

DRAFT Recommendations for CIRM Appeals and Extraordinary Petitions Process

Background

As originally adopted by the ICOC in the CIRM Grants Administration Policy (ie, State regulations that govern CIRM awards), formal appeals have been limited to instances where the applicant must show that a demonstrable conflict of interest (as defined in the CIRM Grants Working Group (GWG) Conflict of Interest (COI) Policy) had a negative impact and resulted in a flawed review. This is the only ground for formal appeal of the GWG review under CIRM regulations.

As members of the public, applicants maintain the right to provide written and oral comments to the ICOC regarding items on the board agenda. As such, applicants may choose to informally appeal the recommendations of the GWG by submitting their concerns to the ICOC. The Extraordinary Petition Policy was adopted to provide guidance to applicants on how to submit comments to the ICOC. Aside from page limits and a submission deadline, the policy does not provide any guidance on what may constitute an appropriate and reasonable petition.

An “Additional Analysis Option” was more recently adopted by the ICOC. This policy was intended as a tool for the ICOC to refer specific questions or issues for limited analysis to CIRM staff and/or the GWG chairs. Where the ICOC could not resolve an issue that was critical for their funding decision, a limited analysis that might facilitate the decision could be performed. The policy was most recently re-adopted to refer several applications to the GWG for additional analysis of claims of new information from Extraordinary Petitioners. The re-adoption of this policy refocused the policy towards the consideration of new information brought forth via the petition process.

Overall, these existing policies have not aligned well and have been a source of confusion for applicants. Where the CIRM Grants Administration Policy sought to limit applicant appeals to demonstrable conflicts of interest, the Extraordinary Petition Policy and Additional Analysis Option have greatly broadened the basis for challenging the outcome of a review. Although these policies were originally developed to address very different issues, they all represent (from the applicants’ perspective) possible avenues for contesting the review and gaining an opportunity to have an application reconsidered or funded.

The Current Formal Appeals Process

Currently, the formal appeals process at CIRM (ie, for COI only) provides applicants up to 30 days from the time the Review Report is made available to submit an appeal request. Once the request is received in writing, CIRM staff assesses the merit of the request in consultation with the GWG chair and other experts as needed. A recommendation is made to the CIRM President, who makes the final decision on the merit of the appeal. If an appeal is meritorious, the application will

receive a new review and the subsequent recommendations are then brought to the ICOC.

Given the typically short time frame (about 2 weeks) between the availability of the Review Report and related ICOC meeting, the request for an appeal could conceivably be made after the Board meets. Even if a request is made quickly, appropriate assessment of the request would in most cases not be resolved before the relevant Board meeting. The policy is not clear about what happens to an application with a pending appeals request when it is considered by the ICOC. Should an appeal request result in a need to re-review the application, current regulations require that the full GWG re-convene to reevaluate the application. Although this may be done via teleconference, assembling a full panel to consider one application has a significant impact on competing, ongoing tasks of the institute. To date, the number of formal appeal requests has been few (about 1 request per 4 review meetings). None have yet warranted a GWG assessment.

This formal appeals regulation provides very specific guidance and parameters for addressing applicant concerns related to COI, and an adequate means for resolving such issues. However, improvements to make the process more efficient and practical are in order, such as removing the requirement to have the full GWG re-convene for a re-review as opposed to a more manageable subset of the chair, expert reviewers, and patient advocates. The timing for submitting appeal requests and processing the requests needs to align better with the rapid pace at which applications are brought to the ICOC. This may require lengthening the overall RFA timeline.

The Current Extraordinary Petition Process

Petitions are generally received by CIRM about five business days prior to the ICOC meeting that will consider the applications. Although CIRM staff examines each petition, there is insufficient time to verify claims made by the petitioner or to have experts assess their merit when necessary. Therefore, limited information can be provided to the ICOC to inform their consideration of a petition.

