

# DISCO Foundation Awards Webinar

**Rosa Canet-Avilés, PhD**

Vice President, Scientific Programs

October 10, 2022



## Part 1: DISCO Overview

1:00 - 1:40 PM

- CIRM Mission, Strategic Plan and Pillars of Funding
- DISCO Foundation Awards
  - Scope and Activities
  - Eligibility Requirements
  - Review Criteria and Process
  - Application Components
  - Common Questions and Mistakes

## Part 2: Q&A

1:40 - 2:00 PM

## OUR MISSION

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



## 2006-2020 (Proposition 71)

- **Five Pillars of Investment**

## 2021 and Beyond (Proposition 14)

- Through CIRM's New Strategic Plan we will **enhance, organize and interconnect** CIRM's proven funding model to achieve the overarching goals.



# Research and Development Pillars



**DISCOVERY**



**TRANSLATION**



**CLINICAL**

**DISC0**  
FOUNDATION  
AWARDS

**DISC2**  
QUEST  
AWARDS

# DISC0: FOUNDATION AWARDS

# DISC Programs: **Expected Outcome and Support**



Outcome	Funding	Duration	Progression
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**DISC0  
FOUNDATION  
AWARDS**

Basic Research	\$1,000,000 (Direct Costs)	36 Months	DISC2 or N/A
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**DISC2  
QUEST AWARDS**

Therapeutic Candidate	\$1,500,000 (Direct Costs)	36 Months	TRAN1
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Technology Candidate	\$500,000 (Direct Costs)	24 Months	TRAN2/3/4 or other
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## What is the **goal** of DISC0?

Address **basic knowledge gaps** in the biology of stem cells and regenerative medicine approaches **relevant to human biology and disease** and to advance stem cell-based tools

- Advance our *understanding of the biology* of “stem cells”
- Advance the *application of genetic research* as it pertains to stem cells or regenerative medicine
- Advance the *development or use of human stem cells as tools* for *biomedical innovation*
- Lead to the *greater applicability of regenerative medicine discoveries* to communities representing the full spectrum of diversity

# IN SCOPE ACTIVITIES

## What **activities** will CIRM fund?

DISC0 supports **exploratory, mechanistic** and/or other **basic research** approaches that will culminate in discoveries that:

- Are grounded in **human biology** and/or **disease pathology**
- Can provide a rigorous foundation for new avenues of investigation, and/or future translational and clinical development work

CIRM **encourages** the submission of proposals focused on increasing our **understanding of the fundamental biology of CNS disorders**



➤ Basic research into **stem cell mechanisms** as they relate to human biology

➤ **Investigating stem cells or their derivatives as tools** for discovering and/or enabling therapeutic or other innovations, for example:

- **Investigating disease mechanisms**
- **Developing human disease models**

➤ **Reverse translation** studies related to stem cell- or gene therapy-based regenerative medicine therapies



Basic **genetic research** relevant to human biology and as it **pertains to stem cells or regenerative medicine**

Basic research or tool discovery to address **bottlenecks in the development of stem cell-based and gene therapies**

Research or tools related to **diversity, equity and inclusion in science**, for example:

- Use of hiPSCs and/or omics **analyses from diverse populations**
- Studying diseases or **disease subtypes more frequently experienced by underserved groups**



➤ Study **primary human cells** and **tissues** as **ground truth** for in vitro SC models or to improve regenerative medicine approaches

