

# Real Life™

Uta Grieshammer, Ph.D.

Shared Resources Laboratories for Stem Cell-Based Modeling

ICOC Science Subcommittee - Concept Plan Presentation

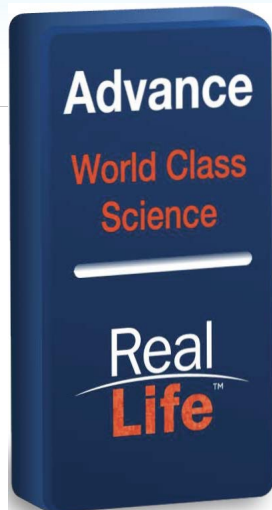
October 14, 2022

**CIRM**  
CALIFORNIA 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

# Stem Cell-Based Modeling - Historical Perspective

**Free from federal limits**

- Dedicated research space
- Specialized instrumentation
- hESC lines, cell culture materials
- Training

2001  
Federal funding for hESC research allowed but restricted to existing lines

2004  
Proposition 71 passes in CA

2007  
CIRM Shared Labs awards start

2009  
Federal limits on hESC research lifted

2016  
CIRM Shared Labs awards end

2020  
Proposition 14 passes in CA

If concept is approved:  
2023/2024  
CIRM Shared Resources Labs awards start

2000

2005

2010

2015

2020

2025

1998  
human embryonic stem cells (hESC)

2007  
human induced pluripotent stem cells (hiPSC)

2012  
CRISPR-Cas9 - genome editing tool

Differentiation protocols  
Disease models

## 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

## 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

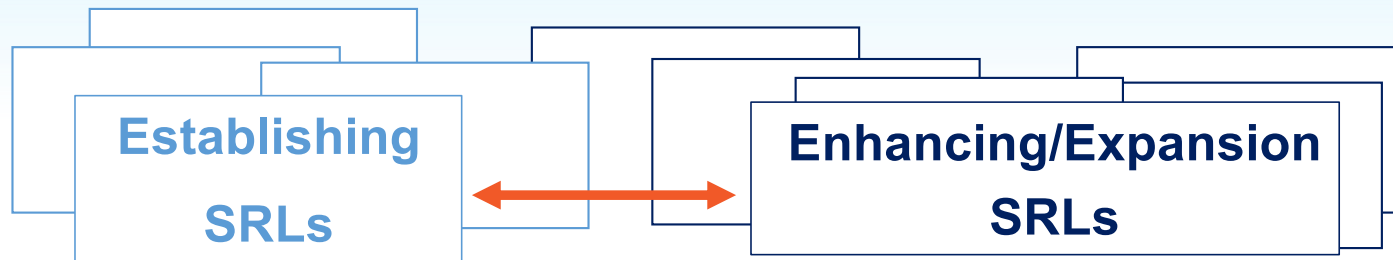
# Shared Resources Labs – Proposed Types

## RFA INFR6.1

## RFA INFR6.2

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

# Shared Resources Labs – Network



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



# CIRM Funding Research Institutions to Build an SRL Network

CALIFORNIA'S STEM CELL AGENCY

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

<b>Program Budget:</b>	<b>\$50 M</b>
Build & Equip:	\$26 M
Operational:	\$24 M

## 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 \*

## 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



## 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**

## 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 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 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



# Real

Life™

CIRM  
CALIFORNIA STEM CELL AGENCY