

**ASSOCIATION OF AMERICAN MEDICAL COLLEGES
RESPONSE TO REQUEST FOR INFORMATION: NIH SYSTEM TO SUPPORT
BIOMEDICAL AND BEHAVIORAL RESEARCH AND PEER REVIEW (NOT-OD-07-074)**

Information:

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1. Challenges of NIH System of Research Support: Please describe any specific challenges presented by NIH's support of biomedical and behavioral research such as the current array of grant mechanisms, number of grants awarded per investigator, and the duration of grants.
 - The array of grant mechanisms utilized by the NIH, and the rampant variation imposed by the different ICD's on the specifics of each mechanism including duration and funding levels, is truly bewildering. The only true analogy is airline fares. This level of complexity hinders fair and efficient allocation of resources.
 - The discrepancy between the state of knowledge provided by research and the application of that knowledge in medical practice (so-called T2 block) is of increasing concern and has stimulated much thought about the challenge of modifying the behavior of physician practitioners. There is a need for creative behavioral sciences research to identify more effective ways to change practitioners' behavior.
 - The NIH intramural research program receives 10% of the NIH budget, conducts research that is not fundamentally different in either content or approach from that conducted extramurally, but is not peer reviewed with the same rigor and has not been systematically reviewed in nearly a decade (Marks-Cassell Committee). This perceived inequity creates tension within the research community.

2. Challenges of NIH Peer Review Process: Please describe any specific challenges presented by the current peer review process at NIH.
 - The increase in biomedical scientists engendered by the doubling of the NIH budget combined with declining NIH resources since 2003 has created a flood of applications and amended applications. This in turn increases the review burden, the need for additional reviewers and study sections, diverts reviewers' and investigators' time away from research, and leads to excessive conservatism in proposals and reviewer micromanagement of research, all without benefit to science.
 - There is a persisting challenge in constituting IRGs such that there is the depth and breadth of expertise to fairly review interdisciplinary and multidisciplinary research.
 - The second level of peer review, i.e. the ICD councils, is tasked with helping ICD's establish the scientific priorities for funding. It is a challenge for these bodies to provide independent and objective input because they report to the ICD director rather than to an independently appointed chair who reports elsewhere, e.g. to the NIH Director.

3. Solutions to Challenges: Please concisely describe specific approaches or concepts that would address any of the above challenges, even if it involves a radical change to the current approach.
- Radical Idea #1 – Service on Study Sections should be mandatory for all investigators receiving NIH awards. Linking the amount of service to either the number of grants or the \$ amount of awards would also ensure that the most successful investigators served. These steps would insure the availability of sufficient, qualified reviewers and bring senior scientists back into the system.
 - Radical Idea #2 – Reduce the length of the grant review and funding cycle from 10 months to a maximum of 6 months or less from submission date to funding date. This is entirely feasible because of electronic grant submission and technologic advances in communication such that applications and critiques can be posted and viewed on secure online sites and meetings can be conducted by teleconference. This concept was successfully carried out at NIH for the Hyperaccelerated Mechanism for several years using a much shorter 3 month cycle: (<http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-05-028.html>). Two formats that are not mutually exclusive could be used. The first would retain the IRG structure, but all work would be via the internet and teleconference including the 2nd level of review. Shorter meetings, e.g., one day or less, would occur more frequently with fewer grants, either monthly or bimonthly. The second format, which would also use internet and teleconference, would constitute a small review group with the required sets of expertise for each application, the paradigm being a manuscript review. This format would be particularly suitable for interdisciplinary and multidisciplinary applications.
 - Radical Idea #3 – An individual would only be allowed to have one APPLICATION per mechanism in the system at a time. This becomes feasible if the review and funding cycle is reduced to 6 months as described above. Individuals could still have multiple grants, but only one application per mechanism under review at any one time. For example, an investigator could get an R01 grant funded in year one and submit a different R01 application in year 2 and so on. An investigator could submit two applications or more in the same year if they were for different mechanisms. This would actually help the most creative scientists who can write fundable applications with regularity because it would stem the flood of applications from less accomplished investigators by imposing self selection of the best science by each investigator upstream of the review process. It would also minimize the need to limit amended applications because of the same self selection process. Continuing to amend an unsuccessful application would prevent submission of a potentially fundable new application.
 - Radical Idea #4 – Permit review groups to interview or query a limited number of applicants where clarification is needed. This might avoid unnecessary amended applications.
 - Radical Idea #5 – Provide ICD councils with a reporting relationship that is independent of the ICD. The ICD council should have an independent chair who reports to the NIH director. This would provide the council with greater independence and would enhance objectivity.
 - Radical Idea #6 – Reorient the NIH intramural research program so that it conducts research that either depends on unique resources available to the intramural program, is of high risk and long-

term focus, or is otherwise distinctive from that conducted by the extramural community. If the intramural program is going to be supported in a fashion fundamentally different from the extramural, i.e., without comparable peer review, then it should be tasked with conducting creative, important research that may not be within the capability of the extramural community or otherwise would not fare well in the peer review system. In this way, the two programs would be synergistic rather than competitive. Areas that come to mind are high risk/high payoff research, early stage drug development research (e.g., target identification and validation), improved information technologies to support basic and clinical research, or large scale research demanded by emergent public health challenges. None of these areas is suitable for trainees planning an academic career who need to develop a track record of productivity and require highly feasible, hypothesis testing projects. Thus, to successfully implement this change the intramural program should be staffed with investigators and highly competent technical staff plus visiting scientists, and should take only highly targeted trainees.

- Radical Idea # 7 – Markedly streamline the number of different funding mechanisms utilized and require consistency in eligibility, funding, duration, etc. across the ICD’s. This is truly a case where less is more useful to science.
 - Radical Idea # 8 – Constitute a blue ribbon panel to advise the NIH on how best to identify and support research that informs on how to move interventions that research has shown to be efficacious into clinical practice (the so-called T2 block). Questions would include: Why does the block exist? How can the block be overcome? What research methods and disciplines are applicable? And who are the end users of such research?
4. Core Values of NIH Peer Review Process: Please describe the core values of NIH peer review that must be maintained or enhanced.
- The core values must restore and maintain fairness, substance, and credibility in the peer review process. The process should emphasize creativity, productivity, and "deliverables" that will enhance fundamental understanding of basic and clinical sciences that underlie health and disease.
5. Peer Review Criteria and Scoring: Are the appropriate criteria and scoring procedures being used by NIH to evaluate applications during peer review? If not, are there changes in either that you would recommend?
- The criteria and procedures are fine as written but only work optimally if the best and most competent reviewers apply them.
6. Career Pathways: Is the current peer review process for investigators at specific stages in their career appropriate? If not, what changes would you recommend?
- For *established* investigators who demonstrate commitment, drive, and marked talent and track record, consider long-term awards (effectively, expansion of the Merit awards mechanism). The NIH should consider a greater emphasis on funding people and not only projects, as this may well enhance creativity as well as productivity and foster attracting the best and the brightest to health science research careers.