AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

aga American Gastroenterological Association

NASPGHAN
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

ACG American College of Gastroenterology

ASGE
American Society for Gastrointestinal Endoscopy

July 13, 2026

Mr. Russell Vought
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: Regulation for Federal Financial Assistance [OMB-2026-0034]

Submitted electronically via regulations.gov

Dear Director Vought:

The undersigned medical societies, representing gastrointestinal (GI) physician specialists and the patients they serve, appreciate the opportunity to respond to several elements of the Office of Management and Budget's (OMB) proposed rule, as published in the *Federal Register* on May 29, 2026, that would revise the Guidance for Federal Financial Assistance and associated government-wide policies and requirements related to the management of grants, cooperative agreements, and other forms of assistance.

Our members conduct medical research or rely upon knowledge from research to advance care for patients living with diseases of the digestive system, including the diagnosis of cancers of the GI tract, such as colorectal, esophageal, liver, pancreatic and stomach cancers. Preserving the integrity of the medical research enterprise is of utmost importance to our societies, our members and the public. Our members also value and support initiatives that broadly advance public health, particularly those that aim to reduce the risk factors associated with cancer and digestive diseases, as well as prevention and early detection of disease, including colorectal cancer which is now the leading cause of cancer death among those under the age of 50. **As expressed in the following comments, we strongly believe OMB's proposed changes will adversely affect the nation's biomedical research enterprise; therefore, we respectfully request that OMB withdraw its proposed rule.**

Our comments focus specifically on the following elements of the OMB proposals:

- Binding Authority of Proposals on All Departments and Agencies
- Pre-Federal Award Requirements and Contents of Federal Awards
  - Section 200.202—Program Planning and Design
    - Section 200.202(e) – Eligibility of entities for research and development awards
  - Section 200.204—Notices of Funding Opportunities
  - Section 200.205—Federal Agency Review of Merit of Proposals
    - Section 200.205(d)—Use of Peer Review
  - Section 200.220—Prohibition of Using Federal Funds for Covered Foreign Collaborations
- Post Federal Award Requirements
  - Section 200.300—Statutory and National Policy Requirements
  - Section 200.340—Termination and Suspension
- Cost Principles
  - Section 200.454—Memberships, Subscriptions, and Professional Activity Costs
  - Section 200.461—Publication and Printing Costs

BINDING AUTHORITY OF PROPOSALS ON ALL DEPARTMENTS AND AGENCIES

This proposed rule makes sweeping changes to the current process of administering federal financial awards and research grants through OMB's uniform guidance for federal assistance. The purpose of the guidance is to "establish uniform administrative requirements, cost principles, and audit requirements for federal awards." (2 CFR 200.100(a)). This guidance primarily addresses how grants are administratively managed for consistency across agencies. It does not prescribe the scientific/policy goals, or eligibility requirements, for each agency. These issues may still be under each individual agency's authority.

As stated in the proposed rule, the Deputy Director for Management of OMB is authorized under 31 U.S.C. 503 to provide ''overall direction and leadership to the executive branch on financial management matters by establishing financial management policies and requirements." (31 U.S.C. 503(a)(2)). This does not expressly authorize OMB to establish substantive eligibility criteria, scientific review standards, programmatic priorities, or award-selection requirements. Congress has delegated such authorities directly to various federal agencies. For example, the Director of the National Institutes of Health (NIH) is statutorily required to:

- "ensure that scientifically based strategic planning is implemented in support of research priorities *as determined by the agencies of the National Institutes of Health.*" (emphasis added) (42 U.S.C. 282(b)(5))

- ensure that research conducted or supported by the NIH is subject to review in accordance with *technical and scientific peer-review requirements* [set forth in 42 U.S.C. 289a]. (emphasis added) (42 U.S.C. 282(b)(9))
- "provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research" (42 U.S.C. 282(h))

These statutory requirements are just a few examples that appear to be in direct conflict with the various proposed changes and eligibility requirements outlined in the rule.

