Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	2
Count	15
Votes for Tier 1	9
Votes for Tier 2	6
Votes for Tier 3	0

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- A score of "3" means that the application is sufficiently flawed that it does not warrant funding

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	**Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?**
Yes: 14	• The proposal is well written and outlines a comprehensive approach to the formal development of an Alpha Clinic network at the applicant institution. The application is well written and if carried out would significantly add to the CIRM efforts in this area. • Incredibly deep therapeutic expertise and a breadth of tools and capabilities. Particular excellence in cardiovascular and neurology. • The institution would utilize their existing RM clinic that has cell therapy experience and clinical staff who are experienced with regulatory, IND and FDA efforts. Extensive software to facilitate crosstalk among network for referrals; an opt-in Biobank; biomanufacturing facility available, telemedicine, and extensive education resources. • Unrivaled expertise in cardiac and neurology. Massive GMP capabilities. I like the imaging and proteomics core as well as the computational expertise. I think this would bring a lot to the network. • The institution has a strong track record of commitment in this area and their proposal reflects this. • The institution's work, as well as their collaboration with other Alpha Clinics and others, will add great value to the Network. • They have a robust track record of being responsive to patient needs, they are a leading health care provider and they work well with industry partners to advance therapy development. • Yes, potentially, although it seems like much of the proposed activities are already active at some scale (i.e. referral networks). • If truly integrated, this Alpha Clinic will bring a significant depth and strength to the network. Whether it will integrate and become a true team member is the question. The PD strengthens the likelihood of this happening.
No: 1	• Concerns were raised about history of collaboration in these spaces, specifically using licensed products.
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**

Yes: 13	• The proposal is well written and well designed. The proposal has significant strengths, especially in the breadth of projects and committed investigators and a high level commitment to the education of individuals in the developing fields of stem cell and gene therapies. • The training component of the proposal is very extensive and exceedingly strong. Offering the Master's program in regenerative medicine to the public is a strength; ensuring it is available to the network or the community at an affordable rate is key. • They have the plan and infrastructure to advance clinical trials. • They have a strong commitment to this, as evidenced by their track record in this area. • Their proposal describes a significant effort related to Lead Offerings. • There are a large number of training programs available. • The conduct of regenerative medicine clinical trials is already in place at the institution, as are the required infrastructure components necessary for product development and manufacturing. The scale and capability of these is not clear - whether they are capable of serving beyond the single institution is not clear but is implied.
No: 2	• The application seemed more focused on specific technologies or therapeutic areas. I did not get a clear picture of the core or central services or offerings that would result from the award.
GWG Votes	**Is the proposal feasible?**
Yes: 15	• The proposal as written is feasible. Multiple Institutional resources are being brought to bear on this project. The sense of organization and enthusiasm for this work is palpable. • They have great experience in this area, no concerns regarding feasibility. • The resources are available and appears feasible. • The institution has the capability to operationalize everything they propose. Their integration or willingness to integrate into the network is less clear.
No: 0	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 14	• Their DEI infrastructure and process reflects the institution's commitment to engaging diverse and underserved communities with a diverse team that is familiar with and responsive to the unique needs of the diverse communities within their catchment area. • The proposal is uniquely designed to be inclusive and to directly address the needs of DEI through out the application. • The applicant stated a good foundation of efforts to engage the underserved population. Tools such as community engagement studios could be useful to consider. • Their programs in this area are newer but that means more room for growth and improvement. • The commitment to DEI appears extensive in a forward-looking manner but is recently implemented with little data of its use or effectiveness yet available. • There were concerns raised about the depth of the DEI program.
No: 0	*none*

Application #	INFR4-13587
Title (as written by the applicant)	The [institution] Alpha Clinic: A roadmap for equitable and inclusive access to regenerative medicine therapies for all Californians
Summary (as written by the applicant)	Our institution is proud of our collaboration and collective accomplishments over the past decade. We have long been a leader in the science of stem cells, regenerative medicine, and gene therapy, and our translational focus has enabled the rapid acceleration of new therapies into the clinic. Our Alpha Clinic facilitated over 40 clinical trials to test new stem cell or regenerative medicine therapies in patients, contributing to two paradigm-changing FDA approvals. Together with our sister sites across the State, we developed and manufactured new therapies, trained a regenerative medicine workforce, and upheld the highest standards in clinical care while bringing these innovative new treatments to patients in need. Looking to the future, our proposal builds on our strengths and accomplishments to create a just and equitable network of cutting-edge clinical care throughout Southern California over the next five years. We aim to deliver novel stem cell and regenerative medicine therapy clinical trials to patients where they are, providing access to the latest innovative therapies coupled with world- class clinical care while keeping patients close to home. This will allow more Californians to take advantage of the tremendous scientific and clinical advances developed through the Alpha Clinic, while also minimizing the disruption to their families, careers, and lives. To accomplish this, we propose an ambitious expansion of our Alpha Clinic. This phased approach will initially deliver stem cell and regenerative medicine therapies in satellite clinics and, eventually, in outlying communities. Our comprehensive approach incorporates several key aspects. First, we invest in community integration and education, working with key stakeholders and placing patient navigators in community settings. Second, we provide resource and logistical support for patients and families while creating the infrastructure required to treat them closer to home. Third, we provide comprehensive training and support for a regenerative medicine workforce based in the community. Finally, we continue our groundbreaking work on developing and translating exciting new therapies to the clinic. Importantly, our plan is tightly integrated with overall expansion plans at our institution, such that the structures and systems we build will be sustainable over the long term. Additionally, our plan is both complementary to and synergistic with proposals developed by other institutions, creating a robust network of sites working in concert to realize the overall vision of the CIRM Alpha Clinics Network. We strongly believe in the democratization of cutting-edge care for patients with cancer, diabetes, and other serious diseases. Innovative new therapies will be available to all patients, not only those with the resources or social capital to access them. We are thrilled to continue our work with the Alpha Stem Cell Clinic Network to ensure that all Californians benefit from the groundbreaking medical advances being developed in our flagship institutions.
Funds Requested	$8,000,000
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.” Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”

Scoring Data

Final Score: 1

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Highest	1
Lowest	1
Count	15
Votes for Tier 1	15
Votes for Tier 2	0
Votes for Tier 3	0

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Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	**Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?**
Yes: 15	• Network partners are well described in the application. It includes the institution's satellite sites and other Alpha Clinics across CA. The proposed network of clinics will definitely accelerate and support patient access to experimental cell gene therapies. • Moving studies from inpatient to outpatient to community is a great model. • One of the most impactful offerings in the short-term would be the establishment of cell therapy infusion clinics outside of FACT-accredited facilities. • Well-developed plan for expanding access through enhancing partnerships with satellite sites. • Proposed clinic provides a detailed strategic plan to accelerate and expand patient access to gene therapy clinical trials, with a major strength being using Alpha Clinic funding to offer guidance in IND-enabling studies, IND preparation, regulatory guidance. • The value proposition is based on the applicant's pioneering experience with innovative cell and gene therapies in oncology and HIV, such as hematopoietic stem cells and CAR-T cells. • Broad portfolio of trials available to patients and strong track record. • Provides expertise in diverse range of translational services ranging from IND-enabling studies to viral vector, and cell product GMP manufacturing and has strong regulatory experience with facilitating pre-IND meetings and IND filings and impressive track record of opening clinical trials. • Existing clinical trial infrastructure has enabled the initiation of over 700 clinical trials in the past 7 years; average time-to-activation 99 days for therapeutic studies. • Provide access to strong clinical trial development and shorten activation time. • Streamlined pipeline of products and clinical studies in a wide variety of areas. • Long history of GMP-level manufacturing that will be expanded. • Strong institutional support. • Solid set of core capabilities with experienced teams. Top manufacturing capabilities are an advantage. Ambitious program to excel in community-based hospitals (with need for quality care and research). Lead offerings are reasonable--nothing particularly innovative, but seemingly solid. • Will they integrate their community hospital plan with other Alpha Clinics? • The 3 lead offering components exist in all Alpha Clinics so its not that impressive. How will it benefit the network if these already exist everywhere?
No: 0	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**