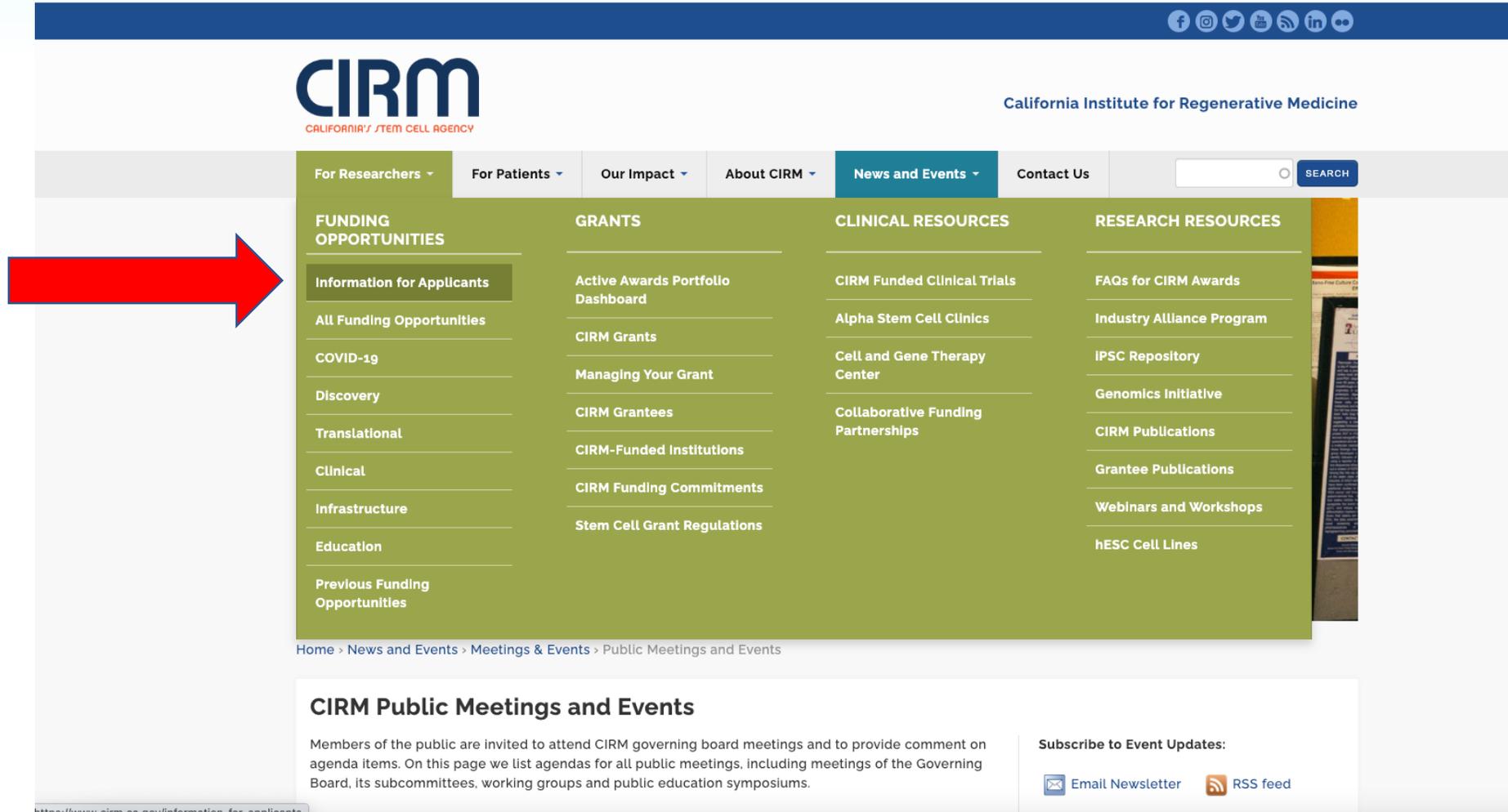
➤ **Auxiliary research activities that support regenerative medicine science, for example:**

- **Target/biomarker discovery & validation**
- Tools for **genome and epigenome editing** or imaging