OMB has cited 31 U.S.C. 503 in the proposed rule as the legal authority to implement these changes, but under that same statute OMB *shall* also "[o]versee, periodically review, *and make recommendations* to heads of agencies on the administrative structure of agencies with respect to their financial management activities." 31 U.S.C. 503(a)(6). (emphasis added). The OMB also cites the Single Audit Act Amendments of 1996 (U.S.C. 7501– 7507) as authority to impose changes to federal grant and research programs. Yet, under this statute, OMB is statutorily required to first consult with the "Comptroller General, and appropriate officials from Federal, State, local governments and nonprofit organizations" *prior to* prescribing any guidance. (31 U.S.C. 7506) (emphasis added)

Thus, our societies urge OMB to seek a separate and independent review of OMB's own purported legislative/regulatory authority before finalizing these changes, including whether underlying statutes cited in the proposed rule provide this authority without further congressional approval.

PRE-FEDERAL AWARD REQUIREMENTS AND CONTENTS OF FEDERAL AWARDS

Program Planning and Design (§200.202)

Proposed § 200.202(a) would require that program goals and objectives "aim to achieve meaningful results" and be "aligned with administration policies and priorities." While our societies support clear, well-articulated program objectives, we are concerned that this language, read alongside the parallel changes proposed for merit review in § 200.205, could disadvantage foundational and translational research in digestive and liver disease. Basic scientific investigations often require years of incremental discovery before "meaningful results" in a programmatic or clinical sense are evident. We are concerned that an undefined "meaningful results" standard, combined with a directive to align with shifting administration priorities, could pressure agencies and applicants toward short-term or politically favored outcomes at the expense of the rigorous, long-horizon science that has historically produced the most significant advances in digestive disease care.

We also wish to comment on proposed § 200.202(c), which would clarify that federal program funds may only be used for public purposes authorized by law and provides an example

excluding the subsidization of "political activities or initiatives unrelated to authorized public purposes." Our societies do not object to the underlying principle that federal funds must be used consistent with statutory authority. However, we are concerned that the proposed example, without further definition, could be read to sweep in activities that are integral to public health research and authorized program purposes. Without clearer boundaries, this ambiguity may cause institutions and investigators to limit or eliminate legitimate community engagement and dissemination activities out of an abundance of caution, undermining the public health impact of the very programs federal funding is intended to support.

We respectfully request that OMB further define "meaningful results" in a manner that accommodates the realistic timelines of basic and translational biomedical research, and clarify that alignment with "administration policies and priorities" under § 200.202(a) does not supersede or substitute for the scientific merit standards otherwise applicable to research awards. We further recommend that OMB provide specific, narrowly tailored examples in § 200.202(c) distinguishing prohibited political activity from authorized public health education, outreach, and community engagement, so that recipients can continue these essential activities with confidence that they remain compliant with the final rule.

Eligibility of Entities for Research and Development Awards (§200.202(e))

The new proposed “domestic-first framework” requires that international elements in a federally funded research and development grant be included only if the federal agency administering the grant determines that such elements “are justified, consistent with program objectives, and in the national interest of the United States.”

The proposed rule states that nothing in the rule prohibits the participation of foreign entities as subrecipients or contractors under a research and development award made to an eligible U.S. entity. However, we are deeply concerned that “domestic-first” as the prevailing approach to federal research funding will disfavor research that benefits from international partnerships. Concerningly, OMB goes as far as to propose that international elements may include “performance,” not just funding, of activities under the federal award outside of the United States or by a foreign entity."

<u>Why International Collaboration Matters</u>

Many important diseases and conditions require international collaboration to generate meaningful scientific advances. For rare diseases and uncommon patient populations, no single institution—or often no single country—has sufficient numbers of affected individuals to conduct adequately powered studies. International consortia are frequently necessary to recruit enough participants, validate findings across populations, and develop evidence-based therapies. Even for more common diseases, important subgroups defined by genetics, age, disease phenotype, or treatment exposure may only be adequately studied through multinational efforts.

In gastroenterology and hepatology, examples include rare liver diseases, congenital gastrointestinal disorders, eosinophilic gastrointestinal diseases, pediatric inflammatory bowel disease phenotypes, and inherited cancer syndromes. One example of international networks is the VEO-IBD ("Very Early Onset Inflammatory Bowel Disease") consortium that relies on international collaboration to understand the genetic, environmental, and immunologic triggers of these rare disorders to best inform treatment recommendations.

International collaboration accelerates scientific discovery and innovation. Collaboration allows investigators to combine complementary expertise, technologies, and infrastructure that may not exist within a single institution or country. Shared resources, harmonized datasets, and coordinated studies reduce duplication of effort and improve research efficiency. Multinational research networks facilitate validation and reproducibility of findings across diverse populations, strengthening scientific rigor and accelerating translation to clinical practice. For adult and pediatric gastrointestinal research alike, international collaborations have been instrumental in advancing precision medicine, microbiome science, cancer prevention strategies, therapeutic trials, and large-scale epidemiologic studies.