Yes: 15	• Proposal is well-planned and feasible with great attention to ensuring lead offerings are meaningful and have widest possible impact. • The lead offerings are not any specific clinical trials but their expertise in translational, regulatory, and manufacturing aspects of cell gene therapy. These offerings are integral to development of novel cell gene therapies. • Broad resources to cover all needs in developing strategies, translation to the clinic, GMP manufacture and clinical operations. • The clinic's operation and structure are well suited and planned for the delivery of lead offerings. • Detailed plan to use the Alpha Clinic to expand capabilities at every stage of translational pipeline, with integration into Research Operations ensures Alpha Clinic priorities are honored at highest levels of institutional management. • The institution seems to be well-networked with other California institutions in regenerative medicine and cell therapies. Timelines/deliverables are well-delineated. • Reasonable proposal and team to implement, particularly impressed by program director and senior leadership team. • Excellent training program that was adopted network-wide in last funding period with particular expertise in nursing education research where they have conducted needs assessment to address the training needs of frontline nurses. • Very strong education component that could become a standard across the US. • Regenerative medicine and cell therapy multi-disciplinary course "train the trainer" model included funding for people learning these skills to come to the local site. • Robust proposed training program. • Training of medical personnel - nurses, coordinators, and faculty are described in the application. However, training of the manufacturing workforce is not described (except the mention of a GMP certification).
No: 0	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 15	• The applicant is well-positioned to carry out the proposed plan. They have held over 100 active INDs in the past eight years, initiating over 100 first-in-human clinical trials with extensive expertise in all aspects of IND studies. Detailed plan to expand these services within network is feasible, and there is clear investment by the institution as well. • Strengths include: 1. Leadership team 2. Experience in clinical trials. 3. Commitment to networking with other ACs. 4. Education/ training of investigators and particularly of staff is impressive. 5. Commitment to a more distributive care model (importance of community sites). • Program and offerings are feasible and within capabilities of an experienced qualified cadre of investigators who have access to an established GMP facility and experienced regulatory group. • The team has a proven record of delivering cell gene therapy clinical trials and is well qualified. • According to the plan, the clinic will expand its capacity and resources if funded by CIRM. • >100 INDs and long track record of investigator initiated trials. • Strong effort to reduce activation time seems to be successful and helps. • Aspiration to move studies to community - not entirely sure how. Very strong plan for how to monitor outcomes. • The infrastructure is in place; question is how it will be used to benefit the network.
No: 0	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 15	• Major theme throughout proposal is democratizing cancer treatment in efforts to improve accessibility and inclusivity. Importantly, there is funding that will help enable the transition of trials from inpatient to outpatient settings across satellite clinics in the area by providing funding for nurse practitioners, cell therapy coordinator, data coordinator, program manager. This promotes a shared-care model that will be made more feasible by the training program.

	• There is a main campus and the institution also operates many clinical network locations that reach ethnically diverse populations. A recent Community Health Needs Assessment identified Access to Care as the top health need in local communities. • The institution has provided funds earmarked for patient resources coordination, transportation and lodging, addressing food insecurity, providing community classes on cancer prevention and community health, and providing community building grants to support wellness efforts. They have a clear plan to facilitate partnerships with satellite sites to increase access for patients to the Alpha Clinic Network by expanding clinical research capabilities and infrastructure into the institution's community network. • Patient navigators will provide personalized support for patients and their families, acting as liaisons between patients and health-care teams. • The institution seems to do this well: patient navigators, interpreters, etc., all seem to point to institutional commitment to serving underserved community members. • The applicant presented a plan for community outreach and providing services for underserved patients population. The project team values and promotes DEI. • Metric-driven needs assessments. Strong commitment to increasing patient access including putting resources on the table. • They have conducted needs assessments for their populations.
No: 0	*none*

Application #	INFR4-13596
Title (as written by the applicant)	Alpha Stem Cell Clinic for Northern and Central California
Summary (as written by the applicant)	The creation of the Alpha Stem Cell Clinic (ASCC) led to significant improvement conducting cell and gene therapy clinical trials by implementing procedures for improved operations and streamlined processes. Since its conception, the ASCC has played a leading role in the development of cell and gene therapy protocols by providing the infrastructure needed for these complicated trials. The ASCC grant renewal will provide the opportunity needed to expand our current successful operation and provide support for even more centralized activities; provide financial support critical to programs that enhance patient recruitment and adherence to protocol requirements; improvement in time/efficiency of the administration of trial therapeutics; initiation of training for new support staff and the provision of regulatory support; advancement toward point of care manufacturing; development of processes for a "platform" utilized for treating rare diseases. The ASCC serves patients throughout Northern and Central California. Home to approximately 6 million people, many who lack access to cell and gene therapies. Our physicians are committed to ensuring these patients are referred to only legitimate sites, avoiding dangerous unregulated clinics where non-FDA approved stem cell applications can cause more harm than good. The ASCC along with the Alpha Clinic Network sites continue to work collectively to ensure that cell and gene therapy clinical trial resources and access are available to a diverse patient population throughout the state of California. The ASCC represents an excellent value proposition for both patients and trial sponsors, demonstrated by the success our Stem Cell Program and the number of cell-based clinical trials brought to our institution through the connections established. ASCC leadership is committed to embracing diversity, equity, and inclusion in their workforce, trainees, and patients. The ASCC staff work closely with the Center for Reducing Health Disparities and the Cancer Center Office of Community Outreach and Engagement, to initiate and maintain activities to enhance inclusion of clinical trial participants by gender and racial/ethnic minorities and to reach the underserved populations. The ASCC presence in the field of cell and gene therapy clinical trials and our strong relationships with statewide and national medical program networks, commitment to access to cell and gene therapy clinical trials, dedication to developing novel therapies for patients with rare diseases and membership in the NIH-funded consortium of CTSC/CTSA academic research institutions, has the resources and ability to continue to increase the overall value of the Alpha Clinic Network. These resources also serve to expand our extensive portfolio of ongoing and planned clinical trials, focusing on a "homegrown" CAR T cell program and point of care manufacturing, creating more opportunities to develop stem cell and regenerative medicine cures for Californians.
Funds Requested	$7,999,997
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG." Patient advocate members unanimously affirmed that "The review was carried out in a fair manner and was free from undue bias."

Scoring Data

Final Score: 1

Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	2
Count	14
Votes for Tier 1	11
Votes for Tier 2	3
Votes for Tier 3	0

- 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, at the applicant's option, may 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

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?
Yes: 13	• This Alpha Stem Cell Clinic is an existing member of the network that serves a geographically unique population. It presently comprises all of the essential elements of such an establishment, with particular strengths in training, telemedicine and GMP manufacturing. • In the accompanying materials they provide an impressive list of clinical trials. There are over 15 active trials, 5 CIRM funded with one originating at the institution. There are 8 trials in process, all but one biotech funded, and over 20 closed trials. As such they do not appear to have been one of the more active ASCCs in originating clinical trials, but have focused more on studies funded by biotech companies. • The proposed Alpha Clinic appears committed to expanding access to rural and underserved areas via telehealth and remote access via local providers. The catchment area is exceedingly large and their program to address it thorough. • Have developed a centralized clinical trial unit specifically dedicated to cell and gene therapy in previous funding period and goals are now to improve timeline to initiate trials and expand services. • Applicant has particular strengths in neurological stem cell and gene therapy clinical trials, therapy of rare diseases and telehealth and a very strong manufacturing track record. • The goal of the expansion is to increase staff, increase patient capacity and establish a 24/7 facility that can provide access to all CIRM Alpha Clinic funded studies. Expansion of this clinic would enable creation of a 24/7 cell and gene therapy outpatient unit with the components necessary for product infusion and patient monitoring. • Meets needs, with major manufacturing strengths. • This ASCC is relatively unique in its geographical location. It is not centered in a large population base but serves a disparate 30+ county area, with a largely medically underserved population. In this context they have established a telemedicine network and created a number of outreach groups, the Center for Reducing Health Disparities, involvement with Spanish language public radio, etc... This ASCC provides an important extension to the network. • In the Section on "Available Organizational Capacities and Resources" mention is made of collaborations with other institutional entities but does not adequately describe how they will be used. Statements such as "secure validated data collection methods ... will be implemented" are rather generic. • Within the catchment area this institution offers perhaps a unique opportunity for patients to participate in new cell and gene therapy trials. It also provides creative training opportunities e.g. in GMP manufacturing and experience in the use of telemedicine. The existing staff is experienced and the facilities are more than adequate. What appears

