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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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

August 16, 2024

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Committee on Energy & Commerce
Washington, D.C. 20510

RE: Framework for Discussion, dated June 2024, seeking input on reforming the NIH

Dear Chair McMorris Rodgers:

Thank you for the opportunity to provide feedback on the proposed framework, *Reforming the National Institutes of Health Framework for Discussion: Framework for Discussion,* issued June 2024.

I write on behalf of the University of California (UC) system. The UC system is comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories. UC stands at the forefront of conducting rigorous scientific investigations and delivering meaningful biomedical advancements. UC's research history includes leading the world's first clinical trial for cancer radiation treatment, developing the first flu vaccine, discovering vitamin K's role in newborn health, conducting the first open heart surgery, inventing modern gene editing, and much more. Many of these achievements were made possible with federal funding, including research dollars from the National Institutes of Health (NIH). In fiscal year 2022, UC faculty were awarded nearly $2.6 billion in total NIH research funding, making NIH the largest research sponsor for UC.

The proposed framework outlines recommendations divided in the following ways:

- **Structural Reform**: The report suggests consolidating NIH's current 27 Institutes and Centers into 15 and combining funding lines of those Institutes and Centers.
- **Policy Reform**: The section focuses on mission and leadership reform, funding transparency, and grant reform.

The UC system appreciates the work of the House Energy and Commerce Committee, especially Chair Cathy McMorris Rodgers, to ensure that the U.S. remains the world's pioneering leader in basic science and biomedical innovation. We share this vision and hope that our feedback aids in bolstering NIH's success for the future. We provide below 1) general feedback on the overall

proposed framework, 2) input on structural reform and policy reform, and 3) other recommendations to include in the framework.

1. General Feedback on the Proposed Framework

NIH is a vast and complex U.S. biomedical research enterprise, distributing nearly 83% of its funding for extramural research to more than 300,000 researchers at over 2,500 research institutions across the nation.[1] Significant changes to NIH's structure and funding can have widespread unintended consequences. UC supports improvements and enhancements to NIH that are piloted before they are implemented across the entire extramural research portfolio. On issues of significant concern and complexity, Congress should collaborate with the scientific community and NIH to develop flexible solutions that address today's challenges without inhibiting the agency's ability to respond to future problems.

NIH is most successful in its mission when it encourages broad participation from the scientific community, welcoming the best and most creative ideas from the nation's brightest minds. The central contribution of NIH – and the federal R&D infrastructure – has been fostering a free market of ideas where the scientific community has a central role in both putting forward their best approaches to scientific exploration and determining which ideas merit funding. Broad participation in that marketplace and a diversity of perspectives and methods are the best drivers of scientific advancement. Congress should ensure that any NIH reform proposals are carefully vetted to enhance this successful approach to science.

2. Feedback on Structural Reform

A. Consolidating NIH Institutes and Centers (ICs)

The University of California is concerned that this proposal to reorganize NIH has been undertaken in the appropriations process without meaningful consultation with the scientific community. Lawmakers should be applauded for their desire to ensure that the NIH runs as efficiently as possible and makes the best use of taxpayer dollars. Careful oversight and review of federal funding agencies is in the best interest of science. Structural reform could have potential benefits for the NIH, including eliminating siloes and better coordination around emerging priorities in biomedical research. However, the proposed reorganization risks significant unintended consequences, including de-prioritizing important scientific goals emphasized by NIH's current organizational structure.

Congress should not undertake an NIH reorganization without meaningful stakeholder engagement that includes an authoritative review by an outside impartial organization with standing in the scientific community. **UC suggests that Congress require a study and recommendations by an independent body of advisors, such as the National Academies of Science, Engineering and Medicine, to evaluate the rationale essentiality for a reorganization of the 27 NIH ICs. UC further recommends that Congress should not act on reorganization until they have been able**

[1] National Institutes of Health. (2024, July 30). Budget: Research for the People. https://www.nih.gov/about-nih/what-we-do/budget

to review the results of such a study. This strategy was used previously to establish sound, scientific-based recommendations for NIH reauthorization of 2006.

For example, the proposed consolidation of the National Center for Advancing Translational Sciences (NCATS), National Institute of Biomedical Imagining and Bioengineering (NIBIB), Advanced Research Projects Agency for Health (ARPA-H) and Common Fund into the National Institute on Innovation and Advanced Research is particularly concerning. The vision behind ARPA-H is a biomedical research agency capable of more nimbly catalyzing biomedical innovations to wider commercial use. The agency holds great promise for improving human health and spurring U.S. economic competitiveness in the world.

