

Appeals and Requests for Consideration of GWG Funding Recommendations

A. Procedure for Filing an Appeal or Request for Reconsideration

1. Repeal of Extraordinary Petition and Additional Analysis Option Policies. This policy supersedes the ICOC's Extraordinary Petition and Additional Analysis Option policies.

2. Scope and Term of Policy. Outside of ICOC Programmatic Review, any challenges to a funding recommendation by the Grants Working Group (GWG) shall be filed pursuant to this policy or Section II.F. of CIRM's Grants Administration Policy for Academic and Non-Profit Institutions (GAP). This policy shall remain in effect for one year, unless earlier amended or extended by the ICOC.

3. Purpose of Policy. Under this policy, applicants for CIRM funding may appeal a GWG funding recommendation on the basis of a "material dispute of fact," or, with respect to Translational Applications (as defined in Paragraph C.1), also seek reconsideration of a GWG funding recommendation based on "material new information," as set forth below. This policy does not apply to pre-applications or applications for conference grants.

4. Requirement to Confer with CIRM Review Office. Before filing an appeal or request for reconsideration, the PI/PD should carefully examine the GWG review report provided by CIRM. Any questions or concerns about the conduct of the review or appeals process must first be raised with the CIRM Review Office (RO). After the PI/PD has conferred with the RO, CIRM may then accept an appeal or request for reconsideration. Failure to confer with the RO before filing an appeal or request for reconsideration may result in an appeal or request for reconsideration being denied.

5. 10-day Deadline for Filing Appeal/Request for Reconsideration. All appeals and requests for reconsideration shall be made in writing and shall be filed with the CIRM RO no later than ten (10) days after the review report was provided in writing to the PI/PD. An untimely appeal or request for reconsideration may be denied. Appeals and requests for reconsideration shall be limited to no more than a three (3) page narrative explaining the grounds for the appeal or request for reconsideration, exclusive of supporting documents, exhibits, or attachments.

B. Appeal Based on Material Dispute of Fact

1. Grounds for Appeal. Grounds for an appeal (other than for a conflict of interest, which is addressed separately in Section II.F. of the GAP) are strictly limited to a "material dispute of fact." In order to demonstrate a material dispute of fact, the PI/PD must clearly and succinctly state facts establishing all of the following criteria: (a) the dispute involves the accuracy of a statement in the review summary; and (b) the dispute pertains to an objectively verifiable fact, rather than a matter of scientific judgment or opinion; and (c) the dispute was not resolved prior to or during the GWG meeting. A "material dispute of

fact” does not include disagreements over interpretation or analysis of facts by the GWG or specialist reviewers.

2. Review of Appeal. (a) CIRM staff will first determine whether the applicant has set forth clear grounds for an appeal pursuant to paragraph B.1., i.e., whether the PI/PD has set forth facts that demonstrate the occurrence of a material dispute of fact. If the PI/PD has NOT set forth clear grounds for an appeal, the appeal will be terminated, the applicant will be so informed in writing, and the GWG’s recommendation will be presented to the ICOC without any further scientific review. If staff determines that the PI/PD has set forth clear grounds for an appeal, staff will initiate an investigation and ICOC consideration of the application will be **deferred** until a resolution is reached.

(b) If staff determines that the PI/PD has set forth clear grounds for an appeal, staff will next assess whether or not the disputed fact was significant in the scoring of the application and could have affected the outcome of the GWG recommendation. In making this assessment, CIRM staff may consult with the review chair of the GWG and GWG scientists involved with the initial review of the application at issue, and/or may consult with additional scientific experts as needed. Based on that assessment, CIRM staff will present a recommendation to the CIRM President. CIRM’s President will then make the final decision whether to grant an appeal based on the following factors: (1) whether the claims are substantiated; and (2) whether the disputed fact may have significantly affected the scoring of the application and may have affected the outcome of the GWG recommendation.

