

Uta Grieshammer, Ph.D. Shared Resources Laboratories for Stem Cell-Based Modeling ICOC - Concept Plan Presentation October 27, 2022





OUR MISSION

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



CIRMO 5-Year Strategic Summary



Develop Competency HubsBuild 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

Real

Life



Stem Cell-Based Modeling - Historical Perspective



CIRM Stem Cell-Based Modeling – **Opportunities & Needs**

Opportunities

- Scientific strength, innovation and expertise in stem cell-based modeling in California
- Leveraging Prop71 Shared Labs as core labs and providers of training and courses

Needs

- Obtain access to stem cell-based models broadly across California
- Support experienced labs in providing access to stem cell-based models and partnering
- Training and education in stem cell-based modeling
- Overcome scientific challenges in stem cell-based modeling field:
 - Limited reproducibility of findings
 - Uncertainty about predictive value for human biology and disease

CIRM Shared Resources Labs – Proposed **Functions**

• 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

CIRM Shared Resources Labs – Proposed **Types**

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 &	Renovate core space				
Equip	Acquisition of major equipment	Acquisition of major equipment			
	 Provide access to core facility, 	specialized services and equipment			
Operations	 Share models/expertise and resources for research broadly 				
	Train researchers				
	 Provide educational resources / activities 				
	 Formal techniques course optional with extra funds 				

CIRM Shared Resources Labs – **Network**



CIRM Funding Research Institutions to Build an SRL Network

	Establishing SRLs	Enhancing/Expansion SRLs				
Award amount (with/without techniques course)	\$5.4 M / \$4.4 M	\$4.3 M / \$3.0 M				
Award Duration	5 years	5 years				
Applicant	In geographic areas where access to models is limited	With cutting-edge stem cell-based modeling expertise				
Main Goal	Establish new resource & expertise, novel impact in local scientific community	Share existing expertise locally & across California				
Funding	Build (renovate)	Equip + Operations				
Funding	Equip + Operations					
Co-funding	Not Required	Required (20% on operational costs)				
Program Budget: \$50 M Anticipated Number of Awards						

Program Budget:	<u>\$50 M</u>	Anticipated Number of Awards		
Build & Equip:	\$26 M	Establishing SRLs:	4	
Operational:	\$24 M	Enhancing/Expansion SRLs:	10	

CIRMON Proposed Award Phasing & Outcome Metrics

Establishing SRLs

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 *

CIRMO Proposed Award Phasing & Outcome Metrics

Enhancing/Expansion SRLs

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*

*see slide 15

CIRC Shared Resources Labs - **Eligibility and Prop 14 Stipulations**

Project Eligibility

 Modeling expertise offered in SRLs - Limited to in vitro models using human stem or progenitor cells

Institution Eligibility

- California non-profit research institutions
- 1 application per institution

PD Eligibility

• Program Directors must commit at least 20% effort

Prop 14 Stipulations

- Operational in 5 years following effective date of initiative
- Prioritize applications that **enhance geographic distribution**
- Prioritize applications that offer matching funds

CIRC Shared Resource Labs - **Diversity**, **Equity**, **Inclusion**

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

CIRM Knowledge & Data Sharing

Must Include 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 Data Sharing and Management Plan

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

CIRM Steering Committee Drives Network Functions

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



Program Budget

• \$50M Total. Build & Equip - \$26 M; Operations - \$24 M

Awards

- Award Caps: E-SRL \$5.4 M / \$ 4.4 M; E/E-SRL \$4.3 M / \$3.0 M
- Allowable costs: Build (E-SRL only), Direct Project Costs, Facilities Costs, Indirect Costs
- Co-Funding: E/E-SRL, 20% on operational costs

Who can apply?

California non-profit research institutions

