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Federation of American Societies for Experimental Biology

---Quality Life Through Research---

April 2, 2008

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Re: Comments on "National Institutes of Health 2007-2008 Peer Review
Self-Study Final Draft"

Dear Drs. Tabak and Yamamoto:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the "National Institutes of Health (NIH) 2007-2008 Peer Review Self-Study Final Draft." FASEB is comprised of 21 scientific societies collectively representing more than 80,000 researchers engaged in basic and clinical biomedical research. The time frame for review of the report was extremely short. Given the importance of this issue, we sent you by email a DRAFT comment on March 17. This is our official comment submitted to NIH.

The NIH peer review system is among the best in the world for evaluation of scientific research proposals. Nevertheless, there are challenges to the system, and we believe many of the problems can be addressed within the current structure through better support and guidance for reviewers and increased consistency in policies and practices.

The self-study report has done an excellent job of outlining seven challenges to the system. This has enabled us to focus discussion on these critical points. We were pleased that many of our concerns and ideas submitted in the FASEB response to the Request for Information (October 3, 2007) are included in the self-study report. FASEB put forth three core principles: enhancing the quality of review; increasing opportunities for new investigators; and maximizing the number of R01 grants. We encourage NIH to move forward with the following actions.

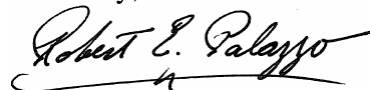
- We support enhancing the quality of review by 1) providing training, guidelines, and feedback to all involved, particularly Scientific Review Officers (SROs), Program Officers (POs), and study section chairs; 2) creating incentives for senior, expert reviewers to participate such as flexibility in service and grant submissions; and 3) piloting potential best practices such as ranking applications at the end of a study section.
- We support efforts to provide more R01 funding to new investigators lest we lose the next generation of biomedical scientists.
- We urge NIH to promote more stable R01 funding to highly productive, senior investigators, and we support a study of grant mechanisms. The decline of R01 share of competing awards should be halted and specific evaluation mechanisms for the types of awards that have supplanted R01 funding should be designed. If specific award types have not been effective, the trend should be reversed.

However, we do not support the concepts of “not recommended for resubmission” and treating all applications as “new,” and we request that these ideas do not move forward into the implementation phase.

While FASEB believes improvements to NIH peer review can be made within the current system, FASEB also supports using pilot projects to assess additional potential mechanisms. These mechanisms should be followed by independent and transparent evaluation of their effectiveness. As part of the ongoing evaluation, we encourage regular feedback be solicited from every reviewer (not just on a random basis as is currently done). Ongoing discussions with scientists are critical for the assessment of all NIH initiatives, and your efforts to engage our community are greatly appreciated.

More detailed comments on the peer review self-study recommendations are provided in the attachment.

Sincerely,

A handwritten signature in black ink that reads "Robert E. Palazzo". The signature is written in a cursive style with a horizontal line underneath.

Robert E. Palazzo, Ph.D.
FASEB President

Challenge 1: Reducing administrative burden on applicants, reviewers, and NIH staff

Challenge 1A: Too many applications in the system burden applicants, reviewers, and administrative staff

Goal: To reduce the number of applications that need to be submitted by helping applicants make faster, more informed decisions to either refine an existing application or develop a new idea.

FASEB supports providing applicants with specific and accurate feedback to enable them to make informed decisions about how to prioritize their future efforts. The NIH Center for Scientific Review is overwhelmed with submissions, and the process is compromised by the addition of more and more A1s and A2s that require just as much work as original submissions and may not necessarily be sufficiently improved or propose scientifically significant ideas.

