

Officers:

Ruth C. Carlos, MD, MS

President

Pamela Woodard, MD

Secretary/Treasurer

Mitchell D. Schnall, MD, PhD

CIBR Chair

Executive Committee:

Katherine P. Andriole, PhD

Miriam A. Bredella, MD

John D. Hazle, PhD

Satoshi Minoshima, MD, PhD

Pari Pandharipande, MD, MPH

Neil Rofsky, MD

Board of Directors:

Prachi P. Agarwal, MD

Aisling M. Chaney, PhD

Manjiri Dighe, MD, MBBS

Christian Eusemann, PhD

Jessica Foley, PhD

Michael F. McNitt-Gray, PhD

Christopher Hess, MD, PhD

Diego Jaramillo, MD, MPH

Jerry G. Jarvik, MD, MPH

Kevin Koch, PhD

Elizabeth A. Krupinski, PhD

H. Charles Manning, PhD

Courtney Moreno, MD

Levon N. Nazarian, MD

Mary S. Newell, MD

Rebecca Rakow-Penner, MD, PhD

Karun Sharma, MD

Gary Ulaner, MD, PhD, FACNM

Judy Yee, MD

Executive Director:

Renée L. Cruea, MPA

The Honorable Cathy McMorris Rogers
Chair, House Energy and Commerce Committee
US House of Representatives
Washington, DC

Delivery via email: NIHreform@mail.house.gov

Dear Chairwoman McMorris Rogers,

Thank you for your leadership in advancing biomedical research and for this opportunity to respond to your Request for Information on the proposed framework, "Reforming the National Institutes of Health." The Academy for Radiology & Biomedical Imaging Research (Academy) is a non-profit advocacy organization based in Washington, D.C. Our primary mission is to advocate on behalf of all the stakeholders in the medical imaging research community for robust and consistent federal investments in medical imaging research at NIH and other federal agencies.

As a stakeholder in the NIH community, we are pleased to provide our thoughts in response to your NIH reform proposal. Should there be opportunities to engage with the wider community in further conversation, the Academy would be interested in joining those sessions.

The Academy agrees with the Committee that trust in the NIH's work and mission is paramount. We support efforts by Congress that will lead to greater trust in the NIH, the biomedical discoveries taking place at the agency, and support for the researchers conducting cutting edge science. Cures and treatments will be ineffective if there is no trust in the underlying science. Policymakers and NIH must work collaboratively to accurately discuss and report on scientific achievements that benefit all Americans.

The Academy also supports committee action that can transform the NIH organization and operations to align with, inspire, and better enable the best science. Any functional and structural reforms must ensure continued scientific advancement and a balanced portfolio of basic, translational and clinical research across all NIH Institutes and Centers (ICs). Additionally, changes to NIH will impact a large and diverse group of stakeholders, not only patients and their families but also scientists and research institutions.

Collectively, they represent an expert and insightful community who understand the Agency and where opportunities for better aligning NIH's structure with its mission may exist. Involving the stakeholder community will result in a better result of any effort to optimize NIH's structure.

The Academy would also point out strong support for Artificial Intelligence (AI) technology. Radiology and imaging are areas in medical disciplines and research making the most immediate use of AI technology. As Congress considers legislative approaches to advancing and regulating health AI, it is critical to learn from successes and challenges in the radiology and imaging community. The Academy convened leaders in radiology and imaging research and developed a draft [white paper](#) on “Artificial Intelligence in Imaging” The Report highlights many opportunities and roadblocks with AI. Among the solutions Congress can address in any NIH Reform bill are:

- Have NIH report to Congress its plans to ensure that AI applications in radiology and imaging reach rural and underserved populations.
- Direct the NIH to create tools and techniques to make AI decisions transparent and understandable to users.
- Direct NIH to conduct population studies that evaluate the effectiveness of opportunistic screening and care coordination for AI solutions that detect chronic disease.
- Direct NIH to support research that assesses the impact of AI on clinical decision-making, hence patient's outcomes; and the impact of AI in medical imaging, interventional radiology, and radiopharmaceutical therapy training and education with respect to clinical skills development and the potential for unforeseen outcomes such as deskilling.

The Academy provides these further thoughts in response to the Reforming the NIH framework.

1. Structural Reform

As the proposal currently stands, the Academy is firmly opposed to merging the National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Center for Advancing Technologies (NCATS), ARPA-H, and the Common Fund. NIBIB is responsible for cutting edge imaging research that transforms medicine and leads to a beneficial impact on human health. NIBIB has been very successful in generating start-ups, leveraging new technologies, and developing clinically translatable AI technology. We risk losing this unique scientific program for radiology, imaging, and bioengineering innovation if NIBIB should lose its autonomy.