	lacking is a vision accompanied by a somewhat detailed plan for future developments to ensure that the Clinic properly maintains its status in the field. ● In summary the details of what clinical trials are ongoing, which new ones are anticipated and when and how additional trials are recruited is poorly organized and presented. There are somewhat conflicting numbers of trials in the application and those with which the ASCC will be involved are not clearly presented. Confusion is added by the poor organization of past, present and future trial proposals in disparate locations. ● In their application they do not provide a real list of upcoming or potential cell and gene therapy trials which they would sponsor, but do mention five ongoing collaborations with Alpha Clinics which may evolve into trials. A current strength is their involvement in industry sponsored clinical trials and the good relationship between their GMP capabilities and industry. However, this opportunity and its potential for expansion and leverage is not covered in the body of the application. ● The evolution of new clinical trials is not dealt with in an organized manner. The Lead Offerings section does not describe adequately what new trials are in development or how new protocols are leveraged. Much of this information comes from an unlabeled Figure 4 in the Tables and Figures appendix, which lists 50+ cell and gene therapy clinical trials ongoing at the institution and 20 more in the pipeline. The upcoming trials are not prioritized and the cell/gene products are not described. ● There are no clear descriptions of how the proposed changes would be implemented beyond statements such as "new space and equipment would be needed". There is virtually no description about how new clinical trials would be recruited or what trials are in the pipeline. The organization structure of the facility is not well described nor are how collaborations will be fostered to attract new activities. ● A weakness is that future investigator initiated trials were only briefly described in a table.
No: 1	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 12	● The aims of the Alpha Stem Cell Clinic (ASCC) reapplication are to 1) centralized administration of trials; 2) Expand clinic/infusion space at the ASCC Infusion Center; 3) dedicate highly trained staff in a suite of supportive services; 4) Increase GMP production capacity; 5) standardize bio-specimen collection and storage and 6) Increase the use of telemedicine. ● Expansion of this clinic would enable creation of a 24/7 cell and gene therapy outpatient unit with the components necessary for product infusion and patient monitoring; this should increase availability and access. ● The long-term goal of the GMP facility is to establish 24-hour staffing to increase manufacturing capacity to increase the number of internal and external clients using the ASCC. ● The GMP facility expansion including the ability to make viral vectors will greatly benefit the network as a whole. The point of care approach is strong but the justification was missing in the proposal itself. The presentation clarified this. ● The training program in Cell and Gene Therapy is longstanding and robust supported by NIH for decades; the co-PI of that increases its voracity significantly. ● An MD training program already exists with the possibility of obtaining a Master's degree during a 2-year training period. The program has both a didactic and mentored research training component. The expansion would add a program for PhDs and graduate students and facilitate an 8-week summer GMP manufacturing course. ● The applicant institution has strengths in education with a 2-year CIRM Cellular Therapy Training Program targeted at MD fellows in the field of cell and gene therapy that they propose to expand to postdoctoral fellows and graduate students and they have also initiated a certification program in Cell and Gene therapy manufacturing. ● Meets needs but a closer partnership with the clinical and translational science center would be useful for training/education, and clinical trial efficiencies. ● It is evident that much of the infrastructure of this ASCC is already in place, and while the proposed goals are laudable and would add to the strength of operations, the means by which they would be accomplished are, in general, poorly described. ● The development of the Centralized Administration and Comprehensive Core states that renewal of funding will provide them with additional support and streamline logistics of

	clinical trial management. The details of how this will be achieved and what improvements will be made over the existing system are not described. ● The current activities of the ASCC Infusion center are described, but again the proposed improvements are not described in any detail. They indicate that with help from the institution's health system they will expand outpatient care for cell and gene therapy to 24/7, but the need for this is not justified, neither is the role for CIRM funding. Mention is made of covering the salaries of several existing clinical coordinators and managers at 100% effort. ● While the institution has been in an excellent position geographically to develop and expand its Telemedicine activities and mention is made of how these would be of use to the ASCC, there is no information on what improvements and additional activities would be anticipated with renewed CIRM funding. ● There is a proposal to increase the GMP Facility productivity by establishing 24/7 staffing. The need for this is not justified by any data on the capacity or the available staffing of the current facility. Later in the application mention is made of establishing localized manufacturing facilities e.g. for preparing CAR T cells. The economics of building and staffing these facilities and the anticipated demand for such activities are not addressed or justified. ● The institution has a current BioRepository Resource but mentions CIRM ASCC funding to standardize bio-specimen collection and storage. No mention is made of the type of improvements to be made or the current activities and procedures used by the BioRepository Resource.
No: 2	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 13	● The institution established an infrastructure in the last funding period to support cell therapy research, training and lead offerings and has strong manufacturing and telehealth. ● The Program Director for this application is also a leader of the GMP Facility. The PD is an experienced transplant physician who has conducted IND studies and been involved with commercially-sponsored trials. The PD has been successful in increasing the volume of transplants by 300% since joining the institution. There is little information about their administrative experience. The PD will report to the Internal Oversight Committee. The PD will devote 30% of his/her time to ASCC. ● A named personnel is in overall charge of the ASCC/CAR-T and Quality Management structure and is mentioned as a no-salary member of the Project Team. They are highly experienced and is the direct supervisor of the PD. Their role in this application is to meet weekly to monthly with various team leaders. ● Key People include a named Program Manager (100%). This individual has 25 years of experience in the clinical stem cell setting, and is probably playing the central coordinating role on this application. Another named personnel has regulatory experience and will manage the Clinical Research Nurse and a number of Clinical Research Coordinators (100%). ● There is a named Clinical Trial Budget Analyst (50%), a no-salary Business Director and a no-salary Clinical Outreach Director. There are no new salaried recruits as part of this application. The team has worked together for a number of years and has the appropriate experience to establish, operate and maintain the clinic. The GMP organization is largely separate from the clinical structure and it is not clear who is responsible for Clinical Quality Assurance activities. ● There are two named Cell and Gene Therapy Specialists (100%) who appear to be responsible for cell product preparation and delivery. Their responsibilities include working for the biorepository core and equipment validations, although they report through the clinical rather than the GMP org chart. ● The Team will follow FAIR data principles to make data available to the broader scientific community. It will utilize NIH-supported and general repositories, the cloud, patient resource sites and clinicaltrials.gov. They state that data will be managed according to GLP and GMP for clinical products. They will follow institution rules and expectations regarding publication of data, make presentations at meetings, hold trainee poster sessions and presentations and utilize websites.

	• They will hold annual Stem Cell Awareness Q and A session in collaboration with the journal Stem Cells and participate in committees. This section is rather typical of the generic responses provided in Data Sharing responses. • There is a listing of various meetings that will be used to foster communication between the team members. These meetings appear sufficient to ensure integration of operations. There does not seem to be a regular meeting with the members of the GMP facility - although these communications may be the responsibility of the Cell and Gene Therapy Specialists. There is no mention of Quality Assurance meetings. • The key people have worked together for some time and are appropriately qualified to operate the ASCC. There are a number of non-salaried staff mentioned in the application, but there are no staff to be appointed to support new activities. Since many of the proposals mentioned in the application are not described in any detail it is not clear whether there are sufficient resources available to support them. The institution will provide $2 million of in-kind support in direct costs. • There is no budget line-item for training activities and these have been successfully supported to date. The lack of detail about Lead Projects and the Pipeline activities makes it difficult to be sure that there are sufficient resources available to support these activities, but a potential lack of support is not mentioned by the applicants. • Meets needs but concern: a closer partnership with the clinical and translational science center would enhance translational research infrastructure, but it's not clear whether this proposed renewal is taking advantage of the clinical and translational science center. • A timeline is provided by the applicants, but it is based upon poorly described activities in the body of the application. The activities listed are somewhat generic e.g. "Increase GMP Manufacturing through addition of Space" - this activity is barely mentioned in the application, how much space, its location, etc... are not discussed and yet a three year time period is allocated. • Since there is no detailed description of how activities are to be accomplished and even, in some cases, what the actual activities consist of, it is difficult to determine whether the provided timeline will be met. For example, "Activity: Additional Pipeline Clinical Trials Initiated" has a timeline 4.5 years but the body of the application only generically mentions pipeline trials, while the Table and Figures section states that there are 20 in the pipeline but provides no timings.
No: 1	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 14	• The ASCC indicates that they will work with the Center for Reducing Health Disparities on assessing meaningful community engagement. They will also work with the Cancer Center for community outreach which works to connect in person and online with community members. The institution also has a program which brings telehealth services to underserved populations. • The program has multiple programs providing outreach and education regarding potential therapies to patients in diverse communities and have student-run clinics in inner-city neighborhoods, providing free health care to uninsured, low-income and other underserved populations. • Strong collaboration with existing community organizations to address unmet clinical needs in underserved populations. • They are leveraging institutional cancer center resources and provide a broad plan for community engagement where they recognize cultural differences in different communities. • The institution has a a county catchment area that serves a population of 6 million throughout Northern and Central California with significant rural and underserved populations. • The geographic catchment of the institution is extensive and plans to decentralize are important. • Creation of a public-private initiative to bring telehealth services to address the health needs of underserved, vulnerable populations in rural communities. This program aims to reach populations who are vulnerable to the worst health outcomes and to provide connections they need to access care. • The outreach and support of underserved communities will be accomplished in collaboration with the Center for Reducing Health Disparities, which has identified nine

	lessons learned in building community programs. They will also collaborate with the cancer center through its Center for Advancing Cancer Health Equity and the Office of Community Outreach and Engagement (OCOE). ● The ASCC will also collaborate with the Comprehensive Cancer Center to leverage its outreach programs e.g. the Clinical Trial Diversity Task Force (which reviews minority enrollment). The OCOE educates community members through a citywide oncology program and two other NIH and institution-funded awareness initiatives. The nature of the ASCC interactions with these groups is not described. ● These DEI programs are not ASCC-specific but will be leveraged by them. There is not much discussion of how the Project Team itself brings diverse and inclusive perspectives and experience to its proposed activities. Many of the ASCC staff have been with the program for many years indicating satisfaction with the environment and employment opportunities. ● Meets needs but concern: the incredibly strong community engagement program is noteworthy, but it is not clear whether these efforts have a tangible impact on patient accrual in clinical trials.
No: 0	*none*

