American Society of Nephrology

July 13, 2026

Honorable Russell Vought
Office of Management and Budget
Executive Office of the President
Washington, DC

Re: Regulation for Federal Financial Assistance (RIN 0991-AC35)

Dear Director Vought:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 20,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to comment on the Office of Management and Budget's (OMB's) proposed rule, *Regulation for Federal Financial Assistance (RIN 0991-AC35)*. The comments that follow focus on provisions that most significantly affect federally supported kidney research. ASN does not address every proposed change, and the absence of comment should not be interpreted as agreement.

ASN respectfully strongly urges OMB to rescind proposed rule, *Regulation for Federal Financial Assistance (RIN 0991-AC35)*.

As written, this proposed rule would fundamentally alter the existing federal framework and negatively impact kidney research and therefore the nation's kidney health. The existing framework has played a central role in driving scientific discovery and technological innovation in the United States by providing stable, peer-reviewed support for basic research, with the result that the United States currently is the world leader in biomedical research. If OMB must continue to advance the proposed rule, then ASN requests that it is revised to:

1. Preserve scientific peer review as the primary basis for federal research funding decisions;
2. Narrow proposed grant termination authorities to provide greater certainty for ongoing research projects;
3. Maintain flexibility for publication, dissemination, conference participation, and professional engagement activities;
4. Ensure that federal research policy promotes long-term scientific innovation and workforce development; and
5. Protect the integrity, independence, and effectiveness of the nation's biomedical research enterprise.

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In biomedicine, sustained federal investment, particularly through the National Institutes of Health, has supported decades-long research pipelines that have led to breakthroughs in vaccines, medical imaging, and cancer treatments. A key strength of this model is its commitment to investigator-initiated, curiosity-driven research that does not require immediate commercial applications or short-term results. By enabling scientists to pursue fundamental questions and build incrementally on prior discoveries, the current system fosters the accumulation of knowledge across institutions and disciplines. This long-term, collaborative approach has created a robust research ecosystem in which universities, federal agencies, and research institutions generate foundational discoveries that ultimately fuel advances in medicine, industry, economic competitiveness, and national security.

ASN is deeply concerned that several provisions of the proposed rule would undermine the stability, predictability, and scientific integrity of federally funded biomedical research. The current funding system supports responsible stewardship of taxpayer dollars and appropriate oversight of federal grants, while the proposed changes would create significant uncertainty for researchers, weaken the role of scientific peer review, impede dissemination of scientific findings, and ultimately slow progress toward preventing and curing kidney diseases. Most importantly, the proposed rule would affect not only research institutions and professional societies, but also the millions of Americans living with kidney diseases who depend on continued scientific advances to improve outcomes, expand treatment options, and reduce the burden of kidney failure.

Kidney Diseases are a Growing Public Health Crisis

Kidney diseases affect approximately 37 million Americans and more than 850,000 have kidney failure, requiring either dialysis or a kidney transplant to live. Despite its high prevalence kidney diseases remain a silent epidemic in America, and 9 in 10 adults do not know they are living with kidney diseases. (1) Kidney diseases are the eighth-leading cause of death in the United States and, of the 120,000 Americans who start dialysis each year, more than 55% die within 5 years. (2, 3)

This comes with an extraordinary economic burden. The **Medicare program spends more than $141 billion annually on care for people with kidney diseases or kidney failure** (representing 36% of total Medicare fee-for-service spending). (3) When examining costs only for people living with kidney failure, **total Medicare costs have increased steadily year after year, rising from approximately $49.8 billion in 2013 and reaching an all-time high of $55.3 billion in 2023**. (3) Yet federal investment in kidney research has historically lagged behind that of many other chronic diseases despite the enormous human and economic toll of kidney disease. (4)

Recognizing this issue, the kidney community recently released the *Transforming Kidney Health Research* report, which developed a national roadmap to accelerate innovation, strengthen the kidney research workforce, improve coordination among federal agencies, and ultimately achieve a future without kidney diseases. (5) The proposed rule would move federal research policy in the opposite direction by introducing uncertainty into the research ecosystem at a time

when sustained investment and stability are urgently needed. According to the Administration, it is a tool for enforcing "administration policies and priorities," "Federal agency priorities," and "the national interest." While the Administration recognizes that some spending programs in the past may have drifted from their specific design scheme articled by Congress, the irony of this rule is that it places the Administration's goals before that of Congress and, therefore the Constitution, thus, not solving the problem the Administration is attempting to solve.