**Note:** Human stem cell/regenerative medicine component must be included in the project

# RESOURCES for APPLICANTS

# CIRM's Existing and Sharable Tools for Disease Research & Drug Discovery



The screenshot displays the CIRM website's navigation menu. A red arrow points to the 'Information for Applicants' link under the 'FUNDING OPPORTUNITIES' section. The website header includes the CIRM logo, the text 'California Institute for Regenerative Medicine', and a navigation bar with links for 'For Researchers', 'For Patients', 'Our Impact', 'About CIRM', 'News and Events', and 'Contact Us'. A search bar is also present. The main content area is divided into four columns: 'FUNDING OPPORTUNITIES', 'GRANTS', 'CLINICAL RESOURCES', and 'RESEARCH RESOURCES'. The 'Information for Applicants' link is highlighted in the first column. Below the menu, a breadcrumb trail reads 'Home > News and Events > Meetings & Events > Public Meetings and Events'. The main heading is 'CIRM Public Meetings and Events', followed by a paragraph: 'Members of the public are invited to attend CIRM governing board meetings and to provide comment on agenda items. On this page we list agendas for all public meetings, including meetings of the Governing Board, its subcommittees, working groups and public education symposiums.' To the right, there is a 'Subscribe to Event Updates:' section with links for 'Email Newsletter' and 'RSS feed'.

**CIRM**  
CALIFORNIA'S STEM CELL AGENCY

California Institute for Regenerative Medicine

For Researchers ▾ For Patients ▾ Our Impact ▾ About CIRM ▾ **News and Events ▾** Contact Us

SEARCH

**FUNDING OPPORTUNITIES**

- Information for Applicants**
- All Funding Opportunities
- COVID-19
- Discovery
- Translational
- Clinical
- Infrastructure
- Education
- Previous Funding Opportunities

**GRANTS**

- Active Awards Portfolio Dashboard
- CIRM Grants
- Managing Your Grant
- CIRM Grantees
- CIRM-Funded Institutions
- CIRM Funding Commitments
- Stem Cell Grant Regulations

**CLINICAL RESOURCES**

- CIRM Funded Clinical Trials
- Alpha Stem Cell Clinics
- Cell and Gene Therapy Center
- Collaborative Funding Partnerships

**RESEARCH RESOURCES**

- FAQs for CIRM Awards
- Industry Alliance Program
- IPSC Repository
- Genomics Initiative
- CIRM Publications
- Grantee Publications
- Webinars and Workshops
- hESC Cell Lines

Home > News and Events > Meetings & Events > Public Meetings and Events

## CIRM Public Meetings and Events

Members of the public are invited to attend CIRM governing board meetings and to provide comment on agenda items. On this page we list agendas for all public meetings, including meetings of the Governing Board, its subcommittees, working groups and public education symposiums.

**Subscribe to Event Updates:**

- Email Newsletter
- RSS feed

<https://www.cirm.ca.gov/information-for-applicants>

## Information for Applicants

CIRM has compiled the following resources to support you and your institution in the application process. Please be sure to read all relevant guidelines and requirements before submitting your application.

### Data Sharing and Management

As articulated in CIRM's 2022-2027 strategic plan, CIRM is committed to building infrastructure that organizes and democratizes data through knowledge networks that foster a culture of open science and advance novel, discovery, translational and clinical research approaches. The CIRM knowledge networks will facilitate effective management, standardization, sharing and collaborative analysis of CIRM-funded research data.

As an important step toward realizing this goal, CIRM requires that data generated using CIRM funds is shared using FAIR principles. Please consult the **Data Sharing and Management Plan (DSMP)** Guidelines for CIRM data sharing requirements and guidance on how to prepare a DSMP for a CIRM application.

- [Data Sharing and Management Plan - Guidelines](#)
- [Data Repositories Guidance](#)

### Clinically Compatible hPSC lines for Therapeutic Development and Commercialization

Any applicant who intends to develop an allogeneic human pluripotent stem cell (hPSC)-derived therapeutic with CIRM funding must establish evidence of disease/injury modifying activity using a **clinically compatible** cell source that can be translated for clinical use. An applicant should plan to select a clinically compatible hPSC line to establish this data during the course of a DISC2 award or must have already established this data if applying for TRAN1 or CLIN1.