Application #	INFR4-13685
Title (as written by the applicant)	Expansion of the Alpha Stem Cell and Gene Therapy Clinic at [institution]
Summary (as written by the applicant)	The overarching aim of this CIRM Alpha Stem Cell Clinic (ASCC) site has been to develop novel, "hands" on approaches to support groundbreaking research in cellular, gene and regenerative medicine therapeutics to provide 1) rapid translation of novel discoveries and therapeutics from bench to bedside; 2) "hands on" approaches to circumvent shared roadblocks in clinical research to accelerate trial activation; and to 3) recruit, develop and train the next generation of diverse regenerative medicine scientists. In the next phase of the ASCC expansion, we will strengthen our prior goals listed above and further build upon these by offering 6 new lead offerings: 1) Growing our already robust and FDA compliant current Good Manufacturing Practice (cGMP) Facility to meet the increasing demand of high quality cellular and gene therapy products across the CIRM ASCC network both with investigator initiated and industry sponsored clinical trials; 2) Leveraging our already existing and far reaching Community Engagement Alliance (CEAL) program to provide underrepresented communities with access to CIRM ASCC clinical trials, education, and community care across Los Angeles County and the state of California. We will focus this lead offering on addressing the California public health problem of Sickle Cell Disease (SCD) which disproportionately affects the Black and Latino population of California and has resulted in excessive morbidity and mortality in our state; 3) Provide access to Research Electronic Data Capture (REDCap) data management resources and de-identified data repository across all ASCC sites to include the electronic medical record of >20 million Californians; 4) Improve FDA filing, regulatory support and communications by developing an FDA Electronic Common Technical Document (eCTD) education and Electronic Investigational New Drug (eIND) filing service for the ASCC Network; 5) Increase oversight and monitoring of cellular and gene therapy clinical trials by providing a robust Data and Safety Monitoring Board (DSMB) service to support compliance with FDA standards; and 6) Institute a network wide coverage analysis reliance to ensure compliance with Medicare regulations and more importantly to protect the patient population we serve from improper financial billing and costs associated with clinical trials. In this ASCC expansion initiative, we are firmly focused on reaching the diverse, populous and under-resourced communities that we serve not just to increase access to groundbreaking regenerative medicine therapeutics but to also deliver basic healthcare and education that is so often lacking. We also believe that there is strength and synergy with collaboration across the CIRM ASCC Network sites statewide. Together we can improve the health outcomes of all Californians serving as pioneers in regenerative medicine across our country and world.
Funds Requested	$8,000,000
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG." Patient advocate members unanimously affirmed that "The review was carried out in a fair manner and was free from undue bias."

Scoring Data

Final Score: 1
Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	1
Count	15
Votes for Tier 1	15
Votes for Tier 2	0
Votes for Tier 3	0

- 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, at the applicant's option, may 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

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?
Yes: 15	• In this proposed ASCC expansion, the applicant plans to partner with their Clinical & Translational Science Institute (CTSI), which encompass a range of health care delivery systems and research environments that include academic medical centers, safety-net hospitals and community clinics. This type of partnership has the potential to expand and accelerate patient access to cutting edge stem cell and gene therapies. • Clearly established program with demonstrated excellence and complementary funding. Key personnel are contributing time proportional to responsibility. Integration with CTSI to expand ASCC offering compelling. Streamlining study activation likely to be successful and have a positive impact. • Major advance proposed is to merge the ASCC with their CTSI, which includes four affiliated medical campuses that span the area, including community care networks • The applicants propose to expand opportunities for more stem cell/gene therapy trials by merging ASCC with their CTSI (one of the largest in US), in existence for many years. Main strength is focus on SCD from a scientific and public health standpoint. • The proposed ASCC expansion will add significant value to the network in terms of broadening the network's geographic reach and providing expertise in new disease areas such as hemoglobinopathies and sickle cell disease (SCD). • The group has significant expertise and a broad network of potential SCD patients. The proposed ASCC expansion plans will leverage their experience with SCD as a model for "ASCC partnership, community engagement and improving healthcare outcomes in California." • The expanded clinical trial infrastructure within the clinical and translational center as well as the staff should be impactful. • Yes, this proposal will provide significant impact for patients, trial sponsors, health care providers and healthcare students and trainees. • PI is co-director of CTSI which is a national network of clinical trial sites and expertise can be leveraged. Broad institute is nearby and team has co-appointments They have prior record of alpha stem cell clinic success; prior track record is strong. • Great lead offerings, community engagement. I liked the coverage analysis, great metrics, workforce development. • Their lead offerings are very strong: CEAL program exists and will be utilized. Workforce development program is strong and includes a high success rate with underrepresented minorities; master coverage analysis program will benefit all trials. • Lead offerings provided by CTSI partner campuses "hands on" clinical/translational research, education/training programs that embrace DEI, community engagement, adherence to strict metric-driven patient and data-monitoring guidelines.

	• State-of-the-art biomedical informatics for big data analysis, cohort discovery, knowledge sharing tools to ASCC network and core services to support biomedical research along the translation research spectrum. • Leveraging CEAL (community outreach), redcap and coverage analyses. • This is an excellent application. Builds on existing strengths by fostering interaction with CTSI. • This is a very strong application with strong examples of work completed informing the work proposed. • While the team focuses on the biostatistics and research design (so much that it is mentioned twice as separate, but the same CTSI focus areas), I think these components are at almost every center that has a CTSI award as a standard part of the Center grant. • I was confused by the CTSI parallel track activation diagram. I don't know how contracting can be completed or even realistically discussed prior to understanding the scope/cost of a project (coverage analysis, coding/pricing/budget). Similarly, the IRB can't really assess this effectively, as there may very well be ICOI-RCOI issues that only come out in the budget, etc. While I see that whatever was done, has improved the time to success, I'm not sure it is represented by this graphic.
No: 0	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 15	• The clinic is supporting and has supported many stem cell and gene therapy trials during its history. • The clinic is well-resourced and has the appropriate organizational structure and physical/data infrastructure to support clinical trials in the stem cell and gene therapy space. • Well-experienced and "deep bench" of investigators and staff. Good breadth of therapeutic areas and variety of platforms ranging from cell therapy to gene editing. Excellent partnership with CTSI utilizing translational research infrastructure. Excellent senior leadership and support. • This team is on point with the science, are focused in areas of strength, and have an exemplary team. The team presentation was excellent. • Well-planned, leverages CTSI, which has extensive clinical trials resources (including planned expansion of ASCC into large new space with shared expanded resources of CTSI). • The six lead offerings are well-designed and span from GMP production to community engagement and electronic data capture for IND and regulatory interactions. Collectively, the six lead offerings are integral to the development of cell, gene, and regenerative medicine therapies. • Yes, in advance of the current submission, the applicant has established collaborations with multiple ASCC sites around California. The applicant anticipates that many of their individual site collaborations will expand into multisite collaborations across diverse geographies. • Exceptionally well-planned and executed. • The proposed training programs span all levels from high school to post-graduate and professional training. Likewise, the proposal does an excellent job of designing training programs that enable broader access and increased diversity within the training programs. • The mentoring program is a laudable effort to grow the pipeline of URMs who will be the future workforce in the space. Amazing success with 44% in medical school or graduate school. This is further developed with attention to undergraduates and to medical students. • Probably most important is the training and support programs for nurses and other support team members. • A number of the training programs are not only thoughtful, but considerate of the roles of individuals in clinical research, the necessity to 'float the whole boat' (e.g. develop skillsets of all), considerate to the next generation of researchers, and thoughtful to DEI and the community. • Adding GMP capacity will be critical to growing the activity in the space. A critical issue will be a robust and qualified labor force in manufacturing to support these initiatives.

	• Plan to adopt CTSI biostatistics, epidemiology and research design and biomedical informatics, especially as applies to generating patient registries and e-cohort finding tools. • They plan to streamline trial activation by utilizing the parallel CTSI processes for clinical trial approvals and activation with hopes of shortening study activation time. • The lead offerings have important elements, though some are redundant to other clinics. • A critical issue in the offerings are the terms of access. Specifically, if the clinic is offering "retail" pricing for some of the core activities, then there is little value added. Then, only services that are truly unique will be a value proposition. The details of how other sites can access the cores and at what price points is a critical, lacking operational detail. This is the mode of failure of many core facilities. • There is less clarity on the CTSI training grant program and this is perhaps aspirational--it will be interesting to hear about its success/impact in future funding requests.
No: 0	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 15	• The institution has world-class infrastructure and access to top-tier academic and clinical resources. The timeline is feasible and is likely to be implemented within the proposed timeline. • Activation time of 150+ days to less than 100 days shows their capability to deliver positive results. GMP facility is strong and perceived as better of the ones shown. • Close to 30 trials from bench to bedside in prior funding; tremendous tool developed and offered to/utilized by ASCC network. • Well-established expertise/performance to date. It is easy to be impressed by past performance. I appreciate a high performing research organization including 360 quality improvements as part of their evaluation/metrics. • The transparent parallel processes for study activation, includes the generation of dashboards to track the recruitment and financial progress of the trial taken from both the Clinical Management System and the electronic medical records making it easier to spot and correct roadblocks in the process without stopping progress in parallel channels of activity. • Yes, this is an excellent team with deep scientific, technical, and clinical expertise. • Appears feasible as relies on existing CTSI infrastructure but may require some modifications during expansion to network. • The lead offerings are in place and will go forward with or without the proposal. • Yes. However this lives or dies upon the throughput and budgets/types of trials BEYOND the lead offerings. Ultimately, the ASCC will need enough indirect costs to cover the infrastructure of the operations, and will require more PIs and trials than are currently present.
No: 0	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 15	• The attention to expanding DEI for trainees and patients was very strong. The prior lessons learned portion of the proposal suggests they will greatly benefit from their COVID experience and will benefit the community. • There is a well-defined community engagement plan via the CTSI. They are leveraging an existing network that was a collaborative that engaged URM for clinical trial participation. • The described CEAL award is being leveraged as one means of community outreach. The impact of evaluating and then widely making available therapy for SCD has a huge positive potential. The expertise evident in the application and discussion are evident and impactful upon review. • I think consideration by the applicants of the importance of ethical community engagement is compelling. • They have presented a strong example of outreach and success with underserved communities. • A strength is planned outreach: The new ASCC will provide cellular, gene therapy and regenerative medicine training and curriculum across the continuum of career development including high school students, undergraduates, med students, predoctoral and postdoctoral trainees and junior faculty.

