August 16, 2024

The Honorable Cathy McMorris Rodgers
Chair, House Energy and Commerce Committee
United States House of Representatives
Washington, D.C. 20515

Dear Representative McMorris Rodgers:

The American Physiological Society (APS) appreciates the opportunity to comment on the proposed framework on reforming the National Institutes of Health (NIH). APS is a global, multidisciplinary community of more than 8,500 biomedical scientists and educators. APS members conduct basic and applied biomedical research in academic labs across the U.S. Funding from NIH is critical in supporting their research and education. APS is interested in the goals of the framework to create a stronger and more effective NIH and offers recommendations in response to several of the proposed updates.

The NIH has a strong history of supporting leading-edge research and innovation that underpins modern medical advancements and drives U.S. global leadership in biomedical science. NIH funding drives economic growth and is essential for training the next generation of scientists. The highly competitive peer review of grant applications helps to ensure investment into the most promising research, while program staff outline broad research goals for the agency to address scientific needs. While there may be opportunities to increase the efficiency of NIH operations, major changes to the agency should be considered carefully and implemented through a transparent process with clear timelines and opportunities for stakeholder input.

Restructuring of NIH Institutes and Centers

The organization of NIH into 27 institutes and centers (ICs) evolved over time and was shaped by a variety of factors. Each institute sets research priorities based on needs and opportunities in its subject areas, coordinates with study sections to manage grant peer review, and manages grant policies and second-level grant review. While there may be redundancies in function across ICs, it should not be assumed that merging ICs will result in increased operational efficiency. It is important that each institute can effectively coordinate a comprehensive research portfolio, adapt to new technologies and research paradigms, support the training and education needs of the research community, and foster multi-disciplinary research and collaborations.

To ensure that ICs continue to effectively support the mission of the NIH, reorganization should be guided by the expertise of the research community. Congress should consider convening an interdisciplinary panel that includes scientific experts and individuals with government and

management experience to provide recommendations for a reorganization strategy. The process for reorganization should be open and transparent with clearly defined goals. To the extent possible, the process should follow a defined timeline for proposing, considering, and implementing structural changes, including adequate time for stakeholders to respond at each stage. Where appropriate, congressional hearings should offer opportunities for researchers and institutions to provide input.

Balancing basic and applied research

Supporting basic science and investigator-initiated research is integral to the success of NIH and the U.S. biomedical research ecosystem. Fundamental scientific research enables advancements in biomedical innovation and is critical for training the scientific workforce. Any restructuring of ICs must ensure that basic science remains a strong focus of the NIH and that no research areas lose support. While some institutes were organized around the study of specific disease areas (e.g., National Institute of Neurological Disorders and Stroke), each institute covers a breadth of research topics and supports multiple stages of healthcare innovation and discovery. Furthering our understanding of the function of biological systems must continue to be a core function of the NIH.

Cross-cutting programs

Programs and initiatives within the NIH Office of the Director help coordinate agency-wide efforts to address research gaps and emerging scientific opportunities. For example, the Office of Research on Women's Health (ORWH) has provided tools to help researchers factor sex as a biological variable into research designs and expanded the inclusion of women in clinical research. These programs help NIH address the causes of health disparities, stimulate research into under-studied topics, and set strategic directions based on input from the research and patient advocacy communities. The important role of cross-cutting programs within the Office of the Director should be preserved.

Institute and center director term limits

Term limits for IC directors are unlikely to improve NIH research programs. IC directors serve a scientific role in developing and implementing long-term research strategies, and these positions require an extensive breadth of scientific knowledge. Term limits can result in gaps in leadership if new directors are not identified and onboarded swiftly (Jeanne Marrazzo, M.D., took the role of director of the National Institute of Allergy and Infectious Diseases more than 8 months after Anthony Fauci, M.D., left the role), and director terms may not be long enough to realize long-term visions. While changes in leadership sometimes bring new ideas, experienced leaders provide stable and predictable direction that is more effective for the scientific community.

Cost of restructuring

The cost of restructuring should be carefully evaluated, both fiscally and in potential disruption or delays to research. Before implementing structural changes to the NIH, there should be a consideration of evidence demonstrating meaningful increases in operational efficiency and a determination that the benefits will outweigh the costs and risks. Gaps or delays in funding

interfere with research progress and can have cumulative effects such as deferred training and career progression. Congress may consider a phased approach to restructuring that minimizes disruption and should provide sufficient resources to NIH to ensure the costs of reorganization are not taken away from research funding.

Limiting grant support per investigator

The recommendations on page 20 of the Framework include limiting grants and awards to principal investigators (PIs) with more than three "ongoing concurrent NIH engagements". This statement needs further clarification as to which grant mechanisms would count toward the limit of three "engagements".

While only a small minority of NIH-funded researchers hold more than three R01s (the most common type of NIH research project grant to support an investigator's research program), many investigators serve as PIs on other types of grants including institutional training, center and conference grants. These types of awards bring shared resources to institutions but do not provide direct support of an investigator's own research program and should be excluded from any policy limiting the number of grants per investigator.

Additionally, there are smaller grant awards (R15, R21) which provide limited resources to investigators for specific purposes. Including these grant mechanisms in the overall count of awards per PI may discourage investigators from seeking these types of smaller awards. Of particular concern would be discouraging investigators from pursuing R21 awards, as these grants support innovative early-stage project development and exploratory research.

Since 2012, NIH has had a policy of requiring special council review for applications from investigators that already receive significant NIH funding. The current policy[1] applies to researchers who receive more than $2 million per year in total costs. Because the policy relies on the dollar amount, as opposed to the number of grant awards, it does not unfairly penalize investigators who receive smaller grant awards as described above.

