CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

CIRM Funding Opportunities: Common Requirements and Definitions

The requirements and definitions below are incorporated by reference, and as amended from time to time, into CIRM's Concept Plans, Program Announcements (PAs), and Requests for Applications (RFAs).

Eligibility Requirements

(1) California Organization

Where specified in Concept Plans and Program Announcements or Requests for Proposals, the applicant organization must be a California Organization per CIRM's definition, below, at the time of application:

A "California Organization" is a for-profit or non-profit organization or is a California-domiciled wholly owned subsidiary of a non-California organization (any entity that does not qualify as a California Organization) that meets all of the following criteria:

i) **Employment and Payroll:**
   - Employs at least one W-2 employee; and
   - More than 50% of its W-2 employees, whether part-time or full-time, who are paid in any manner (e.g., wage, salary, commission, equity), must be domiciled full-time in California and be required to file California state income taxes due to their employment with the organization.

ii) **Management of Award Activities:** The Principal Investigator (PI) must be physically located in California while overseeing all project activities.

iii) **Intellectual Property Rights:** In the case of a California-domiciled wholly owned subsidiary of a non-California organization, the subsidiary must retain exclusive rights to any intellectual property arising out of the CIRM-funded project as well as any pre-existing IP rights held by the parent organization.

(2) Principal Investigator (PI) or Program Director (PD)

To be eligible for consideration for CIRM funding, the PI or PD must satisfy the following requirements:

- Must be an employee or consultant of the applicant organization and be accountable for the conduct of the proposed project to the applicant organization;
- Must be authorized by the applicant organization to conduct the research and assume the responsibilities of the PI or PD;
- Must not currently have another application pending review or approval under the same funding opportunity as the current application; and
- Must not currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.

(3) Co-Investigator (Co-I)

For Concept Plans, Program Announcements or Requests for Applications which have a Co-Investigator (Co-I) role, each Co-I on a CIRM application must satisfy the following requirements to be eligible for consideration for CIRM funding:

- Must be an employee of a California-based organization and be accountable for the conduct of the proposed project to their California-based organization; and
- Must not currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.
- Must meet the same institutional qualifications that would be expected of a PI

(4) Regenerative medicine therapies

The following regenerative medicine-based therapies are eligible for CIRM funding:

- A ***cell therapy*** where human stem or progenitor cells (collectively, "stem cells") either compose the therapy or are used to manufacture the cell therapy.
- Under Proposition 14, "***progenitor cells"*** are "multipotent or precursors cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells."
- A ***genetic therapy*** (i) that targets a human somatic cell for its therapeutic effect, AND (ii) is intended to replace, regenerate, or repair the function of aged, diseased, damaged, or defective cells, tissues, and/or organs.
- CIRM considers "***genetic therapy"*** to mean a human therapeutic intervention that: 1) alters the genomic sequence of cells or 2) introduces or directly manipulates nucleic acids (such as mRNAs, antisense oligonucleotides) in cells. The intervention may include strategies to repair a disease-causing gene sequence, remove or inactivate a disease-causing gene, or introduce new or modified nucleic acids that augment the therapeutic potential of the target cells.
- A ***small molecule*** or ***biologic*** that acts on or is dependent on endogenous human stem cells for its therapeutic effect, that is dependent on targeting human cancer stem cells for its therapeutic effect, that modifies a stem cell therapy, OR where a human stem cell is necessary to manufacture the therapy (e.g. extracellular vesicles).

(5) Good Standing

Prior to submitting, applicants must represent and certify that they and/or any Affiliate are in good standing and disclose any potentially disqualifying events, as follows and as described in the application:

A. Investigations: Disclose any investigation, within the five years preceding the date of application, by a governmental or regulatory body related to the Applicant or any Affiliate involving:

- Any securities or banking filings with any state or federal regulatory agency.
- Fraud or misrepresentation by the applicant or Key Personnel.
- Violations of state or federal securities, banking, health and safety, healthcare, or insurance laws.

B. Criminal Convictions: Disclose any felony or misdemeanor conviction(s), within the five years preceding the date of application, related to the Applicant or any Affiliate involving:

- Any securities or banking filings with any state or federal regulatory agency.
- Fraud or misrepresentation by the applicant or any Affiliate.
- Violations of state or federal securities, banking, health and safety, healthcare, or insurance laws.

- The conduct of the applicant or any Affiliate as an underwriter, broker, dealer, municipal securities dealer, investment adviser, or paid solicitor of purchasers of securities.

C. Court Orders, Judgments, or Decrees: Disclose any order, judgment, or decree by a court of competent jurisdiction, issued within five years preceding the date of application, that prohibits the applicant or any Affiliate from:

- Purchasing or selling any security.
- Engaging in any state or federal securities, banking, health and safety, healthcare, or insurance activities.
- Acting as an underwriter, broker, dealer, municipal securities dealer, investment adviser, or paid solicitor of purchasers of securities.
- Utilizing intellectual property created with CIRM funds.

D. Current or Pending Litigation: Disclose any ongoing or pending litigation related to the Applicant or Affiliate involving:

- Any securities or banking filings with any state or federal regulatory agency.
- Fraud or misrepresentation by the applicant or Affiliate.
- Violations of state or federal securities, banking, health and safety, healthcare, or insurance laws.
- The conduct of the applicant or Affiliate as an underwriter, broker, dealer, municipal securities dealer, investment adviser, or paid solicitor of purchasers of securities.

E. Final Regulatory Orders: Disclose any final orders (no longer eligible for appeal), issued at any time, by federal or state regulators, to the Applicant or any Affiliate including but not limited to:

- Securities, banking, or insurance regulatory agencies.
- Federal agencies such as NIH, FDA, HHS, or CMS.
- Any federal or state health department, agency, or similar entity or governing body.

