July 13, 2026

The Honorable Russell Vought
Director
Office of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503

Subject: Proposed Rule, Regulation for Federal Financial Assistance (OMB-2026-0034)

Dear Director Vought:

The Association for Clinical Oncology (the Association), and its affiliate, the American Society of Clinical Oncology (the Society), collectively ASCO, appreciate the opportunity to provide comments in response to the Regulation for Federal Financial Assistance proposed Uniform Guidance.[1] ASCO is the world's leading professional organization representing more than 50,000 oncology professionals who care for patients with cancer. Through research, education, and promotion of the highest-quality patient care, our members are committed to ensuring access to evidence-based care for cancer prevention, diagnosis, and treatment for all Americans. ASCO supports robust, quality initiatives that enhance clinical practice guidelines, performance measurement and improvement, big data analytics, and the value of cancer care. ASCO is concerned that the collective policies in the proposed rule, if finalized as currently written, will have a detrimental impact on the ability for researchers to continue engaging in critical, life-saving

[1] Regulation for Federal Financial Assistance Proposed Rule. 91 Fed. Reg. 32198. (May 29, 2026). Available at: https://www.govinfo.gov/content/pkg/FR-2026-05-29/pdf/2026-10817.pdf.

scientific research that supports the prevention and treatment of cancer.

In addition to urging the Administration to delay the implementation of this rule, we offer the following recommendations, outlined with more detail in this letter, and address the most devastating operational changes: implementing a political pre-issuance review process, allowing federal agencies to terminate grants at any time for any reason, and prohibiting specific operational and research dissemination costs.

The Association recommends –

1. **Ensuring that peer review is valued by striking the proposed language in section 200.205, stating that political appointees shall not "routinely defer to the recommendations of others, but must instead use their independent judgment" and that panel recommendations are "not ministerially ratified, routinely deferred to, or otherwise treated as de facto binding", and retain the requirement that scientific and technical merit scores determined by scientific and technical merit review panels dictate the primary eligibility and ranking for discretionary research funding.**
2. **Retaining the historical standard that termination must be tied strictly to recipient non-compliance, material failure to meet project goals, or a statutory mandate from Congress by striking the proposed language in sections 200.218, 200.300, and 200.340 allowing termination based on shifting "agency priorities" or "national interest" and disparate impact.**
3. **Preserving and advancing the shared goals of protecting scientific integrity, research dissemination, public access, and the sustainability of the scholarly publishing infrastructure that underpins the nation's research enterprise by striking the proposed language in sections 200.202, 200.205, 200.220, 200.432, 200.454, and 200.461**

<u>Timeline and Implementation of Rule</u>

We respectfully urge the Office of Management and Budget (OMB) to defer implementation of this rule until, at least, January 1, 2027, given the unprecedented volume of public feedback. As a transformational overhaul, these regulations will fundamentally reshape the administration of all federal grants. A deliberate extension for implementation is vital to

allow OMB the necessary time to thoroughly evaluate stakeholder insights and meaningfully refine the proposed policies. Furthermore, this transition period is essential for federal agencies to update their frameworks and train personnel, and for grant recipients to align their operational infrastructure. A measured approach to implementation is the only way to safeguard the scientific enterprise against severe, unintended disruptions.

Additionally, we urge the administration to reconsider classifying the Uniform Guidance as a binding regulation. This restructuring strips individual agencies of their ability to adapt or buffer these sweeping changes for their unique scientific communities, directly contradicting the administration's stated goal of reducing recipient burden.

OMB Objectives for the 2026 Proposed Revisions – Value of Scientific Research and Peer-Review

In the proposed rule, OMB outlines numerous changes that impact federal grants and other financial assistance, with the stated goals of improving transparency, accountability, and oversight for the use of federal taxpayer dollars, clarifying the status of OMB's policies, and reducing recipient burden. However, two of the most significant operational changes are: 1) allowing federal agencies to terminate grants at any time if they decide an award no longer aligns with agency priorities, program goals, or national interest, and 2) implementing a pre-issuance review process during which political appointees determine whether grants are approved. Together, these changes risk significantly undermining the nation's competitive, science-driven medical research enterprise, disrupting the delivery of objective, reproducible data necessary to spur American clinical innovation and secure global leadership in health care. Researchers nationwide are conducting groundbreaking work to uncover the root causes of cancer and other chronic diseases, aiming to improve treatments and ultimately find a cure. To reduce the global burden of disease, it is vital that the scientific community receives sustained funding and uninterrupted support.

