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AADOCR American Association for Dental, Oral, and Craniofacial Research

August 16, 2024

The Honorable Cathy McMorris Rodgers
Committee on Energy & Commerce
United States House of Representatives
Washington, DC 20515

Submitted via email to NIHReform@mail.house.gov.

RE: Feedback on NIH Reform Framework

Dear Chairwoman McMorris Rodgers,

On behalf of the American Association for Dental, Oral, and Craniofacial Research (AADOCR) and the American Dental Association (ADA), we are writing in response to your request for stakeholder input on the discussion framework to reform the National Institutes of Health (NIH) you released on June 14, 2024.

The NIH is America's most vital and trusted government-funded medical research enterprise helping save countless lives in the U.S. and around the world. Its 27 Institutes and Centers (ICs) fund cutting-edge biomedical research at more than 2,500 universities, medical schools, and research institutions in every state across the nation. The NIH maintains the human and scientific resources that enable America to accelerate life-saving research, train scientists, and discover new therapies and cures for the debilitating diseases and illnesses facing millions of Americans.

Structural Reform

First and foremost, any broad structural changes to NIH must be evidence-based and informed by scientific expertise. Reforms should only occur after an open and transparent process that includes input from a variety of key stakeholders from within the NIH as well as the broader research community. Implementing vast changes to the largest biomedical research agency in the world requires a thorough and deliberative assessment of the current NIH structure and operations, an evaluation of potential impacts, and ideally, begin with a smaller pilot program. The process should also follow traditional legislative protocol to include congressional hearings with expert testimony, authorizing legislation, and ample opportunities for public input.

Our deepest concern with the NIH framework is the proposed consolidation of the NIH's 27 ICs into 15 newly renamed centers. A restructuring of this scale would dilute the specialized focus that allows each IC to conduct targeted, effective research in its area of expertise, potentially leading to a loss of the deep specialization that drives progress in health research and, by extension, product innovations.

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Indeed, the Scientific Management Review Board (SMRB), which was created by the *NIH Reform Act of 2006* to "advise HHS and NIH officials on how to use their organizational authorities, including advising the NIH on its most effective organizational structure", concluded in its 2010 report on organizational change and effectiveness at the agency that "a far-reaching overhaul of the NIH structure is neither advisable nor feasible."

The proposed creation of an "Institute of Neuroscience and Brain Research" that includes the National Institute of Dental and Craniofacial Research (NIDCR) is an apt illustration of the inherent flaws in the envisioned NIH reorganization. Founded by President Harry S. Truman in 1948, NIDCR was the third NIH institute, created to tackle the urgent problem of poor oral health, which had disqualified nearly 20% of potential recruits from serving in World War II.

Since then, NIDCR has been on a mission to improve oral health and eradicate oral diseases, the treatment of which pose enormous economic and healthcare burdens. NIDCR continues to lead the way in advancing fundamental knowledge about dental, oral, and craniofacial health and disease and translates those research findings into strategies for prevention, early detection, and treatment that improve both oral and overall health.

Oral diseases impact nearly 3.5 billion people worldwide, ranging from cavities to gum disease to oral cancer, causing pain and disability for millions of Americans. Global oral diseases cost more than $710 billion annually, with U.S. dental expenditures soaring to $162 billion in 2021 - a sharp 11% increase from the previous year[1]. The escalating financial and health burdens make it clear that researching oral diseases is a pressing public health priority.

The complexity of the human body and the myriad number of diseases we face necessitates distinct institutes that are dedicated to specific health priorities like cancer, mental health, and oral health. Individual ICs are also essential in providing research training and career development for the next generation of scientists. The specialized structure of the NIH allows for in-depth and focused research on complex diseases and conditions. Eliminating ICs, which have built up decades of expertise and tailored research agendas, could lead to a loss of institutional memory and stifle scientific progress.

Shifting NIDCR to a broader neuroscience and brain research context will dilute its focus and undermine its entire mission of advancing oral health for all through research. Additionally, the Institute represents much more than neuroscience. As an entry to the body, the oral cavity and its resident microbiome are unique and complex, representing an intricate system of tissues and regulatory mechanisms, many of which are not found elsewhere in the body. Having a dedicated institute centered on the oral and

[1] Oral Health in America: A Report of the Surgeon General. National Institutes of Health, U.S. Dept of Health and Human Services; 2000.

craniofacial system ensures continued research into critical areas like tooth development, gum diseases, cavities, oral cancer, genetics, immunological diseases, orofacial pain, oral disease prevention, and craniofacial birth defects without these issues being overshadowed by broader health concerns.

