

Real Life™

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Vice President Portfolio Development and Review
GWG Recommendations on Shared Resources
Labs

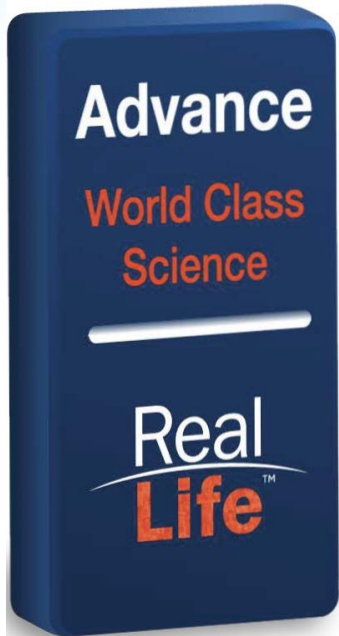
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CIRM
CALIFORNIA'S STEM CELL AGENCY

OUR MISSION

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





- **Develop Competency Hubs**
- **Build Knowledge Networks**



- Advance therapies to marketing approval
- Create a manufacturing partnership network
- Expand Alpha Clinics Network
- Create Community Care Centers of Excellence



- **Build a diverse and highly skilled workforce**
- **Deliver a roadmap for access and affordability**

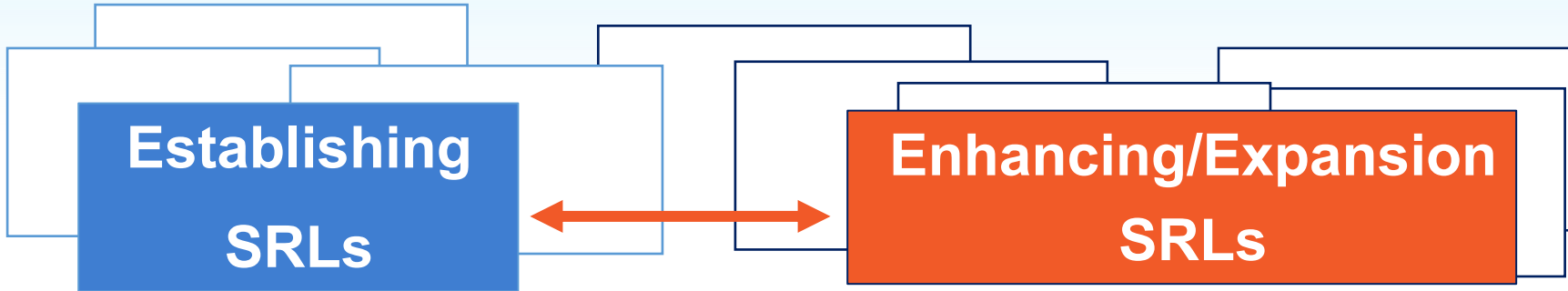
- **Provide researchers, locally and regionally, access to:**
 - Cell culture facility to conduct stem cell-based modeling experiments
 - Highly specialized technologies
- **Provide researchers, locally and across California, access to:**
 - Well characterized unmodified and modified hPSC collections
 - Partially or fully differentiated stem cell-based models
 - Training of researchers
- **Provide educators, regionally and/or across California, access to:**
 - Formal techniques courses for student education
 - Other student experiences with stem cell-based modeling
- **Implement sustainability plans:**
 - Fee for service, recharge
 - Alternative funding sources

RFA INFR6.1

RFA INFR6.2

	Establishing SRLs	Enhancing/Expansion SRLs
Target Institution	Geographic areas where access to models is limited*	With cutting-edge stem cell-based modeling expertise
Renovate & Equip	<ul style="list-style-type: none"> • Renovate core space • Acquisition of major equipment 	<ul style="list-style-type: none"> • Acquisition of major equipment
Operations	<ul style="list-style-type: none"> • Provide access to core facility, specialized services and equipment • Share models/expertise and resources for research broadly • Train researchers • Provide educational resources / activities <ul style="list-style-type: none"> ○ Formal techniques course optional with extra funds 	

*or propose remote, cloud-based approaches to serve researchers and/or educational programs in geographic areas with limited access to stem cell-based models



- **Access** to models across CA
- **Advance** standards and reproducibility
- **Access** to educational opportunities
- **Develop** sustainable SC core infrastructure

	Establishing SRLs 6.1	Enhancing/Expansion SRLs 6.2
Award amount	\$4.4 M (\$5.4 M w/ course)	\$3.0 M (\$4.3 M w/course)
Applicant	In geographic areas where access to models is limited	With cutting-edge stem cell-based modeling expertise
Funding	Build (renovate)	Equip + Operations
	Equip + Operations	
Co-funding	Not Required	Required (20% of operational costs)

Program Budget

\$50M Total:

Build & Equip - \$26 M

Operations - \$24 M

Establishing SRLs (INFR 6.1)