Congress never intended for ARPA-H to be a traditional NIH institute. In fact, the agency was created out of the realization that existing ICs were not intended to facilitate radical innovation and late-stage development spurred by the Department of Defense's Defense Advance Research Project Agency (DARPA) in other scientific and technological fields. In December of 2022, Congress authorized ARPA-H with a presidentially appointed director who reports to the Secretary of Health and Human Services, gave the Secretary the authority to waive certain NIH policies for ARPA-H, and took other steps in authorizing law to ensure an independent structure for ARPA-H. **Congress should**. **Congress should not place this promising program into a new administrative structure before it has had time to develop. The decision to propose merging ARPA-H into NIH and reducing its funding by nearly $1 billion has the potential to set back one of the most important innovations in U.S. competitiveness in recent years and curtail the development of world-changing biomedical advances.**

While UC focused comments on the proposed restructuring of ARPA-H, the other 8 major reorganization steps in the proposed framework also demand in-depth review and discussion by an outside, impartial, and knowledgeable body of scientific advisors, including the NIH. There should be a concerted effort to ensure that any proposal to restructure NIH does not have the unintended consequence of letting key diseases and conditions fall between the newly proposed institutes and thus be neglected for support.

3. Policy Reform

A. General Input on Administrative Burden

Universities and individual scientists devote significant time and energy to meeting regulatory and reporting requirements that come with federal grants. Regulations governing human subject protection, animal care and use, biosafety, cybersecurity, conflict of interest, research security, and grants management all serve important goals but add to the administrative burden of conducting research. According to the Federal Demonstration Partnership, faculty describe spending as much as 42% of their time on administrative tasks, many of which are related to reporting requirements.[2] **Congress should carefully monitor the regulatory burden on scientists and should curtail and remove unnecessary and duplicative regulations resulting in increased administrative burden.**

[2] Schneider, S; Ness, K.; Rockwell, S.; Shaver, K.; Brutkiewicz, R. 2012 Faculty Workload Survey. https://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf

In the 21st Century Cures Act, Congress authorized the creation of the Research Policy Board at the Office of Management and Budget (OMB) to respond to these concerns and harmonize research regulations across different funding agencies – a source of significant regulatory burden. However, successive presidential administrations failed to constitute the board or appoint board members. The Research Policy Board authorization expired in 2021. **Congress should re-establish the Research Policy Board to coordinate the harmonization of regulatory requirements from NIH and other research-funding agencies.**

B. Funding Reform: Input on Reexamining Indirect Costs Recommendation

UC appreciates Congress's long-standing, bipartisan recognition that facilities and administrative (F&A) costs represent reimbursement for the real costs of conducting research at universities and academic health centers. Recouping the full, real costs of research is essential to maintaining the operations of a research university – for everything from keeping pace with increasing federal oversight requirements to ensuring that the labs where life-changing research is conducted are state of the art. The framework's proposed caps on F&A costs would shortchange researchers by neglecting the administrative and physical infrastructure needed to conduct the best science. **Congress should avoid placing new arbitrary caps on F&A. These caps limit the already-strained ability of research institutions to recover the full cost of conducting research.**

Research institutions closely follow OMB's accounting principles for F&A cost, and F&A rates are subject to negotiation with the Department of Health and Human Services. Only the costs associated with the conduct of federally sponsored research are eligible for F&A reimbursement, and there is a rigorous process for identifying, managing, and auditing them. Members of Congress wishing to examine F&A costs should start with the goal of ensuring that rates accurately reflect the true costs of research. **As universities strive to keep pace with increased regulatory and reporting burdens, we urge Congress to take action to raise or eliminate the 26 percent cap on administration costs charged to federal awards.**

C. Grant Reform: Recommendation on Grant Recipients Must Remain Dynamic

The proposed framework suggests a "focus on providing grants and awards only to primary investigators that do not have more than three ongoing concurrent NIH engagements." This proposal fails to take into account the important mentoring role that a principal investigator can play when they win multiple grants and manage teams of younger scientists. Limiting grants to primary investigators will inadvertently harm existing pipelines to advance early career scientists.