	• Clear plan to expand pipeline in regenerative medicine. • The network above has proven ability to engage diverse cohorts. Not clear on the tracking of them.
No: 0	*none*

Application #	INFR4-13878
Title (as written by the applicant)	Alpha Clinic Network Expansion for Cell and Gene Therapies
Summary (as written by the applicant)	This CIRM Alpha Clinic has a four-part mission to advance development of new cell and gene therapies for a variety of human conditions: (a) develop and support clinical trials for cell and gene therapies; (b) engage diverse and underserved communities in those trials, ensuring that the resulting therapies are relevant to all Californians; (c) provide training and education to expand the California workforce for cell and gene therapeutics and create public access to new therapies; and (d) exchange novel expertise and methodologies with other CIRM Alpha Clinics to advance the development of cell and gene therapies. In pursuit of that mission, this CIRM Alpha Clinic will bring together a strong portfolio of cell and gene therapy research, extensive institutional resources to support clinical trials, robust engagement of diverse communities for participation in those trials and their benefits, and the broad expertise of cell and gene therapy researchers locally and across California. The following significant institutional resources will be leveraged and expanded: ● Clinical Research Support: protocol development and conduct; access to trained staff; recruitment strategies and assistance; regulatory support; multi-site trial services. ● Patient Diversity: Community and clinical partnerships coupled with informatics tools for cohort discovery and recruitment; capabilities across Los Angeles to engage diverse communities from pediatrics to geriatrics. ● Community Engagement (lead offering): active partnerships with 191 community organizations and clinics; connect and educate community members and providers to promote trial participation and dissemination. ● Workforce Training & Education (lead offering): expansion of trained workforce for greater capacity, high quality and safety, effective dissemination. ● Manufacturing and Process Development (lead offering): state-of-the-art cGMP facility to expand capacity for product planning and development; collaboration with other Alpha Clinics to enhance efficiency and reduce costs. ● Novel Therapeutic Expertise (lead offering): consultations and collaborations to share with other Alpha Clinics our special expertise in cell and gene therapies for blindness, arthritis, pediatric diseases, and craniofacial and dental disorders. This CIRM Alpha Clinic will create a strong environment for the translation of basic research discoveries into new cell and gene therapy treatments for conditions like arthritis, blindness, cancer, childhood diseases, dental defects, deafness, kidney failure, stroke, burns, and many more. By engaging large and diverse communities, this CIRM Alpha Clinic will ensure that new treatments are effective for Californians from all backgrounds and all ages. With the CIRM Alpha Clinic Network, we will strive to help CIRM achieve its mission of accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.
Funds Requested	$7,999,983
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.” Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”

Scoring Data

Final Score: 1

Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	1
Count	14
Votes for Tier 1	14
Votes for Tier 2	0
Votes for Tier 3	0

- 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, at the applicant's option, may 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

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?
Yes: 14	• This proposal aims to establish an Alpha Clinic (AC) jointly between two institutions. The applicant institution currently serves a large and very diverse population. In the last year they opened nearly 400 new studies and enrolled approximately 6,000 patients. • The proposed AC has the necessary infrastructure to provide a good value proposition to its clients. To accomplish this they will leverage the activities of their existing Comprehensive Cancer Center, Clinical Trials Office, Clinical Research Office and Clinical and Translational Science Institute. These groups currently support over 1,300 clinical trials. • The proposed activities should provide an impactful value proposition for the clients of the new AC. There is considerable experience in addressing patient needs and working with sponsors. • Very well written application from a strong group that brings non-traditional areas of care to the network. • Multiple strengths including utilizing the outstanding CTSI infrastructure and vitally important community engagement activities. • For potential trial sponsors the AC promises to evaluate proposals rapidly, provide efficient and diverse enrollment, conduct the trials effectively and efficiently and provide a growing pipeline of new therapeutics for consideration. They also will collaborate actively with other AC in training, manufacturing technology recruitment, AI, data analysis and support services. • For patients they will make use of their traditional experience in community involvement, ensure well informed participation, share results and opportunities for enrollment and provide education on new treatment options. • In collaboration with the local country Department of Health Services the applicant provides one of the largest safety net health systems in the USA. In addition, they offer a number of resources that would be of benefit to cell and gene therapy trials. • The applicant already partners with close to 200 community organizations and over a dozen community hospitals and clinics. It has over 70 practice locations in California. • The institutions are establishing a track record in cell and gene therapy trials, with previous and current studies directed towards immune deficiencies, and ten CAR-T cells trials. In the pipeline they describe trials for vision loss, musculoskeletal diseases, cranial and dental conditions, pediatric cancer, intestinal transplantation, skin and cardiac repair, hearing loss and stroke. Some of these represent more uncommon cell and gene therapy studies and would add experience to the network.

	• The availability of a new GMP facility with an experienced director is an important element of this application, and could additionally benefit all the AC by providing new expertise and additional manufacturing capabilities. • The applicant has existing relationships with other California academic medical institutions, including the existing Alpha Clinics, and is willing to provide substantial financial investment to ensure the success of this application. • The local population is extremely ethnically and financially diverse. 86% of the population in one catchment area is traditionally underserved. This group is largely foreign born, poorly educated and 29% have incomes below the Federal poverty level. • The disease burden among the applicant patient population is high, with large numbers suffering from cardiovascular disease, cancer, diabetes, substance abuse, dementia etc. This community is historically underserved in clinical trials and would benefit from access to new cell and gene therapy trials. • A partner institution is a strength and differentiator. • Great community outreach. Amazing passion. • Evidence of success to date. Engaged leadership team. Community engagement. • Well organized; responded to panel's questions well.
No: 0	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 14	• This application is well organized and written. It effectively responds to each of the questions in the RFA and provides data to support these responses. The resources that it will provide for stem cell and/or gene therapy trials include its experience with planning, conducting and analyzing clinical trials, an experienced workforce which includes, research, regulatory, manufacturing, analytical and clinical staff. • The application lists seven lead offerings. Each offering should have an important impact on work in cell and gene therapies and fulfill and extend the role of the ACs. • In addition to experience with trial sponsors, the AC will have access to a new GMP facility with an experienced director. This will allow it to expand its manufacturing activities and to extend this resource to other ASCCs. • A major resource that would be available is the unparalleled access to an extremely diverse patient population, which consists of groups displaying wide ethnic, financial, educational and disease diversity. They have demonstrated the ability to recruit this diverse population into ~1200 new clinical trials which consist of 66% of participants from traditionally underserved communities. • The institution currently offers a Master's Degree in Clinical, Biomedical and Translational Investigations and training in the Design and Conduct of Clinical Trials, as well as degrees and certificates in regulatory affairs and drug development. They run master's and degree programs in stem cell biology. • They currently hold two CIRM training grants and propose to create a new 4-unit didactic and workshop course on translational development of cell and gene therapies for those wishing to support or perform regenerative medicine clinical trials. This will involve existing instructors and outside experts. It will cover all aspects of cell and gene therapies, including quality management, intellectual property, hands-on GMP training and clinical and pre-clinical testing, together with assessment of the potential of a scientific discovery. • This impressive course will be a lead offering intended initially for graduate and postgraduate trainees. It is intended to prepare the AC members for "success". The program will also work with other ACs to coordinate training and develop the workforce across the ACs. • Training on Community Engagement will be leveraged through the Cancer Center and the CTSI. It will include Community Engagement Studies, Research Workshops, Town Hall meetings, a Citizen Scientist Program and Provider Education for community providers. • Taken as a whole, the existing and proposed training programs offer a comprehensive introduction and overview of the field. Strengths include the elements on quality management and GMP hands-on training. There is a strong program on community involvement which will benefit the institutional and other ASCCs • The new GMP facility will provide additional manufacturing capacity and expertise to the institution and the network; training of research and clinical staff will improve the quality and numbers of staff available to the field; community engagement is central to providing

