



October 30, 2023

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
U.S. Senate
428 Senate Dirksen Office Building
Washington, D.C. 20510

Dear Ranking Member Cassidy,

The Association of Public and Land-grant Universities (APLU) greatly appreciates your interest in the National Institutes of Health (NIH) stakeholder community's feedback through your request for information related to NIH operations.

APLU is a research, policy, and advocacy organization dedicated to strengthening and advancing the work of public universities. With a membership of more than 250 public research universities, land-grant institutions, state university systems, and affiliated organizations, APLU's agenda is built on the three pillars of increasing degree completion and academic success, advancing scientific research, and expanding engagement. Annually, our U.S. member campuses enroll 4.2 million undergraduates and 1.2 million graduate students, award 1.2 million degrees, employ 1.1 million faculty and staff, and conduct \$48.7 billion in university-based research.

As you know, the NIH is the premier biomedical and behavioral research institution in the world with a mission to support science to improve health and well-being within the United States and globally. Public research universities are important NIH partners in developing new medications, vaccines, medical devices, and immunotherapies. As you look to increase efficiencies at NIH to further its essential mission, it is important to keep in mind the well paraphrased adage of the Hippocratic Oath, "to do no harm" to an agency that is the envy of the world's nations. Competing nations are investing more and more in biomedical sciences. We cannot risk losing the United States' edge through disinvestment or overregulation.

More than 84 percent of NIH funding is awarded through the peer review process to more than 300,000 researchers and 2,500 universities, medical schools, and research institutions in all 50 states. In addition to supporting the research to help Americans live longer, healthier, and more productive lives, NIH funding in fiscal year 2022 help supported over 568,585 jobs (both directly and indirectly) and \$96.84 billion in new economic activity nationwide. To continue U.S. leadership in the biomedical sciences, we must reaffirm our commitment to a strong, well-funded, and trusted NIH.

Increasing the Pace of Science

Public Access:

Public access to data used in federally-funded research in peer-reviewed journals is essential for rigorous science, discovery, and the reproducibility of research. Public universities are committed to sharing the results of their research whenever possible. For this reason, the

Association of Public and Land-grant Universities (APLU), in collaboration with the Association of American Universities (AAU), and with funding from the National Science Foundation and National Institutes of Health, held a series of workshops and conferences with researchers, senior research officers, librarians, chief information officers, and organizations supporting increasing public access to research. This work culminated with the publication of a [“Guide to Accelerate Public Access to Research Data”](#) in 2022. The Guide is a resource to help university administrators develop robust support systems to accelerate sharing of research data.

NIH is a recognized world-leader in facilitating public access to research publications in the biomedical sciences. Earlier this year, NIH [solicited](#) public comments for its “Plan to Enhance Public Access to the Results of NIH-Supported Research.” APLU’s comments included appreciation for NIH’s proposal to allow for flexibility in where researchers publish and that the plan allows researchers to charge reasonable publishing costs to their awards. APLU also recommended that NIH could help address concerns about impacts on small institutions or less resourced investigators to deposit research data by creating an agency-wide repository for data. Such a repository would ensure that research data adheres to the FAIR principles of findability, accessibility, interoperability, and reusability of data. NIH could support both the technical and human infrastructure required to ensure quality data curation. This would increase standardization across the NIH directorates for research data produced in NIH-funded projects. To increase the discoverability of NIH-supported research data, NIH should support infrastructure that would enable searching all NIH-supported research data repositories via a common portal as NIH has done for peer-reviewed publications in NIH’s PubMed Central.

Research and Private Sector Collaboration:

Cross-sector research collaboration is one of the most important elements of a national innovation system. Collaboration is also costly; research partnerships require time and attention to reconcile differences in goals and to address other potential barriers. These costs and barriers may explain why university-industry collaboration is not more common despite the importance of this collaboration to private sector innovation and long-term national economic competitiveness. Industry R&D spending has soared over the past few decades; however, only about one percent of total industry R&D is spent on formal research collaborations with universities, and only six percent of university research funding comes from industry. In 2022, APLU published a report [Driving U.S. Competitiveness Through Improved University-Industry Partnerships](#) based on in-depth interviews with university and industry representatives, including some from the biotechnology industry. Interview respondents indicated that translational research is underfunded, and that additional funding for translational research, gap research, and funding that explicitly supports industry-university collaborative research could help to close the gap between the two independent R&D systems for industry and universities. Developing these programs requires open communication between universities, industry, and funding agencies to ensure success. The NIH National Center for Advancing Translational Sciences (NCATS) is filling an important space in focusing cross-disciplinary and cross-sector approaches to addressing pressing public health needs and rare diseases.

