

**PROPOSED AMENDMENTS TO EXTRAORDINARY PETITION POLICY
AND ADOPTION OF ADDITIONAL ANALYSIS OPTION**

BACKGROUND

A. Extraordinary Petition Policy

Under California’s open meeting laws, members of the public, including applicants for CIRM funding, may provide written and oral comments regarding items on the Board’s agenda. To provide guidance to applicants regarding the submission of written comments, the Board adopted an “Extraordinary Petition” policy.

Although the policy does not define what constitutes an “extraordinary petition”, it imposes a three-page limit on extraordinary petitions and it requires applicants who wish to submit an extraordinary petition to do so at least five business days before the meeting at which the application will be considered. The purpose of this deadline was to provide staff with an opportunity to review the comments and to be prepared to make a recommendation to the Board regarding the application if a Board member asked to discuss the application. Written comments submitted by applicants after the five-day deadline are provided to the Board, and although the policy does not require CIRM staff to review them, the President and CIRM’s scientific officers have, as a matter of practice, been prepared to address them upon request by a Board member.

The Extraordinary Petition policy makes clear that the Board will not automatically consider extraordinary petitions, but instead will only consider a petition if a Board member specifically requests an opportunity to discuss the matter.¹

¹ Extraordinary petitions are sometimes referred to as “appeals.” However, the Extraordinary Petition policy is separate and distinct from CIRM’s appeal process, which is limited to appeals based on conflicts of interest. Pursuant to the appeals process, an applicant may file an appeal alleging that a member of the Grants Working Group had a conflict of interest under the Grants Working Group’s conflict of interest rules. The appeal must be filed within 30 days of receiving the Grants Working Group’s review. Upon receipt of an appeal, the President is charged with reviewing the conflict of interest allegation and determining whether a conflict existed and whether it adversely affected the review. If the President concludes that a conflict of interest existed and that it adversely affected the review, the application is referred back to the Grants Working Group for a new review, excluding the conflicted member. When CIRM’s scientific staff provides applicants with the Grants Working Group’s review of their application, they describe the appeals process and the Extraordinary Petition policy and they notify each applicant of their right to file an appeal and to submit an extraordinary petition.

B. Additional Analysis Option

Subsequent to adopting the Extraordinary Petition policy, the Board adopted an “Additional Analysis Option.” This policy, which expired in March as a result of the inclusion of a sunset clause, permitted the Board to refer an application for additional analysis by the Chair and Review Chair of the Grants Working Group, or a subset of the Grants Working Group, if the Board determined that a material dispute of fact existed which the Board could not resolve at the meeting at which the application was considered. Under the policy, the Board could conditionally deny an application, subject to a limited analysis of the factual issue or issues identified by the Board. The policy required the Chair and Review Chair of the Grants Working Group to review the factual issue to determine whether, in their view, the new information warranted reconsideration of the Board’s conditional decision not to fund the application. If the Chair and Review Chair could not reach a consensus, the matter was referred to a subset of the Grants Working Group, which would review the matter and advise the Board whether reconsideration was warranted.

The policy explicitly stated that the Additional Analysis Option should be reserved only for those circumstances in which the Board was unable to reach a decision at the meeting at which the application was presented because of the factual dispute or question: “Programmatic issues, such as whether the agency’s portfolio is well-balanced among diseases, should not be a justification for additional analysis, nor should clear errors in the review of an application that have been identified by staff and presented to the Board during the meeting at which the application is considered.”

C. Supplemental Information Process

The Board has also adopted a process to permit applicants for Disease Team and Clinical Development awards to submit supplemental information to the Grants Working Group, either prior to, or during, the Grants Working Group’s review. Pursuant to this policy, members of the Grants Working Group and CIRM’s scientific officers identify questions in advance of the meeting, CIRM’s scientific officers communicate the questions to the applicants, and the applicants respond before the Grants Working Group meeting. In addition, if pivotal questions arise during the meeting for which clarification from the applicant is required, CIRM’s scientific officers contact the applicant during the Grants Working Group meeting to obtain a response. If the question requires the submission of new information, the Grants Working Group may defer its recommendation on the application until the applicant has had an opportunity to provide the information and the Grants Working Group has had an opportunity to consider it.

D. Extraordinary Petitions and New Information

At its meeting in July, the Board received nine extraordinary petitions, some of which presented “new” information. In response, the Board exercised its inherent authority to request analysis of new information submitted in connection with five separate applications for Disease Team Therapy Development Awards.

In order to refine CIRM’s policies and to provide guidance to applicants regarding the submission of extraordinary petitions and new information, we propose that the Board consider the following guidelines for the Extraordinary Petition Policy and the Additional Analysis Option.

EXTRAORDINARY PETITION AND ADDITIONAL ANALYSIS GUIDELINES

Extraordinary Petition Policy

Written comments received after the five-day deadline will be provided to the Board as “Other Correspondence” rather than being labeled “extraordinary petitions.” As with all public comments, members of the Board may ask questions about information submitted after the deadline for extraordinary petitions, but responses from CIRM’s scientific staff may be limited, as they will not have had time for a thorough review of late-submitted comments. Whenever possible, applicants should refrain from orally presenting information to the Board that is not contained in an extraordinary petition,

Additional Analysis Option

The Board may invoke the Additional Analysis Option at its discretion if it determines that additional analysis is warranted. The Additional Analysis Option should be complementary to the Supplemental Information Process and it should be reserved for two, limited situations: a material dispute of fact or material new information. Both are further defined below. In both cases, the additional analysis should be conducted by the Review Chair of the Grants Working Group, another scientific member of the Grants Working Group who participated in the review, and the Co-Vice Chair of the Grants Working Group, with the support of the President and CIRM’s scientific staff. In the event of a conflict, another scientific member of the Grants Working Group shall replace the Review Chair and another patient advocate shall replace the Co-Vice Chair.