International collaboration enhances the global competitiveness of U.S. science. Scientific leadership depends not only on domestic investment but also on active participation in international research networks. If U.S. investigators become less able or willing to collaborate internationally, they risk losing access to emerging scientific opportunities, novel technologies, and globally relevant data resources. Other nations continue to invest heavily in multinational research partnerships and international scientific infrastructure. Policies that create barriers to collaboration may inadvertently place U.S. researchers at a competitive disadvantage. Maintaining strong international partnerships helps ensure that the United States remains a global leader in biomedical discovery, innovation, and translation of research into improved health outcomes.

Global health challenges require global scientific solutions. Many of the most pressing scientific and health challenges—including cancer, metabolic disease, inflammatory disorders, infectious diseases, antimicrobial resistance, environmental exposures, and health disparities—are inherently global. International collaboration enables coordinated research efforts, rapid knowledge exchange, and the development of solutions that benefit patients worldwide, including those in the United States. Scientific progress is most effective when knowledge flows across borders rather than being constrained by them.

A framework that promotes transparency and accountability while maintaining opportunities for global scientific engagement will best support continued U.S. leadership in biomedical research and ensure that American patients continue to benefit from the most advanced scientific discoveries worldwide.

Further, while ostensibly promoting domestic benefit, OMB's "domestic first framework" may paradoxically concentrate funding at institutions that can most easily demonstrate domestic

impact narratives, disadvantaging smaller institutions. If awards are made on criteria other than scientific excellence, the resulting research will be of lower quality on average, diminishing the global standing of U.S. science and the return on public investment.

Notices of Funding Opportunities (§200.204)

The proposed revisions to this section create a new exception that allows a federal agency head, or their designee, to approve an exemption from the requirement to publicly post a funding opportunity on Grants.gov when "publicly announcing an opportunity would pose a risk to national security or is in the national interest of the United States." Public posting of funding opportunities has long been a cornerstone of fair, merit-based federal grant competitions, ensuring that any qualified applicant, regardless of institutional size, prior funding history, or geographic location, can identify and compete for available federal support. While our societies recognize that narrowly tailored exceptions are appropriate for classified or otherwise sensitive defense-related research, the proposed "national interest" standard is undefined and considerably broader than the established national security exception under the Federal Funding Accountability and Transparency Act, which is limited to classified information. As drafted, this provision could allow entire categories of grant competitions to proceed without any public notice whatsoever.

If agencies may withhold notice of funding opportunities from public view based on an undefined "national interest" determination, there is a real risk that competitions could be limited, intentionally or not, to institutions with existing relationships or visibility within an agency, narrowing the pool of applicants and undermining the open, competitive process that has historically strengthened the rigor and diversity of federally funded research in our field.

We respectfully urge OMB to refine the proposed exception to align with the existing, well-established national security carve-out for classified information, rather than the broader and undefined "national interest" standard set forth in the proposal. At minimum, we request that any determination to withhold a funding opportunity from public posting require written justification, be limited in duration and scope, and be subject to retrospective public reporting once the underlying basis for non-disclosure has lapsed, so that transparency and public accountability in the use of Federal research funds are preserved without compromising legitimate national security interests.

Federal Agency Review of Merit of Proposals (§200.205)

The proposed revisions would require a senior political appointee to conduct a pre-issuance review of every discretionary award and would expressly state that peer-review recommendations are advisory only and may not bind agency decision-makers. We are concerned that formally subordinating peer review to a parallel political review diminishes the central role that independent scientific evaluation has long played in directing federal research

dollars and introduces significant uncertainty as to how highly rated applications will ultimately be treated.

Scientific peer review has long served as a foundational element of the federal research system and has played a significant role in establishing the United States as a global leader in biomedical science. Independent evaluation by experts helps ensure that federal funding is allocated to proposals with the strongest scientific merit and potential. This process has supported major progress in preventing, diagnosing, and treating disease.

We are concerned that highly qualified research proposals will be overlooked for reasons unrelated to their scientific merit. Such a perception risks discouraging participation in peer review, complicating efforts to engage experienced reviewers, and discouraging researchers from pursuing innovative work. It could also undermine confidence that federal research investments are being directed toward the most impactful projects. These issues are especially important given the already competitive funding environment and the growing pressures facing the biomedical research workforce.