Proposed § 200.202 would require program goals to align with administration policies and priorities; proposed § 200.205 would require senior political-appointee pre-issuance review of discretionary awards for consistency with agency priorities and the national interest; and proposed § 200.340 would allow discretionary termination when an award no longer effectuates program goals, agency priorities, or the national interest. With the exception of § 200.340 that mentions "program goals," giving a nod to statutory directives, each section points to "national interest" and/or agency, ergo, administration, priorities (noting that elections come every four years and administrations can change). This is in direct contradiction to Article I, §8, Clause 2 of the Constitution with gives Congress the power to spend and appropriate federal funds. In short, the proposed rule appears to convert grant management to a general federal policy-making compliance system instead of ensuring that federal funds are used for the specific public purpose Congress authorized.

Impact on Patients Living with Kidney Diseases

The ultimate concern is not the effect on institutions or organizations but the effect of the proposed rule on patients. Every delay in kidney research delays progress toward preventing kidney diseases and kidney failure, toward expanding transplantation opportunities, toward reducing health disparities, and toward improving quality of life for millions of Americans. Patients living with kidney diseases cannot afford a less stable research environment. They cannot afford delays in clinical trials, disruptions in research programs, barriers to dissemination of scientific findings, or reductions in the workforce dedicated to advancing kidney health. The federal government's longstanding commitment to peer-reviewed biomedical research has produced remarkable advances in transplantation, dialysis, immunology, genetics, and chronic disease management. The proposed rule risks weakening the very mechanisms that made those advances possible.

Preserving Scientific Peer Review Must Remain a Cornerstone of Federal Research Funding

ASN is particularly concerned by proposed §§ 200.204 and 200.205, and related pre-award review provisions that would require additional review and approval by political leadership before discretionary awards are issued and reduce the central role of scientific peer review in funding decisions.

For decades, scientific peer review has served as the foundation of federal biomedical research funding. Expert reviews by scientists and clinicians ensure that taxpayer resources support the most promising, innovative, and scientifically rigorous research.

ASN recognizes and strongly supports the appropriate role of elected leaders and agency leadership in establishing broad national research priorities. Congress, the Administration, and federal agencies appropriately determine overarching objectives through legislation, strategic plans, budget proposals, and initiatives that reflect the nation's public health needs and policy priorities. Examples include the establishment of the National Institutes of Health's mission, congressional appropriations directives, the Advancing American Kidney Health initiative, and agency strategic plans that identify priority research areas.

Once these priorities and objectives have been established, however, the selection of individual research projects should be guided by rigorous scientific peer review. This longstanding division of responsibility—where policymakers establish strategic goals and expert reviewers evaluate the scientific merit of specific proposals—has made the United States the global leader in biomedical innovation.

The proposed rule would invert this successful model by shifting the involvement and focus of administration and national priorities from the front end of the process (the annual budget and appropriations process in which goals are identified and funded as described in the preceding section), where broad priorities are appropriately defined, to the back end, where decisions regarding individual awards have historically been based on scientific merit. ASN believes that introducing political review after peer review has been completed risks undermining confidence in the objectivity, predictability, and scientific integrity of the federal research enterprise.

While agencies appropriately consider programmatic priorities, scientific merit must remain the principal determinant of funding decisions. The proposed requirement that political appointees conduct pre-award reviews and ensure alignment with current policy priorities introduces uncertainty into a system that has long been respected worldwide for its objectivity and scientific rigor.

Investigators often spend years developing research programs focused on complex challenges such as preventing the progression of kidney diseases, reducing disparities in kidney health, improving dialysis technologies, expanding access to kidney transplantation, developing regenerative medicine approaches, and advancing precision medicine applications in kidney care.

Many of these efforts require sustained investment over multiple funding cycles before meaningful clinical advances emerge. If funding decisions become more vulnerable to changing priorities, researchers may be discouraged from pursuing innovative, long-term projects that carry scientific risks but offer substantial potential benefit to patients. The likely result would be fewer breakthroughs, a less stable research workforce, and slower progress toward improving care for patients with kidney diseases.

Science cannot be subject to ever shifting political winds. ASN recommends that OMB **revise §§ 200.204 and 200.205 to affirm that scientific peer review remains the primary basis for**

research funding decisions and that political review cannot override peer-review determinations except in narrowly defined circumstances established by statute.

