



August 15, 2024

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

RE: Request for Information – Reforming the National Institutes of Health Framework for Discussion

Dear Chair McMorris Rodgers,

The Infectious Diseases Society of America (IDSA) and HIV Medicine Association (HIVMA) appreciate the opportunity to provide feedback to the House Energy and Commerce (E&C) Committee in response to your proposed framework for National Institutes of Health (NIH) reform. Given the significant scope and scale of the changes outlined in the proposed framework, we recommend that the committee not advance any NIH reform legislation until there has been an opportunity for hearings and for stakeholder and member feedback to be considered and incorporated as appropriate. It is important to better understand the potential impact of these proposed changes before they are implemented, and we welcome the opportunity to stay engaged with you throughout this process. IDSA represents more than 13,000 infectious diseases (ID) and HIV physicians, physician-scientists and other clinicians and public health professionals on the front lines of infectious disease and HIV research, prevention and treatment.

IDSA's and HIVMA's guiding principle regarding potential NIH reform is that our nation's biomedical research agenda continue to be driven by the best available scientific information and scientific experts so that the United States may continue leading the world in scientific advances that improve patient care and public health. It is through this lens that we are pleased to offer feedback.

In considering the future of biomedical research, IDSA's chief concern is that the current capacity of ID and HIV physician-scientists is insufficient to meet our nation's needs and NIH requires greater support to help meet these growing needs. To effectively address the expanding scale and scope of infectious diseases and growing antimicrobial resistance, and to end the HIV epidemic, greater numbers of ID physicians and scientists dedicated to ID research are needed. Therefore, a restructuring of NIH can and should include expanding its support for the pipeline of ID and HIV physicians and researchers. In 2023, just over half of ID physician training programs and only 43% of pediatric ID training programs were filled; by comparison, most other physician specialties filled nearly all of their programs. Any reform of NIH should include finding novel ways to develop early career programs and funding.

In addition to being a major setback to the ID workforce, **we are very concerned that the proposal to split the National Institutes of Allergy and Infectious Diseases into two institutes will compromise scientific discoveries by siloing two inter-related areas of research** and reducing the efficiency and synergy of collaboration, planning, communication and coordination that comes from them being conducted under one institute.

Below we offer detailed recommendations and responses to your proposed framework regarding strategies to ensure NIH continues to support cutting-edge research while maintaining transparency and forward-thinking scientific ideas. We welcome continued dialogue and collaboration with you and the E&C Committee on these topics.

Mission and Leadership Reform

IDSAs support a comprehensive review of NIH and its research portfolio, mission and objectives, and we emphasize that the commission leading the review must be comprised of scientific experts. Regular review of the agency, when done appropriately, can help ensure it remains up to date, and that its institutes are advancing their missions and goals.

IDSAs also support ensuring that NIH has measures in place to manage harassment and misconduct issues. Not properly managing harassment at federal scientific agencies will likely impact groups who are underrepresented in the research field the most, such as women, Latinx/Hispanic and African American, and LGBTQ+ researchers. This in turn drives these researchers out of the field and can lead to a less equitable and representative research workforce. Fostering a culture of support, nonjudgment and inclusion should be a priority in reevaluating how misconduct is handled to ensure that NIH employees feel comfortable coming forward with misconduct cases, and that these cases can be handled in a timely, careful manner. It is important to ensure that NIH continues to be guided by the best available scientific data, and policies regarding misconduct and accountability should not be misused to inappropriately elevate a small minority of individual scientists whose work or views lack appropriate scientific foundations. All misconduct allegations must be handled with due process.

The proposed implementation of term limits for institute and center leadership should be discussed in greater depth, with consideration for both potential benefits and potential drawbacks. If term limits are implemented, a longer term should be considered, such as seven to 10 years, to allow for continuity in leadership in completing research initiatives. Research is complicated, and often highly longitudinal, requiring a steady understanding and consistent leadership. The terms should be flexible to address emerging issues like public health emergencies or ongoing, large-scale institutional projects that require continuity of leadership. In these situations, the NIH director should have discretion and be able to extend a leadership term as needed.

