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from Molecule to  
Organism*

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# The American Physiological Society

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March 17, 2008

Elias Zerhouni, M.D.  
Director, National Institutes of Health  
1 Center Drive  
Bethesda, MD 20892

Dear Dr. Zerhouni,

I am writing on behalf of the American Physiological Society (APS) with comments in response to the Final Draft of the 2007-2008 Peer Review Self Study. We welcome the opportunity to provide input on this important report and we look forward to continuing to work with the NIH in the future as implementation of the recommendations gets underway. We appreciate the working group's thorough review of the peer review process, and the attention paid to maintaining the core values that make this system successful. While we agreed with many of the report's recommendations, there are areas that are of concern to APS members, and the comments below focus on those recommended actions.

**Recommended Action: Provide unambiguous feedback to all applicants. (pg. 30)**

In our original comments submitted in response to NOT-07-074, APS proposed eliminating the practice of not scoring each application and we are pleased to see that the report makes this recommendation. By providing comments and a score for each application, and using the full range of scores (1.0 to 5.0) we feel that the implementation of a Not Recommended for Resubmission (NRR) designation will become unnecessary. In other words, a score of 4.5 should reasonably be interpreted as not recommended for resubmission. In order for this to be effective, reviewers would need to be aware of their obligation to use the full range of scores, and applicants would need to understand the implications of receiving a poor score. Program officers could be involved in counseling applicants about the advisability of resubmitting grant applications that scored poorly.

**Recommended Action: Eliminate the "special status" of amended applications. (pg. 33)**

While we recognize the troubling trend towards not funding applications until the second resubmission, the recommendation to treat all applications as new is of great concern to the Society's members. Many NIH funded scientists find tremendous value in the process of revising grants in response to reviewer comments, and feel that this practice should not be discontinued. Because applications would still be resubmitted, we are concerned that there will be an increase in administrative burden on the new reviewers who will not be able to benefit from seeing the prior reviewers' comments and insights, and that applicants will essentially be trying to hit a "moving target" as they

revise their grant applications. In addition, not providing the previous reviews diminishes the value of the original reviewers' efforts. The APS recommends that the NIH not move forward with this idea.

**Recommended Action: Pilot the use of short, bi-directional “prebuttals” (for applicants and/or reviewers) to correct factual errors or explain factual items in review. (pg. 34)**

We feel that the use of “prebuttals” has the possibility of being useful for reviewers and applicants, but that it may ultimately increase the burden on reviewers by requiring them to complete and post reviews in a shorter time frame. In addition, it may be difficult to define “factual errors” and separate them from what are more often errors of judgment in grant reviews.

**Recommended Action: Rank applications considered by the study section. (pg. 40)**

Our members are concerned that explicitly ranking all of the applications at the end of the meeting, removed in time from a discussion of the pros and cons of an application, will lead to an undesirable degree of arbitrariness in the final scores. The process of ranking also suggests that the success of an application will be directly affected by the quality of the other applications that happened to be at a particular meeting. Instead, we suggest that the applications be briefly discussed at the end of the meeting and the opportunity given to rescore all of the applications.

**Recommended Action: Link potential study-section service to the most prestigious NIH awards. (pg. 48)**

We agree that linking study section service to receipt of NIH awards is a necessary step towards increasing the pool of expert reviewers and ensuring that study sections have experienced scientists contributing to the review process.

**Recommended Actions on pages 54-56 regarding early career investigators**

For early career investigators, we agree that continuing to fund more R01s is an important part of securing the success of the next generation of scientists. We also agree with taking into account the applicant's institutional commitment when evaluating the environment rating criteria. Rather than having early career investigators reviewed by generalists, we feel that evaluating early career investigators in regular study sections and comparing them to each other instead of the general applicant pool is an idea worth pursuing.

**Recommended Action: Use the NIH Director's Pioneer, NIH Director's New Innovator and the EUREKA award programs as starting points to develop a path to invite, identify and support transformative research, expanding the number of awards to a minimum of 1 percent of all R01-like awards. (pg. 60)**

Regarding the expansion of award mechanisms such as the Director's Pioneer, new Innovator and EUREKA awards, we feel that it is important to have some measure of the success of these relatively new award programs before expanding them to a significant fraction of R01-like awards.

**Recommended Action: Determine the underlying causes of submission patterns and results in CSR and IC panels and consider corrective actions if needed. (pg. 63)**

The report notes that concerns about inadequate human subjects protections can cause applications to be scored poorly. We are concerned that reviewers may not have adequate training and experience to proficiently evaluate the appropriateness of human subjects protections in grants.

The “just in time” rule that allows grants to be submitted prior to IRB approval may be adversely affecting the scoring of clinical research grants, and we suggest having a review for human subjects research concerns by experts who are familiar with the OHRP rules that is separate from the review of the merit of the application.

**Recommended Action: Require, in general, a minimum percent effort on research project grants. (pg. 68)**

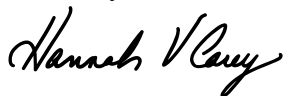
We agree with the recommendation for grants to require a minimum percent effort for Principal Investigators, which would limit the number of grants that one researcher could hold. However, we feel that it is important that there be a process for requesting exemptions from the rule when necessary. There may be cases where requiring a minimum 20 percent effort on a grant causes problems in terms of level of salary support for senior investigators submitting modular grant applications.

**Recommended Actions: Mandate a periodic, data-driven, NIH-wide assessment of the peer review process. Capture appropriate current baseline data and develop new metrics to track key elements of the peer review system. (pg. 71)**

With all of the suggested changes under consideration, we are in favor of continuous review of the peer review system. We feel that it is necessary to pilot as many of the recommendations as possible, and follow up with a transparent evaluation process. Because the peer review system depends on the participation of scientists, it is of the utmost importance that scientists have confidence in the functioning of the system.

In closing, on behalf of the APS I would like to thank you for your efforts and for your consideration of our comments.

Sincerely,

A handwritten signature in cursive script that reads "Hannah V. Carey".

Hannah V. Carey, Ph.D.

President

The American Physiological Society