# **Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)**

### **Appeals of Initial Peer Review**

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The NIH policy for handling appeals of initial peer review is stated in the NIH Notice: OD-11-064: Appeals of NIH Initial Peer Review. The policy defines an appeal as a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria:

- 1) Is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review;
- 2) Describes a flaw or perceived flaw in the review process for a particular application;
- 3) Is based on one or more of four allowable issues (see "Bases for Appeal" below); and
- 4) Displays concurrence from the Authorized Organization Representative (AOR).

This policy applies only to the initial peer review of grant applications; it does not apply to the review of contract proposals.

## **Bases for Appeal**

Bases for appeal include the following:

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

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a "grievance," which is defined below.

## **Grievances and Disputes**

A "grievance" is defined as "a written communication from a PD/PI and/or applicant organization that presents concerns about the peer-review process for a particular application and that does not meet the criteria for an appeal." An example of a grievance is a request for reinstatement of Integrated Review Group (IRG) deleted funds or years, which, depending upon the size of the budget reductions, may be taken to the Advisory Council as a staff

action/recommendation, rather than a formal appeal, or handled administratively by NICHD program and grants management staff.

A concern about referral assignment of an application is considered a "dispute" and is not grounds for appeal. Concerns about assignment of applications to SRGs at the Center for Scientific Review (CSR) should be brought to the attention of the Division of Receipt and Referral (DRR) at CSR prior to review for clarification/resolution. Concerns about assignment of applications to NICHD SRGs should be brought to the attention of the Division of Scientific Review (DSR) at NICHD.

#### **Procedures**

When a PD/PI and/or AOR contacts NICHD staff with concerns about a summary statement, program staff should attempt to resolve the issue(s). The NICHD Program Official (PO) may answer questions about the summary statement and review outcome and provide advice to the applicant regarding the appeals process. In particular, the PO should remind the PD/PI that difference of scientific opinion is not grounds for an appeal. After discussion of the specific concerns, the PO may recommend that the applicant revise and resubmit the application based on the issues that were raised in the review and communicated in the summary statement. For applications that are not eligible for resubmission, the PO may recommend reconsidering the basic intent of the project and submitting a new application that has substantial differences in aims and approach. If the PD/PI and/or an official of the applicant organization still wishes to appeal the outcome of the initial peer-review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO.

The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, from the Contact PD/PI for multiple PD/PI applications, or from an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send his/her concurrence to the PD/PI, who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than the AOR) only or with a "cc" to the AOR will not be accepted.

Appeals will be accepted up to 30 calendar days after the National Advisory Child Health and Human Development (NACHHD) Council meeting to which the application has been assigned. In no circumstance, however, will an appeal letter be accepted before the summary statement has been transmitted to the PD/PI.

Upon receipt of an appeal, the NICHD will contact the applicant, in writing, within 10 working days of receipt of the letter, indicating that the letter has been received and that a decision will be communicated to the applicant within 30 working days after the relevant Council meeting. Next, the PO will provide a copy of the appeal letter to the relevant Scientific Review Officer (SRO) who, in turn, may contact individual reviewers, if necessary, in order to respond to the issues raised in the letter.

(**Note** that if an appeal involves potential conflict of interest or violation of ethical conduct rules on the part of an NIH staff member or other federal employee, the appeal will be referred to the

NICHD Deputy Ethics Counselor for consideration and resolution before any further review of, or action on, the appeal can be taken.)

If both review staff and program staff support an appeal, the original application, without any additional materials or modifications, will be re-reviewed by the same or different SRG. In this case, only the results of the re-review, and not the first review, are made available to Council; information about the appeal is not made available to Council.

If program staff and review staff cannot come to agreement, then the appeal will be presented to Council for formal discussion and resolution. The PO will prepare an appeal package consisting of the appeal letter, summary statement, application, staff recommendation, and written comments from the SRO, who will be invited to attend the Council meeting to answer any questions that may arise. Both the PO and the SRO should be available during Council discussion.

If both review staff and program staff agree that the appeal does not warrant re-review, but the appeal letter is not withdrawn, then the full appeal package will be made available to Council as an information item not requiring discussion. Any Council member may, however, raise any appeal letter for formal discussion. When considering appeals, staff and Council members should address the following:

- Was the review substantially flawed because of error, bias, conflict of interest, or lack of appropriate scientific expertise?
- Is the issue simply a matter of scientific difference of opinion?

When there are factual errors in the summary statement, those errors must be judged in the context of the entire review and the priority score. Minor errors may not be as consequential as substantial or numerous errors. An important question to ask is: Had the error(s) not occurred, is there a reasonable probability that the application would have been in the competitive range for award consideration?

If, after discussion with staff, the PD/PI decides to withdraw an appeal letter, then a formal request to withdraw must be submitted in either hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application.

## **Consideration by Council**

All unresolved appeals will be taken to the NACHHD Council. Appeals for which program and review are not in agreement are taken to Council for full discussion and resolution. Appeals for which program and review agree that the application should not be re-reviewed are taken to Council as information items, but Council may choose to raise for formal discussion any appeal that is presented as an information item.

Every effort will be made to take the appeal to the next Council meeting. If, however, the appeal is received late in the cycle, or if there is insufficient time for staff to investigate all the issues, then the appeal will be taken to the next subsequent Council meeting. (Please consult with the PO regarding the timeline for Council actions.)

Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal and recommend that the application be rereviewed.
- The Council may concur with the SRG's recommendation and deny the appeal.

Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the review and therefore deny the appeal. If the Council decides to take no action on an appeal, this is equivalent to concurrence with the SRG's recommendation.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NICHD through this or another process. At no time should the PD/PI or an official of the applicant organization attempt to contact individual members of the Council to discuss their consideration of an application or appeal, as doing so could jeopardize the confidentiality of the review process.

If the Council recommends that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending upon the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

Upon resolution, NICHD will communicate the Council recommendation to the PD/PI, AOR, and relevant NIH staff no later than 30 calendar days after the Council meeting. A copy of the letter to the PD/PI and AOR will be placed in the official grant file.

# **Reminders for Applicants**

In order to be considered as appeal, the letter must:

- Clearly address one or more of the bases for appeal, as noted above;
- Be signed by both PD/PI and AOR; and
- Be received no later than 30 days after the assigned Council meeting.

When a formal appeal is initiated, the appeal process must be resolved before any funding decision can be made. Therefore, re-review delays the award decision and may not improve the outcome.

Re-review results in a second review of the identical application with all its original strengths and weaknesses. The PD/PI may not make any revisions to the application and may not submit any additional materials.

There is no guarantee that the score will improve upon re-review, and there is a real risk that the new score might be worse. When an application is re-reviewed, only the results of the re-review, and not the first review, are made available to Council for their concurrence. Funding decisions would be based upon the new score, not the previous one.

In light of these considerations, the PD/PI may be better served by revising the application in response to uncontested criticisms or, when resubmission is not possible, redirecting the research ideas and goals into a new application.

#### **For More Information**

Contact the NICHD Office of Extramural Policy.