- [Download the CIRM Guide on Clinically Compatible Human Pluripotent Stem Cell Lines](#)

DSMP



PSC resource



## hiPSC repository (2600 lines)

- Repository managed by FUJIFILM Cellular Dynamics
- Diverse ancestries including African, Admixed American (i.e. Hispanic, Native American), East & South Asian, European
- Standardized consents, iPSC derivation and QC testing
- Pre-negotiated license agreement available for commercial use
- Available Soon: SNP genotyping data on almost entire collection and WGS on 300+ lines





CALIFORNIA'S STEM CELL AGENCY

**CIRM Human Induced Pluripotent Stem Cell Repository**

6 Diseases Classes, 17 Diagnoses  
Matched Controls for All Diseases

- Age-Related Macular Degeneration
- Alzheimer's Disease
- Autism Spectrum Disorder
- Cardiomyopathies
- Cerebral Palsy
- Diabetic Retinopathy
- Epilepsy
- Fatty Liver Diseases
- Hepatitis C
- Intellectual Disabilities
- Major Depressive Disorder
- Movement Disorders (ADCY5)
- Optic Nerve Hypoplasia
- Phelan-McDermid Syndrome
- Primary Open Angle Glaucoma
- Pulmonary Fibrosis

[BROWSE NOW](#)

# ELIGIBILITY REQUIREMENTS

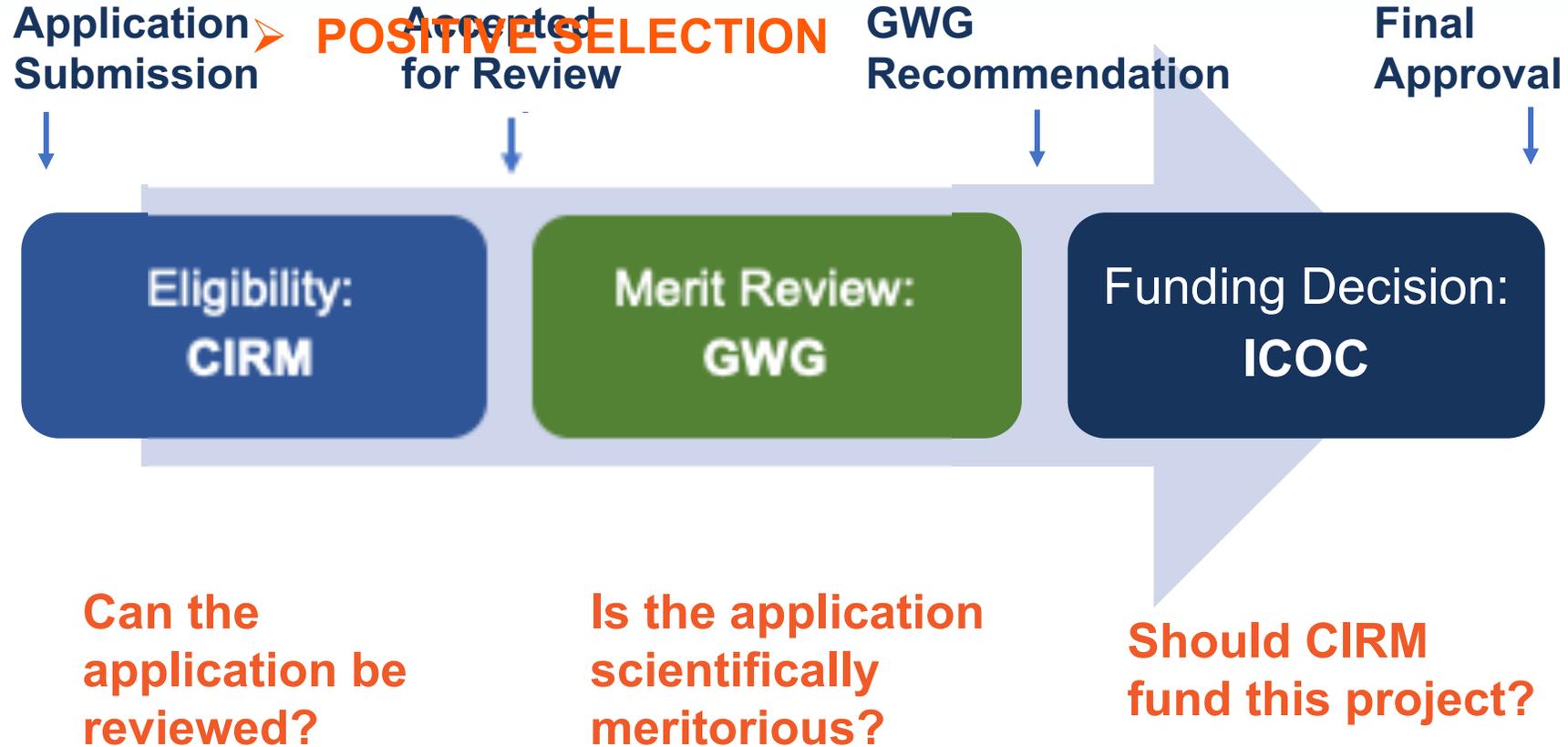
# Who and What is **eligible**?