F. Securities Self-Regulatory Organization (SRO) Sanctions: Disclose any suspension or expulsion from membership in, or suspension or barring from association with, a member of a securities self-regulatory organization (SRO) for the applicant or Affiliate.

G. Denied Parties Lists: Disclose any Key Personnel who are currently debarred by HHS Office of Research Integrity or appear in: the System for Award Management (SAM.gov) exclusions list, the Bureau of Industry and Security Denied Parties List, the U.S. Customs and Border Protection Blocked, Denied, Entity and Debarred Persons Lists; or the Office of Foreign Assets Control's Specially Designated Nationals and Blocked Persons list.

(6) Solvency

For-profit organizations must provide documentation that shows cash on hand or funding from committed sources that will cover the organization’s expenses for 180 days from the date of application submission. These funds must be distinct from, and in addition to, funds for meeting the co-funding

requirement for the term of the project and funds for the applicant's financial contingency plan. The determination of solvency will be made at CIRM's sole and absolute discretion.

(7) Co-funding

When co-funding is required in a concept plan, co-funding may come from any funding source arranged by the applicant but may not include "in-kind" or similar types of support. Applicants must commit at least the percentage of total project costs indicated in the concept and PA or RFA. Documentation demonstrating the commitment of funds to cover the proposed co-funding amount must be provided at the time of application submission (e.g., copy of executed term sheet showing amount of co-funding, conditions, and source). Alternatively, for-profit applicants and for-profit partners of non-profit applicants may elect to fulfill all or a portion of the minimum co-funding requirement by agreeing to issue equity warrants to CIRM. Applicants electing the warrant-based co-funding requirement may request CIRM funding up to the award limit and must issue equity warrants to CIRM to cover the portion of the CIRM award amount that corresponds to the co-funding requirement.

Additional Requirements

Acknowledgement of Funder

CIRM awardees must acknowledge CIRM support of research findings in publications, announcements, presentations, and press releases by the awardees. An example of an acknowledgement is: "The research was made possible by a grant from the California Institute for Regenerative Medicine (Grant Number _____). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California." Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code. For further questions about planned media and press releases, please visit our website or contact press@cirm.ca.gov.

Definitions

"Affiliate" means, with respect to an applicant, any other entity that: (i) is participating in activities set forth within an application, and (ii) directly or indirectly, through one or more intermediaries, Controls, is Controlled by, or is under common Control with the applicant. The term "Control" (including the terms "Controlled by" and "under common Control with") shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management, policies, or operations of an entity, whether through ownership of voting securities, by contract, or otherwise.

"Core Team" refers to the scientific leadership of an application or grant and is used in the context of collaborative or team-based applications or grants such as DISC4. The specific composition and requirements of the Core Team will be described in the specific PA or RFA but generally includes the PI and 1 or more co-Investigators.

"Critical roles" are a subset of Key Personnel who have a minimum effort requirement as described in the specific PA or RFA, and whose absence could cause serious disruption to the project and its operations. This definition includes personnel who are vital to the project's success and who may be

responsible for driving strategic objectives, ensuring operational continuity, and making impactful decisions. A PI, PD, and other Critical Role(s) may also be subject to additional requirements, scrutiny, or publicity as described in the PA or RFA or at CIRM's discretion.

"Data Project Manager" is an individual who must have a demonstrated record of experience in data handling and is responsible for interfacing with a data management team(s), interfacing with CIRM's planned data infrastructure, reporting progress on data management and sharing as well as maintaining the integrity of data during ingestion. The Data Project Manager role can be distributed among multiple people and may be fulfilled by Key Personnel with other Critical Roles.

"For-profit organization" means: a sole-proprietorship, partnership, limited liability company, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations also are referred to as "commercial organizations".

"Genetic research" refers to research that alters genomic sequences of cells (edits, removes, or adds DNA sequences) or introduces or directly manipulates nucleic acids (such as coding and non-coding RNAs, antisense oligonucleotides) in human cells.

"Key Personnel" means (1) the Principal Investigator or Program Director; or (2) any other person, including an independent consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the project in a substantive, measurable way and who is expected to: (a) receive or has been promised income, or anything else of value, of $10,000 or more per year for his or her contribution to the project or (b) contribute one percent (1%) or more effort to the proposed project. "Key Personnel" does not include a person who is expected to be involved in the proposed project but who does not satisfy conditions (1) or (2).

Individuals who do not meet the definition of Key Personnel may be supported with CIRM funds but should not be identified by name in the application. Such unnamed personnel may be referenced indirectly by their role on the project (e.g., technician). The budget includes a line item for requesting support for unnamed personnel.

"Non-profit organization" means: (1) a governmental entity of the state of California; or (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue and Taxation Code section 23701d (2024).

"Operational Milestone" means an objective event that is indicative of project progress occurring as proposed in the application. The successful achievement of an Operational Milestone may trigger the disbursement of additional funds under the award as scheduled in the NOA. The intervals between Operational Milestones are used to divide a Project Period for budgetary, funding and reporting purposes.

"Partner" means an organization that, in exchange for the right to the opportunity for a future financial return, has (1) agreed to provide matching funds for the proposed project or (2) entered into an agreement with the applicant organization relating to the commercialization of the proposed product.

"Project Milestone" means an objective event established by CIRM in which the failure to meet the event grants CIRM the right, at its sole discretion, to suspend payment and/or terminate the project.

"Subcontractor" means an organization (other than the applicant organization) that is expected to: (a) contribute to the scientific development or execution of the project in a substantive, measurable way and (b) receive $25,000 or more through the proposed project. "Subcontractor" does not include suppliers of widely available goods.

"Suspension Event" means a pre-defined condition that triggers a hold of CIRM funding until the suspension event has been resolved, if resolvable.