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Re: NOT-OD-15-084: “Request for Information (RFI): Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research”

Dear Dr. Lorsch,

The Infectious Diseases Society of America (IDSA), the Pediatric Infectious Diseases Society (PIDS), and the HIV Medicine Association (HIVMA) are pleased to offer comments to the National Institutes of Health’s (NIH) request for information on optimizing funding policies and other strategies to improve the impact and sustainability of biomedical research. A robust biomedical research enterprise is critical to confronting the serious infectious diseases (ID) issues facing patients and our nation’s public health, including antimicrobial resistance, HIV/AIDS, emerging infectious diseases, vaccine development, and bioterror and pandemic preparedness for pathogens such as enterovirus D68 and Ebola virus. The NIH provides the foundation for this pursuit, and we continue to advocate for increased federal support for NIH.

In this austere funding environment, our societies also understand that creating more efficient ways to maximize the impact of limited funding must also be considered in order to sustain the development of the lifesaving medical advances urgently needed by many patients. Below, we highlight specific issues regarding administrative burden, sustainability of the biomedical workforce, and efficient prioritization of funding, all of which influence the impact of biomedical research. We also offer recommendations to address these challenges.

Key issues that currently limit the impact of NIH’s funding for biomedical research and challenge the sustainability of the biomedical research enterprise

Administrative Burden

Our societies understand that oversight is required to deliver responsible, effective research. However the ever-increasing administrative burden placed on researchers is now drawing enormous amounts of time away from conducting research. This burden is compounded by institutions adopting risk adverse practices to protect against penalty or liability. [A recent survey](#) of principal investigators (PIs) by the Federal Demonstration Partnership (FDR) found that on average, PIs spend 42% of their time on pre- and post-award administrative tasks for federally supported projects. Investigators who perform research involving animal and/or human subjects with Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board

(IRB) approval are especially affected. This unnecessarily large diversion of time away from research activities negatively affects investigators' productive, efficient use of federal funding.

Sustaining the biomedical workforce

Effective support of researchers at early stages in their careers is also critical to sustaining biomedical research in the United States. Unfortunately, this support has been significantly eroded by the tight funding levels, creating major barriers to success for junior investigators and discouraging many young people from pursuing a career in research. For example, most K-awards have an extremely competitive and time consuming submission process, but do not provide adequate salary, indirect costs allotments, or research support for investigators. Mentoring is also vital to junior researcher career development, but the tight funding environment has created major disincentives for senior mentors to take on this task without remuneration of time and effort. While the NIH sponsors senior mentoring awards to address this issue, these are restrictive in the types of research mentoring that are eligible, leaving few options for the junior researchers whose interests fall outside their scope.

As highlighted by the NIH's [2014 workforce report](#), the consequences of these barriers is particularly evident for physician-scientists, in that the intense competition for NIH support combined with financial debt creates a major disincentive to enter the field of research. It is imperative that the NIH ensure that we do not lose a generation of physician-scientists who provide a unique perspective for furthering the goals of the biomedical research enterprise.

Efficient prioritization of research funding

During an evaluation of its funding portfolio, the National Institute of General Medical Sciences (NIGMS) discovered that 5% of their investigators held 25% of the institute's funding. Moreover, they found the productivity and impact of a researcher stops scaling above a certain funding level, indicating that this concentration of funding to fewer research groups may not be the most efficient means to support biomedical research. With fewer researchers funded, the diversity of perspectives to address research questions in novel ways is reduced, contributing to inefficient research. These observations would not have been possible without an in-depth and publically disseminated portfolio analysis by the institute. Most of the NIH institutes and centers do not regularly perform portfolio evaluations with the same depth and rigor, and are likely missing insights into major trends that could improve the efficient prioritization of funding.

Ideas about adjusting current funding policies to ensure both continued impact and sustainability of the NIH-supported research enterprise

The issues highlighted above negatively affect the efficient, productive, and sustained use of NIH support for research. Here, we recommend several specific improvements to existing NIH funding policies to better address these issues.

Administrative burden: expand the just-in-time grant policies

The NIH is aware that while investigators spend enormous amounts of time developing grants, which include details in excess of the technical proposal needed to establish scientific merit, many are not funded. To address this burden, the NIH has established "just-in-time" (JIT) submissions for grants that are likely to be funded. Under this process, some components of the grant application, such as IRB/IACUC approval documentation, can be submitted later in the

process. This approach holds great promise in streamlining the application process. We urge the NIH to consider expanding the application components that can be submitted later in the review process to include data sharing plans, detailed aspects of the budget, and other areas that are not absolutely needed to establish the scientific merit of an application. We also encourage the NIH to consider restricting this process only to grants with a high likelihood of funding, rather than asking applicants with marginal chances of receiving funding to expend the time necessary to provide JIT application components.