While intended to ensure the responsible use of federal taxpayer resources, these proposals could have unintended consequences—stifling innovation, halting groundbreaking research, and jeopardizing our progress and global leadership. Every stage of the grant lifecycle—from initial application to execution, through to final closeout and federal reporting—demands a significant investment of time and resources. To safeguard

scientific progress, grantees require regulatory certainty, consistent goals, and predictable milestones. The assurance that meeting these benchmarks will preserve promised funding is what guarantees sustainable access to federal resources.

The proposed policies, however, introduce profound instability by expanding the grounds for termination—often for reasons entirely beyond the grantee's control. This unpredictability threatens to act as a severe deterrent to innovative research across the scientific community and will have:

- **A Chilling Effects on Innovation:** Current researchers will be far less likely to risk initiating long-term, high-impact projects that span multiple administrations, ultimately wasting the potential of multi-year funding vehicles.

- **A Drain on Future Talent:** This instability will discourage the next generation of researchers from entering academic medicine, driving talented scientists away from critical fields to seek opportunities with international competitors or abandon research entirely.

Ultimately, disrupting the predictability of federal funding risks unraveling decades of progress and puts the future of cancer treatment in jeopardy.[2] Furthermore, patients will be the ultimate victims of unexpected project cancellations and funding interruptions. Clinical trials—especially for novel oncology drugs—frequently span several years. It is ethically and scientifically essential that participants receive uninterrupted treatment through the full duration of these trials, a reality that these volatile policies directly threaten.

Clinical trial participants willingly assume personal health risks to advance scientific medical progress, and sponsors and investigators bear a profound ethical obligation to ensure participant safety, and continuity of care. If clinical trials are abruptly canceled without a proper transition period, patients could suddenly lose access to necessary, life-saving treatments.

[2] Jalali MS, Hasgul Z. Potential trade-offs of proposed cuts to the US National Institutes of Health. *JAMA Health Forum*. 2025;6(7):e252228. doi:10.1001/jamahealthforum.2025.2228

Delays in award approvals— or inconsistent flow of funds once awards are approved—will make it challenging for researchers to create sustainable research programs or meet established milestones. Consistency in approval processes and the scheduled release of funds once grants are approved are critical to the success of any research project— both will be jeopardized by these proposals.

Rigorous peer-review and scientific journal independence anchor decades of merit-based, federally funded research that has yielded clinical breakthroughs and transformed cancer care. This progress has relied heavily on continuity. Starting and stopping clinical or laboratory studies doesn't just pause progress— it actively destroys it, potentially delaying lifesaving breakthroughs for years. For instance, if an oncology study is abruptly halted, researchers may have to begin the arduous process of collecting specialized tumor samples all over again, impacting the health of patients, alongside massive operational burdens of rehiring highly trained staff and securing laboratory space funded by indirect research funds. Even if a future administration determines the research once again aligns with federal priorities, years of momentum, resources, and risk to patients who volunteered for clinical trials, will have been squandered.

To protect this vital ecosystem, we offer the below comments on specific sections of the proposed revisions of the Uniform Guidance to reduce administrative and patient burden while ensuring true transparency, accountability, and oversight.

[200.205] Federal Agency Review of Merit of Proposals

The proposal requires senior appointees to conduct a pre-issuance review of every discretionary award, directs that awards “demonstrably advance the President’s policy priorities,” and specifies that appointees “must not ministerially ratify or routinely defer to” peer reviewers, whose role is reduced to advisory.

While the role of peer reviewers, including, for example, NIH Study Sections, is currently advisory, we believe the proposed language in the rule of “routinely referred to” or “treated as de facto” sets a dangerous precedent that risks losing the knowledge and experience of subject matter experts who can protect the prudent use of federal grant funds. A study section brings together 20 to 30 experts in highly specialized fields. Their collective brainstorming and debating ensure that grant-funded science is acceptably rigorous,

feasible, and innovative for the field in which the study is conducted. Allowing a political appointee—without guarantee of specialized scientific or medical expertise—to make "independent judgments" in place of trained and experienced subject matter experts, undermines the integrity of our nation's merit-based grant system.

The existing peer-review Study Section system has long ensured that only the most rigorous, high-impact science receives taxpayer funding. We are concerned that political appointees will be unable to appropriately assess complex research designs while ensuring independent technical judgment. Even if an individual appointee has expertise in one scientific discipline, it is virtually impossible for a single person to represent the vast breadth of scientific knowledge required across any federal agency.

In addition, linking grant approvals to the shifting priorities of changing administrations introduces systemic instability and uncertainty. Rather than fostering steady, long-term scientific discovery, research agendas will fluctuate wildly every four to eight years or less, leaving critical medical progress vulnerable to political volatility and administrative turnover.

