

## PUBLIC MEMO

July 2024

### BACKGROUND

Funding of the California Institute for Regenerative Medicine (CIRM) was renewed by the approval of proposition 14, the California Stem Cell Research, Treatments and Cures Initiative of 2020. The ballot measure provides \$5.5 billion to CIRM to support stem cell and regenerative medicine research in California. CIRM structures its funding programs via five pillars that include educational, discovery, translational, clinical and infrastructure programs. CIRM takes great pride in maintaining a rigorous process for evaluating all grant applications by our expert external review panel, the Grants Working Group (GWG), and the members of its Governing Board, the Independent Citizens' Oversight Committee (ICOC) who make final funding decisions. Our goal is to support the highest quality and most impactful research projects directed towards achieving the CIRM mission: to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world. Since 2015, CIRM has provided an open and recurring funding opportunity for clinical-stage projects (CLIN1 and CLIN2) that accepts applications on the last business day of each month. The process brings together, on a monthly basis, members of the GWG to evaluate and score applications and make recommendations for funding. As designed in 2015, the structure has relied on a modest intake of proposals that reflected the still nascent state of the field in reaching clinical trial stage for stem cell and gene therapy research. At this relatively low steady state, the clinical review process has balanced a maximal degree of rigor, speed, and efficiency to serve CIRM's mission.

### ADDRESSING THE INCREASE IN CLIN APPLICATIONS

Over the past year, the CIRM Clinical 1 and 2 programs have received a very large and unprecedented number of submissions per cycle. The high volume of work and the current state of clinical stage application submissions highlights a few key issues.

- The amount of funds requested by all currently submitted clinical stage applications at various stages of the review process exceeds the amount of funds available in the 23/24 fiscal year budget. Based on the historical success rate of 50 to 60 percent, which includes applications that are resubmitted, currently submitted applications have the potential to deplete the fiscal year budget and a continued influx of new applications would most likely increase that likelihood.
- The dramatic increase in application submissions is placing an unprecedented strain on CIRM resources and capabilities, including the GWG (scientific reviewers and the ICOC patient advocates). The CIRM review process for clinical

stage applications cannot reasonably support monthly cycles that experience large volumes, while retaining the level of attention and rigor that we strive to maintain.

## CIRM'S PROPOSED ACTION

Given the large increase in the monthly CLIN application submissions, CIRM has updated our CLIN1 and CLIN2 review process to streamline our operations and improve the overall efficiency of our grant evaluations.

- **New Qualification Process:** When CIRM receives more than five new clinical stage applications (CLIN1 and CLIN2) per review cycle, a qualification step will be applied that will prioritize applications that are most aligned with CIRM goals and program priorities. This step involves a ranking system based on specific criteria. Applications will first be ranked based on a defined set of objective factors that are scored by CIRM staff. If these factors are not sufficient to select the five most responsive applications for a given cycle, a subset of the scientific review criteria (defined in the Program Announcement) will be used by Grants Working Group members to make final selections. This approach ensures that the review panel can maintain a high level of rigor and attention to each application, even with a higher volume of submissions.
- **Ranking and Resubmission Opportunities:** Applications will remain in the competitive qualification pool for up to 3 cycles. That means your application will have up to 3 opportunities to advance to full scientific review. Applications that do not earn sufficient points to be among the top 5 applications after 3 review cycles will be removed from further consideration and cannot be resubmitted for a period of 6 months after the third unsuccessful qualifying attempt.

For detailed information on the objective and subjective criteria used in the new review process, please view the full program announcement [here](#). This document provides comprehensive guidelines to help you prepare a successful application. For additional questions, please refer to our [Clinical Program Updates FAQs](#).