Administrative burden: simplify reporting requirements

While our societies understand the need to monitor an investigator's progress for federal supported research, the FDR estimates that up to 8% of an investigator's time is spent complying with reporting requirements. We recommend that reporting be performed on an annual basis, focusing on research outcomes, with a simplified format that allows for flexibility based upon the size and scope of the grant. A "one size fits all" reporting approach creates barriers to communicating progress clearly and greatly complicates the preparation of reports.

Administrative burden: engage with Institutions to reduce unnecessary requirements

Risk averse attitudes that prevail at many research institutions often result in an environment of "over compliance," contributing significantly to administrative burdens. We urge the NIH to consider developing, in collaboration with institutions, standard metrics or best practices that focus on the most efficient policies to ensure regulatory compliance without creating undue burden. This process can be regularly reviewed by all relevant stakeholders to ensure that policies and practices appropriately keep pace with evolving environments.

Sustaining the biomedical workforce: improve K-awards and related mentoring policies

K-awards must be improved to provide levels of support junior investigators need to launch their research careers. We also support the current measures that the NIH has taken to address disincentives to senior mentoring of K-award recipients such as the K24, a senior mentoring award at 50% effort for 5 years to supervise younger clinical investigators on K23's. However this award is not available to those who wish to mentor basic researchers with K08 awards or those undertaking epidemiological research with K01 support. The NIH should expand the K24 system so more individuals across the research spectrum can receive effective mentorship.

Sustaining the biomedical workforce: improve ways to attract and maintain physicians in basic/clinical investigation

We support many of the measures the NIH's physician-scientist workforce working group is considering to improve its workforce sustainability. Our societies would like to [reaffirm that the NIH focus its efforts](#) on addressing these disincentives. In particular, the NIH should prioritize debt relief for those who enter research careers; while several mechanisms exist, we support the proposed increase of the annual Loan Repayment Program payment from the current \$35,000 to \$50,000. We also support the NIH's recent efforts to improve support to early career physician-scientists, such as the planned "physician-scientist pathway to independence" award, a K99/R00-like award for physician-scientists.

Ideas for new policies, strategies, and other approaches that would increase the impact and sustainability of NIH-funded biomedical research

In this section, we offer several specific recommendations for new NIH policies to further address the issues raised above.

Administrative burden: increase the duration of investigator-initiated research grants

With an average duration of 4.4 years for R01 awards throughout the NIH, many researchers must regularly devote significant time preparing grant applications. Several institutes, like NIGMS, The National Cancer Institute (NCI), and National Institute of Neurological Disorders (NINDS) are piloting extended duration grants to at least 5-7 years. We recommend that the NIH consider increasing the duration of some types of its investigator initiated grants to enable more time devoted to research. Longer award periods will create new challenges that the NIH will need to address in creative ways, including effective monitoring of progress as well as higher initial costs.

Efficient prioritization of research funding: perform regular portfolio analysis to identify trends in research funding

We encourage NIH and its institutes and centers to develop more robust mechanisms to undertake regular evaluations of their funding portfolios with the goal of updating funding priorities. NIH should look to its underutilized Office of Portfolio Analysis as well as its pioneering institutes that have undertaken these measures to develop best practices and metrics for other institutes to follow. It is critical that these analyses be publically communicated and that the NIH seek stakeholder input in analyzing trends in funding.

Efficient prioritization of research funding: consider setting maximum NIH funding limits for a single investigator

We recommend that the NIH undertake a detailed study (see above recommendation) to establish productivity metrics that take into account the funding an investigator receives, drawing on the initial approach developed by NIGMS. If clear inefficiencies at certain high levels of funding are identified, the NIH should carefully consider the pros and cons of setting a maximum funding level that any individual investigator can hold. A funding cap would not only address inefficiencies but also increase the base of support available to the entire scientific workforce. The NIGMS pilot Maximizing Investigator Research Award (MIRA) proposes to establish maximum limits for its investigators, and can be instructive to wider efforts throughout the NIH.

IDSAs, PIDs, and HIVMAs appreciate the opportunity to provide its recommendations to improve the efficient use of NIH funding to support a sustained biomedical research enterprise. Should you have any questions or concerns about these comments, please feel free to contact Greg Frank, PhD, IDSA Program Officer for Science and Research Policy, at gfrank@idsociety.org or 703-299-1216.

Sincerely,



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Chair, HIVMA Board of Directors

IDSA, PIDS, and HIVMA represent over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as Acinetobacter baumannii, Klebsiella pneumoniae, and Pseudomonas aeruginosa, emerging infections such as Middle East respiratory syndrome coronavirus (MERS-CoV), Enterovirus D68, and Ebola, and bacteria containing novel resistance mechanisms such as the New Delhi metallo-beta-lactamase (NDM) enzymes and others that make them resistant to a broad range of antibacterial drugs, including one of our most powerful classes of antibiotics, the carbapenems (carbapenem-resistant Enterobacteriaceae, or CRE).