



August 16, 2024

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

Dear Chairwoman Rodgers:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the more than 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to respond to the *Reforming the National Institutes of Health Framework for Discussion*.

To respond thoughtfully to the framework, ASN solicited feedback from its diverse membership, including members who have direct experience with the National Institutes of Health (NIH). ASN's response, therefore, reflects perspectives of the society's members, leadership, and staff as well as the academic nephrology community at large.

ASN shares your goal of ensuring the NIH is structurally equipped to continue to lead the world in biomedical research. Furthermore, ASN agrees that a "cohesive alignment and effective coordination" across the NIH's activities is needed to meet this goal and to advance the care of people living with kidney diseases. In this response, ASN urges that efforts to reform the NIH should:

- Increase support and investment in kidney health research, including by addressing silos that exist between and within NIH Institute and Centers (ICs), the fundamental challenge for advancing kidney health research.
- Support emerging leaders, foster a diversity of ideas in leadership, and promote accountability.
- Base specific recommendations for reorganization on the highest-quality evidence and ample public discourse and conversation.

Background

An estimated 90 percent of people with kidney diseases are undiagnosed, even though kidney diseases are the tenth leading cause of death in the United States and kidney patients are at a significantly higher risk of cardiovascular hospitalization and death.

The more than 800,000 Americans who progress to kidney failure require either dialysis or a kidney transplant to live. Dialysis, the most common therapy for kidney failure, has a five-year

survival rate of less than 40 percent—worse than nearly all forms of cancer. Patients seeking a kidney transplant, the best therapy for most people with kidney failure, face a nearly 90,000 person-long waitlist, and the wait can be as long as 10 years in some areas of the country. As a result, 12 Americans die every day waiting for a kidney.

These statistics underscore why it is imperative for the federal government to invest in kidney disease research and innovation and ensure that its investment advances patient care. A 2017 Government Accountability Office ([GAO](#)) report found that NIDDK funds the vast majority of kidney health research across the federal government, at the time of publication accounting for 60 percent of the NIH’s \$564 million investment in kidney health research.¹ Additional sources of federal kidney research funding include, the Department of Defense (\$17 million), the Agency for Health Care Research and Quality (\$1.3 million), the Centers for Disease Control and Prevention (\$2 million), the Food and Drug Administration (\$500,000), the Veterans Health Administration (\$21 million), and the Patient Centered Outcomes Research Institute (\$14 million). ASN, as a 501(c)(3) invests more than \$3 million annually in kidney health research.

Despite this, the NIH consistently underfunds and undervalues kidney research, spending an estimated \$18.13 for each American with kidney diseases while spending \$305.57 per cancer patient. Further, from FY 2017-2023 NIH support for kidney research increased at a significantly lower rate than NIH funding increases overall.

NIH Funding ²		% Increase	NIDDK Funding ³		% Increase
FY2017	\$34,300,999,000	---	FY2017	\$2,010,245,000	---
FY2018	\$37,311,349,000	8.77%	FY2018	\$2,120,797,000	5.49%
FY2019	\$39,311,349,000	5.36%	FY2019	\$2,179,823,000	2.78%
FY2020	\$41,690,000,000	6.05%	FY2020	\$2,264,314,000	3.87%
FY2021	\$42,940,500,000	2.99%	FY2021	\$2,281,975,000	.77%
FY2022	\$45,182,990,000	5.22%	FY2022	\$2,345,376,000	2.77%
FY2023	\$47,683,485,000	5.53%	FY2023	\$2,442,171,000	4.12%

This dearth of investment in research ultimately impacts people with kidney diseases who are left with fewer innovations in their care. Innovations in biomedical research and medical care have greatly advanced since the introduction of dialysis more than 50 years ago, but the most common therapy for people with kidney failure has changed little since its development. Areas of research with high levels of federal investment, such as oncology, have seen a large number of advances: in particular, the FDA annually approves more therapies for the treatment of cancer than for kidney diseases. Federal research funding is critical to the entire process of drug development before FDA approval: basic research for understanding the disease process, drug design and validation in animals, and finally, comprehensive clinical trial programs.

