

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

**DISC0
FOUNDATION
AWARDS**

Basic
Research

\$1,000,000
(**Direct Costs**)

36 Months

DISC2
or N/A

**DISC2
QUEST AWARDS**

Therapeutic
Candidate

\$1,500,000
(**Direct Costs**)

36 Months

TRAN1

Technology
Candidate

\$500,000
(**Direct Costs**)

24 Months

TRAN2/3/4
or other

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

What **activities** will CIRM fund?



➤ 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

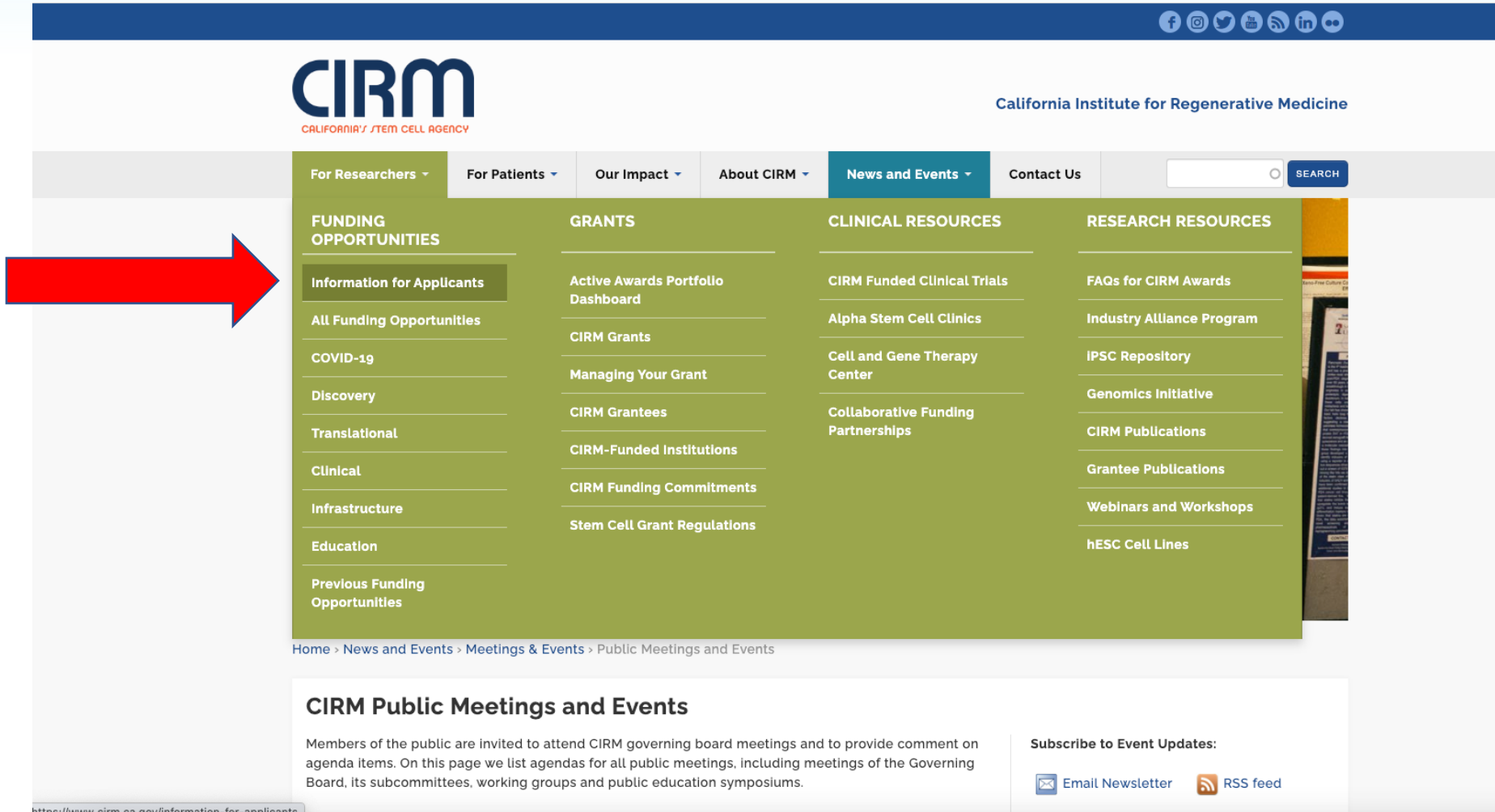
Auxiliary research activities that support regenerative medicine science, for example:

- **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 shows the CIRM website interface. At the top, there is a dark blue header with social media icons. Below this is the CIRM logo and the text "California Institute for Regenerative Medicine". A navigation bar contains links: "For Researchers", "For Patients", "Our Impact", "About CIRM", "News and Events", and "Contact Us". A search bar is also present. A large red arrow points to the "Information for Applicants" link under the "FUNDING OPPORTUNITIES" menu. The menu is organized into four columns: "FUNDING OPPORTUNITIES", "GRANTS", "CLINICAL RESOURCES", and "RESEARCH RESOURCES".