Phase A – 18 months

- SRL renovated, equipped, staffed and operational
- Stem cell-based models established – demonstrated through pilot project(s)
- Established training and educational programs

Phase B – 24 months

- Utilization rate of core facility by researchers
- Sustained enrollment in researcher training and educational programs
- Success rate of projects utilizing the core (data generated, publications, leveraged funding)
- Deliver plan for operations at 50% CIRM funding

Phase C – 18 months *(50% CIRM operational funds)*

- All success metrics from Phase B
- Deliver plan for independent operations at 9 months
- Contribution to SRL Network functions *

Enhancing/Expansion SRLs (INFR 6.2)

Phase A – 6 months

- SRL equipped, staffed and operational
- Stem cell-based models established – demonstrated through pilot project(s)
- Established training and educational programs

Phase B – 30 months

- Utilization rate of core facility by researchers
- Sustained enrollment in researcher training and educational programs
- Level of broad sharing of models across California
- Success rate of projects utilizing the core and shared models (data generated, publications, leveraged funding)
- Deliver plan for operations at 50% CIRM funding

Phase C – 24 months (50% CIRM operational funds)

- All success metrics from Phase B
- Deliver plan for independent operations at 12 months
- Contribution to SRL Network functions

SRL Proposals Must Include Plans to Address DEI

- SRL core users / CA-wide recipients of models & expertise represent diverse goals, approaches, perspectives and backgrounds
- Participation in educational programs by underserved populations
- SRL team represents diverse and inclusive perspectives and experiences
- Ancestral and sex diversity of stem cell lines offered in core

Must include a knowledge sharing plan

Describe plans to establish processes and systems for

- Sharing models, best practices, knowledge, and other resources
- Standardizing cell lines, reagents, and quality control/validation

Must include a data sharing and management plan

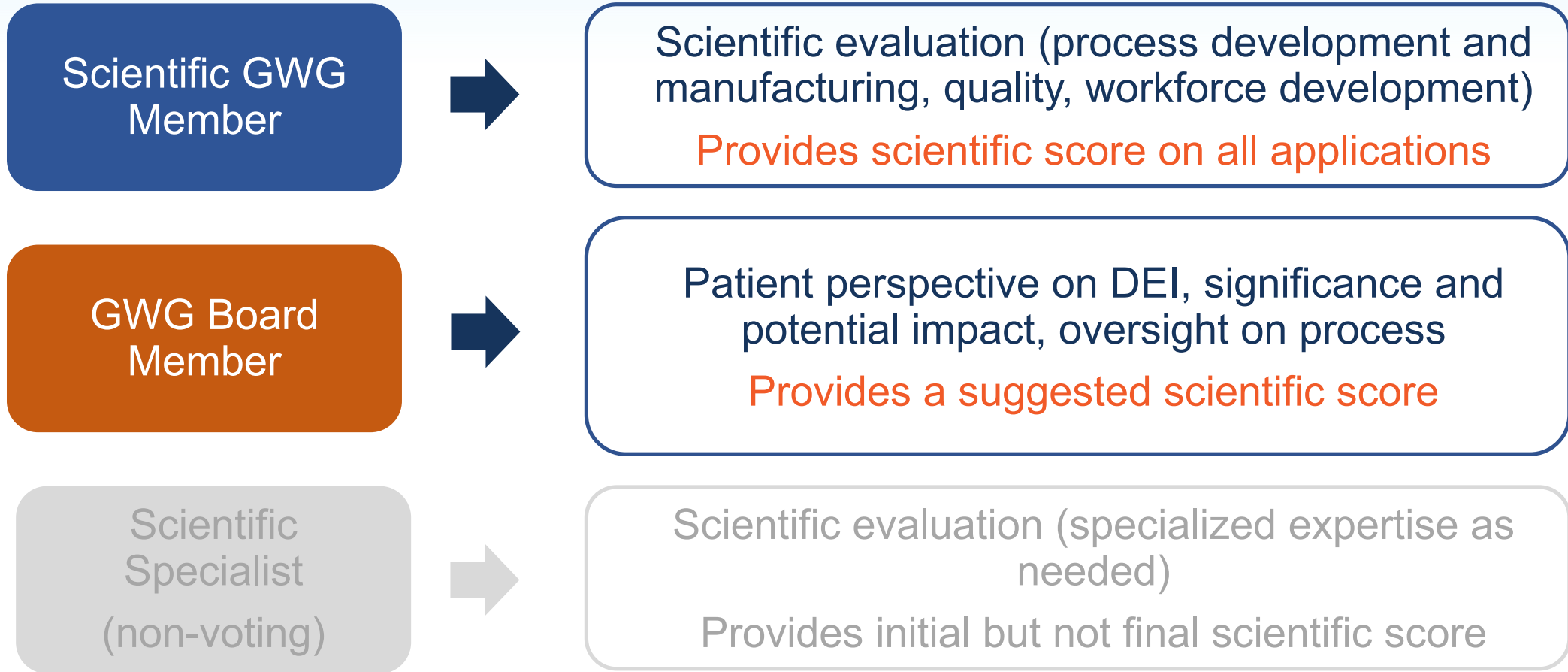
Describe approach to sharing and management of data generated as part of SRL operations

