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President

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BY ELECTRONIC MAIL: PeerReviewRFI@mail.nih.gov

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Re: AAMC Preliminary Comments on the NIH Peer Review Self-Study Final Draft released February 29, 2008

Dear Dr. Tabak and Dr. Yamamoto:

The Association of American Medical Colleges (AAMC) has closely followed the deliberations of the Peer Review Working Group to the NIH Director's Advisory Committee as well as the Steering Committee Working Group, chaired by Dr. Tabak and Dr. Jeremy Berg. The AAMC has further provided comments and testimony and has participated at every opportunity when invited by the working groups, on behalf of all 129 U.S. allopathic medical schools, some 400 teaching hospitals and academic health systems, and 89 academic societies. We have encouraged investigators and administrators at our member institutions, which collectively perform 60 percent of all extramural research sponsored by the NIH, to provide considered comments on the final draft of the 2007-2008 peer review self-study.

Given the inadequate time provided for public comments to the draft final report, the AAMC has not yet been able to collect enough responses to the report to fairly represent the diversity of our membership. However, to meet NIH's deadline, we are submitting the Association's *initial*

comments that convey several general observations of concern and summarize statements received from a limited number of our constituent institutions. The AAMC reserves the prerogative to amend or amplify these comments as planning for and implementation of peer review reform progresses at NIH.

"'Best'" Science

The executive summary of the final draft (p. 3) states:

> Above all, it is critical that the NIH maintain the core values of peer review: scientific competence, fairness, timeliness, and integrity. When striving to fund the "best" science, the NIH must consider many factors, including the scientific quality, public health impact, the mission of an NIH Institute or Center, and the current NIH portfolio.

The self-study is primarily focused on the *initial peer review processes*, and therefore we are very troubled by this statement as a frame for the report's recommendations for peer review. The AAMC strongly believes that initial peer review should focus exclusively, or very nearly so, on the quality of the science, the track record of the applicant, the institutional environment for support of biomedical research, etc., and that this focus should be underscored—not attenuated—at the outset of the document. This view is consistent, we believe, with NIH's own earlier policy statements to Congress and the public.[1,2] The AAMC, of course, fully understands and supports the role of NIH Councils, leadership and staff in overseeing funding decisions and ensuring that public health impact and the missions of the funding institutes or centers are taken into consideration with respect to the funding entity's total research grant portfolio,[3] but these processes of Council review, portfolio management, and ultimate institute and center decision-making are *not,* as we understand it, the focus of this self-study. The report should unambiguously reaffirm that the prime role of peer review is the assessment of scientific quality.

In describing the rating system for grants, the final draft states (p. 39):

> Criterion-specific rating provides flexibility for [Institutes or Centers] to weight those criteria that are important to the mission and/or portfolio of the funding IC. Potential rating areas include impact, investigator(s), innovation/originality, plan, and environment (including institutional support), as well as the overall score that is based on each reviewer's overall sense of the importance of the proposal… Specific scoring criteria should be matched to specific sections of the application to directly address each topic.

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[1] Varmus testimony to Congress, 1997.
[2] Setting Research Priorities at the National Institutes of Health, Sept. 1997. Regrettably, the booklet no longer appears accessible on the NIH's website.
[3] The AAMC's original comments on the challenges for peer review recommended independent chairs for these bodies in recognition of their important roles. Letter, Sept. 6, 2007.
http://www.aamc.org/advocacy/library/research/corres/2007/090607.pdf

In light of our comments on initial review above, the AAMC believes that the "criteria that are important to the mission and/or portfolio of the funding IC" could be interpreted as shifting IRG attention away from the criteria that comprise "scientific quality." Moreover, assessments of "impact" of a proposal, in our view, are almost always recognizable only *after* the fact of the research findings, not before. For example, it was only after Watson and Crick solved the structure of DNA that the structure's illumination of the mechanisms of DNA replication and expression became "obvious" and "transformative;" the same can be argued for David Baltimore's discovery of reverse transcription, the early seminal research with bacteriophages that elucidated the properties and mechanisms of the action of restriction enzymes, and on and on.

Study Section "Mentorship"

As evident in the attached sample of comments from AAMC members, there seems to be broad support in the research community for the role of study sections in providing useful guidance to applicants for further refinement and development of their research proposals and methodology, i.e., mentorship. However, we recognize the apparent distortion of priority scoring and funding decisions that such mentorship has created, and the conclusion of the working group that such mentoring of investigators, including new investigators, should more appropriately be the responsibility of departments and institutions, not of study sections. The AAMC appreciates the very strong arguments that the working group has articulated in favor of such a fundamental policy change. The volume of applications, and particularly amended applications, the stagnant NIH budget, protracted cycles of review, the difficulty in obtaining and retaining qualified reviewers, and other stressors to the grant system reasonably require NIH to make tradeoffs between the integrity and efficiency of review versus the unintended consequences that have resulted from IRG mentoring and the proliferation of A1 and A2 applications.

Accordingly, the AAMC does not oppose this policy change. However, the Association strongly urges that criteria, such as those for assigning a NRR ("not recommended for re-submission") designation to an application, be clearly and unambiguously defined for reviewers and applicants alike. The Association also believes that a responsive, robust appeals process must be made available to applicants who can demonstrate credibly that reviewers misinterpreted or misunderstood crucial aspects of the proposal.

Reducing Stress on the Support System of Science (Challenge 6)

The AAMC agrees that altering current incentives and reducing growth in the number of grantees could certainly reduce the burden on peer review systems and improve sustainability of biomedical research programs overall. NIH and the academic community should explore alternative "business models" for support of biomedical research including increased coordination and collaboration in development of specialized resources, development of research training programs realistically aligned with market demand, etc. Nevertheless, these kinds of

policy decisions seem outside the scope of efforts that would improve the peer review process itself and should be undertaken as a separate initiative.

The AAMC does not take a position on the recommended minimum level of effort for a proposed principal investigator given the lack of sufficient response to this issue received to date from our member institutions. We certainly appreciate the working group's rationale for the recommendation, although whether the limitation should be 20 percent or some other level, e.g., 10 percent, is arguable. Moreover, NIH should explicitly recognize that the denominator related to effort calculations varies widely within the university and academic medical center community due to institutional variation in structure, organization, and practices. The recommendation also would be patently inappropriate for certain mechanisms (conference awards, institutional training awards, many center awards, etc.), and it is unclear how a minimum level of effort should apply to instances of two or more co-principal investigators, as is now allowed to advance multi-disciplinary science. The recommendation is certainly worth further exploration, perhaps by piloting with several appropriate mechanisms.

Innovation

The AAMC is disappointed that the working group did not make strong recommendations for the use of teleconferencing or other practical technologies to conduct review operations over long distances, as had been recommended in AAMC's earlier comments and elsewhere. The National Science Foundation has been particularly innovative in its review mechanisms, and we believe the NIH review process should have given more consideration to the use of new technologies that would reduce reviewer burden, the challenge of enlisting expert reviewers, and NIH expense.

In closing, the concerns noted above should not detract from the Association's immense appreciation of the diligent, strenuous, and timely efforts by the working group and NIH staff and leadership to obtain broad community input and provide a comprehensive set of recommendations for reform. The AAMC looks forward to working with the NIH and the research community in achieving a more effective, streamlined, and broadly participatory peer review system that will be widely respected for its integrity, efficiency, and fairness. For further assistance or clarification of the AAMC's views on peer review, please contact David Korn, M.D., Chief Scientific Officer (dkorn@aamc.org; 202-828-0509).

Sincerely,

Darrell G. Kirch

Darrell G. Kirch, M.D.

Attachment