Limiting the number of grants per investigator may mean being able to support more researchers. However, if grants provide insufficient resources to fully support a lab's research program, less work will get done. APS recommends that NIH research grants provide sufficient resources for investigators to fully implement their proposed research plans. This includes the ability to pay skilled laboratory personnel a living wage and purchase the necessary supplies, equipment and services to carry out the research proposed in the grant.

[1] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-049.html

Support for early-career investigators

APS appreciates the committee's recognition of the importance of supporting early-career researchers. NIH data shows that the age at which investigators receive their first R01s remains high, with the median age of first R01 being 42 years. Current efforts to improve the postdoctoral experience have the potential to smooth the transition to faculty appointments for early-career scientists.[2]

The Next Generation Researchers Initiative, in place for 7 years now at the NIH, has focused on providing strong support for early-career researchers and at-risk researchers (researchers with high-scoring applications but without any current research grants). Data analysis from 2021 showed that this program is successfully increasing the number of early career stage researchers.[3] APS supports efforts to help early-career researchers obtain funding.

In addition to supporting early career researchers, NIH should be mindful of balancing support across career stages. Bringing in more early career researchers than can be supported in the future may lead to attrition of mid-career researchers.

Limiting facilities and administrative costs

Proposed efforts to limit facilities and administrative (F&A) costs could have unintended consequences on researchers who receive NIH funds to support their research. NIH-supported researchers rely on institutional staff to facilitate compliance with requirements for federally funded research. From submitting grants and progress reports to managing budgets and complying with requirements for research security and human and animal subject research, institutional staff are essential to the responsible conduct of federally funded research. F&A costs not only cover expenses associated with lab infrastructure, but also provide support for these essential institutional functions.

If reduced support for F&A costs results in a loss of institutional staff, researchers by necessity will have to take on more administrative burden, further reducing the amount of time that they can devote to conducting research and mentoring the next generation of scientists.

Administrative Burden

Researchers face a substantial and increasing workload of administrative and other non-research tasks. A survey from 2018 found that principal investigators spend an average of 44.3% of

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[2] https://acd.od.nih.gov/working-groups/postdocs.html

[3] https://nexus.od.nih.gov/all/2021/07/12/data-on-implementing-nihs-next-generation-researchers-initiative/

research time on administrative work.[4] The most time-consuming responsibilities include management of project finances and writing reports and project updates. Research that includes clinical trials, subcontracts, international collaborations, or human or animal studies significantly increases the administrative workload. NIH implemented a new Data Management and Sharing Policy in 2023, and while the policy aims to make research data more accessible, this adds to the time spent writing and managing grant proposals. Administrative burden inhibits productivity and is frequently cited as a principal factor discouraging students from pursuing academic careers.

Efforts to address oversight of research funding need to be balanced against mounting administrative load. For example, requiring grantee institutions to self-audit and publicly report information about F&A costs would likely lead to a greater share of administrative work borne by researchers. Unless there are clear instances where current policy has failed (and not cases where individuals have circumvented the policy), research efficiency would be better served by taking meaningful steps to streamline reporting requirements rather than implementing new oversight mechanisms.

Oversight of animal research

Page 21 of the framework recommends ensuring appropriate oversight of animal research. Animal research plays an indispensable role in biomedical research and discovery, and promoting animal welfare helps support reliable and reproducible research. Current oversight is effective at protecting animal welfare, but at substantial administrative cost. Implementing new oversight or transparency measures would be inappropriate without reducing or simplifying current requirements.

Animal research requirements are enforced both by NIH via the Public Health Service Policy on Humane Care and Use of Laboratory Animals, administered by the Office of Laboratory Animal Welfare, and by the United States Department of Agriculture (USDA) through enforcement of the Animal Welfare Act. Together these agencies set and maintain a rigorous set of standards for oversight of research using animal subjects. However, because multiple federal agencies oversee animal research, investigators and administrators must navigate sometimes overlapping requirements from different agencies to ensure that institutions maintain compliance. These policies and regulations have the clear intent to protect animal welfare. However, in accomplishing this mission, substantial administrative burdens are created.

The 21st Century Cures Act, passed in 2018, directed the NIH, USDA, and other related agencies to work together to harmonize requirements and reduce duplicative administrative burden that does not benefit animal welfare. In the fiscal year 2024 report accompanying the Labor, Health and Human Services, and Education appropriations bill, Congress expressed concern that NIH has not been sufficiently responsive to these directives and requested a report detailing further steps the agency plans to take to reduce investigator burden.

APS is concerned that the recommendations put forth in the framework imply that animal care and welfare standards are currently lacking in NIH funded research, while in fact there is

[4] https://thefdp.org/wp-content/uploads/FDP-FWS-2018-Primary-Report.pdf

extensive oversight in place. Any recommendations for new or additional policies relating to animal subject research and animal care should take into consideration what existing policies and regulations are already in place, and how new recommendations would substantively increase animal care without simultaneously increasing administrative burden.

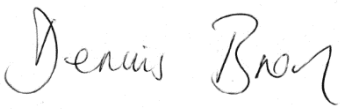
Conclusion

The NIH is the world's largest biomedical research entity, and its highly successful model of operation drives U.S. scientific leadership on the global stage. It will be challenging to create meaningful improvements to its efficiency and effectiveness while preserving the elements that are fundamental to its success. As a general principle, a cautious and evidence-based approach should be taken when implementing major changes to the agency's structure or policies. By working with the research community and other stakeholders, opportunities for positive change can be identified. APS looks forward to continuing to work with Congress to build a stronger NIH.

Sincerely,

Scott Steen, CAE, FASAE

APS Chief Executive Officer



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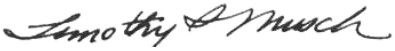
APS Chief Science Officer



Tim Musch, PhD, FAPS

APS President