

SOMETHING BETTER THAN HOPE

**Supplemental Funding for
Active COVID-19 Clinical Trial Awards**

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CIRM
CALIFORNIA / STEM CELL AGENCY

Convalescent plasma and derivatives for treatment of COVID-19 are eligible- Vital Research Opportunity

- Convalescent plasma (and its derivatives) is a biologic that is 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”
- The Board determined that convalescent plasma projects are a potential “vital research opportunity,” the COVID-19 program announcement was amended to include convalescent plasma and its derivatives as eligible for funding.

Amendments Made to the COVID-19 Concept Plan:

- Increase scope to include investigational studies with convalescent plasma and its derivatives as a potential vital research opportunity
- Allow use of the FDA's single-patient emergency IND (eIND) pathway for clinical studies with convalescent plasma or derivatives.
- Allow funded clinical projects to start incurring allowable project costs from the date of the application submission deadline
- Allow supplemental funding for active COVID-19 clinical trial awards to expand their efforts.

Supplemental Funding for Clinical Trial Projects

- Board approved 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.”

For Board Action:

Supplement Approval of Additional Convalescent Plasma Collection and Treatment of COVID-19 Patients

- Facilitate Clinical studies with convalescent plasma collection and treatment of COVID 19 Patients in areas of COVID 19 recent surge in underserved communities:
 - ✓ Orange/San Bernardino/Riverside Counties (Zone 1),
 - ✓ San Diego/Imperial Counties (Zone 2),
 - ✓ Ventura/Santa Barbara Counties (Zone 3),
 - ✓ LA County (Zone 4).