Action: Provide unambiguous feedback to all applicants by establishing a “Not Recommended for Resubmission” (NRR) category

FASEB does not support “NRR” and recommends this idea not move forward. The workload of the Center for Scientific Review (CSR) and the study sections could be reduced, and thus make more time for consideration of the most meritorious applications, by preventing resubmission of grants that are scientifically uninteresting the first time they come for review. We recommend that this could be solved within the current system of review by better instructions to reviewers and enforcement of existing policies. Disparities between specific critiques in the summary statement and the proposal's scientific merit score must be resolved. In addition, if scores or ratings are provided to all applicants as recommended in the following proposed action, applicants would receive clearer feedback. If NRR is tested, it must be clear to reviewers and applicants the types of “fatal flaws” that could lead to such a designation. However, we believe this is not the best way to achieve the goal.

Action: Provide unambiguous feedback to all applicants by providing ratings for all applications

FASEB believes that the process of streamlining (or as it is commonly known in the scientific community, “triage”) should be reconsidered. Our suggestion was to give all triaged grants individual scores from each reviewer. We recommended that triage should be abolished for those scientists seeking their first R01 grant, because it is especially important that these applicants receive feedback on their applications. We also expressed concerns that “forced triage” by averaging preliminary scores and eliminating the bottom 50 percent of applications from further review is against the true intent of triage. An average score that falls into the lower 50 percent may be composed of highly disparate scores. The applicant will receive only the unhelpful and bewildering feedback of two very different reviews. Triage should also not be used in Special Emphasis Panels, which often have a small number of applications of higher-than-usual quality. Even if grants in the lower 50% are not discussed to reduce reviewer time

and workload, we recommend providing average score, percentile, or quartile information to these applicants to assist them in determining if they should re-submit the application.

Challenge 1B: Increasingly, three submission rounds are necessary before an application is funded (“review queue”)

Goal: To focus on the merit of the science presented in the application and not the potential improvements that may be realized following additional rounds of review

FASEB supports the goal of focusing the review on merit of the science. However, we also believe that the peer review process provides constructive feedback to applicants to strengthen their research proposals and this process should be maintained.

Action: Eliminate the “special status” of amended applications by considering all applications as being new.

FASEB does not support the idea of treating all applications as “new” and recommends that this idea not move forward. The experiences of our community of reviewers suggest that the “queue” behavior is not pervasive enough to abolish the amended application system. It can be important for reviewers to see how an applicant responds to previous reviewers’ comments.

We are concerned that currently, when a grant is not funded after a third (A2) review, the applicant can thereafter only submit a new grant on a substantially different topic. In the current funding climate, it is often the case that the A2 actually receives a very strong score, but when the percentiles are calculated, it does not make the cutoff. This may in fact be an idea for which there is much enthusiasm and is often the major focus of the applicant’s lab. While treating all applications as new would eliminate this problem, we recommend that if an A2 application shows a trend of improving scores, and the score falls within a certain percentage of the payline on the third try, the applicant should be allowed to resubmit a similar grant. A study section reviewing an A2 might make a determination on whether or not it would be beneficial for the applicant to resubmit along with specific feedback on what might be improved aspects of the grant for which there is enthusiasm in the critique.

Challenge 1C: The proliferation of NIH funding mechanisms can be confusing and burdensome to applicants, institutional officials, and review staff.

Action: Where feasible, refine and harmonize existing mechanisms unless data-based evaluation suggests otherwise.

FASEB supports NIH undertaking a comprehensive review of grant mechanisms, focusing upon their goals and success in meeting those goals. We are specifically concerned that some mechanisms, such as small exploratory grants, are not being used for their intended purposes and are not being reviewed appropriately. Discussion with scientists has revealed that much of this increase in R21 submissions is because review panels now expect such a large amount of preliminary data demonstrating feasibility that it is virtually impossible to propose a new R01 project deviating from the applicant’s prior research focus. Institutes and Centers (ICs) use R21s differently which makes these applications difficult to review. In the current funding climate, they are sometimes judged inappropriately (for example, criticized for lack of enough

preliminary data which is not required and a level of detail that cannot be realistically achieved in 15 pages). The R21 mechanism is for exploratory or high-risk research proposals, and if successful, should continue in the form of a larger grant. Therefore, data should be collected to determine the proportion of R21 research projects that develop into larger grants. Of course, it is expected that not all of these proposals will be successful given their high-risk or exploratory nature.