Funding Reform

NIAID Funding and Institutional Reorganization

As noted, IDSAs and HIVMA are concerned with the proposal to **split the National Institute of Allergy and Infectious Diseases (NIAID) into two institutes** – the National Institute on Infectious Diseases and the National Institute on the Immune System and Arthritis. The proposal will create the very type of research inefficiencies that the framework is seeking to reduce as studies on ID, autoimmune disorders and allergies rely heavily on immunology-based research. Many of the latest research and advances in the field of ID focus on the immune response to infectious diseases – separating immunology from infectious diseases would be a step backward. Understanding how an individual's immune system responds to infectious disease pathogens is critical to developing effective mechanisms for preventing and treating

infections associated with cancer, transplants and drug use in addition to vaccine development. In addition, our ability to respond to emerging and reemerging infectious disease epidemics and biosecurity threats will be severely weakened by the siloing of ID and immunology research. IDSA and HIVMA support a NIAID budget of **\$7.060 billion, including \$608 million for antimicrobial resistance research**, with a research portfolio representing ID, allergies and autoimmune disorders. This funding spurs ID research and focuses on essential topics for the health of the country, including the following:

- Enhancing basic, translational and clinical research on antimicrobial resistance;
- Supporting training of new investigators to improve ID research capacity;
- Boosting clinical trial infrastructure to boost preparedness, therapeutics, vaccines and diagnostics;
- Developing a clinical trials network to reduce barriers to research difficult-to-treat infections;
- Producing pragmatic research and implementation science to get clinical innovations into health care and the populations with least access.

Inadequate NIAID funding would weaken our ability to address current and future infectious diseases needs like ending the HIV epidemic, researching and addressing long COVID, and mitigating the rising rates of resistant infections. The ID workforce is already incredibly strained, and insufficient research funding would dissuade students from entering the ID field. Without funding intervention and sufficient ID workforce capacity, the country will be more vulnerable to future pandemics and public health emergencies.

IDSA and HIVMA are further concerned the proposed split in NIAID funding between the National Institute on the Immune System and Arthritis and the National Institute of Infectious Diseases may not accurately reflect the research portfolio of NIAID. The proposed budget for the new separate institutes would divide NIAID's total funding of roughly \$6.5 billion in half (\$3.315 billion for each proposed institute). If NIAID is split, a full review should be conducted to ensure that the division of funding accurately reflects how funding is dedicated to different research areas within the Institute.

Consolidation of NIH Institutions

We also are concerned with the framework's proposal to eliminate the Fogarty International Center and the National Institute of Minority Health and Health Disparities by consolidating them into a larger center without an estimate for how much funding would be dedicated to global health research or health disparities. The Fogarty International Center is instrumental to our nation's global standing, global health security and ability to detect and respond to pandemics. More than 80% of Fogarty's extramural grant budget goes to U.S. academic institutions, and 100% of funding engages U.S. scientists and researchers, resulting in breakthroughs on diseases like HIV, tuberculosis and malaria, which cause some of the highest rates of suffering and death globally. The Fogarty Center also serves an ambassadorial function and represents U.S. research, training and collaboration on the world stage. Consolidating this program into the proposed National Institute on Health Sciences Research without a plan for sustained global health research leadership and funding may severely curtail this important work.

Health inequities continue to limit our ability to respond to infectious diseases epidemics, including HIV, viral hepatitis, sexually transmitted infections and infections linked to drug use. Dedicated and increased investments in evaluating how to effectively reduce health disparities and improve health equity for marginalized populations is essential to improve health outcomes and reduce health care expenditures.

While we agree that parts of the NIH portfolio should be evaluated and assessed to determine if consolidation is necessary to avoid unnecessary agency sprawl, the proposed National Institute on Health Sciences Research groups multiple programs with little similarity in missions and research together. Creating a mission for this institute that encompasses such a wide array of different institutes risks leaving out important research areas and stifling certain portfolios as a result. We recommend avoiding needless consolidation of programs. **We further recommend ensuring the Fogarty International Center can continue to fulfill its mission by authorizing a budget of \$116.1 million for this center and a budget of \$526.7 million for the National Institute on Minority Health and Disparities.**

ARPA-H Consolidation

Additionally, the framework's plan to consolidate ARPA-H into the NIH structure through moving it into the National Institute on Innovation and Advanced Research may stifle the innovative nature of ARPA-H's research. ARPA-H was specifically kept separate from other institutes and centers to ensure that its key goals of advanced research with innovative concepts were able to be conducted in a timely and nimble manner.