Additionally, the basis for filing an Extraordinary Petition is not well defined and the policy provides no guidance for what a reasonable and appropriate claim would be. The applicant determines what constitutes an extraordinary circumstance under current policy, and this has led to a diversity of interpretations, from very narrow to quite broad. Petitions, therefore, have included rebuttals to specific reviewer comments or perceived criticisms, claims of new significant information, claims of reviewer bias or lack of expertise, arguments that the proposal represents a unique opportunity for CIRM, or overall disagreement with the review outcomes. Often, petitions will dispute the validity of one or two specific criticisms (actual or perceived), yet the overall recommendation of the GWG is based on many factors. Also, since the petition is a public document, and proprietary information is withheld, the information presented to the ICOC can be incomplete.

The ICOC is not required to raise or act on a petition, but in many cases the petition prompts some consideration by the board and may direct the board's attention towards one disputed issue rather than the overall merits of the application. Some applicants choose to present their case in person at the Board meeting and might be supported by other interested parties that will advocate on their behalf, all which present further challenges.

The Extraordinary Petition policy, by virtue of having little or no guidance, allows a very open avenue for applicants to challenge a review. As this policy was not intended to function as a formal appeals policy, it does not impose a formal assessment on the merit of the claims made by the applicant. Therefore, petitions carry the potential to introduce unvetted information that makes the ICOC's decision-making process less rigorous, more cumbersome and less effective.

Establishing an Appropriate Basis for Appeal of a GWG Review

It is clear that establishing a broad basis for appeals requires more time and resources to assess, manage, investigate, and respond to appeal requests than would a narrow appeals policy. As such, funding agencies (including private agencies) tailor their appeals policies to the resources available and the efficiency with which they want to operate. Some funders (foundations in particular) will have no appeals mechanism in order to maximize efficiency and focus efforts elsewhere. Other large agencies such as the NIH can devote sufficient resources to consider several factors that may form the basis of an appeal.

A look at a few policies from government funding agencies shows some general agreement on the use of COI as a basis for appeal but some agencies may include additional factors. There is also agreement that a difference of scientific opinion should not constitute a basis for an appeal. Importantly, the burden is on the applicant to demonstrate and provide evidence that their claim meets the criteria for an appeal. Below are some excerpts from a few agency policies that specify grounds for appeal of a review.

National Institutes of Health

- "1) Evidence of bias on the part of one or more peer reviewers.*
- 2) Conflict of interest, as specified in regulation at 42 CFR 52h.5. "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more peer reviewers.*
- 3) Lack of appropriate expertise within the SRG.*
- 4) Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially."*

Canadian Institutes for Health Research

*"CIHR will not question scientific evaluations made to the best knowledge of Peer Review Committee members. CIHR will review a committee decision **only** if there was a procedural error in the peer review process."*

Canadian Health Services Research Foundation

“There are only two grounds for appealing a recommendation of a merit review panel: 1) if there were clear misinterpretations of fact contained in an application; or 2) if there was missed/undeclared conflict of interest by merit review panel member(s) that may have contributed to bias in the recommendation.”

UCOP Special Research Programs

“An appeal regarding the funding decision of a grant application may be made only on the basis of an alleged error in, or deviation from, a stated procedure (e.g., undeclared reviewer conflict of interest or mishandling of an application).”

NIH policy also adds that communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals. Generally, agencies follow a rule of thumb that all scientific information related to an application *must first undergo peer review* before it is considered in the funding decision.

As we know, CIRM has very limited staff resources. Establishing an appeals process that is too broad can hinder work towards issuing and reviewing other RFAs, and managing our growing portfolio of funded awards. To come up with an appropriate appeals process, CIRM must balance the available resources, the efficiency and speed in the overall grant-making process, and an interest in resolving issues that might prevent an otherwise good project from moving forward.

Draft Recommendations

The following recommendations are meant to frame a discussion related to resolving issues presented by the current formal appeals process and extraordinary petition policy. Discussion at the Application Review Task Force meeting on October 24 raised many of the concerns summarized in this document, particularly related to petitions, and also presented several ideas for addressing them. This is not a comprehensive set of recommendations that would address all points, but aims to bring together a process that is consistent and compatible with CIRM.