There should be mechanisms to review, evaluate, and phase-out big projects when their goals have been accomplished or when it is determined that the projects are no longer making progress toward intended goals. We urge peer review mechanisms to review big projects and provide mechanisms and incentives for reviewer participation. Given the large investments involved, it is especially important that evaluation is built into such grants.

Investigator-initiated, competitive, peer reviewed grants should remain the core mechanism for distributing research funding. This mechanism allows highly skilled scientists to propose the direction and priorities for further research, based on their own expertise, and provide the resources and timeframe to carry it through. Such grants have been the foundation for much of the progress to date in biomedical science. We strongly urge NIH to re-orient the research project grant portfolio to fund more R01 grants. We are concerned that other mechanisms supplanting R01s are negatively impacting the peer review process and affecting NIH's ability to fund the best science. Specific evaluation mechanisms for the types of awards that have supplanted R01 funding should be designed. If they have not been effective, the trend should be reversed.

Goal: To reduce application length to focus on impact and uniqueness/originality, placing less emphasis on standard methodological details

FASEB recommends that greater attention to significance and potential impact could be improved by better instructions for reviewers and more enforcement of review criteria.

Action: Shorten the length of the application and align it to specific review elements

There was no consensus in our community about shortening the length of research project grant applications. However, we suggested that the section addressing innovation might be moved to an early position in the application. Because innovation is important but difficult to evaluate, SROs should provide better guidance on how innovation is to be considered by reviewers.

Challenge 2: Enhancing the Rating System

Challenge 2A: Improve the usefulness of the rating system to inform decision making for both applicants and the NIH.

Goal: To focus and elevate the level of discourse of the study section

Goal: To provide unambiguous feedback to applicants

Goal: To enhance the consistency of rating and to engage all charter review members in the review of each application

Action: Rate multiple explicit criteria individually. Provide an independent, overall score.

FASEB supports piloting this idea with comprehensive feedback gathered from applicants and reviewers. Education of reviewers and applicants would be especially important to make clear how the rating of each criterion relates to the overall score. Feedback from applicants and reviewers of Department of Defense and NIH SPORE awards may inform how to pursue this idea.

Action: Rank applications considered by study sections

FASEB supports testing whether or not it would be helpful in achieving fairness and accuracy if scores could be briefly revisited and applications ranked at the end of the review process. Often the scoring standards change significantly from the first to the last application reviewed, and this can lead to mistakes and failure to rank the applications accurately. This could prevent the current “bunching” of scores often seen in the present situation.

Challenge 3: Enhancing Review and Reviewer Quality

Challenge 3A: Improving review quality means addressing the larger problem of changing the culture of review.

Goal: To enhance review quality

FASEB believes that the quality of review must be improved, and urged attention to this matter as one of our core principles for the peer review self-study. To ensure quality review, all applications should receive fair review by expert reviewers and be based upon appropriate and consistent criteria. Lapses in review quality can have a devastating impact on individual careers and, most importantly, inhibit the ability of NIH to fund the best science. The decline in quality of review is due to a number of factors, including decreasing numbers of senior investigators willing to participate, but also to inconsistency in policies and practices including enforcement of review criteria.

Action: Engage more reviewers per application through continuing to pilot two-stage review for some types of research (interdisciplinary) and by increasing the use of electronic-assisted review

Reviewers in the FASEB community have had mixed experiences with phone and web reviews, and most of them prefer in-person meetings. Improving collegiality and interaction between reviewers may require minimizing electronic reviews unless necessary for very specific expertise.

In addition, the effort by CSR to shorten review meetings to one-day shortchanges valuable discussion needed to fairly review applications. For most reviewers, a one-day meeting does not significantly change the time away from home because much of this time, particularly for reviewers who must travel from west of the Mississippi and/or take connecting flights, is spent in travel. Many reviewers do not support the one-day review meetings for these reasons.

Challenge 3C: There is a need for standardizing reviewer, study-section chair, and scientific review officer training.