To preserve transparency, accountability, and confidence in the federal research enterprise, we urge OMB to ensure that scientific merit remains the primary basis for funding decisions and that any departure from peer-review recommendations be limited, clearly documented, and based on articulated programmatic considerations. Existing scientific advisory councils and expert review bodies should continue to play a meaningful role in funding decisions affecting digestive and liver disease research, and applicants should be afforded clear, timely information regarding the basis for funding determinations, any award conditions imposed, and the avenues available for administrative review.

"Gold Standard Science"

Our societies oppose the proposed requirement for grant recipients to demonstrate compliance with "Gold Standard Science" benchmarks as a condition of Federal financial assistance. As proposed in Section 200.205, agencies would be directed to "prioritize institutions demonstrating rigorous and reproducible scholarship" and "incorporate benchmarks for measuring performance of 'Gold Standard Science'" in making award decisions. We believe this requirement is substantively flawed and will undermine medical research, including in the diseases and conditions our members treat.

The proposed rule does not define "Gold Standard Science" or establish the criteria by which compliance would be assessed. Our societies assume that the proposal refers to the definition in Executive Order 14303, Restoring Gold Standard Science. It states, "Gold Standard Science means science conducted in a manner this is:

(i) reproducible;
(ii) transparent;

(iii) communicative of error and uncertainty;
(iv) collaborative and interdisciplinary;
(v) skeptical of its findings and assumptions;
(vi) structured for falsifiability of hypotheses;
(vii) subject to unbiased peer review;
(viii) accepting of negative results as positive outcomes; and
(ix) without conflicts of interest."

NIH released an implementation plan in August 2025. Even with this guidance, it is not clear how the standard will be further defined, updated, or contested. A standard that will govern eligibility for Federal financial assistance across all government agencies must be clearly defined and should be subject to notice and comment rulemaking. As drafted, the proposal grants agencies and political appointees complete discretion to determine which science qualifies and which does not. That discretion is unconstrained by statutory text, regulation, scientific consensus, or procedural safeguards. The OMB has not articulated how grantees and institutions will demonstrate compliance or how agencies will apply it consistently.

Additionally, our societies are concerned about the application of this standard to research on rare GI diseases and conditions like alpha-1antitrypsin deficiency, primary biliary cholangitis, achalasia, microvillus inclusion disease, pseudoobsruction, eosinophilic gastrointestinal diseases, intestinal failure, congenital malformations, Hirschprung's disease and others that affect children and adults. Research on rare conditions that have generated the most significant advances include longitudinal cohort studies, natural history studies, and observational analyses of claims data; these approaches are methodologically rigorous and scientifically valid but may not qualify as reproducible. Excluding these methodologies from Federal funding eligibility would not improve the quality of medical research. It would halt progress on many conditions lacking cures and no viable Federal research pathway.

Use of Peer Review (§200.205(d))

Our societies believe the proposal in section 200.205(d) is extremely damaging to medical research, and, therefore, should be withdrawn. As proposed, this section provides that peer-review recommendations "remain advisory and are not ministerially ratified, routinely deferred to, or otherwise treated as de facto binding by senior appointees or their designees." Along with section 200.205(b), this provision subordinates scientific peer review to political review during the final stages of the award process, after merit review has been completed, without establishing a standard to which the political review must adhere, any procedural protection for applicants whose awards are denied on non-merit grounds, or any transparency that would allow the scientific community to understand why funded and unfunded applications were treated differently.

In addition, adding another layer of review on top of existing review processes increases administrative burden and slows down the grantmaking process. Grantees of Department of Health and Human Services (HHS) agencies have already been experiencing significant delays in

the disbursement of funds because of the existing policy requiring approval by a political appointee within the Department. As an example, NIH grants used to only be subject to two rounds of review – a merit-based peer review process, followed by approval of grants by the Advisory Council – and now there are an additional two layers of political review at the NIH Office of the Director and HHS. In some cases, HHS requests substantive changes to the grant, which then must be returned to the agency to send back to the grant applicant who makes those changes for the grant to undergo another round of review by the agency and HHS prior to final approval. This has significantly delayed grant review determinations and added administrative requirements.

