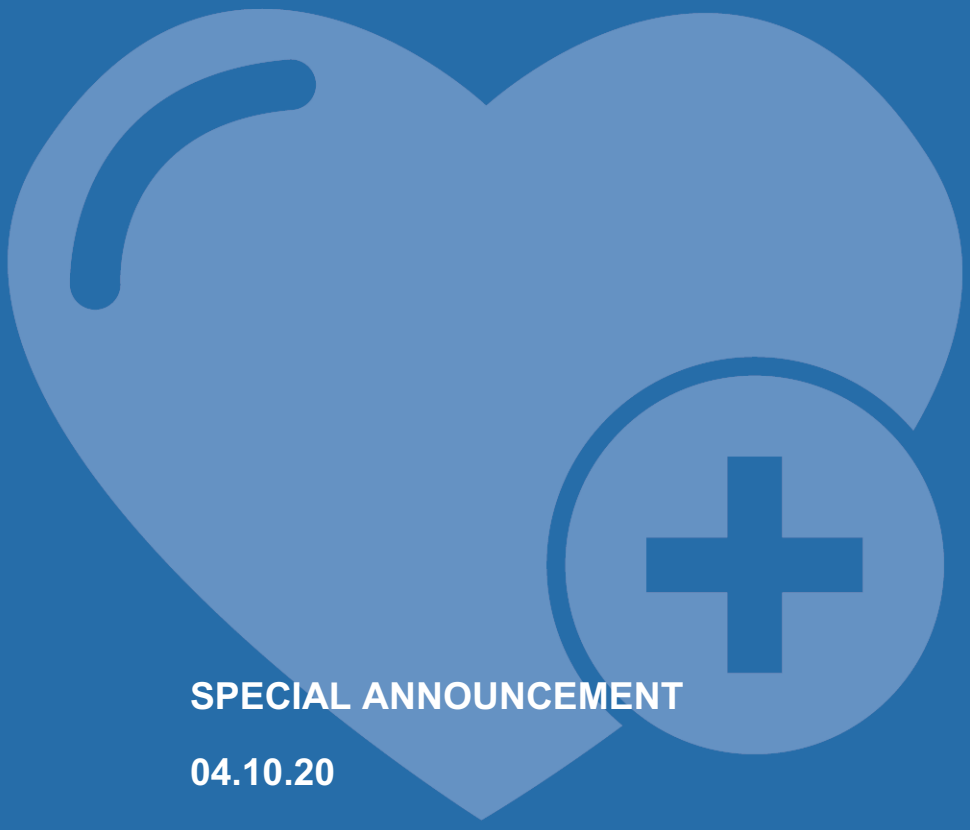
CIRM
CALIFORNIA'S STEM CELL AGENCY

Special Call for COVID-19 Projects

Partnership Opportunities in Support of Discovery, Translational and Clinical Trial Stage Activities



SPECIAL ANNOUNCEMENT

04.10.20

Special Call for COVID-19 Projects

Partnership Opportunities in Support of Discovery, Translational and Clinical Trial Stage Activities

Objective

The mission of California Institute for Regenerative Medicine (CIRM) is to accelerate stem cell treatments to patients with unmet medical needs.

Given the growing surge of COVID-19 cases in California and throughout the world, CIRM is issuing this special announcement to support promising discovery, preclinical and clinical trial stage projects that could quickly advance treatments to COVID-19 patients in need.

CIRM is utilizing its established partnering opportunities across Discovery (DISC2), Translational (TRAN1), and Clinical (CLIN1,CLIN2) stages to provide support for COVID-19 related projects. This Program Announcement will describe the unique and applicable requirements for supporting COVID-19 projects but will refer to the specific program stage announcements for additional details.

The requirements described in this special announcement for COVID-19 projects (such as award amounts, duration, or eligibility) supersede those described in the specific program announcements referenced below. All other requirements described in the respective Programs Announcements apply.

Please refer to the following Program Announcements for more detailed description of the Discovery, Translational and Clinical programs.

Project Stage	Specific Program	Program Announcement
Clinical trial	CLIN2	CLIN 2: Partnering Opportunity for Clinical Trial Stage Projects
Late stage preclinical	CLIN1	CLIN 1: Partnering Opportunity for Late Stage Preclinical Projects
Translational	TRAN1	Partnering Opportunity for Translational Research Projects
Discovery	DISC2	DISC 2 Program Announcement - Partnering Opportunity for Discovery Stage Research Projects: The Quest Awards

Award Information

CIRM has allocated a total of $5 million to support projects related to COVID-19. Award amounts and duration will be limited based on the project stage as shown in the table below.

Award Amount and Duration Limits

Project Stage	Specific Program	Award Amount*	Award Duration
Clinical trial	CLIN2	$750,000	24 months
Late stage preclinical	CLIN1	$400,000	12 months
Translational	TRAN1	$350,000	12 months
Discovery	DISC2	$150,000	12 months

*Award limits are for Total Funds Requested (i.e., limit includes direct facilities costs and indirect costs)

What activities will CIRM support?

CIRM resources will support the activities described in the respective Program Announcements for DISC2, TRAN1, CLIN1, and CLIN2 with the following exceptions.