Action: Enhance reviewer, study section, and scientific review officer training

FASEB agrees that consideration should be given to providing more formalized training and feedback to study section members and NIH review staff. All involved, particularly NIH review staff, should strive to support the peer review process, the reviewers, and the applicants. Greater educational resources for chairs and members are needed to strengthen skills to act in a study section environment. Perhaps a video or web cast of how a chair should conduct study section as well as presentation of reports by spokespersons and general discussion of the fundamentals of a study section would be helpful. These tools would demonstrate good practices and poor practices. More reminders for all reviewers about appropriate criteria for judging the merit of an application would be helpful. POs should also be provided with training and feedback. Applicants whose grants are assigned to a particular PO should be given the opportunity to provide anonymous feedback on the effectiveness of the PO in providing useful feedback and advice.

Challenge 3D: There is a continued need to attract the most qualified (“best”) reviewers.

Goal: To enhance reviewer quality

Action: Create incentives for reviewers, including more flexible service and flexible deadlines for reviewer grant submissions

FASEB agrees that CSR needs to implement more incentives, and remove significant disincentives for experienced scientists to serve as reviewers. An increased ability to attract and maintain the best qualified reviewers to the process is essential.

Reviewer assignment workloads should be fair and balanced. Establishment of guidelines concerning reviewer workload could ensure that there is consistency in the maximum assignments reviewers can expect when serving on a committee and that the maximum is reasonable.

We strongly recommend that reviewers be given a choice of the standing review panel that they believe is appropriate to review their applications, or to request that it be assigned to a Special Emphasis Panel. It will never be possible to increase participation in the review process when reviewers’ own applications are put at a distinct competitive disadvantage by their service. Reviewers are quite often serving on the study sections most appropriate to review their own grants, which are then closed to them.

We support flexible service for reviewers. The total size of the permanent study section could be set at a number that allows each reviewer to attend two out of three annual meetings. A variation on this idea is to allow two experienced reviewers to “share” a single position, with each attending half the meetings. The intensive task of reviewing a substantial number of applications three times per year is likely contributing to the number of investigators who decline an invitation to serve, and increasing the percentage of “ad hoc” reviewers needed for each study section meeting.

NIH has recently abolished all deadlines for appointed members of all chartered CSR study section members, and we encourage NIH to collect feedback from reviewers to assess the feasibility and satisfaction of this initiative.

Action: Link potential review service to the most prestigious NIH awards

We support the concept that NIH begin a dialogue with mid-career and senior NIH grant recipients to indicate that service on NIH review panels is an expectation of funded investigators. FASEB believes that maximizing the quality of review requires recruitment and retention of expert, senior reviewers. The idea of linking service to some awards is a good way to begin discussion of how a culture in which grantees expect to serve can best be created.

Challenge 3E: Is there adequate participation of clinician scientists in peer review?

Action: Analyze patterns of participation by clinician scientists in peer review and provide more flexibility to ensure their continued involvement in review

FASEB supports more flexible service for all reviewers as one incentive to encourage participation by experts. It is important that clinical researchers review clinical research applications, both as chartered members and ad hoc reviewers. The quality of the insight of the reviewers is important.

Challenge 3F: Is there adequate participation of patients and/or their advocates in the peer review process?

Action: Continue piloting the use of patients and/or their advocates in clinical research review

FASEB is concerned about including non-scientists in the first tier of the peer review process. The purpose of study section review is to assess the quality and merit of the proposed research. While patients and patient advocates may provide meaningful input into the non-scientific aspects of the grant (e.g., human subjects protections, diversity of patient samples, and public health impact), but they do not necessarily have the expertise to evaluate the scientific and technical aspects of proposals. If the use of patients and patient advocates in peer review is to be implemented more widely, evaluation of ongoing pilots must show convincingly that they add information that can not be achieved by scientific reviewers alone.

Challenge 4: Optimizing Support for Different Career Stages and Types

Challenge 4A: Early-career investigators encounter lower success rates at every stage of new (type 1) R01 application submissions.