Expanded Grant Termination Authorities Threaten Long-Term Research Programs

ASN is deeply concerned by proposed revisions to § 200.340 and related provisions that would substantially expand agency authority to terminate discretionary awards if the agency determines termination is in the agency's interest, including if the award does not effectuate program goals, federal agency priorities, or the national interest as they exist at the time of termination. ASN believes that it is appropriate for grants to be terminated if they fail to meet the underlying requirements that are part of the grant agreement.

Kidney health research is an inherently long-term enterprise, requiring long-term investments that extend over many years. Studies evaluating the progression of kidney diseases, transplantation outcomes, health disparities, healthcare access, precision medicine approaches, and novel therapeutics often require sustained support before meaningful results emerge.

Under the proposed framework, grants would be subject to short-term, staccato-like review, which we believe to be wholly inconsistent with the very methodical problem-solving approach the federal government has taken since President Trump signed Executive Order 13879 "Advancing American Kidney Health". The Executive Order, one of maximum importance to ASN and millions of kidney patients, recognized that kidney research had been left decades behind all other common chronic diseases when it came to research and development, and that the need for a comprehensive, long-term plan was paramount in addressing the overwhelming costs associated with kidney disease and action must be taken. Unfortunately, § 200.340 could discourage institutions from investing in new research programs, impede recruitment of trainees and early-career investigators, and reduce willingness to undertake ambitious scientific projects. The kidney community has already experienced the consequences of underinvestment in research. Additional instability could further weaken the pipeline of future kidney health investigators at a time when strengthening the physician-scientist workforce remains a national priority.

OMB should revise the proposed rule to make clear that administration policies, agency priorities, and national interest may be considered only to the extent they are expressly authorized by statute, germane to the specific federal program, clearly stated in advance, and consistent with the Constitution. OMB should further provide that no federal agency may deny, condition, suspend, or terminate federal financial assistance based on a recipient's refusal to enforce, assist in enforcing, administer, or implement federal, state, or local law in a manner not expressly required by Congress as a condition of the specific award.

ASN recommends that OMB **revise § 200.340 to ensure that compliant research awards cannot be terminated solely because agency priorities change** after an award has been made.

Restrictions on Activities Addressing Kidney Health Disparities Could Impede Patient Care

ASN is concerned by proposed §§ 200.218 and 200.300 and related provisions that could create uncertainty regarding the allowability of longstanding, evidence-based efforts to identify, understand, and address critical disparities in kidney health outcomes among populations.

ASN supports compliance with all applicable federal civil rights laws and opposes unlawful discrimination in any form. However, the proposed rule's broad and ambiguous language could have unintended consequences for kidney research and patient care by discouraging activities designed to improve outcomes for populations disproportionately affected by kidney diseases. Significant disparities exist across the care continuum. Black Americans are more than four times more likely than White Americans to develop kidney failure, while Hispanic Americans, American Indian and Alaska Native individuals, Native Hawaiians, rural communities, and people with lower incomes all experience higher burdens of kidney diseases and, specifically, kidney failure.

As written, proposed §§ 200.218 and 200.300 could create uncertainty regarding the allowability of activities such as:

- Research examining differences in kidney disease incidence, progression, treatment access, and outcomes among patient populations;
- Recruitment strategies designed to ensure broad participation in clinical trials yielding generalizable results;
- Community engagement initiatives that improve access to screening and treatment in underserved communities;
- Workforce development programs that address shortages of kidney care professionals in underserved areas; and
- Collection and analysis of demographic data necessary to identify disparities and evaluate interventions.

These activities are essential to advancing scientific knowledge and improving patient outcomes. Policies that discourage research into kidney health disparities or impede efforts to improve access to care could delay progress toward better outcomes for the tens of millions of Americans living with kidney diseases.

ASN recommends that OMB **revise §§ 200.218 and 200.300 to clarify that nothing in the rule prohibits lawful research, data collection, outreach, workforce development, or educational activities designed to identify, monitor, or address documented health disparities or improve access to evidence-based kidney care**.

Restrictions on Publication and Dissemination Will Slow Translation of Discoveries into Patient Care

ASN strongly opposes proposed revisions to §§ 200.454 and 200.461 that would significantly limit the allowability of publication fees, conference participation, professional engagement activities, and other activities essential to the dissemination of scientific knowledge.