- ✘ Proposals for development or clinical testing of a device or tool candidate will not be supported, except under the DISC2 opportunity.
- ✘ Manufacturing of product to supply a follow on clinical trial.
- ✘ Any activity unrelated to development or testing of a therapeutic for COVID-19.

How will funds be awarded?

CIRM will disburse funds pursuant to a Notice of Award. Awardees may elect, upon completion of their award, to treat their award as a loan pursuant to CIRM's award conversion policy.

Eligibility

What types of projects are eligible for partnering?

To be eligible, the proposed project must satisfy the requirements described in the respective Program Announcements for DISC2, TRAN1, CLIN1, and CLIN2 with the following additions.

(1) Only projects pursuing the development or testing of a candidate for COVID-19 will be considered.

(2) The applicant must be ready to initiate work on the funded project within 30 days of approval.

With an urgency to address the needs of COVID-19 patients, CIRM expects that projects, regardless of stage, will be ready to initiate proposed activities following approval and will quickly advance their therapeutic product toward the clinic.

(3) All projects must propose to achieve a clear deliverable within six months of project initiation to demonstrate progress toward the goal.

(4) For clinical trial projects (CLIN2), applicants must propose to initiate enrollment and collect data within 6 months from the project start date.

(5) For late stage preclinical projects (CLIN1), the proposed date of IND filing must be within 6 months from the project start date.

(6) For translational projects (TRAN1), the proposed date of Pre-IND meeting or equivalent interaction with the FDA must be within 6 months from the project start date.

(7) For discovery projects (DISC2), applicants must propose to have data for a viable candidate that has a likelihood of progressing quickly to the clinic.

(8) Eligiblity of cell therapy and gene therapy candidates are as described in the respective program announcements. Generally, cell and gene therapy candidates are defined as follows:

- A cell therapy where stem[1] or progenitor[2] (collectively "stem cells") either compose the therapy or are used to manufacture the cell therapy.
- A gene therapy[3] approach (i) that targets a stem cell for its therapeutic effect, OR any other somatic cell if deemed a "vital research opportunity" by the CIRM Grants Working Group; AND (ii) is intended to replace, regenerate, or repair the function of aged, diseased, damaged, or defective cells, tissues, and/or organs

(9) Small molecule or biologic (e.g. monoclonal antibodies) candidates are eligible for all programs and clinical trial phases if they meet the following criteria:

A small molecule or biologic that acts on or is dependent on endogenous stem cells for its therapeutic effect, that modifies a stem cell product, OR where a stem cell is necessary to manufacture the therapy.

(10) Proposals to study convalescent plasma or its derivatives (e.g., immunoglobulin) for the treatment of patients with COVID-19 will be considered a therapeutic candidate eligible for CIRM funding.

- Proposals to use convalescent plasma must include a written plan in the application for outreach and study participation by underserved and disproportionately affected populations. Priority will be given to projects with the highest quality plans in this regard.
- Clinical studies of convalescent plasma may propose use of the FDA's single-patient emergency IND (eIND) pathway to satisfy the CLIN2 eligibility requirements for a traditional IND.

(11) Allowable costs for clinical projects (CLIN1 and CLIN2) may include project costs incurred on or after the submission deadline date of the application, provided that the applicant shall be at risk for these funds if the application is not approved for funding.

[1] Under Proposition 71, stem cells are "capable of self-renewal and have broad potential to differentiate into multiple adult cell types."
[2] Under Proposition 71, progenitor cells are "multipotent or precursor cells that are partially differentiated, but retain the ability to divide and give rise to differentiated cells."
[3] For the scope of this solicitation, CIRM considers gene therapy to mean a human therapeutic intervention intended to: 1) alter the genomic sequence of cells or 2) alter the cellular lineage via gene delivery (i.e., direct lineage reprogramming). The intervention may include strategies to repair a disease-causing gene sequence, remove or inactivate a disease-causing gene, introduce new or modified genes that augment the therapeutic potential of the target cells.

Schedule and Deadlines

Applications Due	2:00 pm (PDT/PST) on April 7, 2020 and approximately every two weeks thereafter.
Grants Working Group (GWG) Review	Approximately 14-21 days post submission
ICOC Review and Approval	Approximately 30-40 days post submission
Award Start	Must start within 30 days of award approval

Application Review Information

Pre-submission Consultation

Prospective applicants are strongly encouraged to contact CIRM before applying with questions or to discuss their project's eligibility, scientific, or budget considerations.

Eligibility Review

CIRM will assess whether the proposed project meets eligibility requirements sought under this Special Announcement and the respective Program Announcements (DISC2, TRAN1, CLIN1, CLIN2).

Scientific Review

The scientific merit of each application will be assessed by the GWG, which is composed of fifteen subject matter experts from outside California, seven patient advocate members of the ICOC, and the Chair of the ICOC. The list of scientific members who may participate in the GWG review can be found at http://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed at http://www.cirm.ca.gov/GoverningBoard.

The fifteen participating scientists on the GWG will evaluate the applications and score them according to scientific and technical merit, applying the review criteria described in each Program Announcement. The GWG will score each application and make one of the following specific recommendations to the ICOC's Application Review Subcommittee: 1) fund the project based on its exceptional merit, if funds are available or 2) do not fund the project.

The ICOC's Application Review Subcommittee will make final funding decisions giving consideration to the GWG recommendations and any CIRM team recommendations.