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March 9, 2023

Noni Byrnes, PhD

Director, Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive MSC7768
Bethesda, MD 20892-7768

Submitted online via RFI website on March 9, 2023

RE: Request for Information on Proposed Simplified Review Framework for NIH Research Project Grant Applications

Dear Dr. Byrnes,

On behalf of the members of the American Society for Pharmacology and Experimental Therapeutics (ASPET), we appreciate the opportunity to submit comments on the National Institutes of Health (NIH) Request for Information: *Proposed Simplified Review Framework for NIH Research Project Grant Applications*.

ASPET is 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases.

ASPET's mission is to be the professional home for educators, students, researchers, healthcare practitioners, and others working to advance pharmacological sciences and increase the impact and influence of this scientific discipline.

NIH's proposal is commendable on its goal to reduce implicit bias and minimize workload within the grant review process. While maintaining the necessary rigor that NIH holds its grantees to, the transition from nine areas of review to three main areas with additional areas shows a willingness to streamline the review process. ASPET appreciates this condensing of requirements; however, with any rearrangement, there needs to be adequate time and consideration to education and training of the reviewers as the process goes forward.

The three proposed factors, 1) Importance of the Research, 2) Rigor and Flexibility, and 3) Expertise and Resources, demonstrate that NIH is moving in a common-sense scientific approach within the review: Should the research be done? Can the research be done well? Are the resources in place to ensure it will be done? This approach is easy to understand not only by the scientific community, but also the public who are the ultimate stakeholder in this process.

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The first two factors, Importance of Research and Rigor and Flexibility, will allow the reviewer to select from a 1-9 scoring system. ASPET supports this proposal. Having a range to choose from removes the “all or nothing” approach and still will capture the necessary answer of whether the research should be done and can it be done well. ASPET would note that it expects NIH to provide education on the scoring system clarifying how it views and expects the reviewer to view each score between 1-9 to alleviate any bias that may occur. ASPET asks that NIH produce a report to the scientific community after the proposed scoring takes effect to examine how the scoring is occurring and whether additional education or changes need to take place to achieve NIH’s desired outcome. The reports would show that NIH is being transparent in its efforts to remove bias from the process.

The third factor, Expertise and Resources, will be assessed as “fully capable,” “appropriate,” “additional capability/expertise needed,” or “additional resources needed” with the selection of the latter two criteria requiring explicit explanation of what is needed. This will assist in removing the bias of the investigator(s) and their institution and turn the focus to the scientific merit of the research. ASPET appreciates this assessment of the third factor as it should not matter at which institution/setting a lab is located; the only assessment that should matter is whether the resources are in place to conduct said research. ASPET asks that the NIH produce a report to answer whether the change from individually scoring Investigator(s) and Environment to the proposed Expertise and Resources factor is accomplishing the hoped for goal of a less biased assessment of the resources in place.

ASPET would like to see special emphasis on this factor not only in the education of reviewers, but possibly within the application itself to provide the investigator(s) an option to submit a narrative should the investigator(s) feel one is necessary. There needs to be heightened awareness that an investigator may appear to be “lacking in productivity,” but there may be more to the story. As with the rest of society, the COVID pandemic created a gap of time that changed things. COVID negatively impacted productivity with the shutting down of labs, culling of animals, and individuals with or affected by COVID. Other life factors also may play a part into “lack of productivity” such as maternity/paternity leave or caring for a sick child/family member as examples.

ASPET supports the proposed pull-down selection utilization for the Additional Review Criteria to “appropriate” or “concerns.” This will reduce the reviewer’s workload and keep the focus on the scientific merit of the application. Reviewers will only be required to provide a narrative if they choose “concerns” which will focus the reviewer to provide a narrative on that specific area.

Any change to the grant application, review, and award process will take time to become commonplace. During this time of change, ASPET strongly encourages NIH to work with its stakeholders to prepare the community for this change. NIH is encouraged to provide detailed timelines for not only alerting the community of the change, but also when the change is going to occur. NIH should work with stakeholders on educational materials to train all members of the grant application process so that when the changes are implemented, there is little to no disruption.

ASPET is encouraged by NIH’s approach to enhance its peer review structure to reduce implicit bias and reduce reviewer workload while maintaining a strong scientific based merit structure. ASPET appreciates the opportunity to provide feedback on this RFI and looks forward to continuing dialogue with NIH on these important issues. If you have any questions about our comments or would like to continue this dialogue, please contact Carter Alleman, Director, Government Affairs & Science Policy at calleman@aspet.org.

Sincerely,



Michael Jarvis, PhD, FBPHS
President
American Society for Pharmacology and Experimental Therapeutics (ASPET)