	new therapies to traditionally underserved patient populations and the four areas for the development of new protocols are diverse and represent an extension into some new disease types. ● Excellent integration within AC network. ● Yes, and good list of lead offerings to advance the broader network. ● Overall excellent proposal and no concerns. ● Personnel recruitments are key to their success and the potential for that is unclear.
No: 0	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 14	● The proposal presents a well organized and detailed application which aims to extend its cell and gene therapy activities by becoming a CIRM-supported AC. The application more than adequately demonstrates that it has the capability and resources to support all the required activities of such a center and to actively participate in the ASCC network. ● The proposed activities are well documented in the body of the application. The timeline provided details these in a logical manner, starting with new staff recruitment to occur within the first three quarters. This is followed by a logical progression of activities resulting in starting the advance and support of clinical trials (local and network) in the last quarter of Year One. ● The request for support is focused on funding of mainly senior staff who would have the responsibility for bringing together the appropriate elements to form the clinic. This seems to be a sensible arrangement whereby the relevant seniority and authority is available to create a new entity. ● The institution is a very experienced medical center with a diverse and large patient population. It has excellent financial and infrastructure resources. Its staff are experienced and have experience in cell and gene therapy studies. It references clinical trials that are relevant to CIRM's mission. ● They have identified 40 investigators with >$50M in NIH-funded cell and gene therapy research, in addition to several with CIRM-funded projects. It also has an active Cell Therapy Program, Trial Support Resources, Community Engagement and Training Programs, all of which are important components of CIRM's AC requirements. ● The proposed team appears adequate in terms of training and numbers to support the proposed activities. In addition to the requested CIRM budget their clinic has an institutional commitment of more than $12M annually. This puts it in a very comfortable position to achieve and further expand its goals. ● Training activities and participation in AC network activities would start immediately and continue throughout the period of funding. The proposed timeline seems commensurate with the proposed activities. A potential delay could be in recruitment of new staff, but three quarters have been allocated to this task. ● There is an eight member lead offering team. Other staff have appropriate training and expertise. There are two TBD positions. ● The program director is the Vice Dean for Research and the founding director of the CTSI. The program director has the necessary experience to direct all activities and will provide 30% effort which is reasonable based upon other responsibilities. ● The associate director and executive Director of the GMP facility appears well trained in manufacturing regulatory affairs and training activities. They will direct two of the lead offerings and will allocate 20% of their time. This seems to be a little low based upon the overall responsibilities. ● The third leadership position is also the Director of the Cancer and Blood Diseases Institute who will be the partner site program director. They will direct the pediatrics lead offering and will allocate 10% effort. Their administrative activities are not described. ● Two important full-time staff appointments are to be made: the Program Manager and the Community Liaison. There is sufficient community engagement expertise that the program could manage if the latter position was not filled rapidly. A concern is that the program manager needs to be brought on board as soon as possible - three quarters of Year 1 are allocated to do so, which should be adequate. ● Yes. Key question is whether the associate director should be devoting more time to the grant since program director has such broad leadership responsibilities. ● The applicants were not clear about the location of their delivery of care.
No:	*none*

0	
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 14	• The applicant has a long track record of serving minority and underserved communities. Approximately 65% of clinical trial participants come from traditionally underrepresented groups, and 70% have public or no insurance. They will make primary use of the CTSI and Cancer Center community engagement cores, who have great experience in serving minority communities and fostering their involvement with new clinical trials. • The institution has a long track record of inclusivity in clinical trials and in community outreach. They have achieved impressive recruitment of ethnically, financially and educationally diverse populations to their studies. They also have programs dedicated to promoting diversity at all levels of their operations. • The impressive track record with community engagement adds credence to their ability to recruit, retain and track diverse patient populations. This is a major strength of this application. • Yes, and outstanding record of recruiting trial participants from under-represented minorities. • They propose to examine each AC project to determine optimal approaches to community engagement and possible clinical trial locations. Patient Care Coordinators and the Community Liaison Group will engage with local community health centers. Other activities will include provision of patient, clinician and researcher education, facilitation of trial accrual and retention and brokerage of research agreements. • The community outreach activities consist of several components: Community Listening Sessions, Engagement Studios, Research 101 Workshops, the Our Community/Our Health Program, Patient Navigator Training, the Citizen Scientist Program and Provider Education. These interact with a variety of target audiences ranging from community residents, research teams to healthcare providers. • Exceptional comprehensive definition of DEI and community engagement. Community listening and engagement studio is outstanding. • Evidence in proposal that health disadvantaged groups considered: I appreciated the broad(er) definition of DEI with respect to how this affects health disparity/health service access. • They gave solid examples of work with underserved communities. • The application mentions a number of national and local research networks that they will use to "standardize datasets for easier interoperable exchange'. This response does not really address the RFA question.
No: 0	*none*

Application #	INFR4-13952
Title (as written by the applicant)	A hub and spoke community model to equitably deliver regenerative medicine therapies to diverse populations across four California counties
Summary (as written by the applicant)	Our CIRM Alpha Stem Cell Clinic (ASCC) was founded in 2014 and has established a proven track record. We currently have over 35 active clinical trials, with an additional 25 in pipeline; these trials span 20+ disease indications, including neurological disorders, hematologic and solid organ malignancies, rare metabolic and genetic diseases, and inflammatory disorders and enroll a diverse patient population (66% under-represented minority). Fueled by our passion for world-class science, our dedication to finding cures by delivering transformative stem cell and regenerative medicine treatments, and our unwavering commitment to addressing health disparities and patient equity, we propose to develop a novel ASCC micronetwork centered around our existing ASCC. Our micronetwork will incorporate established partners (a children's hospital, a Veterans Administration Health Care System, and a recently established medical school), span four California Counties, and serve all age groups - from children to our nation's veterans. The proposed micronetwork will enable increased access to CIRM-funded and FDA-authorized clinical trials to patients with unmet medical needs, facilitated by strong partnerships in neighboring communities (from hospitals to CIRM Community Care Centers of Excellence). We will achieve our goals by employing a multi-pronged living laboratory approach in which we: build a hub and spoke network model; analytically evaluate the know-how and infrastructure needed by hospitals and clinics with different levels of previous involvement in clinical research; engage in workforce development by providing training certificates for medical professionals and for clinical research coordinators involved in regenerative medicine studies; and drive community outreach and education. In each of these, we will emphasize diversity, equity, and inclusion in addressing the needs of underserved communities and all Californians. Our ASCC will lead all cell and gene therapy studies within our academic health center and satellite clinics (including two Federally Qualified Health Care Centers), serving as the conduit to translate discovery research into clinical research. At the state level, our unique neurotherapeutics focus will empower us to lead the way in bringing novel regenerative therapies for neurological diseases into the ASCC network. Institutional support for our ASCC is exceptional, with extensive infrastructure investments over the past three years (two new research clinics, a GMP facility, two cell processing laboratories and a future inpatient unit in our new hospital), as well as strong support for faculty and staff. The expanded operations enabled by this RFA will further enhance access to cell and gene therapies for underserved California populations. Together, our micronetwork model and expanded infrastructure will provide value-added to the CIRM ASCC network and the regenerative medicine ecosystem in California and beyond.
Funds Requested	$8,000,000
GWG Recommendation	Tier 1: warrants funding
Process Vote	All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG." Patient advocate members unanimously affirmed that "The review was carried out in a fair manner and was free from undue bias."

Scoring Data

Final Score: 1

Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	2
Count	13
Votes for Tier 1	9
Votes for Tier 2	4
Votes for Tier 3	0

- 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, at the applicant's option, may 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

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?
Yes: 11	• This is a renewal proposal from a Program Director who leads a comprehensive cancer program and institution with significant clinical infrastructure. • Establishing the micronetwork, examining the gaps at various clinics (people, facilities, process) and the educational opportunities are very strong aspects of this application. The Program Director and the historical success of the ASCC are very impressive. • The described 'micronetwork' appears pragmatic and potential significant foundation for future clinical research: as described this would appear to be a truly novel partnership to enhance access to therapeutics including a strong focus on DEI communities served by partners. I appreciate the network covers a breadth of age/patient groups (e.g., pediatric through adult). • Gap analysis informed the strategies proposed for adding sites, partners, and addressing needs of partners in clinical trial patient accrual. • The micro-clinics and gaps assessment will improve patient access. • Strategies to accelerate clinical trials are described with examples of such strategies (IRB reliance agreements, etc...), leading to confidence that these will work for the proposed center. • A strength is the partnership with an outstanding pediatric hospital with major research potential. • Geographic reach and reach into underserved communities is proposed with the addition of two new partnerships. • Development of training programs which are inclusive are a strength. The stem cell clinical professional training programs and clinical research coordinators training programs are particularly well described. • Key personnel time commitment suggest high level of engagement. • Good partnerships with industry-funded trials. • Good clinical and translational science hub infrastructure. • It remains unclear how the micro-clinic approach works in terms of trial design, patient access and IRB issues among very different institutions. • As a lead offering for the Alpha Clinic Network, it is unclear if the artificial intelligence/machine learning (AI/ML) approach will be platform independent, be specific to one brand of electronic health record (EHR) software, or only work on one EHR software tailored within the institution's facilities. • The AI/ML approach for 'scouring' electronic health records for potential research subjects is not compelling. Some aspects presented in the application appear discordant with this