This change in procedure has moved political influence from the beginning of the grant cycle when determining what grant applications are solicited, to the final stages of the review process. This is an unnecessary change to existing practice. Agencies have always had formal legal authority not to fund certain grant applications that score well in peer review but traditionally peer-review scores and panel ranking have been the primary determinant of award decisions. The proposed rule explicitly states that peer-review recommendations must "remain advisory" and not be "ministerially ratified or routinely deferred to" by senior appointees, language that goes beyond preserving agency discretion and affirmatively instructs political appointees to treat peer-review conclusions as inputs to be weighed, not outcomes to be implemented. Our societies believe that this change will undermine science, particularly because in most instances political appointees do not have the expertise necessary to properly evaluate scientific merit.

The result is a system in which no investigator can reliably predict whether their application will be funded based on the scientific quality of their work. That unpredictability is not a theoretical harm. It will suppress applications from early-career investigators who cannot afford repeated cycles of unfunded high-scoring applications and from institutions that lack the political relationships or reputational visibility to navigate a system in which merit is necessary but not sufficient. The deterrent effect of section 200.205(d) will fall hardest on precisely the investigators and institutions whose continued engagement is most essential to maintaining that pipeline.

Prohibition of Using Federal Funds for Covered Foreign Collaborations (§200.220)

OMB proposes a new government-wide rule prohibiting recipients and subrecipients from using federal funds to support bilateral or multilateral collaborations, agreements, programs, or activities with covered foreign countries or covered foreign entities, unless expressly authorized.

OMB states this provision is intended to ensure that federal financial assistance is not used, “directly or indirectly,” to support activities that may pose a risk to U.S. national security, defense, or intelligence interests.

Concerningly, the prohibition would apply regardless of whether federal funds are used for direct programmatic activities, research, technical assistance, travel, or indirect costs allocable to such collaborations.

While legitimate national security concerns exist with certain foreign entities, this provision is sweeping enough to severely disrupt international partnerships that have been foundational to U.S. leadership in fields, including medical research.

The United States has long been the global leader in biomedical research not because it operates in isolation, but because it serves as the world's leading hub for scientific collaboration. American investigators lead many of the international research networks, clinical trials, and scientific consortia that drive discovery and innovation. These partnerships allow U.S. researchers to access specialized expertise, diverse patient populations, unique datasets, and emerging technologies that may not be available domestically.

Numerous clinical advances in the gastrointestinal health of U.S. children are the product of global collaborations, including the discovery of oral rehydration solutions for the treatment of diarrhea, the development of an effective rotavirus vaccine, the use of multiple micronutrient supplements for vulnerable populations, and the implementation of targeted anti-viral regimens for HIV/AIDS.[1]

Policies that discourage or impede international scientific collaboration risk placing American researchers at a competitive disadvantage. While the United States withdraws from global research networks, other nations will continue to build collaborative partnerships, share resources, and accelerate discovery. The result would not be a strengthening of American science, but a gradual erosion of U.S. leadership in biomedical research and innovation.

Scientific progress increasingly occurs through multinational teams working across institutions and borders. Restricting engagement with international collaborators may delay discoveries, reduce the competitiveness of U.S. investigators in securing scientific advances, and limit America's ability to shape the future direction of global research. Maintaining appropriate research security safeguards is important, but these safeguards should be balanced with policies that preserve the international collaborations that have been fundamental to America's scientific success.

The question is not whether international collaboration benefits other countries; it does. The question is whether the United States will continue to lead those collaborations or cede that leadership to others. American patients, researchers, institutions, and industries benefit when the United States remains at the center of the global scientific enterprise.

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[1] Duggan CP. Adverse Effects on Child Health from United States Retrenchment on Global Scientific Collaboration: Examples from Gastroenterology, Hepatology, and Nutrition. J Pediatr. 2025 Nov;286:114744. doi: 10.1016/j.jpeds.2025.114744. Epub 2025 Jul 18. PMID: 40685116.

If the United States is not actively participating in and leading international scientific collaborations, the rest of the world will continue to advance without us—and American science, innovation, and competitiveness will ultimately fall behind.

POST FEDERAL AWARD REQUIREMENTS

Statutory and National Policy Requirements (§200.300)
OMB proposes that all federal award funds are prohibited from being used to "fund, promote, encourage, subsidize, or facilitate" diversity, equity and inclusion (DEI), DEI Accessibility, or "gender ideology" policies or practices.