Extramural Research Program

Facilities and Administrative (F&A) Costs:

F&A costs have been included in federal grants since the 1940s, recognizing that institutions incur expenses related to research that may not be directly attributable to only one project, but are essential to conducting research, e.g. building heat, lights, power, and water, information

technology, and increasingly safety and research security to protect federal research investments. Biomedical research, which receives the largest share of federal science funding, depends also on research in clinical environments and medical facilities, use of extensive tissue and sample collections, and scores of professionals to ensure compliance with federal, state, and local regulations on human and animal subject research protections, privacy, health, and safety, and for management and technical support. Attributing these costs individually on every grant would be an inefficient, arduous, and expensive process, both for the federal government and for the grant recipients.

While F&A costs are often referred to as “indirect costs,” they are very **real** costs that are absolutely required for the ongoing research. Universities are not close to being fully reimbursed for the expenses they incur to provide the necessary infrastructure and support to conduct federal research. According to data collected by the National Science Foundation (NSF), in FY20 universities contributed approximately \$5.7 billion in facilities and administrative expenditures not reimbursed by the government. In addition, the Office of Management and Budget (OMB) specifically limits how much universities can be reimbursed for administrative costs, even as required administrative responsibilities continue to increase due to new federal security requirements and other regulatory changes. In fact, a recent [report](#) by COGR cataloged a 126 percent increase in new regulations, new policies or modified regulations impacting federal research in the last ten years.

The process by which the federal government and institutions negotiate F&A rates is complex. It is based on an extensive information collection that includes the age and condition of facilities and building, maintenance, utilities, and administration cost that may vary by institution and region (payroll, accounting, or information technology). Further caps or reductions in F&A rates would lead to the deterioration of research facilities and capabilities and limit participation in biomedical research to only the most well-resourced institutions. This would have downstream impacts on the preparation of the biomedical workforce and the contribution to the economy in the regions with fewer well-resourced institutions. Such an outcome would run counter to the federal priorities to broaden participation in research by under-represented groups and institutions.

Expanding the Biomedical Workforce:

Our nation’s continued leadership in the biomedical sciences is dependent up recruiting and maintaining a pool of highly talented and diverse researchers. Congress should support NIH’s continuum of programs from pre-college summer research programs, to undergraduate education and scholarships, to doctoral level fellowships and training that help attract our nation’s best and brightest from underrepresented groups, individuals from disadvantaged backgrounds, individuals with disabilities, and all parts of the country both urban and rural.

Recognizing growing concerns about the postdoctoral training system and recruiting qualified postdoctoral candidates, NIH convened the Advisory Committee to the Director (ACD) Working Group on Re-envisioning NIH-Supported Postdoctoral Training. I am proud to currently serve on this working group which plans to release recommendations in December. NIH charged the working group to evaluate the decline in PhDs pursuing postdoctoral training, assess the factors influencing this trend, find ways to improve support and retention of postdoctoral trainees, and engage key stakeholders to understand and strengthen postdoctoral training in the US. The working group released [an interim report and principles](#) in June 2023, which included an analysis of the complex forces that are impacting postdoctoral training. The final report to be

released in December will have recommendations for both NIH and institutions to better support postdoctoral training.

Institutional and Geographic Diversity:

APLU recognizes the value in both institutional and geographic diversity in participation in NIH programs. APLU's member universities are in all 50 states and include a wide range of institutional types such as R1 high intensity research institutions, R2 classified institutions and Minority Serving Institutions (MSIs), including Historically Black Colleges and Universities (HBCUs). There is space within NIH's many programs to promote both the best scientific ideas and increase the capacity of institutions looking to expand their biomedical research footprint.

NIH programing is reaching rural states and institutions. A recent report by United for Medical Research, focused on 7 rural states, found that in 2022 NIH funding supported an average of 2,300 jobs and \$353 million in new economic activity per state, or \$2.3 dollars of economic activity for each dollar of NIH research funding. The Institutional Development Award (IDeA) is an important program that has a significant impact on institutions in rural areas. One IDeA state health science center recently reported that over 70% of its primary investigators had received funding from the program at some point in their career.

Through the recently passed CHIPS and Science Act, Congress authorized several new capacity building programs at the National Science Foundation (NSF) to build the research capacity at MSIs, HBCUs and other emerging research institutions not just through physical infrastructure programs but also administrative structures to support better grant development and support. Faculty at emerging research institutions often lack the support to develop competitive proposals, investigate the full panoply of federal funding opportunities, and manage grant submission and award management compliance. NSF launched the Growing Research Access for Nationally Transformative Equity and Diversity (GRANTED) to provide support to emerging and developing research institutions including R2, R3, and other smaller institutions by examining ways to enhance access to the administrative and support services and develop best practices to supplement the efforts of STEM faculty to competitively apply for federal grants. NIH should consult with NSF as this program gets off the ground and look for commonalities as it continues to build programs in its Division for Research Capacity Building (DRCB).

