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Vice President, Portfolio Development and Review
Application and Review Overview
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Mission Statement



OUR MISSION

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world





Recurring Funding Opportunities Program Announcement (PA)

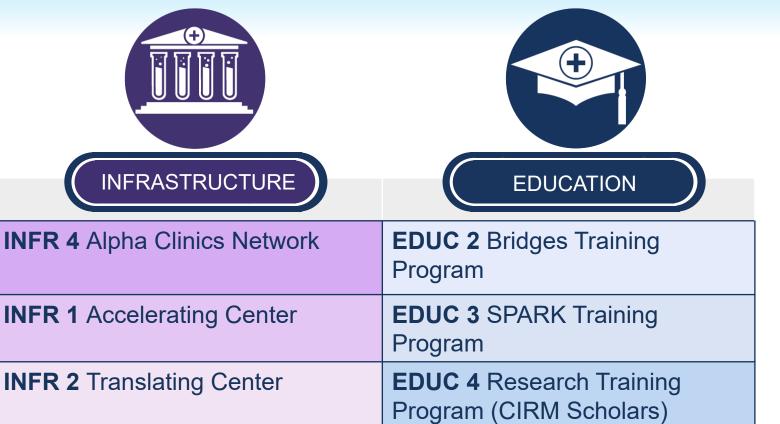


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DISCOVERY	TRANSLATION	CLINICAL
DISC 0 Fundamental biology research (1-2 cycles per year)	TRAN1 Therapeutic candidate development	CLIN1 IND-enabling studies (12 cycles per year)
	TRAN 2 Diagnostic candidate development	
DISC 2 Quest – Product candidate discovery research (2 cycles per year)	TRAN 3 Medical device candidate development	CLIN2 Clinical trial studies (12 cycles per year)
	TRAN 4 Tool candidate development	
	(2 cycles per year)	



Non-recurring Funding Opportunities Request for Applications (RFA)





EDUC 5 COMPASS Program



RFA or PA Describes Funding Opportunity





What is CIRM looking for and how do I partner with CIRM to achieve the mission?







Can the application be reviewed?

Is the application scientifically meritorious?

Should CIRM fund this project?









ELIGIBILITY: Can we accept the application?



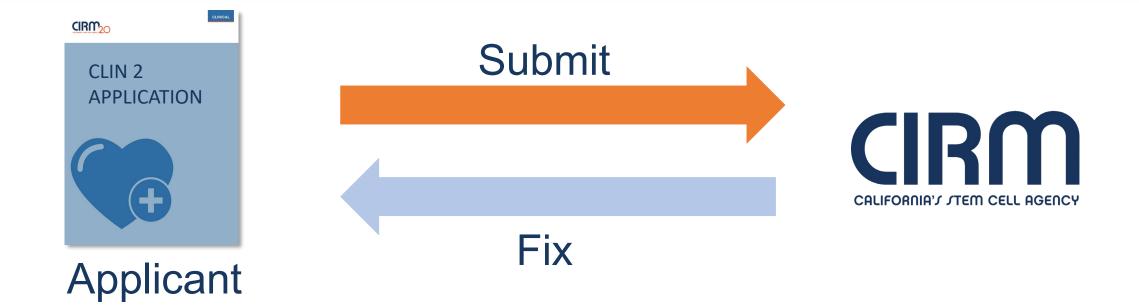
- ✓ Complete and accurate
- ✓ Solvency (if a company)
- ✓ Co-funding requirement
- ✓ Status as a California-based organization
- ✓ Is program in scope under CIRM rules





Application Will Not Advance Until Ready

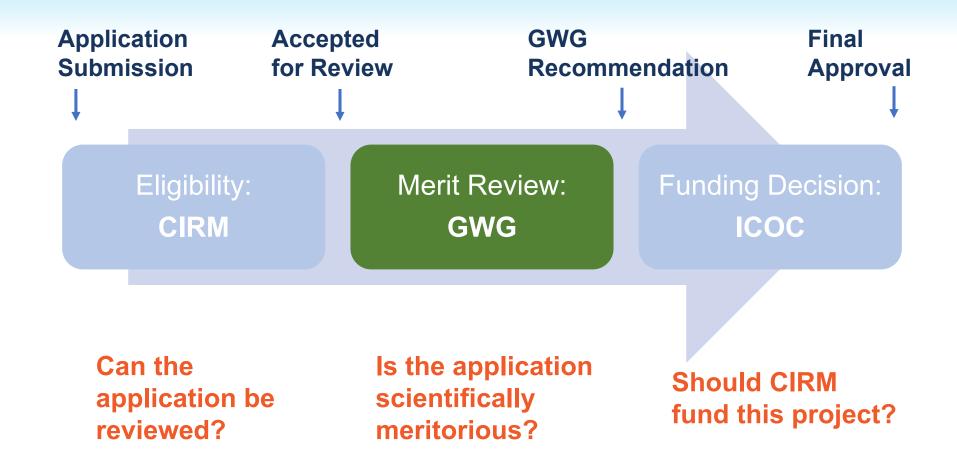














M CIRM Grants Working Group



- The CIRM Grants Working Group (GWG) is responsible for evaluating the scientific merit of all applications submitted to CIRM and to provide funding recommendations to the ICOC.
- The GWG must evaluate proposals across all five pillars of Discovery, Translation, Clinical, Education and Infrastructure.
- Expert GWG panels are assembled to meet the needs of each review type.