Challenge 4B: The average age of early career investigators has increased.

Challenge 4C: There is an increasing gap between principal investigator appointment and first research project grant.

Goal: Early-career investigators should, at a minimum, be on par with established principal investigators, in application success rates.

The definition of “early-career investigator” should be clearly defined. Is a first-time competitive renewal still going to have special consideration?

Action: Continue to fund more R01s for early-career investigators

FASEB believes that new investigators must be given opportunities and support to start their research careers, lest we lose the next generation of biomedical scientists. FASEB proposed that NIH consider establishing a separate pool of funds for those investigators seeking their first R01 grant. NIH has issued guidelines to fund the same number of new investigators as the average of the last five years. To gauge the amount of funding that might be needed for new investigators, it might be worthwhile to consider how many new investigators must get started to replace at least 80 percent of investigators by the time they retire.

Action: Pilot the review of early-career investigators separately by generalists, to enhance risk-taking and innovation or uniqueness by applicants

FASEB recommended that new investigators be reviewed in regular study sections by experts in their field, and not by generalists. There should not be dramatically different standards for new investigators. While they should not be penalized heavily for less than stellar grantsmanship or few preliminary results, their plans, background, and environment need to be first rate. Nonetheless, it is important that reviewers are reminded of special guidelines for the review of new investigator applications (e.g., giving extra points). ICs vary widely in how they seek to promote new investigator proposals, and this is affecting how new investigators target their proposals. To help reviewers adhere to guidelines, new investigator applications could be grouped together in review as well as by the IC so that the appropriate POs are in attendance to ensure applicants have feedback.

Challenge 4D: There is a need to enable greater productivity of highly accomplished NIH investigators, with less administrative burden to applicants and reviewers.

Goal: To enable greater productivity of highly accomplished NIH investigators, with less administrative burden to applicants and reviewers

FASEB agrees that it is important to stabilize the funding of research projects being performed in the laboratories of advanced, highly successful investigators.

Action: Refine the NIH MERIT/Javits/NIH Director's Pioneer Awards and, perhaps, other mechanisms to enhance productivity of the most accomplished investigators and to add to the pool of accomplished investigators available as potential reviewers.

FASEB recommends that funding policies should promote the R01 as the principal funding mechanism. NIH should strive to maintain a supportive structure for productive applicants with meritorious proposals. It is important to stabilize the funding of research projects being performed in the laboratories of advanced, highly successful investigators. Investigator-initiated, competitive, peer reviewed grants should remain the core mechanism for distributing research funding. This mechanism allows highly skilled scientists to propose the direction and priorities for further research, based on their own expertise, and provide the resources and timeframe to carry it through. Such grants have been the foundation for much of the progress to-date in biomedical science.

Challenge 4E: The NIH needs to better understand the career needs of research associates/staff scientists.

Action: Develop a census of research associates/staff scientists as an initial step towards exploring approaches to providing more stable support for these individuals.

FASEB is also concerned that interruptions in funding are temporary but long enough to lead to the irreversible loss of critical laboratory personnel.

Challenge 5: Optimizing Support for Different Types and Approaches of Science

Challenge 5A: There is a need to seek out and support the most transformative research ideas.

Goal: To provide clear opportunities for applications proposing transformative research

Action: Use the NIH Director's Pioneer, NIH Director's New Innovator, and the Exceptional, Unconventional Research Enabling Knowledge Acceleration (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.

FASEB urges NIH to evaluate the relative success of previous awards of this type before moving forward with this proposal. An example of such an award is the National Cancer Institute's "Outstanding Investigator" award. In addition to evaluation, we recommend that the total funding for these research awards begin at no more than 1% of the funding for R01 equivalent awards.

Challenge 5B: There are differences in success rates for applications proposing clinical research than applications not proposing clinical research

Challenge 5C: For applications reviewed in CSR, "non-clinical" R01s fare better than "clinical" R01s, in part, because clinical research applicants appear less likely to send in amended type 1 (new) submissions or type 2 (competing continuation) submission.