Scientific discovery does not improve patient outcomes unless new knowledge is communicated, evaluated, and incorporated into clinical practice. Publication of research findings, participation in scientific meetings, collaboration with peers, and engagement in professional societies are not ancillary activities; they are essential components of the biomedical research enterprise and critical pathways through which federally funded research benefits patients.

The United States leads the world in biomedical innovation not only because it invests in research, but because it has built an open scientific ecosystem that rapidly disseminates new knowledge. The current framework appropriately recognizes that publication, scientific meetings, and professional engagement are integral components of the research process rather than optional activities that occur after discovery. Researchers can share findings, receive critical feedback, validate results, establish new collaborations, and accelerate the translation of promising discoveries into clinical practice.

This system has produced extraordinary advances in kidney care. Federal investments in basic science, clinical trials, and collaborative research networks, combined with robust dissemination through peer-reviewed journals and scientific meetings, have contributed to major improvements in kidney transplantation, expanded use of home dialysis therapies, development of sodium-glucose cotransporter-2 (SGLT2) inhibitors for kidney diseases, and more precise approaches to diagnosing and treating glomerular diseases. These advances occurred because investigators could openly communicate findings, replicate results across institutions, and rapidly share emerging evidence with practicing clinicians.

Restricting support for dissemination activities risks slowing the pace at which federally funded discoveries reach the patients they are intended to help. For investigators, the proposed restrictions could have several significant consequences:

- Reduced opportunities to disseminate federally funded research findings through peer-reviewed publications;
- Fewer opportunities for investigators to present findings at scientific meetings and receive critical feedback;
- Reduced collaboration among researchers working across institutions and disciplines;
- Additional barriers for early-career investigators seeking to establish independent research programs;
- Slower translation of scientific discoveries into evidence-based clinical practice; and
- Limited dissemination of new scientific and medical understandings among the affected patient population.

Policies that make dissemination more difficult ultimately slow the translation of federally funded research into improved patient care and patients ultimately bear the consequences when dissemination of scientific findings is delayed. Breakthroughs in transplantation, dialysis, acute kidney injury, and glomerular diseases become meaningful only when physicians can access, evaluate, and implement new knowledge.

ASN recommends that OMB should retain publication, conference, and professional engagement, and related activity costs as allowable expenses when they directly support dissemination and implementation of federally funded research.

Preserving Scientific Collaboration is Essential to Biomedical Innovation

ASN is concerned that the cumulative effect of proposed § 200.205, §§ 200.331–200.333, and other enhanced oversight provisions throughout could discourage the collaborative research partnerships that have long been a defining strength of the United States biomedical research enterprise.

Scientific breakthroughs rarely occur in isolation. Today's most significant advances in kidney research increasingly rely on multidisciplinary teams that bring together basic scientists, clinician-investigators, engineers, data scientists, industry partners, patient advocates, and researchers across multiple institutions. These collaborations enable investigators to combine expertise, share resources, validate findings across diverse patient populations, and translate discoveries from the laboratory into clinical practice more rapidly than any one institution could accomplish alone.

The kidney community illustrates the value of this collaborative model. Advances in precision medicine, artificial intelligence, transplantation, dialysis technologies, rare kidney diseases, and therapies for kidney diseases have been accelerated through collaborative research networks, multicenter clinical trials, public-private partnerships, and national and international scientific consortia. These efforts have strengthened the quality, reproducibility, and clinical relevance of federally funded kidney research while maximizing the return on taxpayer investment.

The proposed rule’s expanded oversight requirements, heightened scrutiny of funding decisions, and increased administrative burden could create uncertainty that discourages institutions from establishing or maintaining complex research partnerships. This is particularly concerning for multicenter clinical studies, national patient registries, shared data resources, and collaborative research infrastructures that depend on stable federal support and clear, predictable grant administration.

For patients living with kidney diseases, the consequences of reduced scientific collaboration could be substantial. Collaborative research enables investigators to study rare kidney diseases that no single institution sees in sufficient numbers, enroll diverse patient populations in clinical trials, validate discoveries across health systems, and accelerate the development of new therapies. Weakening these collaborative networks would slow scientific progress and delay the translation of research into improved patient care.