Peer Review:

APLU is encouraged by NIH's [recent announcement](#) to simplify the grant review process to improve the focus on the scientific merit of research grant applications and mitigate elements that have the potential to introduce reputational bias into review. Rigorous and ethical peer review is the bedrock of scientific progress. Critical review of proposed work requires expertise from across the nation to ensure that all aspects of the work are duly considered. NIH should proactively encourage diversity of host institution, career stage, and geography in peer review panels to ensure the breadth of the country's perspectives are considered.

Administrative Opportunities and Challenges

Inter-Agency Collaboration/Computing and AI:

As you noted in your recent white paper "Exploring Congress' Framework for the Future of AI," artificial intelligence has enormous potential to improve and speed up the development of new drugs, devices, and healthcare delivery systems. NIH by necessity should work with other

federal research agencies to bring together expertise across many fields including biomedical sciences, computer and information technology, cognitive science and psychology, economics and game theory, engineering and control theory, ethics, linguistics, mathematics, and philosophy. NSF is currently co-funding AI Institutes with the U.S. Department of Agriculture, Department of Homeland Security, and industry partners. More of this cross-agency collaboration and coordination should be encouraged if the U.S. is to harness this powerful technology while also managing the potential liabilities.

Generative AI is of great interest and concern to university leadership. At the upcoming APLU Annual Meeting in November in Seattle, we have a pre-meeting workshop for institutional teams to better understand the impact of AI on education and research at public research universities. Additionally, APLU senior research officers have formed an AI Working Group. Some of the issues they have raised that need to be addressed by researchers, institutions, law makers, federal agencies, private foundations, industry, and publishers are:

1. How can AI be used to reduce the risk of data manipulation, fraud, and plagiarism in research?
2. How can we leverage AI to aid in evaluating the quality, novelty, and significance of research submissions? What requires human intelligence that AI cannot and must not do? How do we mitigate the risk of bias in these evaluations?
3. In what ways can AI automate administrative tasks related to research grant applications, reporting, and compliance, reducing the administrative burden on researchers, institutions, reviewers, and program officers?
4. How can AI be leveraged to better understand collaboration networks among researchers to identify influential researchers and institutions within a given field? How about connections between research domains on promising new areas of research?

NIH could help address some of these questions about the impact of generative AI on the research enterprise by supporting convenings across the biomedical community.

Improving Transparency and Oversight

Research Policy Board:

One of the core recommendations made in the 2016 National Academies report [“Optimizing the Nation’s Investment in Academic Research: A new regulatory framework for the 21st century”](#) and subsequently included in the 21st Century CURES Act, was the creation of a Research Policy Board. Specifically, the language in the CURES Act directed OMB to establish the Research Policy Board and envisioned a process to include federal employees, university representatives, and university affiliated non-profit organizations. In addition to the CUREs Act, 2016’s American Innovation and Competitiveness Act also called for an *Interagency Working Group on Research Regulation* “for the purpose of reducing administrative burdens on federally funded researchers while protecting the public interest through the transparency of and accountability for federally funded activities.”

Unfortunately, all the legislative momentum of 2016 resulted in little action from OMB. The Government Accountability Office followed up with a [2021 report](#) recommending Congress should extend authorization for the Research Policy Board.

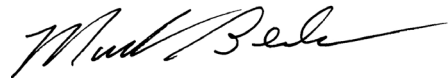
According to the Federal Demonstration Project [2018 study](#), primary investigators estimate that an average of 44.3 percent of their research time associated with federally-funded projects was spent on meeting requirements rather than conducting active research. Therefore, APLU

remains supportive of the creation of a Research Policy Board to advise the federal government on the effects of federal research regulations and reporting requirements and recommend ways to modify, streamline and—most importantly—harmonize them across agencies.

On a final note, NIH can only currently afford to fund one in five research proposals. While efficiencies can likely be found in many areas, ultimately the long-term success of NIH to save lives and support our nation's international and economic leadership requires consistent and robust annual growth in appropriations. APLU urges your continued partnership with the biomedical research community to support the funding need by NIH to invest in many more important proposed research projects.

As stated at the outset, protecting and amplifying the impact of NIH as the world's premier biomedical and behavioral research institution is a laudable goal that I know we share. We appreciate the opportunity to provide feedback and look forward to working with you, Senate HELP Committee Staff, and your Senate colleagues to ensure NIH reauthorization may move forward. Please do not hesitate to contact me or APLU's Associate Vice President for Research Advocacy & Policy [Deborah Altenburg](#), if we can be of any assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Becker", with a long, sweeping horizontal line extending to the right.

Mark Becker
President, APLU