FUNDING OPPORTUNITIES	GRANTS	CLINICAL RESOURCES	RESEARCH RESOURCES
Information for Applicants	Active Awards Portfolio Dashboard	CIRM Funded Clinical Trials	FAQs for CIRM Awards
All Funding Opportunities	CIRM Grants	Alpha Stem Cell Clinics	Industry Alliance Program
COVID-19	Managing Your Grant	Cell and Gene Therapy Center	iPSC Repository
Discovery	CIRM Grantees	Collaborative Funding Partnerships	Genomics Initiative
Translational	CIRM-Funded Institutions		CIRM Publications
Clinical	CIRM Funding Commitments		Grantee Publications
Infrastructure	Stem Cell Grant Regulations		Webinars and Workshops
Education			hESC Cell Lines
Previous Funding Opportunities			

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](#)

Share



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

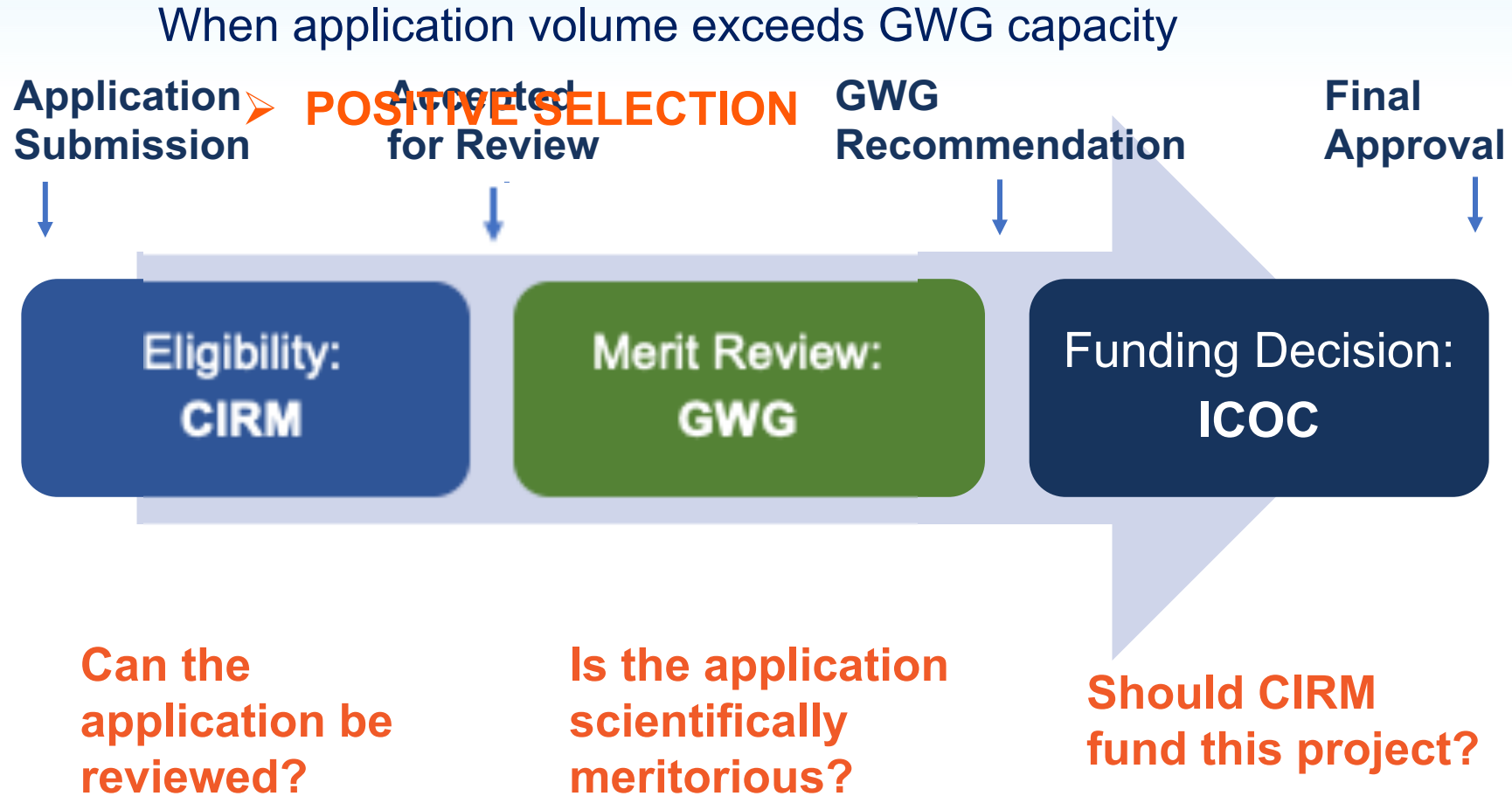
ELIGIBILITY REQUIREMENTS

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



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

* When application volume exceeds GWG capacity

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)

Application – 2 major Components

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*

Application Form: Overview

Online Sections

Attachments, Templates

[Open Programs](#) / Grant App DISCO-14320

DISCO-14320

[Instructions](#)
[Print View](#)

Eligibility

[Eligibility](#) Incomplete

Personnel

[PI and AOO](#) Incomplete
[Key Personnel](#) Incomp (1)
[Partners](#) 0 Entries
[Review Exclusions](#) 0 Entries

Project

[Title & Duration](#) Incomplete
[Positive Selection Preview](#) Incomplete
[Information for Review](#) Incomplete
[Keywords](#) Incomplete
[Public Information](#) Incomplete

Funding

[Consultants / Subcontracts / Service Contracts](#) Empty
[Co-funders](#) Empty
[CIRM Funds Calculator](#) Incomplete
[Budget Justification](#) Incomplete

Certifications

[Institutional Approvals and Oversight](#) Incomplete

Uploads

[Document Uploads](#) Incomplete

DISCO 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.