¹ <https://www.gao.gov/products/gao-17-121>

² <https://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-2>

³ <https://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-1>

Year	FDA Novel Drugs Approvals to Treat Cancer ⁴	Year	FDA Novel Drug Approvals to Treat Kidney Diseases ⁵
2021	9	2021	2
2022	4	2022	1
2023	5	2023	3
2024	3	2024	1

Since the 2017 GAO report was published, the number of patients with kidney diseases and associated costs to the taxpayer have risen. There are more than 808,000 Americans living with kidney failure, and Medicare spends \$52.3 billion managing kidney failure and \$86.1 billion managing kidney diseases, not counting expenditures from Medicare Advantage which covers roughly half of Medicare-eligible enrollees. Ultimately, this spending accounts for approximately 1 percent of all federal spending. Greater investment in kidney research is required to deliver better outcomes for patients and bring greater value to the Medicare program, and thus kidney research funding should remain an urgent priority.

In 1972, Congress made a commitment to treat all Americans with kidney failure through the Medicare End-Stage Renal Disease (ESRD) Program—the only health condition for which Medicare automatically provides coverage regardless of age. This unique commitment underscores the imperative for Congress to ensure that the NIH fosters the innovation and discovery in kidney research that advances care and why ASN welcomes the opportunity to discuss how to improve the NIH ecosystem and federally funded kidney research.

In its efforts to improve kidney research and thereby the nation’s kidney health, ASN strongly urges Congress to increase funding for kidney research and innovation, remove silos obstructing kidney research, ensure a secure workforce pathway for kidney researchers, and anchor these reforms through earnest engagement of the patient and medical and scientific research communities.

Structural Reform

ASN believes that silos that exist between and within NIH Institute and Centers (ICs) are a fundamental challenge for advancing kidney health. The majority of kidney disease research is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which is further subdivided into the Kidney, Urologic, and Hematologic (KUH) division. Success rates for kidney researchers applying for NIDDK funding are high relative to other areas of the NIH, experiencing a 25.3% success rate in FY2023 when applying to NIDDK compared to the

⁴ <https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda>

⁵ <https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda>

overall NIH success rate of 23.5%.⁶ This means that kidney health researchers who apply to NIDDK are more likely to get funded compared to other institutes.

However, this high success rate could also be explained by a low number of kidney health researchers applying for NIDDK funding. The incoming workforce of kidney health researchers has declined steadily, in part responding to perceptions of fewer funds available for kidney health research.

Researchers have expressed frustration that outcome criteria used by KUH to determine application eligibility are narrow, and there is often a lack of clarity among kidney investigators of the institute most interested in their work. For example, KUH is typically interested in research with outcomes solely in the kidney. As kidney diseases impact numerous organ systems and are co-morbid with other diseases, such as diabetes and hypertension, it is often unclear which IC is most-likely to fund investigator-led kidney health research. Because of this dynamic, potential NIDDK-funded investigators are increasingly seeking funding from other ICs, including the National Institute of Aging, the National Heart, Lung, and Blood Institute, and the National Institute on Minority Health and Health Disparities.

This same dynamic is especially acute for researchers studying kidney transplantation. For example, the National Institute of Allergy and Infectious Diseases (NIAID) funds the majority of transplant research, but the Institute is primarily interested in research questions related to the immunology of transplantation. In turn, transplant research funded by NIDDK must include outcomes generalizable to the overall population of people with kidney diseases. It is often unclear which institute funds questions specific to kidney transplant, such as the long-term care of people with kidney transplants or the influence of social determinants of health on access to transplantation. More coordination of kidney transplant research across the NIH is needed.

Congress should increase the amount of funding for kidney health and transplant research and encourage the NIH to provide specific allocations for kidney disease and kidney transplant research.

National Institute on Body Systems Research

The *Reforming the National Institutes of Health Framework for Discussion* proposes addressing silos by creating a National Institute on Body Systems Research, merging NIDDK with the National Heart, Lung, and Blood Institute and the National Institute of Arthritis and Musculoskeletal and Skin Diseases. ASN appreciates the focus on removing silos by the proposed reorganization, however ASN is concerned that the proposed structure will further de-prioritize kidney health research.

In its current structure, kidney health research is siloed within NIDDK, which combines kidney health research with other areas of research that are not academically aligned, such as digestive diseases. As a result, kidney health research must compete internally for resources with other

⁶ <https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/success-rates>

important areas of research. Past efforts by NIDDK to consolidate funding opportunities, including [moving from the T32 training grant mechanism](#) solely focused on fostering future generations of kidney researchers to the KUH U2C-TL1 training mechanism which promotes kidney, urologic, and hematologic training, have throttled support for kidney health research and concentrated funding at larger institutions.

