

SOMETHING BETTER THAN HOPE

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CIRM
CALIFORNIA / STEM CELL AGENCY

COVID-19 Program

- Given the urgent need to develop treatments for COVID-19, CIRM launched a solicitation in support of promising discovery, translational, preclinical and clinical trial stage projects that could quickly advance treatments to patients in need.
- CIRM is utilizing its established partnering opportunities in Discovery (DISC2), Translational (TRAN1), and Clinical (CLIN1,CLIN2) stages to facilitate the application, review and funding process.
- The CIRM Governing Board approved a total allocation of \$5 million to support this new program.

COVID-19 Program

Support under the DISC2, TRAN1, CLIN1, and CLIN2 program announcements is provided with the following award limitations:

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)

COVID-19 Program

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

Program	Ready to Start	Six-Month Goal
CLIN2	IND filed/approval to treat patients	Initiate enrollment and data collection
CLIN1	Pre-IND with FDA completed	File IND with FDA
TRAN1	Therapeutic candidate w/ disease-modifying activity identified	Conduct pre-IND or equivalent interaction w/ FDA
DISC2	Proposal to identify a candidate for development	Have data for a viable candidate that could progress quickly to the clinic

COVID-19 Program

CIRM increased program scope to allow consideration of investigational studies with convalescent plasma (or its derivatives) as a potential Vital Research Opportunity

- 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.

GWG Recommendations

	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score 85-100	3	\$1,049,997	\$5,000,000
Not recommended for funding Score 1-84	9		

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

Recommended Applications

Application	Score (Median)	Project Type	Therapeutic Product	Applicant Request
CLIN2COVID19-11775	85	Clinical Study	Convalescent plasma	\$749,999
DISC2COVID19-11817	95	Discovery	Tool for vaccine/T cell therapy development	\$150,000
DISC2COVID19-11764	85	Discovery	Small molecule drug	\$149,998