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**MEMORANDUM**

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**TO:** CIRM GOVERNING BOARD  
**FROM:** CIRM LEADERSHIP  
**SUBJECT:** Clinical Program Application Processing  
**DATE:** FEBRUARY 12, 2024

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**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.

## PROBLEM CIRM SEEKS TO ADDRESS

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 leadership believes it is critical to uphold the integrity of the GWG review process, and thus CIRM must ensure it continues to reflect the utmost standards of rigor and quality. Additionally, it is essential to consider how the increased number of submissions impacts the broader spectrum of outcomes, including the fiscal-year and CIRM's overall long-term research budget. Generally speaking, the annual research budget is crafted to ensure meritorious grant proposals submitted during that fiscal year will find sufficient funding. Therefore, CIRM must carefully manage the flow of applications entering the system to ensure that quality of review is maintained and that the output aligns with the institute's budgetary goals.

About a decade ago, CIRM postponed the launch of new programs to assess the effectiveness of our processes and plan responsibly. This resulted in a more streamlined and productive grants process. Success of this organization has relied on periodically evaluating its systems to ensure that we are functioning at our best as is expected by the people of California who created us. Accordingly, CIRM Leadership proposes management of the unprecedented influx of clinical grant applications by temporarily postponing acceptance of new applications within the CLIN1 and CLIN2 programs. It is important to note that this action will not interfere with current submissions moving forward or the processing of any resubmissions that are responding to a GWG review (tier 2 applications). In addition, CIRM, per its commitment to its mission, will be opening in the next weeks a CLIN 4 program grant application for advanced pipeline projects moving to biologics license applications (BLA) in agreement with FDA. These measures

ensure that the current annual fiscal budget will support the current submissions and resubmissions while also developing an alternative mechanism for responsibly managing review of applications and advancing pipeline grants towards potential registration.

This action on CLIN1 and CLIN2 programs and CIRM's progress towards addressing these critical issues will be re-evaluated at the June 2024 Board meeting.