The proposed restrictions could have unintended consequences for medical and health disparities research, as well as public health programs, aimed at reducing disparities in health outcomes. Many federally funded initiatives are specifically designed to identify and address higher rates of disease, lower screening utilization, and poorer outcomes among underserved populations, including racial and ethnic minority communities. For example, programs that seek to increase colorectal cancer screening rates or reduce the disproportionately higher mortality associated with colorectal cancer in certain populations could face uncertainty if efforts to identify and address disparities are interpreted as prohibited DEI activities. The absence of a clear definition of DEI may create ambiguity for researchers, institutions, and funding agencies, potentially discouraging important population health research and intervention programs.

Further, we are concerned that university or research institutions that conduct DEI or gender research or engage in DEI or gender equality activities, even with entirely separate, non-federal funds, could still face grant termination if any such activities are found to conflict with federal award conditions. We seek clarification from the OMB in these regards.

Diversity is integrated into the research process to ensure a balanced and heterogenous population of subjects. Under this proposal, rather than try to anticipate what research projects might violate OMB's proposed restrictions in the use of federal award funds to "fund, promote, encourage, subsidize or facilitate" DEI policies, research programs may find it easier to stop efforts to recruit diverse populations. Since most research programs are based in urban settings, even in states with smaller urban footprints, this would mean loss of generalizability of findings to populations living in more rural, agrarian and suburban areas. Such populations are an important segment of the American population and their systematic disenfranchisement from groundbreaking research runs counter to our obligation to use funds to benefit everyone.

Lastly, these proposals may also adversely affect medical education and workforce development initiatives that prepare physicians to care for increasingly diverse patient populations. Training programs that focus on cultural competence, health disparities, social determinants of health, and improving access to care are important components of developing a health care workforce capable of meeting the needs of all communities and advancing equitable health outcomes.

Termination and Suspension (§200.340)

Our societies object to the sweeping discretion that political appointees would be given to terminate federal awards if it is decided that termination is in the interest of the federal agency or pass-through entity, including if a federal award "does not effectuate program goals, federal agency priorities, or the national interest as they exist at the time of the termination" to the extent permitted by law. The Uniform Guidance already provides federal agencies a mechanism to terminate discretionary grants in appropriate cases "if an award no longer effectuates the program goals or agency priorities." That guidance is appropriate in scope and should be reaffirmed.

Unlike federal procurement contracts, which are primarily intended to acquire specific goods or services for the direct benefit of the government, federal research grants are assistance mechanisms designed to support the generation of new knowledge, innovation, and public benefit.

The proposal, if implemented, would direct federal agencies to include termination provisions in each Federal award or to expressly incorporate these provisions by reference. As such, OMB contends that applicants and recipients who enter into awards will do so with full knowledge of the risks and conditions associated with accepting the Federal award. It would be precisely because of these new risks that medical, other scientific and public health researchers will be disincentivized from pursuing Federal grants to support their work.

For decades, the United States has led the world in academic innovation and thought leadership due to the current stability of the research infrastructure. The clear unintended consequence of OMB's termination policy proposal is a clear abdication of that position. Furthermore, the proposal would compromise the integrity of the science, shrouding it under a veil of political alignment rather than driven by the best data-driven hypothesis generating science.

Researchers spend years developing preliminary data, fostering collaborations, training and developing personnel to support their research enterprise and can not spend time, effort and money to apply for grants that may be changed or taken away based on changes in political landscape allowed with this new rule. Changes in funding allowed with this new rule would jeopardize support for their time (which is planned with the entire academic or calendar year in mind), their ability to support their employees and trainees (including graduate students and post-doctoral fellows who invest years into projects and if funding is lost would delay completion of their degree or program) and staff who are hired for projects with the guarantee of being supported for the duration of the funded project (e.g., 5 years). Subjecting grants to possible termination whenever an election causes a change in governmental policy could result in terminations of a substantial portion of a research portfolio before fruition. Paradoxically, within one five-year grant term, a research idea might be deemed in scope for agency priorities, out of scope, and then back in scope again.

The proposal would also have a significant impact on universities and research institutions that typically commit matching funds, hire personnel, and build infrastructure around awarded grants. Sudden termination creates stranded costs and institutional debt, discouraging institutions from investing in research capacity.