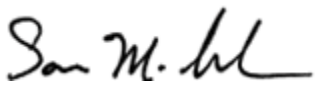
ASN recommends that OMB ensures that implementation of the **final rule preserves and encourages collaborative research by minimizing unnecessary administrative barriers to partnerships among academic institutions, health systems, professional societies, nonprofit organizations, industry partners, and other research collaborators**. Federal financial assistance policies should continue to promote, not discourage, the multidisciplinary and multi-institutional collaborations that have made the United States the global leader in biomedical innovation.

Conclusion

The United States has long been the global leader in biomedical innovation because of its commitment to rigorous peer review, scientific excellence, and stable federal investment in research. At a time when kidney diseases affect 37 million Americans and impose enormous human and economic costs, federal policy should strengthen, not weaken, the research ecosystem that drives discovery and improves patient care.

Again, thank you for the opportunity to provide comment on OMB's proposed rule titled *Regulation for Federal Financial Assistance*, and ASN stands ready to provide additional information or offer access to its expert members as OMB considers future proposed rules impacting the nation's kidney health. To discuss this letter, the proposed rule, or ASN, please contact Ryan Murray, Senior Manager of Policy and Government Affairs, at rmurray@asn-online.org.

Sincerely,



Samir M. Parikh, MD, FASN
President

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Appendix A. Summary of ASN Recommendations by Regulatory Section

The American Society of Nephrology (ASN) respectfully requests that the Office of Management and Budget revise the proposed rule as outlined below to preserve the integrity of the biomedical research enterprise, protect patients living with kidney diseases, and ensure continued progress toward improving kidney health.

Proposed Section	ASN Concern	Recommended Revision
§ 200.204	The proposed changes diminish the central role of scientific peer review in federal funding decisions and create uncertainty regarding the weight of scientific merit relative to policy considerations.	Explicitly affirm that scientific peer review shall remain the primary basis for evaluating and selecting biomedical research awards. Clarify that additional reviews may not supplant or override peer-review determinations except where required by statute.
§ 200.205	Expanded pre-award review requirements would introduce subjective considerations unrelated to scientific merit and increase uncertainty for investigators and institutions, and increased political review of awards would discourage innovative, long-term, or high-risk research and create instability within the biomedical workforce.	Limit pre-award reviews to financial, compliance, and programmatic risk assessments. Ensure that scientific merit remains the principal factor in research funding decisions. Preserve longstanding safeguards that insulate scientific funding decisions from changing political priorities while maintaining agency oversight.
§ 200.205 and §§ 200.331–200.333	Increased oversight requirements and administrative complexity would discourage collaborative, multi-institutional research partnerships that are essential to biomedical innovation and translation of discoveries into patient care.	Clarify that implementation of the final rule should facilitate, rather than impede, collaborative research among academic institutions, health systems, professional societies, nonprofit organizations, industry partners, and other research collaborators.

Proposed Section	ASN Concern	Recommended Revision
§ 200.218 and § 200.300	Ambiguous language would discourage lawful research and public health activities designed to understand and address documented kidney health disparities.	Clarify that lawful research, clinical trial recruitment, data collection, workforce development, community engagement, and educational activities aimed at identifying, monitoring, or reducing health disparities remain allowable uses of federal funds when conducted in compliance with applicable laws.
§ 200.340	Expanded agency authority to terminate awards based on evolving priorities threatens long-term biomedical research projects that require sustained support.	Limit termination authority to circumstances involving noncompliance, misuse of funds, failure to perform, or other clearly defined conditions. Protect compliant research awards from termination solely because agency priorities change after award issuance.
§ 200.454 and § 200.461	Restrictions on publication, scientific meetings, professional society participation, and collaborative engagement would impede dissemination of federally funded research, weaken scientific collaboration, slow translation of discoveries into patient care, and undermine workforce development.	Preserve the allowability of publication costs, conference participation, professional society memberships, and related scientific engagement activities when they directly support dissemination, implementation, workforce development, collaboration, or advancement of federally funded research.
§§ 200.331–200.333	Additional administrative requirements would increase compliance burdens and divert resources away from scientific and educational activities.	Streamline reporting and monitoring requirements while preserving accountability. Avoid duplicative requirements that increase administrative

Proposed Section	ASN Concern	Recommended Revision
		costs without improving oversight.
§ 200.205 and §§ 200.331–200.333	The cumulative effect of increased oversight, expanded termination authorities, and dissemination restrictions would discourage participation in federally funded research and weaken the biomedical research ecosystem.	Ensure that implementation of the Uniform Guidance continues to support scientific innovation, workforce development, collaboration, and long-term research investments that improve public health.