GWG Composition and Roles



GWG Scientists

15 Members



Scientific evaluation (disease area expert, regulatory, CMC, product development)

Provides scientific score on all applications

GWG Patient
Advocate or Nurse
7 Members



DEI evaluation, patient perspective on significance and potential impact, oversight on process

Provides DEI score on all applications

Provides a suggested scientific score

Scientific Specialist (non-voting)



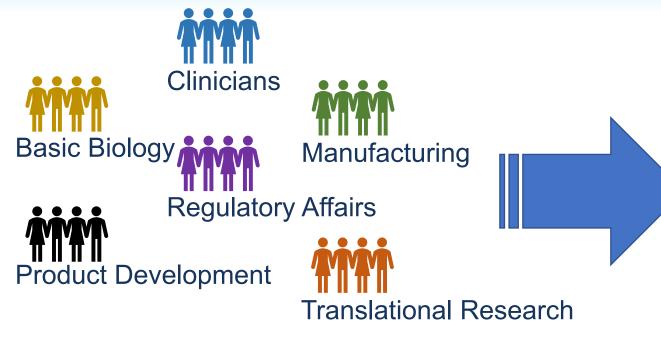
Scientific evaluation (specialized expertise as needed)

Provides initial but not final scientific score



CIRM draws from a large pool of experts to cover expertise needs











GWG Panels

15 scientific members that create a diverse panel with varied perspectives and relevant expertise for each review



250 to 300 members





GWG Scientific Scoring



Clinical

Scores:



Warrants funding



Needs improvement



Do not fund

Each application is assessed independently

A score of "2" allows applicants to respond to reviewer concerns and resubmit a corrected application without starting over.

Discovery & Translation

Scores:



Applications are ranked by score

Applicants with a score below 85 are encouraged to apply for the next cycle with guidance from CIRM on revisions.
Applicants with scores of 80-84 can bypass positive selection, if applicable.



DEI Scoring System for CLIN Board Members



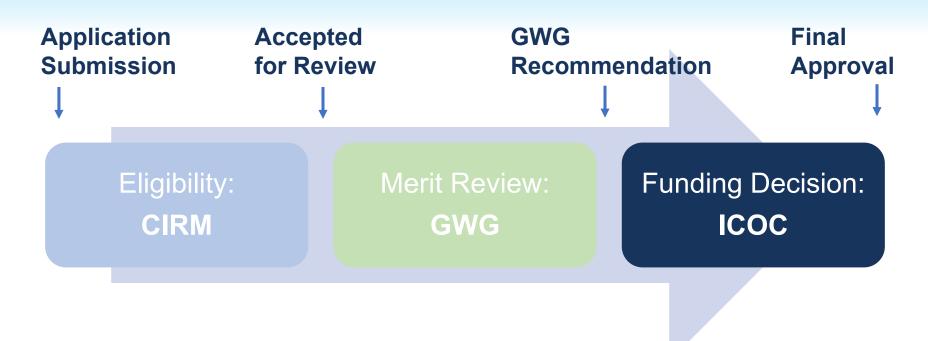
- Score of "0-2"
 Not Responsive
- Score of "3-5"
 Not Fully Responsive
- Score of "6-8"
 Responsive
- Score of "9-10"
 Outstanding Response

Use the DEI Rubric Table

Applications are scored on DEI by <u>all GWG Board Members</u> (patient advocates/nurses) with no conflict.







Can the application be reviewed?

Is the application scientifically meritorious?

Should CIRM fund this project?



Should CIRM fund the project?



- Application Review Subcommittee
- Occur monthly
- Presentation of GWG recommendations
- Includes scores and summary of key strengths/weakness.
- Conducts Programmatic Review
- Vote to fund or not to fund





Programmatic Considerations



- Scientific score and overall ranking of applications
- Alignment with CIRM mission and objectives of opportunity
- Potential impact of project to patients
- CIRM portfolio of projects
- DEI score
- Availability of funds





Article on CIRM Funding Process: April 2020



Forum

Translating Science into the Clinic: The Role of Funding Agencies

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https://doi.org/10.1016/j.stem.2020.03.010

CIRM has created a unique funding process and structure aimed to make a meaningful impact on translating science into the clinic. By sharing some of the lessons learned by CIRM, we hope to provide insights into concrete improvements that have made a difference in our efforts.