CIRM will coordinate Steering Committee of awardees & external stakeholders to facilitate:

- Development of processes and systems for sharing network-wide offerings, best practices, knowledge, and resources
- Implementation of quality standards, materials and cell lines across the network
- Development of collaborative approaches toward improving reproducibility of stem cell-based models

Working Group Reviews

INFR 6.1	Number of Apps Reviewed	Requires GWG Review	Requires FWG Review
INFR 6.1 (Establishing)	6	YES	YES
INFR 6.2 (Expanding/Enhancing)	14	YES	NO
TOTAL	20		



- **Score of “1”**

Exceptional merit and warrants funding.

May have minor recommendations and adjustments that do not require further review by the GWG

- **Score of “2”**

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.

GWG should provide recommendations that are achievable (i.e., “fixable changes”) or request clarification/information on key concerns.

- **Score of “3”**

Sufficiently flawed that it does not warrant funding.

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

Scientific Review Criteria

Basis for Scientific Score

1. Does the project offer a significant value proposition?
2. Is the project well planned and designed?
3. Is the proposal feasible?
4. If proposed, is the Stem Cell Techniques Course well designed?
5. Does the project uphold the principles of diversity, equity, and inclusion?

Real Estate
Experts



Scientific evaluation (process development and manufacturing, quality, workforce development)

Provides a score on all applications

Board Members



Patient perspective on significance and potential impact, oversight on process

Provides a score on all applications

- **Score of “1”**

Exceptional merit and warrants funding.

May have minor recommendations and adjustments that do not require further review by the FWG

- **Score of “2”**

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 Facilities Working Group's review.

FWG should provide recommendations that are achievable (i.e., “fixable changes”) or request clarification/information on key concerns.

- **Score of “3”**

Sufficiently flawed that it does not warrant funding.

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

Facilities Review Criteria

Basis for Facilities Score

1. Does the proposed renovation/facilities improvement project support the applicant's proposed SRL core research and educational activities?
2. Are the SRL renovations/facility improvements feasible as proposed?
3. Does the proposed SRL facility include the appropriate research equipment and laboratory configuration in support of the proposed SRL activities?
4. Are the renovation/facility improvement costs appropriate?
5. Does the applicant ensure diversity, equity and inclusion goals for design and construction?

Recommendations

INFR 6.1	GWG Evaluation	FWG Evaluation	Number of Apps	CIRM Recommendation
	Warrants funding	Warrants funding	1	Fund
	Warrants funding	Needs improvement	2	Revise facilities
	Needs improvement	Warrants funding	3	
	Does not warrant funding		0	
INFR 6.2	GWG Evaluation	FWG Evaluation	Number of Apps	CIRM Recommendation
	Warrants funding	N/A	4	Fund
	Needs improvement	N/A	6	
	Does not warrant funding	N/A	4	Do not fund

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

INFR 6.1 Applications with a FWG Score of “2” and GWG Score of “1”

App Number	Title	Funds Requested	FWG Score	1	2	3
INFR6.1-15363	Stem cell-based Partnership Resource for Investigating Human Diseases and Training (SPRINT)	\$5,055,863	2	0	8	0
INFR6.1-15366	Shared Research and Training Facility for Bio-Fabrication of Organs for Regenerative Medicine (Bio-FORM) in Underserved Areas	\$5,400,000	2	0	8	1

The CIRM Team recommends that the 2 applications with a score of “2” from the FWG (and GWG score of “1”) be given the opportunity to revise and resubmit their application and allow the FWG to evaluate the revisions.

Recommendations

INFR 6.1	GWG Evaluation	FWG Evaluation	Number of Apps	CIRM Recommendation
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	Needs improvement	Warrants funding	3	
	Does not warrant funding		0	
INFR 6.2	GWG Evaluation	FWG Evaluation	Number of Apps	CIRM Recommendation
	Warrants funding	N/A	4	Fund
	Needs improvement	N/A	6	
	Does not warrant funding	N/A	4	Do not fund

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

App Number	Title	Funds Requested	GWG Score	1	2	3
INFR6.2-15440	Shared Resource Laboratory for Stem Cell-Based Modeling: Resources for Exploring the Biological Underpinnings of Aging and Age-Associated Pathologies	\$3,759,999	2	4	9	1
INFR6.2-15457	Shared Resources Laboratory for Stem Cell-Based Modeling in Stem Cell Biology and Engineering	\$3,999,995	2	0	15	0

The CIRM Team recommends that 2 applications shown above, out of the total 9 applications receiving a score of “2” from the GWG be funded. Remaining budget would allow only 2 applications from this group to be funded.