



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 130,000 Researchers

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February 11, 2019

Advisory Committee to the Director
National Institutes of Health
c/o Gretchen Wood
One Center Drive, Room 126
Bethesda, MD 20892-0147

Submitted electronically via email: woodgs@od.nih.gov

Dear Committee Members,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the efforts of the Advisory Committee to the Director's (ACD's) Next Generation Researchers Initiative (NGRI) Working Group to develop a framework and recommendations for approaches to develop and enhance programs and funding mechanisms to support Early Stage Investigators (ESIs) at the National Institutes of Health (NIH). We have reviewed the report and recommendations issued by this group in December, and offer the following feedback for your consideration, organized by theme.

Theme 1: Modify the original NGRI policy

FASEB acknowledges the considerable efforts of the Working Group to refine the parameters for ESI status to ensure flexibility for investigators at a critical point in their careers. We agree with the Working Group's final recommendation to maintain the definition of ESIs as individuals within 10 years of receipt of terminal research degree or post-graduate clinical training. FASEB also supports the Working Group's recommendation to more clearly communicate eligibility policies and timelines to trainees to ensure better awareness and preparedness for pursuing independent funding.

Recommendation 1.3, which proposes special funding consideration for "at-risk" investigators, generated much discussion among the members of FASEB's Training and Career Opportunities Subcommittee. While the general consensus was that the intent of the "at-risk" designation would be helpful for preserving meritorious research programs previously receiving NIH support, there were concerns that there would be difficulty equilibrating this recommendation across NIH's 27 Institutes and Centers (I/Cs). This group also echoed concerns about the

potential negative connotation of designating this population as “at-risk,” and use of a more positive designation, such as “under-resourced” or “opportunity limited.” Another question pertained to how or whether “at-risk” status would be determined for Multi-Principal Investigator (MPI) or subprojects within Program Project (P) grants. Although recommendation 2.2 indicates a preference to preserve ESI status for eligible applicants after the first MPI award, it is not clear if the “at-risk” status would be applicable to subsequent MPI applications by the same investigator.

Theme 2: Develop methods to identify and support “at-risk” investigators and ESIs

FASEB appreciates the Working Group’s consideration of strategies to increase uniformity in the processes utilized by the NIH’s individual Institutes and Centers (I/Cs) to identify and support “at risk” investigators and ESIs. In addition to the recommendations already included in Theme 2, we encourage NIH to provide transparent guidelines regarding ESI success rates across the individual I/Cs and reinforce the importance for scientists to apply to the I/Cs and/or programs that are the best fit for the science rather than focusing on probability of funding. A clear set of guidelines regarding the implementation of the NGRI policy across NIH I/Cs is critical for applicants and reviewers as well as future assessment of the policy.

FASEB agrees with the sentiment of recommendation 2.3 which calls for separate review, comparison, and scoring of ESI applications within study sections. We believe that this will improve the accuracy of the success rates for ESIs moving forward. There is, however, lack of clarity within the existing NGRI policy regarding how resubmissions of ESI applications would be handled by study sections. Therefore, we strongly recommend that the policy be updated to provide more information about how ESI resubmissions will be handled.

The increasing dependency on grant funds to support salaries of PIs/Co-PIs is a long-standing concern of the FASEB community, and we support the detailed analysis of salary support proposed in recommendation 2.9. As noted in the Working Group’s report, there are many caveats to consider when seeking to transition investigators to “hard” money for salary support, including shifting investigators’ workloads to require more teaching or clinical effort, reducing time available to engage in research activities.

Theme 3: Promote sustainable training opportunities that incorporate diversity and inclusion

Many of the recommendations in this theme build upon those made in the 2012 ACD Biomedical Workforce Working Group report, and FASEB continues to support initiatives to enhance career

development and foster a diverse, inclusive, and representative biomedical research workforce. We particularly appreciate recommendation 3.6, which seeks to expand upon the resources developed through the Common Fund support of the National Research Mentoring Network (NRMN) and Building Infrastructure Leading to Diversity (BUILD) programs – initiatives for which activity is steadily increasing now that critical infrastructure and frameworks have been established. Several of the recommendations, particularly 3.3, 3.5, and 3.7, require additional context when defining policies, guidance documents, or other resources intended to ensure replicable implementation and foster adoption.

Theme 4: Monitor outcomes and optimize workforce stability through improved metrics and further research

FASEB is pleased that the Working Group emphasized the need for clear metrics for monitoring and evaluating outcomes of the NGRI policy, and recognized the importance of both I/C-specific and NIH-wide assessments. Similar to our comments on recommendations on other themes, while we can agree that the overall goals are laudable, a detailed implementation plan is required to ensure attainment.

We do note that recommendation 4.3 presents a significant change in approach to evaluating a PI's contributions, both in terms of emphasizing mentorship and service and the designated timeframe, which emphasizes the seven years prior to the application. We agree with the assessment that the actual application should not be changed. The application Biosketch has undergone numerous updates in the past decade, and further updates will increase administrative burdens for all investigators seeking NIH support. We also caution against strategies that rely solely on study section review. In the past five years, numerous policy changes, including rigor and reproducibility, clinical trials, and inclusion across the lifespan, as well as increased utilization of specialized program announcements, requests for applications, and adoption of new funding mechanisms such as the R35, have increased the workload of reviewers. Care must be taken not to overburden study section volunteers with the review of policy compliance in addition to scientific merit.

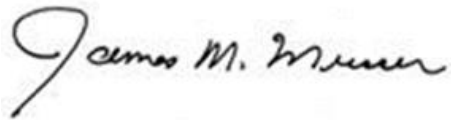
Theme 5: Continue transparency efforts and engagement with scientists across career stages to inform policy decisions

FASEB applauds the Working Group's acknowledgement of the need to engage the research community more broadly in policy development and implementation. In particular, we appreciate acknowledgment in recommendation 5.2 for the need to provide multiple – yet clear –

avenues for individual scientists to engage in policy discussions. That said, traditional formats, such as Requests for Information, must still be in place to allow groups or organizations to provide input. We are also pleased to see a desire to continue with the model of appointing scientists from a range of career stages, institutional type, geographic location, and other life experiences to NIH working groups and committees. In a November 2018 letter to Dr. Collins, FASEB expressed a desire to assist in identifying potential candidates from the over 130,000 scientists it represents for such appointments.

FASEB thanks the ACD, and specifically the NGRI Working Group, for its efforts in developing this report and recommendations; we recognize that this group was charged with a task for which there are no easy solutions. Throughout these comments, we have highlighted areas for which additional context and clarity are needed to ensure an appropriate implementation strategy. We strongly urge NIH to actively engage the broader research community in this process.

Sincerely,

A handwritten signature in black ink that reads "James M. Musser". The signature is written in a cursive, flowing style.

James M. Musser, MD, PhD
FASEB President