Criteria for Material Dispute of Fact

A material dispute of fact should meet five criteria: (1) An applicant disputes the accuracy of a statement in the review summary; (2) the disputed fact was significant in the scoring or

recommendation of the GWG; (3) the dispute pertains to an objectively verifiable fact, rather than a matter of scientific judgment or opinion; (4) the discrepancy was not addressed through the Supplemental Information Process and cannot be resolved at the meeting at which the application is being considered; and (5) resolution of the dispute could affect the outcome of the Board's funding decision.

Criteria for Material New Information

New information should: (1) be verifiable through external sources; (2) have arisen since the Grants Working Group meeting at which the application was considered; (3) respond directly to a specific criticism or question identified in the Grants Working Group's review; and (4) be submitted as part of an extraordinary petition filed five business days before the Board meeting at which the application is being considered. The extraordinary petition should identify the new information, explain how it is verified and the date it became available, and identify the specific criticism or question to which it responds. Neither an extraordinary petition nor the submission of additional information should be seen as an opportunity to re-write the proposal. The basic research plan should be the same, and no new aims or approaches should be proposed. In addition, the filing of an extraordinary petition in no way guarantees that the Board will exercise the Additional Analysis Option.

Examples of externally verifiable information include: approval by the Food and Drug Administration to initiate a clinical trial; a documented, enforceable agreement between the applicant and a commercial partner; a final court decision or administrative action; and documentation confirming that a manuscript has been accepted for publication in final form. Information submitted as part of the Supplemental Information Process will not be considered "new information." Similarly, new scientific data will not be considered "new information" unless it has been peer reviewed and published.

CIRM's scientific staff, under the direction of the President, will review new information submitted in an extraordinary petition to advise the Board whether, in the view of scientific staff, the information meets the criteria identified above and warrants reconsideration by the Board of the Grants Working Group's recommendation.

Suggested Process for Board Referral for Additional Analysis

If a Board member wishes to make a motion to refer a material factual dispute for additional analysis, the motion should expressly identify the factual issue to be resolved, e.g., I move that the Board refer Application XYZ for additional analysis of the following question [insert

question] and that the review be limited to analyzing this question and recommending whether it warrants reconsideration of the Grants Working Group's recommendation.

If a Board member wishes to make a motion to refer material new information for additional analysis, the motion should expressly identify the new information to be considered, e.g., I move that the Board refer Application XYZ for additional analysis of the following new information [insert new information] and that the review be limited to considering this information and recommending whether it warrants reconsideration of the Grants Working Group's recommendation.

Although the process described above outlines one possible course of action, this in no way constrains members of the Board from recommending a different process or course of action.

Supplemental Information Process

Before Grants Working Group Meeting

- GWG members and CIRM scientific officers identify and communicate questions to applicants.
- Applicants respond with supplemental information before GWG meeting.

At Grants Working Group Meeting

- If questions arise during meeting, CIRM’s scientific officers may contact applicant to obtain response.
- If questions require submission of new supplemental information, GWG may defer recommendation on application until information is provided and GWG considers it.

Complimentary to, but separate from

Extraordinary Petition Policy

Written Comments

Format: 3 pages or less, Arial typeface, 11-pt. font, 1” margins on all sides; indicates information to be redacted

Before 5 business-day deadline

After 5 business-day deadline

“Extraordinary Petition”

- Directed to ICOC Chairman and President, distributed to ICOC, and posted on website.
- CIRM may redact proprietary or confidential information.
- President, in consultation with scientific staff, prepares recommendation.
- If ICOC member requests discussion, staff provides analysis and recommendation to Board

“Other Correspondence”

- Limited review of written comments by CIRM President and Scientific Officers

ICOC Board Meeting

- Extraordinary petitions and other correspondence provided to Board.
- Board discusses extraordinary petitions / other correspondence *only* upon request of Board member.
- President and CIRM scientific officers provide input upon request.
- If new information is included, President and CIRM scientific officers advise Board whether new information meets criteria for “material new information” and warrants additional analysis.
- Board members may make motions to fund, deny funding, or refer for additional analysis.

Board member moves to refer material factual dispute or material new information for additional analysis

Additional Analysis Option

Material Dispute of Fact

1. Applicant disputes accuracy of statement in review summary
2. Disputed fact significant in GWG scoring or recommendation
3. Dispute of objectively verifiable fact
4. Discrepancy not resolved through Supplemental Information Process
5. Resolution of dispute affects Board funding decision

Material New Information

1. Verifiable through external sources
2. Arisen since GWG consideration
3. Responds to criticism(s) and/or question(s) from GWG review
4. Included in extraordinary petition submission (before 5 business-day deadline)

Additional Analysis

Additional analysis is conducted by the Co-Vice Chair, the Review Chair, and a scientific member of the GWG, supported by the President and other scientific staff. When Co-Vice Chair is conflicted, a patient advocate will review. When the Review Chair is conflicted, another scientific member of the GWG will review.