Moreover, grant-funded projects frequently support subawards to collaborating institutions and contracts with vendors, research organizations, and community partners. Unexpected termination of a grant could disrupt these downstream agreements, create financial liabilities, jeopardize employment and research infrastructure, and undermine the ability of recipient institutions and their partners to successfully complete scientific work that advances public health and medical knowledge.

If finalized, it is more likely that researchers will pursue other forms of funding, thus jeopardizing the strong role NIH, Department of War and other federal funding agencies have historically played in shaping research priorities in the United States. For example, the Cancer Moonshot progress will be slowed and research progress and the associated biomedical developments with real, tangible, positive impacts on the health of Americans will be compromised.

This proposal poses a particular threat to early career scientists whose entire career trajectories rely on stable, multi-year funding. Securing tenure, keeping a lab open, and retaining highly specialized staff require predictable commitments. Forcing these researchers to take on the risk of sudden, mid-cycle termination will inevitably drive the next generation of scientists away from Federal public health research and into the private sector. Consequently, the United States risks losing its global leadership and standing in science and research.

OMB's proposals also do not seem to consider their impact on human research subjects, including those enrolled in clinical trials. The proposed rule could risk, for example, the possibility that a patient with refractory illness, responding to an investigational therapy, could lose accessibility to this therapy with abrupt cessation of funding or risk exposure to an adverse effect of an intervention without fully evaluating risk and benefit.

Many research studies rely on human subjects providing informed consent. That consent is predicated upon knowing a study will be completed and scientifically valid conclusions will be established. Every study subject is exposed to some risk, sometimes minor (like a data breach), and sometimes major (like risk of physical harm). To enroll human subjects with the potential that their risk may be for naught if a study is simply shut down because of a change in political climate, runs counter to federal regulations and agency-specific policies aimed at ensuring American citizens are protected from amoral research practices. The proposed changes in regulation impact animal research in much the same way.

For patients enrolled in federally funded clinical trials, even temporary suspensions can result in invalidation of years of investigation and lead to harms to enrollees and to development of

critical future treatments. Under the OMB's proposal, there is no mechanism to request review of these suspensions or discontinuations to objectively assess potential harms to patients. Before a study can be suspended or terminated, input from an entity, such as study Data Safety Monitoring Boards that are mandated for all clinical trials, should be required.

COST PRINCIPLES

Memberships, Subscriptions, and Professional Activity Costs (§200.454)

OMB proposes that the only allowable costs under Section 200.454 are those necessary to fulfill award requirements. The proposed rule specifically states that subscriptions to professional, academic, and technical journals are made categorically unallowable.

We call to the OMB's attention that NIH Director Jay Bhattacharya, MD, PhD, has said the NIH aims to "restore confidence in scientific knowledge through a culture change and elevate replication and reproducibility as an essential component of gold standard science."[2]

We oppose the proposal to disallow costs associated with subscriptions to professional, academic, and technical journals, as well as participation in professional scientific societies.

Access to scientific literature is foundational to rigorous science. Researchers cannot design innovative studies, identify knowledge gaps, avoid unnecessary duplication, or appropriately evaluate whether a proposed project is confirmatory or novel without access to the current scientific literature. If reproducibility and replication are to remain key measures of scientific merit, investigators must have the ability to review and assess prior work comprehensively. Restricting access to journals directly undermines the ability of researchers and peer reviewers to determine whether proposed studies build appropriately upon existing evidence.

Professional societies are essential components of scientific quality and accountability. Scientific societies develop clinical practice guidelines, establish research standards, create data-sharing networks, conduct educational programs, and facilitate scientific peer review. Membership in these organizations allows investigators to remain current with advances in their fields and participate in the scientific communities that establish best practices for rigorous research. These activities support many of the core principles that OMB identifies as hallmarks of high-quality science.

The proposed restrictions would disproportionately harm early-career investigators and smaller institutions. Large research-intensive institutions may have extensive library systems and institutional resources to absorb these costs. Smaller institutions, community hospitals, rural health systems, and emerging research programs often rely on grant support to maintain access to

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[2] NIH Strategic Vision and Plan for Strengthening Replication and Reproducibility: Advancing the Rigor of Gold Standard Science. NIH Director's Update to Council of Councils; January 29, 2026. Jay Bhattacharya, M.D., Ph.D., Director, National Institutes of Health. https://dpcpsi.nih.gov/sites/g/files/mnhszr346/files/2026-01/1215PM-NIH-Update-Bhattacharya.pdf

scientific literature and professional activities. The proposal could therefore exacerbate existing disparities in research capacity and opportunities.