Goal: To ensure optimal review of clinical research

Action: Determine the underlying causes of clinical research application submission patterns and results in the CSR and NIH IC panels and consider corrective actions if needed.

Failure to address these challenges may ultimately impede the progress of important clinical research. FASEB urges NIH to continue to test hypotheses and potential remedies, including increasing the proportion of clinical researchers on review panels, through pilot projects in addition to evaluation of existing data. NIH should also consider allowing applicants for whom reviewers have raised human subjects concerns, but who otherwise have strong applications, to address these concerns in a "prebuttal" rather than requiring them to revise and resubmit their grants.

Challenge 5D: Interdisciplinary research needs a space to be reviewed and supported.

Goal: To ensure optimal review and support for interdisciplinary research

Action: Enhance trans-NIH approaches to provide support space for highly meritorious interdisciplinary research.

FASEB urges NIH to evaluate previous awards of this type to inform decision-making about trans-NIH programs. Data to inform policy decisions might be collected by the newly-created Office of Portfolio Analysis and Strategic Initiatives. FASEB also recommended that there should be mechanisms to review, evaluate, and phase-out big projects when their goals have been accomplished or when it is determined that the projects are no longer making progress toward intended goals. We urge peer review mechanisms to review big projects and provide mechanisms and incentives for reviewer participation. Given the large investments involved, it is especially important that evaluation is built into such grants.

Challenge 6: Reducing the Stress on the Support System of Science

Challenge 6A: The NIH funding system has finite resources.

Goal: To ensure the optimal use of NIH resources

Action: Require, in general, a minimum percent effort for investigators on research project grants.

FASEB supports a reasonable minimum percent effort for investigators on R01 applications. A minimum percent effort of 10-20% would ensure investigators are devoting sufficient time to R01 funded research.

Challenge 6B: Universities continue to build additional research facilities, populated increasingly by people on “soft money,” non-tenure track positions.

Goal: Optimize the system used by the NIH to support principal investigators and other research personnel.

Action: Analyze the incentives inherent in the NIH system of funding that have been driving the rapid expansion of the U.S. biomedical research system in recent years and explore with stakeholders whether these incentives should be reduced or eliminated.

FASEB agrees that a study of NIH factors involved in the growth of the biomedical research system would provide important data. The growth of “soft money” positions is concerning because it can destabilize the research system. But mandating increasing institutional research support may result in less available research positions which would further negatively impact early-career investigators.

Challenge 6C: The number of tenure-track positions in academia, and scientist positions in all sectors, is straining to keep up with the number of postdoctoral fellows being trained.

Action: Analyze the NIH contribution to the optimal biomedical workforce needs including the number of trainees being supported and a census of research staff.

FASEB supports efforts to analyze the biomedical research workforce with a goal of sustainability. To gauge the amount of funding that might be needed for new investigators, it might be worthwhile to consider how many new investigators must get started to replace at least 80 percent of investigators by the time they retire.

Challenge 7: Meeting the Need for Continuous Review of Peer Review

Challenge 7A: The biomedical and behavioral research enterprise is highly dynamic and peer review must evolve to keep pace.

Goal: To assure the core values of peer review

Action: Mandate a periodic, data-driven, NIH-wide assessment of the peer review process.

FASEB supports NIH regularly assessing the system of research support and peer review. There should be some clearly articulated goals and some specific metrics by which pilot projects will be evaluated. As part of data collection, regular feedback should be solicited by every reviewer (not just on a random basis as is currently done) to build a database of “best practices” that could be tested for widespread use. FASEB supports using pilot projects to assess possible mechanisms to improve the grant review process, followed by independent and transparent evaluation of the effectiveness of these new mechanisms. In addition, we encourage ongoing extramural input into the makeup and functioning of study sections.

Action: Capture appropriate current baseline data and develop new metrics to track key elements of the peer review system.

FASEB strongly encourages research on the current peer review system to develop a baseline against which new pilot programs can be evaluated.