Take for example how NIBIB responded to the urgent need for COVID-19 tests. To accelerate innovation in the development of testing technologies needed during the COVID-19 pandemic, NIBIB introduced the Rapid Acceleration of Diagnostics (RADx®) technology. RADx led to development, production scale-up, and deployment of accurate, rapid, point of care and at home tests across the country. Now that we have past the urgent needs associated with COVID, NIBIB is applying the RADx approach to solve a range of health problems, including developing technologies to address the maternal health crisis in the United States, technologies to reduce the spread of HIV, diagnostics to support the elimination of hepatitis C in the United States, and much more.

In fact, recent data has shown that more patents have been filed from NIBIB than any other NIH institute. It is not only a catalyst for researchers looking to expand current imaging technologies, but also an economic driver that produces innovations and patents, which in turn lead to more inventions, greater start-up activity, and lower unemployment.

There is no complimentary IC at NIH that can scale advances in imaging and radiology technology and innovation like NIBIB. The Academy urges the Committee to maintain NIBIB as an independent Institute.

The Academy does recognize Congressional interest in realigning the NIH to better serve science and medicine in the 21st Century. Any new restructuring, however, must be thoughtful and deliberative and

cause the least amount of disruption to the scientific enterprise. We suggest the following as you approach actions to consolidate ICs. This includes:

- Hold hearings and engage with a broad array of scientific and patient representatives.
- Realize the costs associated with a wholesale consolidation of NIH's ICs.
- Consider the massive disruption to the scientific enterprise and limit the administrative and staffing disruption.
- Look for administrative redundancies that can be streamlined.
- Re-establish the Scientific Management Review Board with a directive to realign NIH's overall structure, portfolio, and future direction.

2. Grant Reform

The Academy is also highly concerned with the proposal to cap principal investigators at three active grants. It is exceedingly difficult to run a productive lab with three or fewer grants. Research costs, use of new technologies, and staff salaries continue to increase. However, the size of the average NIH Research Project Grant has remained the same for decades. Thus, the ability of an average NIH Research Grant to support current research costs has diminished. Any grant cap policy will inherently hurt the US research infrastructure. We must ensure we are keeping our best people working in America and allow them to continue training the next generation of U.S. S&T leaders. Without this, we risk diminishing the pool of top scientific talent in the US, slowing the pace of both clinical and bench research.

3. Addressing Misconduct

Published studies show investigators leave biomedical research for primarily two reasons: 1) funding opportunities are limited, forcing them to find alternative careers, and 2) researchers, particularly women, people of color, and other underrepresented individuals, feel unsupported (at best) or face openly hostile environments (at worst) such that they leave the field.

That people leave the field because of a lack of support, or discriminatory environments is unacceptable. NIH can and must do better in this regard. While issues of harassment, intolerance, and other hostile environments are first handled by the research institution, NIH can better wield the leverage it has over grant funding to ensure those creating a negative environment are not rewarded for their behavior. Moreover, through its policies, NIH can continue creating a research environment where individuals with different needs and lived experiences are supported and welcomed into the community.

4. Facilities & Administrative (F&A) Cost Reform

Since World War II, the federal government and research institutions have partnered in a cost sharing relationship that has led to discoveries that have cured diseases and improved the quality of life for people around the world. That partnership through F&A made possible the creation of a biomedical research enterprise that has made the U.S. a leader in innovation and economic competitiveness. F&A costs allow an institution to support biomedical research—the cost of the lab space, for instance, or the salary of administrative support staff.

Like all complicated policies, the F&A reimbursement process is not perfect, and merits periodic evaluation. We ask that the Committee carefully consider evidence-based evaluation and not draconian cuts or caps that would irreparably damage the research enterprise. Congress could choose to request a detailed analysis and assessment by the National Research Council (National Academies of Sciences, Engineering and Medicine) to inform a nuanced F&A reimbursement process revision. The academic research community would cooperate fully in such an oversight exercise.

5. Term Limits for Institute and Center Directors

As the Committee is aware, section 2033 of the 21st Century Cures Act made term limits for IC Directors a requirement and set term limits of five years, renewable. The Academy can see the benefits of term limits for IC Directors. We believe it could help ensure that the ICs are nimble, well-informed, and capable of incorporating the latest scientific advances and knowledge to set their mission and funding priorities. However, we are concerned that five years may be too brief a term for a position as critical as an IC Director and would dampen recruiting talented future Directors. We recommend that the 21st Century Cures be amended to propose 10-year terms, renewable. This would be more attractive when recruiting productive scientists to leave the bench and transition to an administration position. We also urge a phase-in process to address new leadership at the ICs. It would be very disruptive to the scientific process if NIH lost most IC Directors at one time.

Thank you again for the opportunity to join these discussions at the initial stages. The Academy looks forward to being a stakeholder in these efforts as these conversations continue.

Sincerely,

A handwritten signature in dark ink, reading "Renee L. Cruea". The signature is fluid and cursive, with the first name "Renee" being more prominent.

Renee L. Cruea, MPA
Executive Director
Academy for Radiology & Biomedical
Imaging Research