ASN is concerned that combining three large institutes into a single National Institute on Body Systems Research will further deprioritize kidney research, entrench research silos, and provide fewer opportunities for researchers. Investigators, many of whom already face confusion about which institute is best to support their research, may face additional complexity in the grant application process. Further, combining existing institutes into one with a much broader portfolio will also increase the difficulty of accurately and efficiently capturing data about specialty-specific workforce pipelines and tracking early-stage investigators.

ASN shares concerns of the American Society of Pediatric Nephrology of the proposed reorganization's impact on pediatric-specific kidney disease research, vital to the nearly 10,000 American children and adolescents experiencing kidney failure. To continue to advance our understanding of pediatric kidney disease, any new institute must have expertise in this area. In a new, much larger institute, the review process may become a barrier to research investment. There is a certain depth of subspecialty scientific knowledge that reviewers must possess to assess grant proposals that may be lost. Already, potential grantees share that their grants are not being reviewed by reviewers with pediatric expertise. Any further dilution of the expertise by grant reviewers could be catastrophic to the future advancement of the field.

ASN recommends that any structural reorganization of the NIH utilize an evidence-based approach with ample opportunities for engaging patients, researchers, and the public. Any proposed reorganization should be based on the medical and scientific content areas of each institute and seek to avoid unintended consequences of further entrenching research silos by deprioritizing certain disease states, particularly kidney health research. With this understanding, ASN supports efforts to reform the NIH but encourages an increased engagement with bipartisan and bicameral policy makers, leadership across the NIH, and patient and researcher communities who benefit from the \$48 billion agency.

National Institute for Disability Related Research

The framework proposes combining the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) with the National Institute on Deafness and Other Communications Disorders into a new National Institute for Disability Related Research. ASN is very concerned about what will happen to the research on child health and life span research supported by NICHD. When the NICHD was first authorized in 1962, it was the first NIH institute to focus on the entire life course rather than a specific disease or body system. This purpose appears consistent with your goal to support life span research.

From the framework, it is not clear how child health-focused research will fit within an institute focused on disabilities research. ASN cannot stress strongly enough the importance of investing

in general pediatric and pediatric subspecialty research to ensure that children grow up to be healthier adults. By understanding and treating chronic kidney health conditions manifesting in childhood, there is an opportunity to ensure the future adult population is healthier and defray increasing Medicare expenditures on kidney failure.

National Institute on Innovation and Advanced Research

The Advanced Research Projects Agency for Health (ARPA-H) was modeled after the Department of Defense's successful Defense Advanced Research Projects Agency (DARPA) program which aggressively pursued high-risk, high-reward technologies and capabilities. In order to accelerate life-changing health solutions, ASN believes that ARPA-H must be free of the traditional bureaucratic reins and silos that exist within the NIH.

[ASN continues to advocate for ARPA-H](#) to maintain as much independence and autonomy from the NIH as possible and is concerned that embedding ARPA-H inside of the proposed National Institute on Innovation and Advanced Research—alongside the National Center for Advancing Translational Sciences and the National Institute of Biomedical Imaging and Bioengineering—would be a major obstacle to its success.

ARPA-H's creation was one of Congress's largest commitments to funding health innovation in decades and ASN is committed to ensuring its success, particularly as it [invests in the development of bioartificial organs](#). **ASN urges Congress to break down the existing silos in medical and scientific research and innovation by encouraging increased collaboration between ARPA-H and other ICs, while still maintaining ARPA-H's independence.**

Mission and Leadership Reform Recommendations

Support Innovation – ensure the NIH is committed to and focused on promoting and bolstering innovation of new treatments and cures, including by encouraging public-private partnerships and collaboration. Resist the use of misguided tactics to pursue a specific agenda and manipulate commercial markets, thus derailing and stifling America's leadership in biomedical innovation.

The framework proposes that the NIH support innovation by encouraging public-private partnerships and collaboration. ASN believes that public-private partnerships can serve key roles in fostering innovation and applauds NIH for engaging with the kidney community through several existing initiatives.

[KidneyX](#) is a public-private partnership between ASN and the Department of Health and Human Services that seeks to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. Through a series of prize competitions, KidneyX has de-risked several early-stage technologies for investment by private markets, including an artificial kidney now being considered by ARPA-H. The [Kidney Health Initiative](#) is a public-private partnership between ASN and the Food and Drug Administration that aims to help the nephrology community collaborate to improve patient safety and develop novel therapies in a precompetitive environment. The

Kidney Health Initiative has served as a vital pre-competitive space for the private sector to engage with patients and the scientific community, developing a roadmap for the adoption of the artificial kidney.