3. Further Scientific Review. If the President grants an appeal, the application will be referred to a GWG subcommittee consisting of not less than three scientific members of the GWG, including the GWG review chair, and not less than one patient advocate member of the GWG, for further scientific review. If the review chair has a conflict of interest with the application, a new review chair will be appointed by CIRM. Further scientific review shall be limited to an assessment by the scientific members of the subcommittee whether the disputed fact, if it had previously been correctly determined, would have changed or changes the GWG’s funding recommendation. The recommendation of the scientific members of the subcommittee, based on this assessment, will then be presented to the ICOC, which will make the final decision on funding the application in question.

C. Request for Reconsideration Based on Material New Information – Translational Applications ONLY

1. Grounds for Reconsideration. Grounds for reconsideration are strictly limited to “material new information” in connection with a Translational Application. A “Translational Application” means an application where the goal is to achieve a Development Candidate, an IND filing, or to complete a clinical trial. Requests for reconsideration based on material new information will not be entertained in connection with other applications for funding. In order to demonstrate the existence of material new information in connection with a Translational Application, the PI/PD must clearly and succinctly state facts establishing criteria (a) through (c), as follows: (a) the new

information consists of one of the following: (i) approval by a regulatory body, such as the Food and Drug Administration, to initiate or continue a clinical trial; or (ii) a documented, enforceable agreement between the applicant and a commercial partner; or (iii) a final court decision or administrative action; or (iv) documentation confirming the availability of critical material(s) necessary to carry out the proposed project; (v) a manuscript containing relevant new scientific data that has been peer reviewed and published or peer reviewed and accepted for publication in final form; (vi) a filed patent application containing relevant new scientific data; or (vii) confidential data in the possession of a for-profit applicant that is unpublished but that the applicant is willing to make available for consideration of the application and (b) the new information became available to the applicant after the GWG review meeting at which the application was considered; and (c) the new information responds directly to a specific criticism or question addressed in the review summary.

2. Review of Request for Reconsideration. (a) CIRM staff will first determine whether the application has set forth clear grounds for reconsideration pursuant to paragraph C.1., i.e., whether the PI/PD has stated facts that demonstrate the existence of “material new information” in connection with a Translational Application. If the PI/PD has NOT set forth clear grounds for reconsideration, the request will be terminated, the applicant will be so informed, and the GWG’s recommendation will be presented to the ICOC without any further scientific review. If staff determines that the PI/PD has set forth clear grounds for reconsideration, staff will initiate an investigation and ICOC consideration of the application will be **deferred** until a resolution is reached.

(b) If staff determines that the PI/PD has set forth clear grounds for reconsideration, staff will next assess whether or not the criticism or question addressed by the new information was likely significant in the scoring of the application and could have affected the outcome of the GWG recommendation had it been available at the time of the review. In making this assessment, CIRM staff may consult with the review chair of the GWG and GWG scientists involved with the initial review of the application at issue, and/or may also consult with additional scientific experts as needed to evaluate the merit of the request. Based on that assessment, CIRM staff will present a recommendation to the CIRM President. CIRM’s President will then make the final decision whether to grant a request for reconsideration based on the following factors: (1) whether the claims are substantiated; and (2) whether the new information addresses a criticism or question that may have significantly affected the scoring of the application and may have affected the outcome of the GWG recommendation had it been available at the time of the review.

3. Further Scientific Review. If the President grants a request for reconsideration, the application will be referred to a GWG subcommittee consisting of not less than three scientific members of the GWG, including the GWG review chair, and not less than one patient advocate members of the GWG, for further scientific review. If the review chair has a conflict of interest with the application a new review chair will be appointed by CIRM. Further scientific review shall be limited to an assessment by the scientific members of the subcommittee whether the new information, if it had been available previously, would have changed or changes the GWG’s funding recommendation. The recommendation of the

scientific members of the subcommittee, based on this assessment, will then be presented to the ICOC, which will make the final decision on funding the application in question.