# Initiating a Special Call for COVID-19 Projects

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 proposes to launch a solicitation in support of promising discovery, translational, preclinical and clinical trial stage projects that could quickly advance treatments or vaccines to COVID-19 patients in need.

CIRM plans to utilize its established partnering opportunities in Discovery (DISC1, DISC2), Translational (TRAN1), and Clinical (CLIN1,CLIN2) stages to facilitate the application, review and funding process. The requirements described within each program announcement will apply, except as outlined in this document, to best align them with projects related to COVID-19.

CIRM requests an allocation of $5 million to support this new program. We propose use of unallocated recovered funds (currently $812,042) and an additional $4,187,958 from the Cure Sickle Cell Disease program to create the $5 million allocation. Future recovered funds would first be used to replace the amount borrowed from the Cure Sickle Cell Disease Program.

We plan to create an expedited application and review cycle that would allow Grants Working Group review of applications within 14-21 days and board approval within 30-40 days of submisison.

**Program Announcement Modifications**

We propose opening the DISC1, DISC2, TRAN1, CLIN1, and CLIN2 program announcements with the following modifications:

**1. The proposed award amount 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 | $250,000** | 12 months |
| | DISC1 | $150,000 | 12 months |

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

** DISC2 projects developing a tool/technology candidate (other than one for vaccine development) are limited to $150,000 in Total Funds Requested.

**2. Only projects pursuing the development, testing, or discovery of a candidate for COVID-19 will be considered. In the case of DISC1, CIRM will support projects to test new, potentially transformational ideas that could greatly impact the field of COVID-19 research, but which require**

**the generation of additional data to be competitive for larger funding opportunities through CIRM or other sources.**

**3. 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.

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

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

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

**c. For translational projects (TRAN1), completion of studies within 6 months of the project start date that allow for the production a well-prepared briefing package with supporting data for a Pre-IND meeting or equivalent interaction with the FDA.**

**d. For Quest discovery projects (DISC2), applicants must propose to have data for a viable candidate within 6 months that for a) therapeutic candidates has a likelihood of progressing quickly to the clinic or for b) a tool/technology candidate, will support feasibility for intended use.**

**e. For Inception discovery projects (DISC1), applicants must propose to have data to confirm or reject their hypothesis within 6 months.**

**5. 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.

**6. Proposals for development or clinical testing of a device or tool candidate will not be supported, except under the DISC2 opportunity.**

**7. Manufacturing of product to supply a follow on clinical trial will not be allowed.**

**8. 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 to apply for CIRM funding.**

**9. 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.**

**10. Studies that propose novel or accelerating approaches to vaccine development for COVID-19 will be considered eligible to apply for discovery (DISC1, DISC2) or translational (TRAN1) stage funding from CIRM.**

**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.**

**12. All clinical trial proposals 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.**

### Supplemental Funding for Existing CLIN2 COVID-19 Grants

CIRM proposes the use of up to $1 million from the COVID-19 program allocation for supplemental funding of active COVID-19 clinical trial stage awards (CLIN2COVID19) that expand existing activities towards COVID-19. Supplemental funding cannot exceed $250,000 and cannot be used to cover project costs that were already covered under the original award. To be considered for supplemental funding for an existing award, the program must be making sufficient progress in the launch or conduct of their current project. The awardee must submit a formal request to their CIRM Science Officer outlining how the supplemental funds would improve upon the delivery of the therapeutic candidate and/or facilitate the treatment of more patients under the funded COVID-19 clinical studies. The grantee must indicate the specific activities for which funds are requested and the amount requested. The CIRM team would then provide a recommendation to the Governing Board's Application Review Subcommittee, which makes the final decision on supplemental funding.

### Proposed Modification to GWG Review Process

CIRM will create an expedited review cycle that will make use of one GWG panel and teleconference meeting (held approximately every two weeks) to review all applications under this program. In order to align the scoring of all applications, we propose to apply the current scoring method used for non-clinical programs (scale of 1-100) to the clinical programs as well. The scoring method as described in the GWG bylaws for non-clinical programs is as follows:

(A) For purposes of making funding recommendations to the Application Review Subcommittee of the ICOC for applications for non-Clinical Program awards, each application shall be assigned to one of two categories based on the median score and shall be ranked within that category based on the average score as follows:

1. Recommended for Funding = median score 85 and above, representing applications that have exceptional merit and that warrant funding, if funds are available; or

2. Not Recommended for Funding = median score below 85, representing applications that are not recommended for funding.

(B) The grants review office will inform reviewers of these tiers in advance of the GWG meeting so that this guidance may be incorporated into their reviews and scores.

(C) At the conclusion of the consideration of all applications, the Scientist Members will have a final opportunity to review their individual scores and make any changes they wish as to any application in which they are able to participate (not in conflict). After an appropriate amount of time, the Scientist Members will then submit final scores. After final submission, the scores may not be changed.