The framework's goal of promoting and bolstering innovation of new treatments and cures is admirable and shared by ASN. In addition to innovation and development of new products, ASN affirms its support of basic research and discovery funded by NIDDK, a necessary and vital precursor for such innovation. **Robust funding for basic research, which has potential to lay the foundation of medical and scientific understanding and spur significant innovation, must remain central to the NIH mission.** Advancements of both scientific breakthroughs for nephrology and therapeutic advancements for kidney patients can only be possible by prioritizing basic research funding. Basic research funding enables kidney scientists to understand detailed mechanisms of kidney diseases, which must be done before designing potential life-changing clinical treatments.

ASN seeks clarification on whether public-private partnerships will be limited within the proposed reorganized NIH to only the Institute on Innovation or encouraged within each IC. ASN strongly supports eliminating silos across the NIH and believes that housing public-private partnerships only within the Institute on Innovation may have the unintended consequence of increasing silos.

Introduce Term Limits for IC Leadership – limit every IC Director to a five-year term, with the ability to serve two, consecutive terms, if approved by the NIH Director.

The 21st Century Cures Act established 5-year, renewable term limits for NIH Institute Directors to promote accountability and allow for the growth of new leadership. As Congress considers additional reforms to the NIH, further enforcement of these term limits, including expansion of similar systems to Institute Division Directors, should be considered. While successful leadership should be rewarded, the success of the US research enterprise relies on the diversity of thought among its leadership and the fostering of new generations of leaders. These goals can be stymied by static leadership.

ASN agrees with the need to balance leading scientific expertise with new ideas and thoughts from emerging leaders. Periodic reviews to ensure public accountability is wise but should not arbitrarily result in the removal of sound scientific and medical leaders. A balance of institutional knowledge and new ideas is important.

ASN urges Congress to support the NIH's enforcement of term limits and encourages Congress to consider adopting similar policies for NIH Division Directors to provide opportunities to grow and diversify leadership. Lastly, ASN believes that Congress should encourage a diversity of experience and background when IC Directors are identified. The current sprawling number of diseases states and research groupings within any given IC necessitates that consecutive IC Directors do not hold the same medical and scientific background.

Eliminate Silos Between ICs – require every IC to issue a biennial report outlining how the individual IC is utilizing a life stage approach throughout its activities, grant funding decisions, and research portfolio and priorities, including appropriately considering distinctions and factors related to sex and age, as well as rare diseases within each center's purview.

As discussed above, ASN strongly believes that silos between and within ICs inhibit kidney health research and must be eliminated. ASN cautions that a biennial report as described above may not achieve the goal of eliminating silos. **ASN urges Congress to consider more programmatic solutions to eliminate silos, such as encouraging project-specific funding mechanisms such as the successful [Kidney Precision Medicine Project](#).** Additionally, Congress should explore the grant review process to ensure it is not inadvertently reinforcing silos.

Address Misconduct and Expect Accountability – ensure the NIH is issuing and implementing comprehensive policies and procedures that enable full and robust oversight of investigations into allegations of misconduct, including sexual harassment, in both intramural and extramural research programs, as well as ensuring NIH whistleblower protections, trainings, and processes are sound. This should include clear processes for accountability and responsibility for actions, including designating appropriate chains of command and facilitating accessible reporting mechanisms.

ASN affirms its support of a safe environment free of harassment in both intramural and extramural research programs. **ASN is supportive of continuous efforts to achieve such an environment and applauds the language included in the Senate Fiscal Year 2025 LHHS appropriations bill and [report](#) strengthening the NIH's commitment to fostering a safe environment.**

Funding Reform Recommendations

Reexamine Indirect Costs— consider alternative mechanisms to limit indirect, or F&A, costs, such as tying the indirect cost rate to a specific percentage of the total grant award, either universally or for certain designated entities; capping indirect costs at a graduated rate dependent on a recipient's overall NIH funding; or providing incentives or preferences to recipients with established and proven lower indirect costs.

ASN appreciates and supports Congress reexamining and considering alternative mechanisms to limit indirect costs, more commonly referred to as “facilities and administrative” (F&A) costs. F&A costs supplementing research are essential to supporting research staff and maintaining equipment and research facilities.