Specialized institutes are not just for advancing research, but for building a dedicated research community with specialized training programs to foster the next generation of researchers, build expertise, and offer mentorship opportunities from experts in the field. Additionally, this community can continue its close partnership with specialized sectors of the health care industry to align provider and patient needs with emerging technologies and scientific discovery, including at sites that might otherwise be overlooked.

Finally, the existence of specialized institutes helps raise awareness among policymakers and the public about specific public health challenges and lesser-known diseases. For example, NIDCR – the largest oral health research organization in the world – not only advances our understanding of oral health but champions oral health initiatives that raise awareness about the critical role oral health plays in ensuring overall wellness.

Policy Reform

Mission and Leadership Reform

The NIH framework includes a proposal to establish term limits for IC directors to 5-year terms with the ability to serve for 10 years. We support the underlying goal of imposing term limits on leadership to allow for new approaches and perspectives, accelerate innovation and modernization, and to create pathways for underrepresented talent.

In 2020, the NIH did implement changes to its intramural program by imposing 12-year term limits on mid-level leadership positions. There is room for expanding this policy to senior-level leadership positions, however, we caution the committee to carefully consider the appropriate term length to allow leaders enough time to implement their visions for the ICs they are steering, and to ensure the NIH can continue attracting and recruiting top scientific talent.

We support the worthy objectives in the framework that seek to enhance transparency, accountability, and responsiveness at the NIH. While there are existing NIH policies that address conflicts of interest and misconduct, including sexual harassment, there is an opportunity for NIH to demonstrate its commitment to these principles by implementing some of the recommendations from the framework, such as ensuring NIH officials abide by financial transparency requirements; setting guidelines for public-private partnerships to prevent the appearance of corporate influence on research; disclosing all third-party financial benefits; and implementing new policies and protocols to enhance oversight of investigations into allegations of misconduct.

Funding Reform

The framework recommends NIH reexamine facilities and administrative (F&A) or indirect costs and to consider alternative mechanisms for bringing down costs, such as tying the indirect cost rate to a specific percentage of the total grant award or capping indirect costs at a graduated rate dependent on a recipient's overall NIH funding. It also suggests requiring institutions to publicly report on their F&A costs.

The implication of this recommendation is that F&A costs have risen and create inefficiencies, however, indirect costs have remained flat for more than 20 years at approximately 27-28% of total grant funding[2]. The expenses are reimbursed based on a formula negotiated between the research institution and federal auditors. All F&A costs are also auditable to confirm they are reimbursable under OMB regulations.

Limiting the F&A reimbursement structure would negatively impact research institutions that incur significant costs related to performing federally sponsored research, including construction and maintenance of research facilities, utility expenses, labor costs, research and data processing, disposal of hazardous waste material, and compliance obligations, among other things. Cutting or capping F&A expenses would force research institutions to cut back their research programs inhibiting scientific progress.

Grant Reform

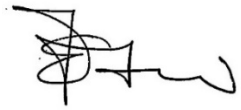
One of the recommendations under this section is that research be "credible, reliable, and timely" and encourages bolstering and supporting early-stage investigators. We support this objective and welcome legislative proposals to strengthen the research workforce by ensuring early-stage investigators (ESIs) are awarded funding opportunities that help advance their careers. The NIH has prioritized this goal by supporting dedicated grants for ESIs even when uncertainty regarding federal funding (due to the federal government operating under a continuing resolution) forced ICs to implement interim paylines and reduced awards. The NIH's ability to continue this support, however, is constrained by the agency's authority, funding, and regulations from other agencies. Policymakers are urged to address this issue by supporting more predictable funding models such as grants that are more flexible and funded for longer than one year. Such models could be made more broadly available and complement existing funding mechanisms so that investigators, particularly ESIs, can pursue academic research careers with more certainty and more stable funding.

Thank you for the opportunity to consider our views on the proposed NIH discussion framework. We share the committees' goal of ensuring the NIH remains at the forefront of innovation and that it is equipped with the funding and regulatory oversight it needs to continue driving scientific advances and identifying new treatments and cures that improve the health of all Americans.

[2] CRS Report R41705; *The National Institutes of Health (NIH): Background and Congressional Issues*; Johnson, Judith A. and Sekar, Kavya.

If we can provide additional information or answer any questions, please contact Yehuda Sugarman with AADOCR at ysugarman@iadr.org or Jennifer Fisher with ADA at fisherj@ada.org.

Sincerely,



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