- Only **CA institutions**
- PI – **At least 20%**
- PI **no other application pending review or approval** under this funding opportunity/ substantially similar **or overlapping** activities pending review or approval under **any** opportunity.
- Start **within 90 days** from ICOC approval
- Projects generating **omics** data – **Dedicated PM**
- **For-profit** applicants must demonstrate **solvency**

# REVIEW CRITERIA and PROCESS

# Application Review Process

When application volume exceeds GWG capacity



## Review Process for **High Volume\* Programs**

- **Stage 1: “Positive Selection”**- **GWG members** conduct a pre-review of all applications to identify subset that they believe are most impactful and responsive
- **Stage 2 : Applications selected** by any given GWG member in Stage 1 move to, Stage 2, the CIRM Standard Review Process
- **Unselected Applications:** do not advance to Stage 2 nor receive critiques, but may consider reapplying

1. Does the project hold the necessary **significance and potential for impact**?
2. Is the **rationale sound**?
3. Is the project **well planned and designed**?
4. Is the project **feasible**?
5. Does the project **uphold the principles of diversity, equity and inclusion (DEI)**?

# Application COMPONENTS and CONSIDERATIONS (I)

## 1. **Online** section

- a. **Basic** application **details**
- b. **Positive Selection** Preview Page

## 2. **Uploaded** attachments

- a. **Required** - *must use provided template*
  - a. *Proposal*
  - b. *DSMP*
  - c. *Other Support*
  - d. *Biological Sketches*
  - e. *Financial Feasibility and Solvency (For Profit Only)*
- b. **Optional**
  - a. *Letters of Support*
  - b. *IP Licenses and MTA*

Online Sections

Attachments, Templates

Home / Open Programs / Grant App DISCO-14320

## DISCO-14320

<a href="#">Instructions</a>	
<a href="#">Print View</a>	
<b>Eligibility</b>	
<a href="#">Eligibility</a>	Incomplete
<b>Personnel</b>	
<a href="#">PI and AOO</a>	Incomplete
<a href="#">Key Personnel</a>	Incomp (1)
<a href="#">Partners</a>	0 Entries
<a href="#">Review Exclusions</a>	0 Entries
<b>Project</b>	
<a href="#">Title &amp; Duration</a>	Incomplete
<a href="#">Positive Selection Preview</a>	Incomplete
<a href="#">Information for Review</a>	Incomplete
<a href="#">Keywords</a>	Incomplete
<a href="#">Public Information</a>	Incomplete
<b>Funding</b>	
<a href="#">Consultants / Subcontracts / Service Contracts</a>	Empty
<a href="#">Co-funders</a>	Empty
<a href="#">CIRM Funds Calculator</a>	Incomplete
<a href="#">Budget Justification</a>	Incomplete
<b>Certifications</b>	
<a href="#">Institutional Approvals and Oversight</a>	Incomplete
<b>Uploads</b>	
<a href="#">Document Uploads</a>	Incomplete

### DISC 0: CIRM Foundation - Discovery Stage Research Projects

The mission of the California Institute for Regenerative Medicine (CIRM) is to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

The objective of the DISCO Foundation Awards is to support rigorous studies addressing critical basic knowledge gaps in the biology of stem cells and regenerative medicine approaches and to advance stem cell-based tools. Projects funded through the Foundation Awards should propose impactful or innovative research that culminates in a discovery or technology that would:

- Advance our understanding of the biology of stem or progenitor cells (collectively, "stem cells") that is relevant to human biology and disease; or
- Advance the application of genetic research that is relevant to human biology and disease and pertains to stem cells and regenerative medicine; or
- Advance the development or use of human stem cells as tools for biomedical innovation; or
- Lead to the greater applicability of regenerative medicine discoveries to communities representing the full spectrum of diversity.