Additionally, the proposed framework overlooks the meticulous effort NIH employs to ensure that scarce funding resources are being awarded to proposals scored as the most scientifically meritorious. NIH employs a policy that requires ICs to provide additional reviews of applications from principal investigators who receive more than $1 million in direct costs per year from NIH to determine if additional funds should be provided to already well-supported investigators. **In looking for strategies to improve the distribution of grants, Congress should avoid approaches that circumvent peer review decision-making, like capping the number of grants a principal investigator can hold. Congress should also look to existing policies and efforts to review how effective they are, before proposing additional measures that could have unintended consequences on earlier career researchers.**

D. Grant Reform: Recommendation on Research Being Credible, Reliable, and Timely

UC appreciates that the proposed framework recommends NIH consider opportunities to bolster and support early-stage investigators. NIH has made significant strides in improving funding rates for early-stage investigators through programs like the Next Generation Researchers Initiative; however, the agency needs additional support and resources to address these concerns.

Specifically, Congress should address the financial challenges that early career scientists face. The allowable maximum stipends have not kept up with inflation, meaning many postdoctoral scholars across the country face a shrinking real value of their income as they contend with rising prices of food, housing, and other necessities. While UC applauds NIH's action to increase the National Research Service Award (NRSA) postdoctoral stipend award amount by 8 percent to $61,008 in fiscal year 2024, this still falls short of the NIH Advisory Committee to the Director's (ACD) recommendation to increase stipends to $70,000. **Congress should encourage NIH to offer more robust annual increases to the stipend limits for NRSA post-doctoral fellowships. Congress should also consider adding a geographic cost of living adjustment for postdoctoral researchers on training grants.**

E. Grant Reform: Recommendation on Continued Prohibition of Gain-of-Function Research

Gain-of-function is a broad term encompassing many types of research aimed at understanding biological workings of many different organisms. Many facts and tools used in basic research are the result of gain-of-function research. UC understands certain types of gain-of-function research – for example, Gain of Function Research of Concern – raise biosafety and/or biosecurity concerns. However, these are a small subset of gain-of-function experiments that require a higher level of review and are subject to strict regulations and protocols. We recommend that rather than pausing all gain-of-function research, Congress help ensure that this research is conducted ethically, safely and securely by trained professionals at facilities that comply with strict physical containment procedures.

F. Grant Reform: Recommendation on Incorporating a National Security Review and Mandating Foreign Grant Reporting

UC takes seriously the concerns with threats of research security. Indeed, UC has taken action to safeguard research and technology that is deemed sensitive. At the same time, the federal government has taken steps to strengthen its protections of federally funded research against foreign interference and exploitation, while maintaining an environment that fosters research discoveries benefiting our nation and the world. Specifically, since 2019, the federal government has implemented a number of research security requirements, such as:

- National Security Presidential Memorandum (NSPM-33) implementation guidance requiring universities receiving more the $50 million in federal research funds annually to develop comprehensive research security plans focused on cyber security, foreign travel security, insider threat awareness and research security training, and export control training and compliance;
- Higher Education Act Section 117 requiring institutions to disclose foreign gifts and contracts above $250,000;
- NIH Requirements for Disclosure of Other Support, Foreign Components, and Conflicts of Interest; and

- NIH requirements for access to copies of foreign subrecipients' lab notebooks, data, and documentation that support the research outcomes described in progress reports.

UC respectfully ask that the proposed framework keep these efforts in mind and avoid new requirements that are duplicative, unnecessary, or counterproductive.

G. Grant Reform: Recommendation on Supporting Independent Community Review Oversight Boards

During the COVID-19 pandemic, millions of lives were saved with vaccines and treatments that could only be developed quickly because of the knowledge from years of scientific research with the pathogens most likely to impact humans. UC supports a risk-based approach to reviews of dual use research of concern, select agents, and research with pathogens with enhanced pandemic potential. These areas of research can be critical to developing lifesaving knowledge. Biosafety and biosecurity must be a priority for researchers and research institutions operating in these fields as well. Policies for review and oversight of this critical work should be targeted to research that scientists agree is high-risk to avoid adding significant regulatory burden to unrelated projects or low risk projects. Any attempt to increase oversight at the campus or national level must rely on the views of those with detailed knowledge in the complex scientific subfields implicated by the research in question as well as the biosafety professionals who have practical experience implementing appropriate levels of protection. Proposals for requiring campus-based oversight of these research projects should look to successful models like Institutional Review Boards (IRBs), Institutional Animal Care and Use Committees (IACUCs), and Institutional Biosafety Committees (IBCs), which provide oversight with the appropriate level of expertise and community engagement.

