

## FAQs on the Updated Clinical (CLIN1 & CLIN2) Grant Review Process

The California Institute for Regenerative Medicine (CIRM) would like to announce updates to the CLIN1 and CLIN2 (Clinical) grant review process. These changes are designed to streamline our operations and improve the overall efficiency of our CLIN grant evaluations.

Please read the FAQs below to learn more about these updates.

### 1. Why did CIRM postpone acceptance of new CLIN1 and CLIN2 applications?

In February 2024, CIRM postponed the acceptance of new CLIN1 and CLIN2 applications due to an unprecedented influx of clinical grant applications. This temporary measure was necessary to carefully manage the flow of applications to ensure the quality of review was maintained while aligning with our budgetary goals. The significant increase in submissions placed a strain on CIRM resources and capabilities, including the Grants Working Group (GWG) and ICOC patient advocates and nurses. Additionally, the amount of funds requested by all currently submitted clinical-stage applications exceeded the available budget for the 2023/2024 fiscal year.

### 2. Has CIRM lifted the postponement of CLIN1 and CLIN2 applications?

At the June 2024 Independent Citizens Oversight Committee (ICOC) meeting, CIRM's board approved changes to the CLIN1 and CLIN2 concepts and GWG bylaws that allow CIRM to implement the qualification process for applications. The board also approved the reopening of application submissions for the CLIN program.

### 3. When is the first deadline for the new CLIN application submissions?

The first deadline for the new CLIN application submissions is July 31, 2024. Subsequently, applications will continue to be accepted with deadlines on the last

business day of each month except September. If the process proceeds as planned, the earliest approval of a CLIN application could occur in November.

#### **4. When will the CLIN applications be available?**

CLIN applications will be available no later than July 9. You will be able to access the application via the Grants Management System (<https://grants.cirm.ca.gov>).

#### **5. Can I use an old CLIN1 or CLIN2 application or do I need to complete a new one?**

With the opening of application submissions, we are also launching a new set of applications that incorporate changes approved by the ICOC in December 2023 (e.g., warrant options, increase in CLIN1 award amount). You must use the new application forms and templates when submitting an application.

#### **6. Why is a qualification process needed?**

The demand for CIRM funds from prospective awardees is now significantly exceeding the number of projects that CIRM is able to support. CIRM's process for evaluating clinical stage applications is known to give careful consideration to each proposal and provide opportunities for improvement. A large number of applications can overwhelm this established process of review, impacting the rigor of evaluation and the quality feedback that underpins applicant's opportunities for improvement. Therefore, applying a new qualification step to prioritize applications that are most aligned with CIRM goals and program priorities provides an added mechanism to manage the number of applications entering the system while maintaining the rigor of the process.

#### **7. How does qualification differ from eligibility?**

To be "eligible" an application must meet the specific eligibility criteria described in the PA. These are strict requirements that determine whether CIRM can or cannot accept an application under the funding opportunity. On the other hand, an application that qualifies has a set of favored qualities that prioritize it over other competing applications based on a point system. An eligible application

may or may not qualify, but an ineligible application cannot be considered for CIRM funding.

## **8. How does the new CLIN grant review process address the increase in the number of applications?**

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.

## **9. How does this impact the review timeline?**

The qualification step will add a month to the standard clinical review cycle such that the time from application submission to earliest award approval will increase from 3 months to 4 months.

## **10. How many opportunities do I have to qualify?**

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.

## **11. What happens if my application doesn't qualify after 3 cycles?**

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.

## **12. Who determines whether my application qualifies?**

Applications will be scored on objective criteria by CIRM review team staff members and on scientific review criteria by Grants Working Group experts as needed. Ultimately, the total points earned and the relative rank against other applications in the pool will determine which applications qualify.

## **13. What are the qualifying criteria?**

CIRM staff will prioritize applications that:

- Develop a cell therapy candidate derived from pluripotent stem cells;
- Develop a therapeutic candidate that is a genetic therapy, exosome therapy derived from stem cells, or stem cell therapy (excluding unmodified HSC and minimally manipulated cells);
- Are submitted by a California-based organization;
- Advance a previously CIRM-funded project to the next stage;
- Are at a later stage of development than competing applications; and/or
- Target a disease of the brain or central nervous system.

CIRM GWG will prioritize applications based on the following criteria, which are a subset of the current scientific review criteria in the CLIN1 and CLIN2 PAs:

- How impactful would the proposed treatment be for patients if successfully developed?
- How significant is the unmet need that is being addressed?
- How practical and feasible is the proposed treatment for it to be adopted by patients and healthcare providers?
- How responsive is the proposal in providing a DEI plan?

## **14. Will the criteria used for qualification remain the same or might they change at a later time?**

The criteria that will be used are generally aligned with the goals of the current CLIN1 and CLIN2 programs as well as Prop 14. The ICOC may approve changes to these programs to ensure they are responsive to our overall strategic plan. Qualification criteria may therefore be adjusted to ensure continued alignment with any updated program goals and priorities.

## 15. How are points assigned?

For objective criteria, CIRM staff will assign one point for each of the criteria met.

For subjective criteria, the GWG experts will score each criterion question on a scale of 1-5. The GWG experts will also assess if the application includes all necessary components for proper evaluation. Any application that is missing adequate information for review will be removed from consideration and the applicant will be asked to revise and resubmit.

## 16. What can I do to maximize the chance of qualifying?

- Contact the CIRM Therapeutics Development team ([clinical@circm.ca.gov](mailto:clinical@circm.ca.gov)) before completing an application for guidance and advice on developing a competitive application.
- Make sure your application is complete and provides all requested information including a complete CMC plan, FDA correspondence, and clinical protocol if applicable.
- Carefully consider whether your project is aligned with the goals and priorities of CIRM.

## 17. How does the Strategic Allocation Framework relate to the new CLIN process?

The Strategic Allocation Framework and the addition of a qualification step to the CLIN review process are separate, parallel efforts. While the Strategic Allocation Framework focuses on broader strategic priorities, the CLIN qualification process aims to efficiently handle the increasing volume of clinical applications.

**Resources**

CLIN Program Update FAQs – February 2024

New CLIN Review Process – June 2024 PPT

For application questions, contact the CIRM Review office at [review@cirm.ca.gov](mailto:review@cirm.ca.gov).