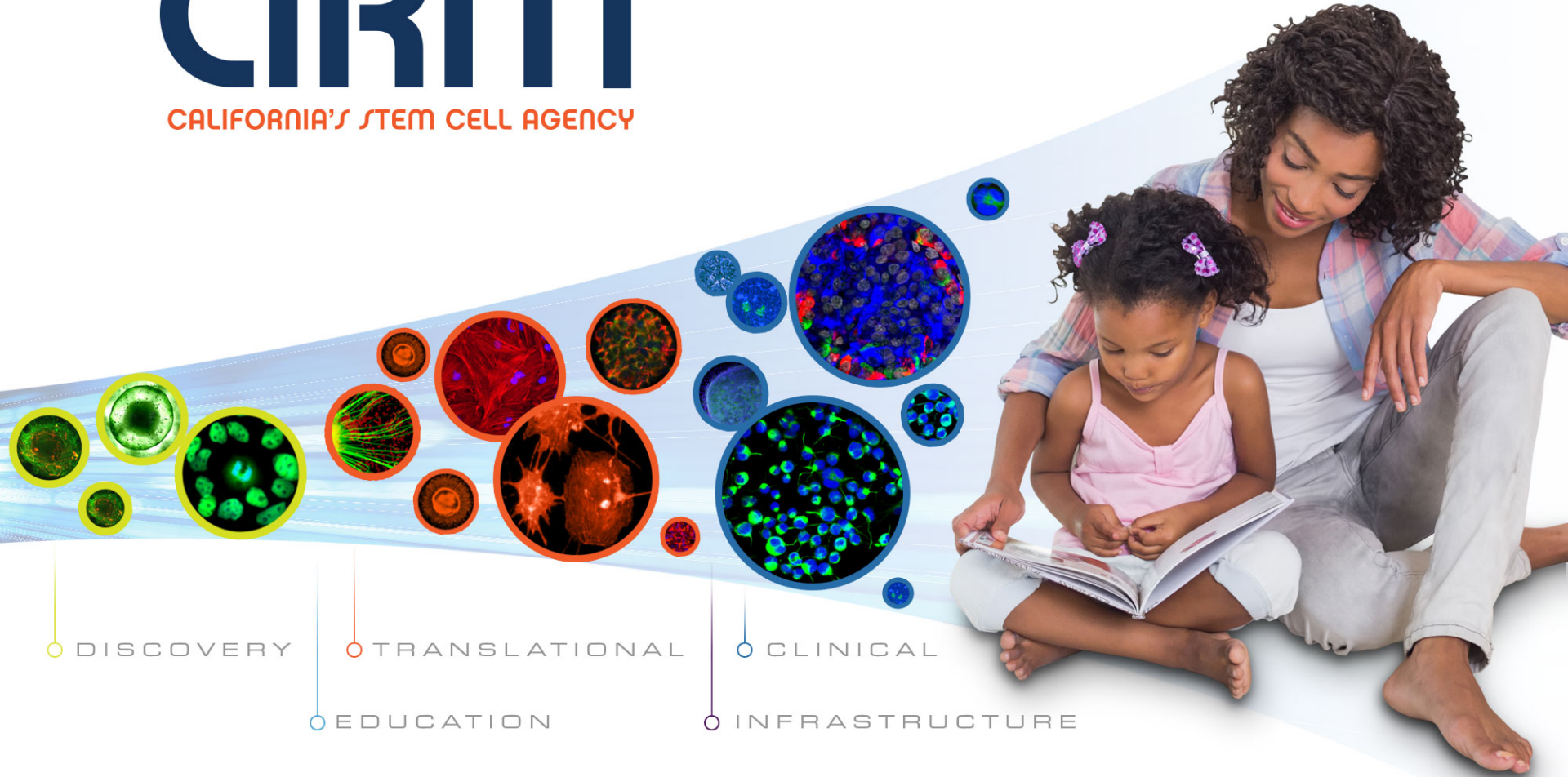


CIRM

CALIFORNIA'S STEM CELL AGENCY



○ DISCOVERY

○ TRANSLATIONAL

○ CLINICAL

○ EDUCATION

○ INFRASTRUCTURE

Translating Center GWG Review and Recommendations

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CIRM Infrastructure Programs

Program	Goal	Role
Translating Center	Shorten time to clinical testing	<ul style="list-style-type: none">• Process Development• IND-enabling activities
Accelerating Center	Accelerate clinical research	<ul style="list-style-type: none">• Regulatory Submissions• Trial management
Alpha Clinics Network	Conduct high quality clinical trials	<ul style="list-style-type: none">• Specialize in cell therapy clinical trials• Develop AVARs (Accelerating and Value Add Resources)

Translating Center



- CIRM funding for a Stem Cell focused Preclinical Research Organization
- Operating within California
- Up to \$15 million over five years

Translating Center Core Services

- Consultation Services
- Project Management
- Preclinical Development Research
- Process Development
- Product Manufacturing
- Regulatory Filing Support

Services will be proportional to the needs of the projects

Sustainability

- Through acquisition of unique insight and experience by supporting CIRM's projects, the TC will be positioned to develop specialized approaches and services for cell therapy trials
- The TC is expected to leverage these assets to create a sustainable platform for support of cell therapy development and stem cell clinical trials

GWG Review Criteria

- Does the proposed center hold the necessary significance and potential for impact?
- Has the applicant developed a plan designed to successfully establish and operationalize the center?
- Is the proposal feasible?

“Pitch”

- Applicant teams were invited to give a 15 minute presentation before the GWG to address vision, value proposition, and sustainability.
- GWG had opportunity to ask questions directly of the team members.

Scoring System

- Score of “85-100”

Exceptional merit and warrants funding, if funds are available.

Only the application with the highest average score will be recommended for funding.

- Score of “1-84”

Not recommended for funding.

Applications are scored by all scientific members of the GWG with no conflict.

Final Vote (2 parts)

1. *All members*: “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.”
2. *Patient advocate members*: “The review was carried out in a fair manner and was free from undue bias.”

All members voted unanimously in favor of 1 (20-0)

Patient Advocate GWG members voted unanimously in favor of 2 (5-0)

INFR2: GWG Recommendations

	Apps	Funds
Score 85-100 Exceptional merit and warrant funding, if funds available	1	\$15M
Score 1-84 Not recommended for funding	3	

INFR2-09298

SCORE	Median	SD	High	Low
89	90	5	95	75

CIRM Team Recommendation: Fund (concur with GWG recommendation)

Award Amount: \$15M

INFR2-09233

SCORE	Median	SD	High	Low
<60				

CIRM Team Recommendation: Do not fund (concur with GWG recommendation)