The Association recommends ensuring that peer review is valued by striking the proposed language in section 200.205, stating that political appointees shall not "routinely defer to the recommendations of others, but must instead use their independent judgment" and that panel recommendations are "not ministerially ratified, routinely deferred to, or otherwise treated as de facto binding", and retain the requirement that scientific and technical merit scores determined by scientific and technical merit review panels (qualified by relevant training and experience) dictate the primary eligibility and ranking for discretionary research funding. This protects the integrity of merit-based science, ensuring that taxpayer dollars fund the most rigorous and promising research rather than politically determined projects.

[200.340], [200.218], and [200.300] Termination and Suspension

The proposal expands grant termination authority based only on "agency priorities," and a brief written rationale. It does not require any findings of non-compliance by the awardee and compares this process to the termination-for-convenience clause in federal procurement. A grant is not a purchase of a deliverable; it is a multi-year commitment

around which a laboratory hires and trains staff, enrolls and incurs ongoing ethical obligations to human research participants, and structures years of work that cannot simply be paused and resumed. Procurement and financial assistance are legally and operationally distinct. A procurement contract buys a specific product for the government's direct use, while a federal grant supports a public purpose. Applying a corporate "termination-for-convenience" model to scientific research threatens human participants and wastes taxpayer investments mid-stream. Discretionary, mid-stream termination converts every federal award into a contingent liability and will push investigators and institutions away from ambitious, long-duration projects toward only low-risk, low-reward, short ones. With the average cancer clinical trial requiring three to five years to complete—and standard NIH R01 research grants spanning four to five years—such arbitrary cancellations risk erasing up to five years of data and human trial progress overnight.

The proposed rule also prohibits all federal funding related to diversity, equity, and inclusion. This proposed revision will restrict comprehensive patient-data research and compromise our nation's ability to improve survival rates for all Americans. A patient's physical location, insurance coverage, and local access to clinical trials are critical, practical variables that dictate whether they survive a cancer diagnosis. Removing these metrics from federally funded research weakens the clinical trial pipeline, making it harder to deliver targeted, efficient, and life-saving treatments to the patients who need them most.

The Association recommends striking the proposed language in sections 200.218, 200.300, and 200.340 allowing termination based on shifting "agency priorities" or "national interest" and disparate impact. We also recommend retaining the historical standard that termination must be tied strictly to recipient non-compliance, material failure to meet project goals, or a statutory mandate from Congress. This recommendation restores the necessary baseline stability for multi-year scientific research, ensuring that a change in political administration or agency leadership does not result in the arbitrary elimination of ongoing research.

[200.202], [200.205], [200.220], [200.432], [200.454], and [200.461]

Gold Standard Science and Cost Provisions

Research conducted but not shared with the collective research community and practicing physicians is research that stays in the dark. It has been the longstanding philosophy of U.S. federal agencies that the results of federally funded research be published in peer-reviewed journals. Journals play a critical role by facilitating peer review of results, holding authors to community standards, curating the most impactful research, and widely disseminating research through sophisticated and robust online platforms and infrastructure networks. The proposed revisions would make publication costs, article processing charges (APCs), and open access fees presumptively unallowable, in direct conflict with existing federal public access policy by funding the research but not the important next step of validating and disseminating. The proposal states that a general requirement to make results public "must not be construed as authorizing publication costs," stranding the public's investment at the point of delivery.

Disallowing subscriptions from federal grants and institutional facilities and administrative (F&A) costs will disrupt public scientific conversations that take place in peer reviewed journals and diminish the impact of the federally funded science. Federal agencies have long understood the need for researchers to access each other's work and have encouraged institutions to use negotiated F&A rates to subscribe to content—often a significantly cheaper option than purchasing access article-by-article.

In addition to facilitating expert peer review to improve submitted manuscripts, journal staff and physician editors routinely conduct intensive integrity reviews. This process includes verifying trial registrations, IRB approvals, CONSORT compliance, authorship criteria, financial disclosures, data availability, and the absence of plagiarism or figure manipulation. Maintaining these rigorous integrity tools requires dedicated staff, specialized platforms, and extensive ongoing training.

On May 23, 2025, President Trump issued an Executive Order on Restoring Gold Standard Science. Several important provisions in that Executive Order are in conflict with the proposed OMB rule. By restricting publication fees and, therefore, publication opportunities, these Gold Standard Science requirements are at risk:

- **Politicization vs. Scientific Merit:** While the Executive Order mandates science that relies on unbiased peer review, the OMB proposal explicitly states that peer

review remains merely advisory and places approval of funding in the hands of political appointees.