We fear this proposal, if finalized, could weaken U.S. scientific competitiveness. The United States remains a global leader in biomedical research because investigators are deeply engaged with international scientific communities and have immediate access to the latest discoveries. Limiting access to journals, scientific societies, and professional engagement risks isolating researchers from emerging knowledge and reducing the competitiveness of the U.S. research enterprise.

Publication and Printing Costs (§200.461)

Our societies strongly object to the proposal that all journal publication costs, including article processing charges, open access fees, and similar fees, are unallowable under federal awards by default, requiring either a specific statutory mandate or case-by-case agency pre-approval.

We are particularly troubled by the statement in the proposed rule that publication costs "…are not inherently necessary to carry out the core programmatic objectives of most Federal awards," and that publication is "discretionary" and "may serve institutional, professional, or reputational interests rather than the specific objectives of the Federal program."

OMB's proposal directly conflicts with longstanding federal open access mandates, including the 2022 Office of Science and Technology Policy (OSTP) memorandum that requires all U.S. federal agencies to make taxpayer-funded research publications and their underlying scientific data freely and immediately available to the public.

Our objections to this proposal rest on four fundamental concerns:

1. **The proposal creates a direct conflict with federal open-access requirements.** Federal agencies increasingly require publicly funded research results to be made freely available to the public. However, compliance with open-access mandates often requires payment of article processing charges. Prohibiting the use of grant funds for these costs creates an untenable situation in which researchers are expected to comply with federal dissemination requirements while being denied the resources necessary to do so.

2. **The proposal will create inequities across institutions and investigators.** Researchers at well-resourced institutions may be able to draw upon institutional funds, philanthropy, endowments, or departmental support to cover publication expenses. Investigators at smaller institutions, community hospitals, safety-net systems, and minority-serving institutions often lack such alternatives. As a result, the ability to publish scientific findings could become dependent on institutional wealth rather than scientific merit. This outcome runs counter to the principles of merit-based science.

3. **The proposal will impede scientific dissemination and transparency.** Research findings generate public benefit only when they are disseminated, scrutinized, and incorporated into future scientific inquiry. Publication is not merely a final administrative step in a project—it is the mechanism by which scientific findings are evaluated, reproduced, challenged, and translated into improved patient care. Restricting publication support would slow dissemination, delay incorporation of new knowledge into clinical practice, and hinder scientific progress.

4. **The proposal will reduce the return on federal research investments.** Federal agencies invest billions of dollars annually to generate new scientific knowledge. Preventing researchers from disseminating the resulting discoveries diminishes the value of that investment. Unpublished or inaccessible findings cannot be replicated, incorporated into future studies, translated into clinical practice, or used to improve public health outcomes. The public receives the greatest benefit from federally funded research when discoveries are broadly shared and made accessible to researchers, clinicians, policymakers, and patients. If taxpayers fund the science but researchers cannot publish, disseminate, or access the resulting knowledge, the nation is paying for discoveries that cannot fully benefit patients or future research.

Publishing open access allows authors to share their research freely, without cost to readers. In order to maintain revenue, publishers often charge "Article Processing Charges" (APCs) if an author wishes to publish open access. Other journals only publish open access, thus levying this charge for all published articles. Our societies publish scientific journals, and our publishing revenue is routinely reinvested into education, workforce development, standards setting, and other programs. Society publishers also strengthen the marketplace of ideas by sustaining independent, mission-driven outlets for scientific exchange. While publication costs are a very small percentage of overall research investment, OMB's proposal will have an outsized impact on scientific journals, non-profit scientific societies, and the overall research enterprise.

CONCLUSION

While we support OMB's commitment to promoting accountability and the responsible stewardship of federal funds, the proposed changes risk irreparable harm to the U.S. biomedical research enterprise and efforts to advance public health. **OMB should withdraw the proposal and instead work collaboratively with federal agencies, research institutions, and other stakeholders to preserve the Uniform Guidance's core principles of efficiency, consistency, and risk-based oversight while pursuing targeted, evidence-based reforms that strengthen accountability without impeding federally supported research.** At a minimum, the OMB should postpone finalizing and enacting this rule. This delay will give stakeholders more time to review the details and allow the agency to fully process all public feedback.

Should you have any questions or require additional information, please contact the following organizational representatives:

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