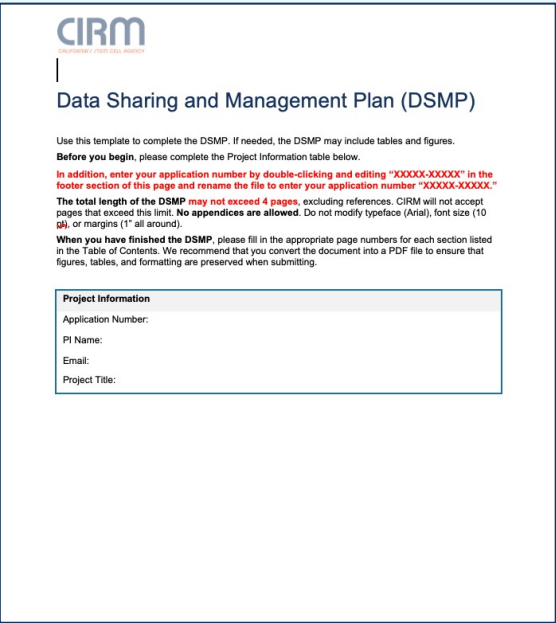
CIRM anticipates that the number of applications submitted will be very high for this competition. When the number of applications received in a cycle is significantly in excess of the number that can be reviewed by the Grants Working Group (GWG) panel, the GWG members conduct the review in two stages. 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 DISCO 0 will be accepted by CIRM.

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

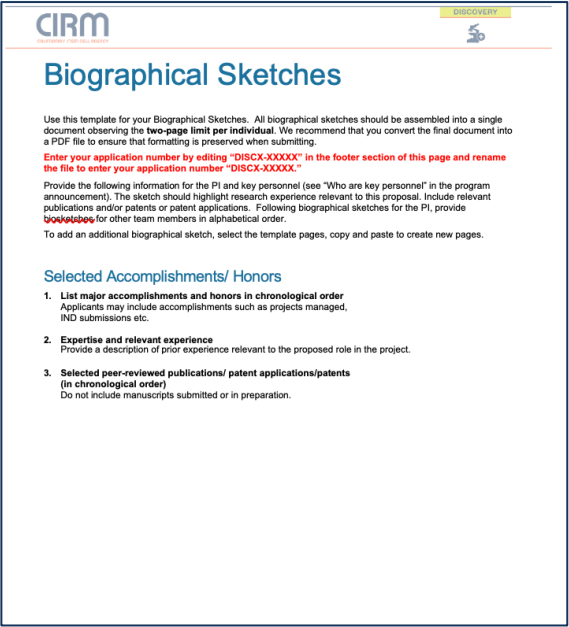
Required Application Components: Uploads



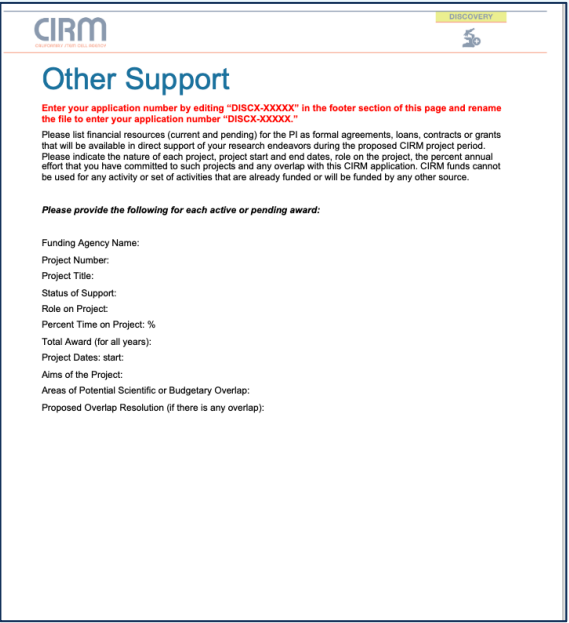
Proposal



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
Sources of Cash						
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
Total	\$0	\$0	\$0	\$0	\$0	\$0
Uses of Cash						
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
Total	\$0	\$0	\$0	\$0	\$0	\$0
Ending Cash Balance	\$0	\$0	\$0	\$0	\$0	\$0

← 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

Application Components: **Proposal Template**

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 1 page)

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

Common Issues (Affecting Merit)

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 8th 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@cirm.ca.gov

Q & A