Please read through the Program Announcement [Discovery Stage Research Funding Opportunity for Foundation Awards](#) carefully to ensure that you understand all the requirements for this opportunity before completing the application. CIRM awards approved under this partnering opportunity are also subject to the [Grants Administration Policy for Discovery, Translation, and Education Programs](#), the [Intellectual Property and Revenue Sharing Requirements](#) as well as additional regulations that can be found [here](#). CIRM awards will be executed under the following template [Notice of Award](#)

To start the application process, you must first complete the Eligibility section, which will take you through each of the specific requirements and certify that you meet the requirements to apply. Once you have completed this section, you may then complete other parts of the application.

The application includes all the sections shown on the left navigation bar and the items required in the upload section.

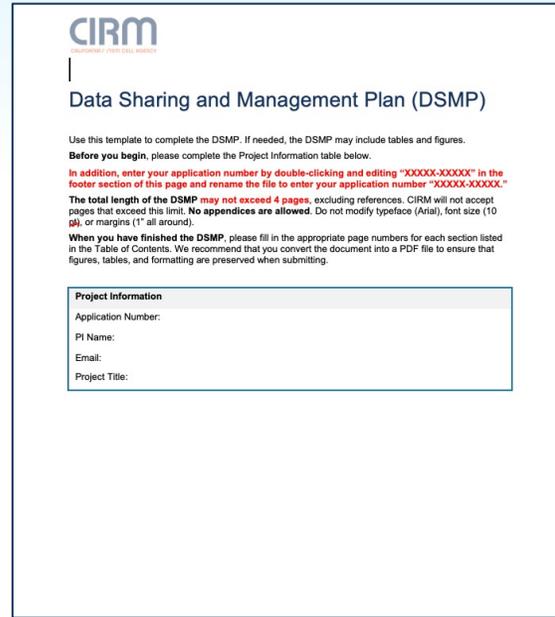
CIRM anticipates that the number of applications submitted will be very high for this competition. When the number of applications received in a cycle is significantly in excess of the number that can be reviewed by the Grants Working Group (GWG) panel, the GWG members conduct the review in two stages. In the first stage, CIRM and the GWG conduct a pre-review of applications (called "Positive Selection") to identify applications that are most responsive to the funding opportunity and hold the most potential for impact. Positively selected applications advance to the full GWG review; the remainder are not considered further. When conducting the first stage of review, CIRM and the GWG have access to the full application including the uploaded components (e.g., the proposal), but may focus on the Positive Selection Preview section of the application as it is designed to capture responsiveness and potential impact. Applicants are advised to address this section thoroughly and carefully, as it may determine whether an application proceeds to full review. Only applications that are complete and meet the eligibility criteria as set forth in DISC 0 will be accepted by CIRM.

<b>Applications Due</b>	Applications must be fully submitted by 2:00 pm (PDT/PST) on Tuesday, Nov 8, 2022.
<b>Grants Working Group (GWG) Review</b>	Approximately 90 days post submission
<b>ICOC Review and Approval</b>	Approximately 120 days post submission
<b>Award Start</b>	Must start within 90 days of award approval