H. Grant Reform: Recommendation on Ensuring Appropriate Oversight of Animal Research

Animal research at UC is conducted with the highest regard for animal welfare, in accordance with federal and state regulations and laws. All ten UC campuses are fully accredited by Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC International), which monitors laboratory animal welfare. While we support developing alternatives to the use of animals in biomedical research, there are currently no adequate replacements for these research methods. This research is heavily regulated and has been integral to developing treatments, cures, and vaccines for a variety of conditions and diseases in both humans and animals.

4. Additional Recommendations to Consider in the Proposed Framework

A. Encourage NIH to Adjust Grant Size to Compensate for Inflation

In 1999, NIH adopted a policy that limited R01 grants to a total direct cost of $500,000 per year. Grants over that size require additional review and approval processes from the agency. This policy was introduced to ensure a more equitable distribution of NIH funds across research projects while still allowing for higher budget requests with proper justification and prior approval. However, NIH has not adjusted the policy since its initial implementation.

Today's $500,000 per year limit – adjusted for inflation using the Biomedical Research and Development Price Index (BRDPI) would only equal $229,394 in 1999 dollars. Likewise, if NIH's

1999 policy had adjusted the direct costs limit via BRDPI, it would be set at over $1 million per year today. Similarly, the limit for a modular grant – which includes a streamlined budgetary review process – remains at $250,000, or $114,697 in 1999 dollars.

The University of California is concerned that the rising costs of research and static limits on grant size is causing researchers to limit the scope of their inquiry and miss opportunities for scientific breakthroughs. Moreover, today's early career scientists will oversee smaller research programs than their predecessors, placing them at a disadvantage. This structure also subjects an increasing number of grants to a level of regulatory and reporting burden that may not be warranted by the size of the project, and further exacerbates the challenges of researchers focusing on administrative tasks rather than on the science. **Congress should require NIH to review and consider adjusting these policies for inflation to ensure they are not limiting the allocation of resources to the best science.**

B. Supporting Basic Science Research

Underlying every major biomedical advance are decades of incremental scientific discoveries. Many of the most impactful advancements of the last 20 years have long lineages that trace back to groundwork laid in basic science. For example, CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), the basis of the genome editing technology, would not exist if microbiologists were not curious enough to probe the functions of repeated DNA sequences found in bacteria. While excitement and enthusiasm often follow in later stages of scientific inquiry, technology development, and commercialization, it is important for lawmakers to continue to safeguard investments that make those later stages possible. **Congress should consider ways to place continued emphasis on basic science research as part of any NIH reorganization.**

C. Encourage NIH to Build a Diverse Pipeline of Researchers

Every American has a stake in getting the best and most productive research from the US investment in NIH. Improving the participation of underrepresented groups produces better research by increasing the breadth of ideas and promoting novel approaches to complex problems. Numerous studies indicate that diversity in the STEM workforce is beneficial for teamwork and problem-solving—two central features of the modern research environment. Not only are diverse teams associated with better problem-solving, but studies have also shown that the diversity of problem-solvers has a greater impact than individual ability.[3,4,5] Creating a diverse, equitable, and inclusive workforce and research enterprise will result in more creative teams and approaches to research that are critical to maximizing research innovation and excellence, eliminating health disparities, and achieving health equity. ***Congress should expand programs that support the hiring, retention, mentoring, and professional development of historically excluded groups.***

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[3] Hong, L. and Page, S. (2004, November 8). Groups of diverse problem solvers can outperform groups of high-ability problem solvers. https://doi.org/10.1073/pnas.0403723101

[4] Rock, H. & Grant, H. (2016, November 4). Why Diverse Teams are Smarter. https://hbr.org/2016/11/why-diverseteams-are-smarter

[5] Wiley, Z.; Hanna, J.; Kobaaidze, K.; Franks, N. (2023, March 21). Team Science: Advancing Women and Black, Indigenous, and other People of Color on the Pathway of Conducting Clinical Research. https://doi.org/10.1177/20499361231159501

Congress should continue encouraging NIH institutes and centers to fund research on health disparities.

The University sincerely appreciates the opportunity to submit a response to the request for information and promote scientifically driven decision-making that maximizes the U.S. potential for advancing research that benefits all. We look forward to continuing to work with you on this important endeavor to modernize the NIH. If you have any questions, please contact Kent Springfield at (202) 993-8810 or kent.springfield@ucdc.edu.

Sincerely,

Theresa A Maldonado

Theresa A. Maldonado, Ph.D., P.E.
Vice President for Research & Innovation