## **NHGRI Appeals Process**

NIH has recently revised the <u>formal process</u> to correct flawed initial reviews of research and National Research Service Award applications. A formal appeal must be based on one or more of four specific issues listed below, and must include concurrence from the authorized organization representative (AOR). The four specific issues that can serve as the basis for an appeal are:

- 1. Evidence of bias on the part of one or more of the peer reviewers.
- Conflict of interest (COI), 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 of the peer reviewers.
- 3. Lack of appropriate expertise within the review panel.
- 4. Factual error(s) that could have substantially altered the outcome of review made by one or more of the reviewers.

Before beginning the appeals process, the applicant is strongly advised to speak with the assigned NHGRI program director responsible for the application. The program director can explain the options and their consequences and is often in a position to help the applicant understand the study section's recommendation. In most cases, issues can be resolved at this stage. Applicants cannot be denied the right to appeal a review recommendation.

For those cases that cannot be resolved by discussion, the first step in the appeals process is the submission of a formal *appeal letter*. An appeal is a written communication from the principal investigator (PI) and the applicant institution and must:

- 1. describe a flaw or perceived flaw in the review of the application according to one or more of the four criteria listed above;
- 2. be received after issuance of the summary statement and up to 30 calendar days after the second level of peer review; and
- 3. include concurrence from the AOR.

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\*, and will not necessarily be taken to the National Advisory Council for Human Genome Research.

An appeal letter submitted after study section review should be sent to the program director in NHGRI. Upon receipt, program and review staff will analyze the concern(s) expressed and try to resolve the issue(s) and take the appropriate action. If the issue(s) cannot be resolved by staff, the appeal letter and all relevant information will be made available to the National Advisory Council for Human Genome Research, which conducts the second level of review for research applications. Appeals to NHGRI as primary are due three weeks before the applicable Council meeting (Council meeting dates). Consideration of appeals received after this date may be deferred to the next Council meeting. At no time should the PD/PI or an official of the applicant organization attempt to contact individual Council members to discuss the application or appeal, as doing so could jeopardize the confidentiality and integrity of the appeals process.

The Council may agree with either the study section or the applicant. If the Council agrees with the applicant, it will recommend a re-review. If re-review is recommended, the same application, not a revised or updated version, will be re-evaluated. If the Council agrees with the study section, the review is considered to be valid. The Council's recommendation concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

In the case that the Council determines that the review was valid, the applicant should contact the program director, who can often give valuable advice about how to proceed.

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- \* A grievance is a written communication from a PD/PI and/or applicant organization that presents concerns about the peer review process for a particular application and does not meet the criteria for an appeal. Examples of a grievance are, but not limited to:
  - 1. recommended reductions in budgets and project duration;
  - 2. scientific differences of opinions;
  - 3. submission of additional information not in the application;
  - 4. or a plea for funding.

A Program Director (PD) has the discretion to raise these concerns with Council.