

**SOMETHING
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**Concept Proposal: Amendments to
Special Call for Projects Related to COVID-19**

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Background

- Given the urgent need to develop treatments for COVID-19, the CIRM Governing Board approved the launching of 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 Board approved an allocation of \$5 million to support this new program.

Proposed Amendments to the COVID-19 Concept Plan:

- Increase scope of early stage opportunities (DISC and TRAN) to include vaccine development studies as a potential vital research opportunity.
- Include opportunity for studies on novel ideas and biological mechanisms by opening the DISC1 program announcement.
- Allow supplemental funding for active COVID-19 clinical trial awards to expand their efforts.
- Include requirement for outreach to underserved populations in all clinical trial proposals
- Increase award limit on DISC2 projects and adjust language on 6-month deliverables.

Determine if vaccine development studies for COVID-19 should be eligible to apply

- Vaccine development does not necessarily involve stem or progenitor cells and such projects are not currently eligible for entry into CIRM funding opportunities.
- Under Proposition 71, CIRM is permitted to fund projects that are not stem cell-related only if they are deemed a “vital research opportunity”.

“Vital research opportunity means scientific and medical research and technologies and/or any stem cell research not actually funded by the institute under subparagraph (C)...which provides a substantially superior research opportunity vital to advance medical science”
- If the Board determines that vaccine development projects are a potential “vital research opportunity,” the COVID-19 program announcement would be amended to include vaccine development as eligible for funding at the discovery and translational stages. Those programs would undergo GWG review based on the “vital research opportunity” process used for gene therapy applications.

Why vaccine development may offer a potential vital research opportunity

- Control of SARS-CoV-2 infection will ultimately require the development of immunity by the broad population.
- Effective vaccines are key to providing such immunity, but development often requires years to produce successfully.
- Supporting multiple efforts and novel approaches to vaccine development may increase the likelihood of identifying a successful vaccine within a shorter timespan.
- Leverage California's scientific establishment towards innovative vaccine development efforts.

Open DISC1 Program Announcement

Include opportunity for studies on new ideas and biological mechanisms by opening the DISC1 program announcement.

- Award limit of \$150,000
- Maximum award duration of 12 months
- Six-month deliverable: data to confirm or reject hypothesis

Supplemental Funding for Clinical Trial Projects

- 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 grants that expand efforts.
 - Supplemental funding cannot exceed \$250,000 and cannot be used to cover project costs that were already covered under the original grant award.
 - Requests for funding would be brought to Governing Board's Application Review Subcommittee.

Outreach to Underserved Populations

Include requirement for outreach plan to underserved communities in all clinical trial proposals.

“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.”

Adjustment to DISC2 and TRAN1 Requirements

- Increase DISC2 award limit to \$250,000 (previously \$150,000)
- Clarify that DISC2 projects allow for tool/technology development
- Adjust 6-month deliverable for TRAN1 projects to completing studies by the six-month mark but allow pre-IND meeting to occur after.

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