Grant Reform

IDSA and HIVMA support strong accountability measures in federal research to ensure transparency and ethical conduct. However, certain aspects of this outlined area in the RFI should be further clarified before moving forward. The RFI specifies a public, independent oversight entity to review, modify, approve or reject research and experiments for certain gain of function research proposals. However, it is unclear who would be on this committee and making the decisions on this type of research. IDSA recommends clearly specifying the membership for this committee, including federal scientists and experts from the relevant field of the research being reviewed.

Gain of Function Research

Additionally, using the term "**gain of function**" may constitute an unreasonable amount of oversight on projects that do not pose a national security risk. Gain of function research is a broad term that can encompass almost any type of research used to alter the function of an organism in such a way that it is able to do more than it used to. This type of research is used broadly in applied life science research and is important because it can help us understand potential human-pathogen interactions, assess their likelihood of emerging in a pandemic and inform preparedness efforts, including surveillance and developing medical countermeasures. Gain of function research is essential for pandemic preparedness and national biosecurity when conducted with clear guidance and strong oversight. IDSA recommends focusing on specific categories of gain of function research that could pose national security threats, such as research on enhanced potential pandemic pathogens (ePPP) and dual use research of concern (DURC). These types of research represent a smaller portion of gain of function research and, while

necessary for scientific research in areas like vaccine development, should have strong oversight to ensure that biosafety and biosecurity concerns are addressed and mitigated. It is important to balance responsible oversight and a focus on biosafety practices with an environment wherein critical research is supported.

Any oversight and policies regarding these types of research should be developed in conjunction with the **National Science Advisory Board for Biosecurity (NSABB)**. In February 2022, the U.S. government charged NSABB – which is comprised of members with significant expertise in science, research methodology, biosecurity and bioethics – with reviewing policies governing gain of function research and DURC. Federal science should ensure it is unified in its standards to ensure that they are clear to researchers conducting experiments utilizing ePPP or DURC research.

Supporting the ID Workforce and Early Career Researchers

We appreciate the focus on ensuring funding for **early career researchers who may feel NIH grants are inaccessible to them**. The ID field is incredibly short staffed; in 2023, just over half of ID physician training programs and only 43% of pediatric ID training programs were filled. By comparison, most other physician specialties filled nearly all their programs. This means there are also fewer ID physicians pursuing training as physician-scientists, despite the urgent need for ID physician-scientists to bridge the gap between clinical ID care and research. The persistence of emerging and reemerging infectious diseases threats, the growing trend of AMR and the necessity of ID expertise and support throughout other medical specialties make strengthening the ID clinical and research workforce a priority. Novel intervention is needed at NIH and NIAID to make federal grants more accessible and equitable for early career researchers. To that end, IDSA recommends the following:

- Promote other avenues of sustained funding beyond traditional resources, such as the Research Career Development Awards (K awards). More and different types of funding opportunities are needed to reduce barriers for new researchers.
- Address low paylines that limit the pool of researchers able to secure NIH funding.
- Recruit from a diverse pool of researchers, including nurse practitioners, physician assistants, pharmacists and physicians in community-based settings, by enhancing training opportunities and pathways for clinicians to connect with clinical trial and research networks.
- Increase investment in the “K to R transition” for early career physician-scientists through increased paylines of R01s for new investigators and opportunities unique to scientists who have not received a major NIH grant.
- Increase early career physician-scientist funding through the expansion of K, T and F grants, and increase K award paylines to pre-2016 levels. Grant evaluations should focus on research commitment and potential, rather than past achievements.
- Ensure that the Loan Repayment Program continues to be funded. This will allow for physician-scientists to pursue scientific careers while not worrying about the amount of debt accrued during their education and training.

IDSA recognizes the need to more efficiently use NIH funds for research, prompting an evaluation of potential caps on facilities and administrative (“indirect”) funds provided to institutions. Transparency on how indirect costs are spent could similarly increase cost efficiency. IDSA recommends that the impact, pros and cons of implementing caps on indirect funds be carefully evaluated. Different caps for different types of grants and funding opportunities should be considered.

IDSA and HIVMA welcome continued collaboration on developing these important topics. If you have questions about these comments or would like to connect, please contact Eli Briggs, IDSA director of public policy, at ebiggs@idsociety.org, or Andrea Weddle, executive director of HIVMA, at aweddle@idsociety.org.

Sincerely,



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