	application. The success of the prior tool is unclear, as well as why it was taken offline and how the 'new' approach will be better. ● Seemingly good productivity from ongoing trials. ● A concern is the depth of high-quality investigators who are having their own biomedical questions addressed via investigator-initiated studies. ● Unclear on the types of clinical trials to be offered; and few appear to be internally driven but rather external industry driven trials.
No: 1	*none*
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 10	● Good leadership, strong infrastructure from clinical and translational science hub, and experience with Alpha Clinic network. ● The institution has been effective in the first ASCC funding period. ● It is an ambitious plan, that if successful, will benefit the community and advance therapeutic discovery. ● The ASCC is designed to reach across the age-span not seen in other clinics. Geographic and social diversity expansion are clear cut, addressing patients with the lowest socioeconomic status in CA. ● DEI outreach is excellent. ● The investigator group has expanded rapidly and now includes ~80 clinical researchers from 20 clinical departments, and the micronetwork partner has 15 investigators involved in cell and gene and therapy trials. Translational research partnerships with clinician scientists will expand topics researched. ● The establishment of the micronetwork is important. ● Current funding will be used to add resources such as a clinical protocol writer. Proposed salary support for new investigators to address gaps in clinical trial dissemination. ● Proposed disease oriented teams implemented to increase focus on new areas of research in collaboration with clinician scientists. ● Clinic operations are well planned with seasoned staff. Strategies to inform the community, expand sites, and disseminate clinical trial information through translational research collaborations are well established. ● Strong training program for clinical research coordinators is described with relevant and strong curriculum and evaluation plan. Scholarships available for such training through center and matching institutional funds. ● Partnerships and expansion of clinical trials to additional sites and Network partners are well described. Plans have strong potential for adding value to the Network. ● The education program proposed is impressive and rigorous. ● The program director is very impressive. ● The training program is a particularly well developed aspect of the application. The quality by design initiative is perhaps not as well described, but has significant potential for impact.
No: 2	*none*
GWG Votes	**Is the proposal feasible?**
Yes: 12	● The proposed implementation plans are well developed and feasible. The timeline is appropriate and reasonable. ● Researchers and staff are well qualified, have longevity with the center, and operational plans are accessible and well developed. ● Team has the capability and resources to support clinical research, training and lead offering(s), as evidenced by strong examples described to illustrate most initiatives/strategies. ● Strong and feasible organizational integration plan to maximize broad access to sponsors developing regenerative medicine treatments. Increasing access to treatments to patients most likely to benefit. ● Integrates cell and gene therapy expertise into other clinical care units and across partners by offering a value-added model and ensuring broad access to treatments for all Californians. ● Promise in the micronetwork and integrates DEI principles.

	• Getting disparate groups to work together as new partners is no small feat; however, this makes the promise of impact on clinical research somewhat aspirational. However, I think if the network operates as described, there is a significant potential for impact. • I am impressed with the description of participation in CIRM-funded clinical trials to date. There appears to be a major focus on industry funded research. This is not meant as a criticism, but this appears highlighted within the application compared to a focus on grant funded work. • Pipeline projects suggest potential for ongoing significant impact. • The majority of clinical trials have been sponsored by industry. This could be seen as an advantage or disadvantage. • Sponsor-initiated clinical trials primarily to date so this may affect ability to complete studies. • Need more details on the actual working of the micronetwork. Would like more detail on the therapeutic areas (likely neurology, muscular dystrophies, sickle cell disease and pediatrics). Specifically what competencies does the ASCC have to lead participation in trials in these therapeutic area? • Questions remain regarding the feasibility of the plan. Time will tell, but it appears that they are leveraging their experience as an ASCC to expand their vision and approach. • A concern is the strength of the broader leadership team, with the program director deeply involved in multiple networks.
No: 0	*none*
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 12	• They appear to have a strong commitment to DEI and see the value of the micro-clinics as a vehicle for engaging underserved communities. • This is a strength of the proposal. Project team is quite diverse in composition and training. Good commitment to diversity both in terms of recruitment and retention. • DEI outreach and training through the micronetwork is excellent. • Throughout the application there is strong mention of opening access to underserved individuals, accessing these communities through outreach and evidence-based strategies such as dissemination planning for each study, and digital outreach and conventional mailings for deep and broad reach inclusive of primary care providers and community groups. • The application is more focused on examples of how the partners/hospitals/health care groups serve health disadvantaged communities. There are some examples provided which would support that they will be effective in the inclusivity of these communities in research initiatives supported by CIRM. • The application is more focused on examples of how the partners/hospitals/health care groups serve health disadvantaged communities. There are some examples provided which would support that they will be effective in the inclusivity of these communities in research initiatives supported by CIRM. • The project team is diverse in experience and training; the commitment to DEI through organizational designation and workplace environment, training record of the PI, and stated plans to consider DEI in training. • The plan will increase catchment area. There is assessment of what is missing in outside community locations and identified barriers to participation at clinical trial micro-network. Very good. • Good record of community outreach, and community engagement; solid foundation for outreach to various community-based sites. • Perhaps given the application's 'strong focus on community outreach…engagement in our operations', it may be fair criticism to note that there are not community advocates/patient engaged representatives as part of the governance plan. • There is little information provided about retention strategies; however, outreach to underserved communities is well-described such as community engagement studios, medical record search with AI for eligible participants, surveys of investigators to assess their planned use of community engagement services. • I was unable to find information in the application on underrepresented minority accrual to current trials. • A concern is the quality of work done at the community sites, so careful assessment of community-based capabilities and quality is needed.

	• Unclear if new partnerships added much diversity.
No: 0	*none*

Application #	INFR4-13597
Title (as written by the applicant)	[Institution] Health CIRM Alpha Stem Cell Clinic
Summary (as written by the applicant)	For the benefit of patients in California and beyond, our CIRM Alpha Stem Cell Clinic (ASCC) renewal grant objectives are to 1) develop, 2) accelerate implementation, and 3) ensure completion of innovative and accessible regenerative medicine clinical trials related to three major disease areas, including therapeutically recalcitrant malignancies, metabolic diseases, and neurological disorders with a special emphasis on our growing cell and gene therapy trial portfolio, which constitutes 50% of our clinical trials and will expand with new philanthropic funding for our Stem Cell Institute. Consisting of 43 clinical trials with 275 patients enrolled, our portfolio has been built through the engagement of a network of trial experts and ASCC network partners as well as surrounding companies. Together, we have combined CIRM and philanthropic funds that established a robust stem cell research infrastructure at our institution into a three-fold increase in grants, philanthropy, and industry-sponsored clinical trials. These efforts led to ASCC milestone achievement, including launching a CIRM-funded Phase 1/2 stem cell gene therapy clinical trial for patients with a rare inherited disease; completion of a Phase 1 neural stem cell trial for spinal cord injury that showed improvements in motor function; and FDA approval for a Phase 3 registration trial of a CIRM and Industry-sponsored cancer stem cell-targeting monoclonal antibody for a blood cancer that will provide biomarkers for IND enabling studies with a related CAR-T cell product. Our overarching objective for this ASCC grant renewal is to enhance the initiation of innovative stem cell and gene therapy clinical trials by expanding our trial expert team to include more translational scientists, clinicians, and key industry sponsors that draw from internationally recognized faculty members as well over 600 local biotechnology and pharmaceutical companies in the region. To enhance DEI and improve patient accessibility to our clinical trials, we will launch regenerative medicine clinical trials at our second medical center location that primarily serves priority populations and expand our knowledge networks with a Community Accessible Regenerative Medicine Acceleration program that provides ASCC trial education and screening services. Our CIRM ASCC team, conducts all outpatient and inpatient regenerative medicine clinical trials and serves as a fulcrum for investigational new drug (IND) enabling studies, which are bolstered by our CIRM training programs as well as institutional and ASCC infrastructure. Our expanded lead network offerings include: 1) a GMP-compliant cell manufacturing facility, 2) a Strategic Advisory Research Team (START), 3) a Surgical Training Center, 4) a Molecular Imaging Core, 5) a Stem Cell Bioinformatics Core, 6) a Data Management Core, 7) an ASCC Patient Registry framework, and 8) ASCC clinical trials personnel and space in the outpatient clinic and inpatient hospital space.
Funds Requested	$8,000,000
GWG Recommendation	Tier 2: needs improvement, could be resubmitted
Process Vote	All GWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.” Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”

Scoring Data

Final Score: 2

Up to 15 scientific members of the GWG score each application. The final score for an application is the average of the individual member scores. Additional parameters related to the score are shown below.