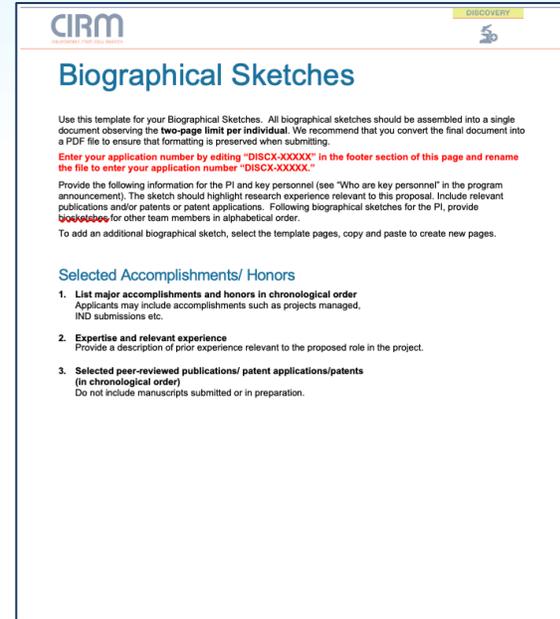
# Required Application Components: Uploads



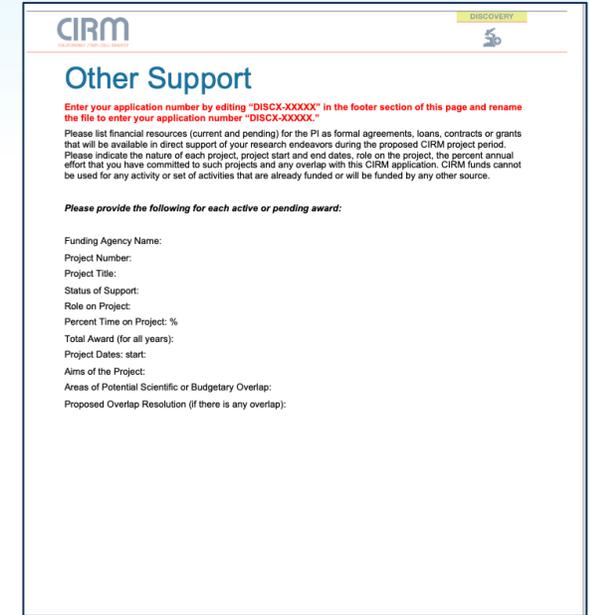
Proposal



DSMP



Biosketch



Other Support

Templates Found in Uploads Section

# For Profit Applicants Only: Required Uploads


DISCOVERY

## For-Profit Applicant Feasibility Assessment

**DIRECTIONS**

Before you begin, enter your application number by editing "DISCX-XXXX" in the footer section of this page and in the filename.

This document is used to enter profile information on the for-profit applicant organization as well as to provide supporting documentation for assessment of the 180-day solvency requirements. The for-profit organization must submit one complete set of responses and supporting documents in this Financial Feasibility Assessment form. All sections of this form must be completed, appended with any attachments, and uploaded to your application in the CIRM Grants Management Portal.

### Section A: Financial Feasibility Questionnaire

- Company name: \_\_\_\_\_  
 Year created: \_\_\_\_\_  
 Website: \_\_\_\_\_  
 Form of organization: C-Corp  S-Corp  LLC  Other \_\_\_\_\_  
 CA or State Corporation #: \_\_\_\_\_ Federal EIN: \_\_\_\_\_  
 If publicly traded, please provide company's stock symbol: \_\_\_\_\_  
 Total Current Employee Count (W-2): \_\_\_\_\_  
 Current California Employee Count (W-2): \_\_\_\_\_
- Is the company presently a named defendant in a litigation matter that, in the event the company receives an adverse judgment, could threaten the company's ability to operate as a going concern? If "Yes," please provide additional comments in the space indicated at the end of this form.  
 YES  NO
- Is the company or any of its officers the subject of any governmental investigation or similar proceeding? If "Yes," please provide additional comments in the space indicated at the end of this form.  
 YES  NO
- Does the company have any outstanding tax liens with the Internal Revenue Service, the CA Franchise Tax Board, or any other State agency?  
 YES  NO  If "Yes", please describe below.