- **Bans on International Collaboration:** The Executive Order requires science to be collaborative and interdisciplinary. In direct contrast, the OMB rule seeks to expand the "Wolf Amendment" across all federal agencies. This threatens essential international research exchanges and co-authorships.
- **Transparency of Conflicts:** The Executive Order demands transparency regarding financial and professional conflicts of interest. The scientific community operates under rigorous, transparency standards. Financial and professional conflicts of interest are strictly regulated and publicly disclosed through the peer-review, journal publication, and conference presentation processes run by professional societies—rendering additional government-mandated reporting systems redundant and administratively burdensome.
- **Clarity on Study Limitations:** The Executive Order mandates precise and accurate limitations and constraints in scientific findings. Expert journal editors review manuscripts to ensure that abstracts, titles, and conclusions are not overstated, and limitations of the study are included in the publication.

In short, journals and conferences largely operationalize key components of President Trump's Executive Order on Gold Standard Science. Scientific journals serve as a critical step in "quality control" that standardizes the tenets of the Executive Order into verifiable, and public-facing reality. The OMB proposed rule will task the agencies with single-handedly enforcing Gold Standard Science requirements.

Sustaining public access to taxpayer-funded research requires a stable funding model for publishing infrastructure, which ensures rigorous peer review and strict quality control. The proposed revisions risk disrupting this ecosystem by restricting where federally funded authors can publish and under what licenses. Ultimately, these limitations will curtail public access to the very science citizens have funded.

Furthermore, forcing researchers to find funds elsewhere to cover publication costs will reduce total research output. This financial strain will heavily disincentivize the publication of negative results and secondary endpoint analyses. When negative findings go unpublished, the scientific community loses critical data, leading to a duplication of effort.

Future researchers risk wasting public resources by inadvertently repeating studies that have already yielded a "no."

Supporting authors in publishing high-quality, fully vetted manuscripts is essential to maintaining a robust scientific pipeline. Ensuring a sustainable publishing model directly protects the federal investment in science, equips clinicians with evidence-based data for patient care, and drives better public health outcomes.

Professional societies like ASCO provide the vital, independent framework required to vet and validate federally and privately funded research. Through objective expert reviews, conflict-of-interest policies, and rigorous research integrity processes, these societies preserve the accuracy of scientific literature. Medical journals publish discoveries continuously, and scientific conferences compress this knowledge into high-focus, rapid-dissemination events. Conferences are where results are presented, critiqued before publication, turned into collaborations, and operationalized. Presenting critical clinical trial data at independent meetings often establishes a new global standard of care within days, directly saving lives and improving patient outcomes.

The proposed revisions would allow conference attendance only if pre-approved and written into the award at issuance. A researcher cannot anticipate at award time which meeting in year three will matter. Imposing a discretionary, per-conference approval gate adds an unnecessary administrative hurdle that stifles peer-to-peer engagement, slows down global collaboration, and delays the translation of laboratory discoveries to the patient's bedside.

The Association recommends revising and striking the proposed language in sections 200.202, 200.205, 200.220, 200.432, 200.454, and 200.461 to preserve and advance the shared goals of protecting scientific integrity, research dissemination, public access, and the sustainability of the scholarly publishing infrastructure that underpins the nation's research enterprise.

Conclusion

Federally funded research best demonstrates its value and returns on investment when the entire scientific lifecycle—from initial grant approval to clinical trial execution and final publication—is evidence-based, predictable, and apolitical. The proposed revisions

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introduce systemic instability that threatens this lifecycle at every stage. Allowing political appointees to override specialized peer-review panels and permitting mid-stream grant terminations for shifting "agency priorities" fundamentally undermines the research enterprise.

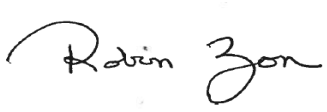
These volatile policies do not merely create administrative burdens; they create profound ethical and physical risks for vulnerable patients who rely on the continuity of multi-year cancer clinical trials. Furthermore, restricting vital research into geographic and regional barriers to care while dismantling the financial mechanisms supporting independent peer-reviewed journals and scientific conferences – will isolate American medical breakthroughs, stifle our global leadership in biotechnology, and delay life-saving treatments for families across the nation.

Far from being ancillary components, stable multi-year funding, objective merit-based review, independent scientific conferences, and widely accessible peer-reviewed literature are the essential pillars required to translate federal investments into enhanced public health and improved patient survival.

Thank you again for the opportunity to comment on these impactful proposed changes and for your serious consideration of our recommendations. We welcome the opportunity to collaborate with you to protect the integrity of the nation's scientific enterprise and ensure that evidence-based care continues to advance public health.

Please contact Shimere Williams Sherwood, PhD at Shimere.Sherwood@asco.org with any questions or for further discussions.

Sincerely,



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