- 1. Applicant issues or concerns that challenge the GWG’s review and recommendation should be addressed via a singular and uniform appeals policy.** Claims made by an applicant that require verification, investigation, and/or expert assessment (such as a material dispute of fact, material new information, or a COI) should be vetted via the formal appeals process. A full assessment of such issues often involves confidential and proprietary information that cannot necessarily be presented through the petition process or adequately assessed at a Board meeting. The ICOC should be well informed when

considering the merit of an application. As such, CIRM Scientific Staff in consultation with GWG Review Chair or other scientific experts as needed should evaluate the merit of any claim and prior to ICOC consideration.

2. **The appeals process must allow appropriate time to examine claims that meet the strict criteria for an appeal.** To allow adequate time for examination, the submission of an appeals request that meets the criteria for an appeal would remove the application from consideration at the Board meeting until a resolution is achieved. To allow for this, appeal requests would ideally need to be submitted prior to the Board meeting, but the typical timeline provides a short window of time for applicants to make a considered decision to appeal. Establishing a proper appeals process will likely require lengthening the overall RFA timeline to make such accommodations.
3. **The grounds for an appeal should be limited.** Currently, the grounds for an appeal are limited to a demonstrable COI, but strict additions to this policy should be considered. For example, the two situations that currently qualify for the Additional Analysis Option (as defined under amendments approved by the ICOC in Sept) may be discussed: material disputes of fact or material new information. In all instances, a claim would be expected to have changed the overall GWG recommendation to have merit. Expansion of the current appeals process will result in a need to devote more resources to this effort and likely extend the overall RFA process. However, the current petition and additional analysis policies are already requiring a shifting of resources to address putative material disputes of fact and material new information. Therefore, the need to devote more time and resources is true whether the appeals process is expanded or if we move forward with the recently approved amendments to the Extraordinary Petition Policy and Additional Analysis Option. A key question is whether the grounds for appeal or petitions should instead be narrowed for efficiency and speed.
4. **The Extraordinary Petition policy should be modified and renamed.** The term “petition” is largely a synonym for the term “appeal” and leads to significant confusion. The analogy to an appeal also suggests that there is a formal vetting process prior to ICOC consideration. The term “extraordinary” should either be removed or defined more clearly. A suggestion of “Board Correspondence” may be more appropriate. The modified policy should also provide guidance on what is reasonable and appropriate “correspondence” to the Board. Correspondence would not include any claims that meet the criteria for an appeal request. Any correspondence containing such claims would be routed to the appeals process. The modified policy should maintain an open door for applicants to communicate with the ICOC. However, an underlying principle for submissions should be that the correspondence should aim to inform or advocate for the programmatic value of the submitter’s application. Challenges of the review should be referred to the appeals process.
5. **Applicants should first raise concerns with the CIRM Review Office to ensure consistent guidance about appeal options and process.** This is currently a requirement under the formal appeals regulation and is analogous to NIH, NSF, and other agency policies. The aim of such a policy is to ensure

consistent and appropriate guidance to applicants about options for appeal but also to provide applicants a better understanding of the review and perhaps remedy any concerns. Board members and Executive staff that receive communications from applicants that are consistent with a possible appeals request should direct the applicants to the CIRM Review Office.

6. **The Board should establish a firm policy of declining to re-evaluate the *scientific* assessments of the GWG.** The Board makes all final decisions in grant applications, and is always free to reject the recommendations of the Grants Working Group. The Board is constituted to include members with a range of expertise and perspectives, and the Board is well-positioned to consider whether non-scientific grounds exist for funding an application with a scientific score below the top rank, or declining to fund an application with a high score. As many Board members have observed over the years, the Board is *not* in a good position to independently assess scientific merit, or to resolve differences of scientific judgment. By clearly communicating this position to applicants, the Board would encourage applicants to focus their communications on appropriate areas.