Questionnaire Comments:

## Financial Feasibility Assessment Form

### Financial Solvency Template

*Directions: Cells containing blue text and numbers should be used to input information. Black text and numbers are calculations and should NOT be used to input information.*

(\$ in thousands)

Submission Information						
Company name	CIRM Inc.					
Date of application submission	1/1/22					
CIRM program announcement	Discovery					
Current cash & cash equivalents	\$0					
Date of most recent cash balance	1/1/22					

← Provide supporting documentation in upload section of application

Solvency Analysis						
	180 Cash Flow Analysis					
	Jan-22	Mar-22	Apr-22	May-22	May-22	Jun-22
<b>Sources of Cash</b>						
Beginning Cash Balance	\$0	\$0	\$0	\$0	\$0	\$0
Financings	0	0	0	0	0	0
Grants (CIRM, Approved Awards Only*)	0	0	0	0	0	0
Grants (non-CIRM, Approved Awards Only*)	0	0	0	0	0	0
Other sources of capital	0	0	0	0	0	0
<b>Total</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<b>Uses of Cash</b>						
Operating expenses	\$0	\$0	\$0	\$0	\$0	\$0
Capital expenditures	0	0	0	0	0	0
Change in working capital	0	0	0	0	0	0
Other uses of cash	0	0	0	0	0	0
<b>Total</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<b>Ending Cash Balance</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

← Input figures in this section ONLY if you provide letters of financial commitment in the upload section of the application. \*Append Notice of Award or Approval for all listed Grant Funding to Financial Questionnaire

← Inputs in this section must be negative to represent an outflow of cash. Co-funding allocations for any grants must be included in this

## Financial Solvency Spreadsheet

Funding Opportunity  
for Discovery Stage  
Research Projects:  
**The Foundation  
Awards**



- **Use the required** Word Template
- **Adhere** to prescribed page limits
- **Maintain preset formatting** (font, size and margins)
- **Follow Instructions** for each section
- **Convert to PDF** when finished to upload
  
- **Do not alter** margins, font size, etc.
- **Do not exceed** page limits per section

# Application Process: Resubmitting

- For resubmissions that did **not pass Positive Selection:**
  - *Submit as a **new** application*
- For resubmissions that **received a merit score and GWG feedback** from a previous review:
  - **Designate as a resubmission** by selecting “yes” in the Information for Review Section
  - **Complete a Resubmission Statement** found in the Proposal Form (Uploads)

## Substantially Similar Resubmission

*Are you resubmitting a substantially similar proposal that addresses GWG reviewer comments?*

Yes  No

## Table of Contents

When you have finished the Proposal, please in the Table of Contents below.

### Proposal Sections

Resubmission Statement (up to 1 page)

Statement of Significance and Impact (up to

# COMMON ISSUES – LESSONS LEARNED

## Projects that:

- Focus on animal rather than human biology; missing human cell validation study
- Not framed around filling knowledge gap / overcoming bottleneck, even if proposing allowable activities
- More appropriate for DISC2, TRANs or CLINs programs
- Not using the appropriate template(s) for required Uploads
- Omics projects not assigning a Data Project Manager
- < 20% PI effort

## Project that are:

- Too exploratory, not enough preliminary data to support rationale or likelihood of impact in the duration of grant
- Too unfocused, or not CIRM-y enough (superficial link to stem cells or regenerative medicine)
- Sometimes- interdependencies of aims
- Important expertise missing from team (Address in Key Personnel)
- Poor grantsmanship, poorly written, difficult to follow
- Failure to acknowledge relevant, existing literature
- Poor DEI Statement

Applications due **November 8<sup>th</sup> 2022 @2PM PST**



**Rosa Canet-Avilés, PhD**  
Vice President



**Kelly Shepard, PhD**  
Associate Director



**Uta Grieshammer, PhD**  
Sr. Science Officer



**Maziar Shah-Mohammadi, PhD**  
Sr. Science Officer



**Candida Toribio, MBS**  
Project Manager

We are hiring!

<https://www.cirm.ca.gov/about-cirm/employment-opportunities>

For information and assistance with this program please email:

**[discovery@circm.ca.gov](mailto:discovery@circm.ca.gov)**

Q & A