Highest	1
Lowest	2
Count	14

Votes for Tier 1	6
Votes for Tier 2	8
Votes for Tier 3	0

- 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, at the applicant's option, may 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

Key Questions and Comments

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

GWG Votes	Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?
Yes: 9	• The proposed center will bring expansion and acceleration to the Network; this is well described through sustaining existing partnerships and adding new relevant ones. • The PI is outstanding as are many of the other personnel of the ASCC. The track record is strong. One point of disagreement in the GWG concerned the relevance of several of the applicant's clinical trials to stem cell and gene therapy. An example is a trial involving monoclonal antibody therapy of patients with cancer. While it is true that this treatment modality is not stem cell or gene therapy in the narrow sense, the use of this antibody was informed by basic research showing that inhibiting the target of the monoclonal antibody reduced the "stemness" of the cancer cells, and thus their neoplastic behavior. This represents an important translation of basic stem cell research. Overall, I feel that a broader definition of stem cell and gene therapy will foster greater likelihood of CIRM achieving its goals and benefiting the citizens of California. • I don't believe the Network's reach will be significantly increased but specific expertise for stem cell and gene therapy is well established in this application; strengths seem to lie in the management of clinical trials with existing dashboards and seasoned long-term personnel. • The surgical simulation center is a big positive. • Strong existing physician-scientist community of investigators. • Outreach and training need to be further developed. • Providing access to underrepresented participants is not well-described with no goals for underrepresented groups enrollment set. • Concerns: (a) Need deeper engagement with breadth of URM communities. (b) There is little discussion about clinical operational efficiencies. (c) Questionable productivity of existing trials.
No: 5	• The surgical simulation center is a very, very important addition and demonstrates foresight/insight into what is needed for some of these treatments to move forward vis a vis implantation strategies. These aren't trivial roadblocks, and this would allow uniform training for investigators. • Surgical simulation center is important and unique. • The clinic can clearly support the Clinical Regenerative Medicine Fellowship as described within the application. I'm not certain that this is proposed specifically as a lead offering, but this appears as integrated and appropriate. • There are niche areas that would be impactful, and perhaps as part of the bigger network, it would function well. As a total package, I think it falls short. • The oral presentation was somewhat more compelling than the written application. Within the written application, there is not the same breadth/depth of demonstrated effectiveness specific to stem cell/gene based therapy (there are examples of monoclonal antibody therapy).

	• My principal concern with this proposal is the track record of the number of patients enrolled in stem cell/gene therapy trials seems low. The proposal highlights a number of things that wouldn't really be considered "advanced therapies": namely, a COVID treatment, and another monoclonal antibody trial. I recognize that CIRM funded it, but this is neither a cell, gene nor particularly advanced therapy. • CAR-T cell therapies could be considered advanced, but these are no longer early stage with some moving into more regular use. It is my opinion that the focus should be on the work more in line with their spinal cord program, etc. • Injectable hydrogels have been around for a long time and are neither a stem cell, gene therapy. I understand that this may be new company, but I don't believe these examples provide the depth of innovative experience that reassures the reviewers that the program will accelerate the space. • Limited number of patients enrolled clinically in stem cell and gene therapy trials. • Training program not strong as presented. • Application has significant gaps.
GWG Votes	**Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?**
Yes: 8	• The methods for implementation are well described and feasible. There is a wide range of expertise among key personnel and PIs. Systems are in place and tested for enrollment and reporting. • The proposal outlined was well organized for all of the stated goals. • Strengths are the Master's Program and the Surgical Training Center. Other strength is nursing training in regenerative medicine-related clinical activities and is an often-forgotten component of these clinical programs. • In this proposal several systems are described that may well benefit others in the network; although specific methods to deliver these to other network partners were not immediately evident, the capacity appears to be there. • The applicant has the capacity to deliver the lead offerings to the network but need the details on how these will be executed. • The lead offerings have some redundancy with other clinics, but that is minor point. A significant issue is how do outside entities access the core facilities. In terms of the value proposition, the access needs to be at a reduced/subsidized cost. If it is at full price, then this will limit engagement to only unique services., i.e.. no one will use the cGMP facility from outside, for example. • The training program is described but lacks specific details about career development of junior researchers and staff. • Weakness is the lack of a true Physician-Scientist Training Program and relying on another program for this element. • Retention planning was underdeveloped. • Could not find a clear description of pipeline projects. This was not really clarified during the applicant's presentation.
No: 6	• The specific training programs described are not as comprehensive as other applications. There is particular focus/detail related to a fairly narrow surgical training program that is somewhat specific to neurosurgery but likely expandable to other disciplines. The molecular regenerative medicine fellowship is appropriate but perhaps could have had more detail. Training to other personnel not as well developed. • Training of next-generation investigators and staff should be better delineated. • Relatively weak in describing regenerative medicine training. • The lead offerings as presented are reasonable, but are not necessarily unique, or if unique particularly value added. I do think the Molecular Imaging Facility is an exception. Much of the lead offerings are replicated across other AC network partners. Not convinced about strategic advisory research team or surgical training center value adds. • Missed opportunity to discuss the depth and breadth of offerings. There is a lack of attention to detail in the application for past or future studies. • A number of listed therapeutics are not truly stem cell and gene therapy.
GWG Votes	**Is the proposal feasible?**
Yes: 13	• Top notch team leadership and organization. Well thought out plan on operations of clinic. • The team is extremely well qualified. There are excellent resources available to the clinic's operation.

	• The PD is an effective presenter and is obviously knowledgeable regarding activities to date/potential. • The proposed plan for implementation, training, and lead offerings are reasonable and feasible and build on past work of 30 trials over 7 years. • Capability to support clinical research, training is all well described. Several described implementation plans are already in place and tested. • The organizational chart and integration are well developed. Data sharing plans are robust and feasible. • There is a viable organization chart and plan for organizational integration. • Absolutely. The fact that the institution has received a large amount in a gift was viewed negatively by some GWG members, but I view it positively as it ensures resources should be available to implement the AC goals, and it more than meets the priority stated by CIRM that AC funding be "leveraged" by the institution. • The reporting structure suggests high level engagement/reporting responsibility; however, this has not translated within the application demonstrating potential effectiveness of meaningful/accelerated activity. • Principal nominated applicant possesses capacity to deliver; the reporting structure demonstrates engagement of institutions and their leaders. The key personnel listed is not of the same breadth/depth/accountability/role as with other applications. • Uncertain---so neither yes or no. A careful evaluation should be provided of past history as an Alpha Clinic, lessons learned, and how these lessons should influence upcoming funding, if granted.
No: 1	• The use of antibodies and other therapies utilized are not stem cell and gene therapies. They appear out of scope for an Alpha Clinic.
GWG Votes	**Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?**
Yes: 9	• Outpatient environment for treatment is a plus for engaging underrepresented communities. • General strategies are described for outreach to underserved communities. The primary strategy appears to be a mobile van and web-based strategies. This fails to consider those underserved groups that don't usually access healthcare via digital means. • Underdeveloped portion of proposal. Ability to effectively increase DEI in enrollment seems to be there but so many aspects of recruitment, retention, etc... were missing. • Costs and other competing demands (childcare; time off work; language - health literacy, vernacular; medical mistrust) are not addressed. Some mention is made of 'cultural tailoring' with no description of whether this means personalization to each individual (definition of tailoring) or targeting to cultural norms (aiming to access a group). • Expected outcomes of these strategies to reach underserved groups are not described nor are strategies for course correction if initial plans do not work. • Recruitment and retention of underrepresented groups is not well developed. It is not clear if the strategies have worked in the past, are new to the center, and what outcomes/goals are set for engagement and recruitment and retention.
No: 5	• This is a well-developed plan and approach. • This was a major weakness within the application. From the application, it is unclear that there is a careful consideration of inclusion of DEI, and/or health disadvantaged/underserved communities. • I was left unclear as to the DEI initiatives. The provided example of an outreach bus was not a compelling example. I'm surprised after so many years that they "will establish" (rather than have) a community advisory board, and that they "will consult" (again rather than have an established process) for DEI advisors. It would appear that the community engagement manager is to be recruited (again, rather than someone who is already established). • Not particularly obvious, so metrics to communicate advances is required. • Underdeveloped, although possible to enhance catchment region. • A minor point is how does the institution disclose their conflict of interest in recruiting underrepresented patients. The institution will derive benefit disproportionately for enrolling underrepresented patients into trials. The more diverse patients enrolled enhances competitiveness for millions of dollars of funding when compared to others.

Minority Report

If an application receives a Final Score of 2 and 35% or more of the scientific members of the GWG recommend an application for funding, then a Minority Report is provided that summarizes the perspective of those scientific members.

Six GWG reviewers scored the application Tier 1 (funding recommended); eight GWG panelists scored the application Tier 2 (needs improvement). Overall, most GWG panelists voted 'yes' on whether the applicant had met the key review criteria: significant value proposition, the proposal is well-planned, the proposal is feasible, and the proposal addresses the needs of underserved groups.

The reviewers who scored Tier 1 (funding recommended) thought the team is well qualified, has established expertise in stem cell and regenerative medicine, strong clinical trial management and the capacity to deliver systems that may benefit the network. They thought that support for a broad scope of regenerative medicine projects would ultimately be more likely to further CIRM goals and benefit California citizens. For example, a clinical trial for a monoclonal antibody may not be considered a stem cell or gene therapy in the narrow sense but represents an important translation of basic stem cell research. In addition, the institution has received a large amount in a gift that ensures resources should be available to implement Alpha Clinic goals and leverages funding.

However, in agreement with the majority reviewers, minority reviewers also noted concerns with a lack of detail on the training program, unclear value add to the Alpha Clinics network though the capacity seems to exist, and a DEI section with unclear expected outcomes and lack of detail for recruitment and retention.