



August 2, 2017

Lawrence A. Tabak, DDS, PhD Principal Deputy Director Office of the Director National Institute of Health Building 1, Room 126 Bethesda, MD 20892

Dear Dr. Tabak:

The Infectious Diseases Society of America (IDSA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS) applaud the efforts of the National Institutes of Health (NIH) to enhance the sustainability of the biomedical research workforce through the Next Generation Researchers Initiative (NGRI). The NIH is the most important source of funding for biomedical research in the U.S. However, its approach to awarding funding based on competitive peer review of applications, combined with an essentially flat NIH budget for many years, has resulted in established investigators having an advantage in securing funding compared to new and mid-career investigators.

Funding is not the only driver that threatens the biomedical research workforce. We are also concerned by the decreasing number of trainees pursuing research careers. This will have a lasting negative impact on the U.S. biomedical research enterprise and ultimately translate into a lessened ability to drive the discovery of new treatments and cures. Given the current funding environment, it is critical to find new ways to support early- and mid-career researchers to facilitate and stabilize the career trajectory of scientists and ensure that progress in lifesaving biomedical research remains unimpeded. IDSA appreciates that NIH is beginning to look systematically at spending trends in an effort to steady the biomedical research workforce and to optimize return on investment. We commend the efforts of the NIH Office of the Director to swiftly respond to early stakeholder feedback on this issue and look forward to working with NIH to bolster funding support for the next generation of researchers.

We would like to offer specific recommendations and questions on the Next Generation Researchers Initiative below. We hope our comments will be useful in your endeavors. We also would greatly appreciate the opportunity for continued dialogue with NIH on this important issue.

Support for the NGRI and Approaches to Implementation

IDSA supports the NGRI's goal of stabilizing research funding for mid-career investigators to enable resiliency and ensure that researchers have protected time to compete for grant renewals. Mid-career investigators are often unable to maintain research funding when they are no longer eligible for NIH early stage investigator (ESI) support. Attaining their next grant can be very challenging, particularly when transitioning from a K award to a R01 (which has less salary support) or when trying to renew an initial R01. Increased support is especially important for investigators in Institutional Development Award (IDeA) program states, which broaden the geographic distribution of NIH funding for biomedical research, and other less well funded institutions, where mentorship and guidance are not always locally available.

In order to stabilize the trajectory of researchers competing for their first grant renewal, we urge NIH to recognize the potential of mid-career researchers to act as mentors for young investigators. K award

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mentorship is essential for teaching young investigators how to conduct high quality research and move toward independence. This is particularly important for physician scientists, who will need the guidance of other physician scientists as they balance clinical and scientific responsibilities. One option for instituting a mechanism where mentors can be rewarded is to incentivize more established researchers to lead program projects or other multi-project grants under which less senior investigators can serve as Principal Investigators (PIs) on sub-projects. This approach could simultaneously satisfy the desire of senior investigators to maintain their research efforts while facilitating the careers of earlier stage investigators.

Another possibility to promote stability for early career investigators that the NIH may wish to consider is linking the K and the R track. NIH could convert the K award to a 5-7 year award with clear milestones for continued funding, providing R01 level funding in the latter half of the award. This would mean that a mentored award in years 1-3 would transition in years 4-5, then move to R01 level funding in years 6-7. This approach is similar to the NIH Pathway to Independence Award (K99/R00) for early career PhD and MD researchers.

IDSA supports NIH's efforts to create a central inventory of early- and mid-career investigators in fundable ranges to help ensure the NGRI is effectively implemented across its Institutes and Centers (ICs). For ESI grants that score on the cusp of the 25th percentile but ultimately are not chosen for payline or select pay funding, the agency may consider developing a formal mechanism to shift promising awards to complementary NIH entities. For example, if a researcher working on antibiotic resistance is transitioning from K to R and does not quite hit the funding line, perhaps their application could be passed on to the NIAID-funded Antibacterial Resistance Leadership Group (ARLG) for consideration.

Questions and Additional Considerations

IDSA appreciates NIH's receptivity to stakeholder feedback throughout this complex process. We would like to offer our member expertise to work with the Advisory Committee to the Director (ACD) on NGRI implementation considerations. We look forward to additional opportunities for collaboration and we have included some questions about the execution and potential impact(s) of the NGRI below.

- The impact of NGRI funding will be assessed by a working group comprised of ACD members. These individuals are well-established in their careers and normally represent top-tier institutions that enjoy substantial NIH funding. How will NIH ensure that the voices of early stage investigators will be heard and valued throughout the NGRI implementation process? IDSA recommends coordinating a joint coalition of external stakeholders from IDeA states and historically underfunded institutions to broaden research community input into the implementation process.
- To help evaluate the impact of the NIH portfolio, agency leadership has recommended using the <u>Relative Citation Ratio</u> (RCR) a metric that uses citation rates to show the scientific influence of one or more articles relative to the average NIH-funded paper. Is this the most robust way to help measure the impact of increased funding to ESI, when more established researchers may be cited more often based on recall and name recognition? This may not reflect the value of the work on early- to mid-career investigators and may unintentionally reflect poorly upon them. Moreover, there are many examples of initially poorly cited research that latter proves to be the foundation for transformative changes in our knowledge of science as well as the medicine of human health.

Another related consideration is that research is becoming increasingly team-based, whereas many aspects of the NIH system appear to reward individual achievement. It can be difficult for study sections to identify individual contributions on group efforts. NIH also lacks efficient

mechanisms that reward team science. How can we ensure that teams – particularly those including young investigators – are appropriately recognized?

- The NGRI is an attempt to fulfill the 21st Century Cures mandate to promote earlier independence and to increase funding for new investigators. If NIH's goal is to fund most early-career investigators with R01 equivalent applications that score in the 25th percentile (or an impact score of 35 if the application is not given a percentile), whose research will go unfunded in exchange?
- NIH ICs will have the flexibility to allocate their funding toward the NGRI as they see fit; however, without a net increase in the NIH budget, they may have to consider measures such as grant caps, decreased pay lines, or reduced funding for solicited programs such as Requests for Applications (RFAs) and Program Announcements (PAs). How can NIH provide opportunities and stable career trajectories for early- and mid-career researchers while maximizing funding? What steps are being taken to help identify and mitigate unintended effects?

We recognize that addressing the funding challenges faced by early- and mid-career researchers will require a collaborative effort by stakeholders, NIH, and other federal agencies. We stand ready to aid NIH as it refocuses efforts on early- and mid-career investigator support. We look forward to working together to ensure the sustainable support of a diverse biomedical research infrastructure that facilitates new advances in patient care.

Sincerely,

Bill Founder

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