



MEMORANDUM

TO: CIRM GOVERNING BOARD
FROM: CIRM LEADERSHIP
SUBJECT: Proposed Amendments to DISC2 and CLIN2 Concepts for 2020
DATE: JULY 22, 2020

At the June 26, 2020 meeting of the Governing Board, the Board approved a budget allocation of \$2M for a launching of the DISC2 funding opportunity and the allocation of all remaining and future unallocated research funds to the CLIN2 funding opportunity. To effectively implement these programs within CIRM's operational timeline and allocated budget, some changes in award duration, award amounts, and administrative requirements were proposed. This memo presents the specific changes to the DISC2 and CLIN2 opportunities for which we seek Board approval to update and implement the funding opportunities.

Proposed Amendments

DISC2: Quest Awards

1. Adjust the maximum allowable total funds requested for a DISC2 award to \$250,000 with a maximum award duration of 12 months.
2. Given the shorter duration and reduced budget of the opportunity, we propose reducing the PI percent effort requirement from 20% to 10%.
3. With a need to launch awards quickly, we also propose that applicants be ready to initiate the proposed studies within 30 days of approval instead of 120 days.
4. All applicants for the DISC2 program will be required to provide a statement describing how their overall study plan and design has considered the influence of race, ethnicity, sex and gender diversity. Applicants should discuss the limitations, advantages and/or challenges of their research proposal in developing a product or tool that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities. Examples include use of models

and tools that account for population diversity (e.g. HLA types, gender, genomics data, cell models).

The GWG and CIRM's governing board will consider these statements in their evaluations and funding recommendations. Priority will be given to projects with the highest quality plans in this regard.

CLIN2: Clinical Trial Awards

1. Adjust the maximum allowable total funds requested as shown in the following table.

Applicant Type	Phase 1, Phase 1/2, Feasibility Award Cap*	Phase 2 Award Cap*	Phase 3 Award Cap*
Non-profit	\$9M	\$11.25M	\$7.5M
For-profit	\$6M	\$11.25M	\$7.5M

2. Adjust the award duration to not exceed 3 years with award completion no later than (November 2023).
3. With a need to launch awards quickly, we propose that applicants be ready to initiate the proposed studies within 30 days of approval instead of 45 days.
4. 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.

The proposed changes above for maximum award amounts, duration and start time will not apply to sickle cell disease projects expected to be funded under the CIRM/NHLBI Cure Sickle Cell Disease joint Initiative.

Requested Action: CIRM requests the Board approve the proposed amendments to the DISC and CLIN concept plans.