In principle, ASN supports Congress' efforts to limit F&A costs to ensure more funding is used for research and to keep small institutions competitive. As highlighted in the framework, extensive amounts of grant funding support F&A costs, effectively an institutional tax on

individual investigator's funding. For already well-funded institutions, these costs could come at the expense of funding additional discovery.

However, certain mechanisms to limit F&A costs may have a variety of unintended consequences at a time when research is already underfunded. ASN is concerned that limiting F&A costs without additional funding to support necessary research expenses will require many researchers to stretch and exhaust their already limited financial resources while disproportionately disadvantaging smaller institutions that cannot shoulder the F&A costs like their larger counterparts. Even a graduated cap may discourage new lines of research and disincentivize innovation as investigators limit inquiries to fit existing research infrastructure.

Demand Transparency on Indirect Costs – require any entity receiving grants or awards to report publicly and make searchable their indirect F&A costs, including fixed capital costs, administrative overhead, and labor costs.

ASN strongly supports efforts to increase transparency surrounding institutions' receipt of indirect or F&A costs. ASN believes that increasing the amount of publicly available data on F&A costs is a necessary precursor for instituting new policies directed at F&A reform. Such data will help elucidate what infrastructure expenditures are necessary for conducting research, including those supported through F&A costs.

Grant Reform Recommendations

Grant Recipients Must Remain Dynamic – focus on providing grants and awards only to primary investigators that do not have more than three ongoing concurrent NIH engagements.

ASN shares the framework's goal of cultivating new generations of researchers and supporting new ideas and science. ASN is concerned that the proposed limitation of three concurrent NIH engagements for primary investigators may inadvertently harm the nation's research ecosystem, particularly if an NIH engagement is defined more broadly than the traditional R01 mechanism. For instance, if training grants are included under the definition of NIH engagement, ASN is concerned that some investigators may avoid applying for training grants in favor of other mechanisms, inadvertently shrinking the research workforce.

ASN asks for clarity on what Congress defines as an engagement with the NIH. Limiting the number of engagements with the NIH could discourage successful lines of research, hinder mentor-mentee relationships within labs exacerbating challenges facing the workforce, and stifle innovation by not funding the best science.

ASN recommends Congress and the NIH build other mechanisms to diversify the pool of grant recipients. For instance, early-stage investigator grants are currently limited to those within 10 years of completing their degree or post-graduate clinical training. Extending this cap to other grant mechanisms could diversify the pool of grant applicants.

Research Must Be Credible, Reliable, and Timely – consider opportunities to continue to bolster and support early-stage investigators; encourage systematic replication studies across research portfolios and fields; and prevent research and data waste, fraud, and misconduct.

ASN fully supports the goals described in the framework and believes they will help address existing challenges in kidney research. Replication is the foundation of scientific understanding, however there is a current dearth of replication studies due to pressures from today's scientific culture. Currently, many NIH grant applicants are commonly discouraged through peer review from using established methodologies as they are deemed not innovative in summary critiques. A commitment to replication must be acknowledged by NIH leadership, and grant reviewers must be educated and encouraged to support the replication of methodology. ASN also believes that lack of consistent and robust research funding prevents opportunities to support replication studies.

Concluding Points for Consideration

The 37,000,000 Americans living with kidney diseases—and their need for prevention and targeted treatments—deserve that the NIH remains the world's foremost medical research center, as does the federal government, which dedicates an estimated 1 percent of its annual budget to providing kidney care.

While considering reforms to the NIH, ASN urges Congress to continue to improve the nation's kidney health by increasing funding for and removing silos for kidney and transplant research, reducing barriers to research opportunities to encourage early career investigators, and anchoring NIH reform in robust engagement with the patient and research communities.

On behalf of Americans living with kidney diseases, the kidney research community, the academic nephrology community, and ASN's members, leadership, and staff, thank you for the opportunity to provide comments on the *Reforming the National Institutes of Health Framework for Discussion*. ASN stands ready to support you and your staff in any manner to ensure a strong research enterprise that fosters kidney health.

To discuss this letter further, please contact Zach Kribs, Senior Manager of Congressional and Government Affairs at zkribs@asn-online.org and 202-618-6991, or Ryan Murray, Senior Manager of Policy and Government Affairs at rmurray@asn-online.org and 202-400-2485.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President