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Helping hematologists conquer blood diseases worldwide

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July 7, 2026

Russell Vought
Director
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Executive Office of the President
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Submitted electronically via regulations.gov

Re: Regulation for Federal Financial Assistance (OMB-2026-0034)

Dear Director Vought,

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide these comments on the Office of Management and Budget's (OMB) proposed regulation for Federal Financial Assistance (OMB-2026-0034). We are gravely concerned that this proposal, which would convert the Uniform Guidance for federal financial assistance to a regulation, will weaken the nation's medical research enterprise and public health. Therefore, we request that this proposal be rescinded.

ASH represents more than 18,000 clinicians and scientists committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematology (non-malignant) conditions like sickle cell disease (SCD). In addition, hematologists are pioneers in advancing medical research and continue to be innovators in the areas of stem cell biology, transfusion medicine, and gene and cell therapies. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

While ASH supports OMB's goals to improve transparency and accountability and reduce burden, we believe that this proposal will have the opposite effect. The United States' medical research and public health systems have supported the development of cures that have transformed the practice of hematology and other fields of medicine. Research supported by the National Institutes of Health (NIH) has resulted in new therapies for hematologic diseases and disorders, including stem cell therapy to cure SCD and chimeric antigen receptor (CAR) T-cell therapy for blood cancers. These discoveries would not be possible without federal investment awarded through the peer review system. However, this proposed rule would sideline merit-based scientific decision-making by expanding political discretion over research funding and renewals, which will ultimately affect the advances available to patients. Additionally, the new requirements will reduce research productivity by creating new administrative burdens without improving accountability despite OMB's claims to the contrary. The uncertainty and the administrative burdens the policies in this rule will inject into the research and public health enterprise will weaken the medical research and public health workforce; it will discourage long-term investments diminishing the United States' scientific

leadership that will reduce the return on federal funding. Ultimately, patients will bear the consequences through delayed discoveries, fewer clinical trials, and slower development of lifesaving therapies. While ASH's comments here are limited to the impact on medical research and public health, we believe given the broad scope of this proposal there will be more widespread impact.

We wish to comment specifically on the following sections of the proposed rule:

- Binding Authority of Proposals on All Departments and Agencies
- Federal Agency Review of Merit of Proposals [Section 200.205]
- Termination and Suspension [Section 200.340] and Opportunities to Object, Hearings, and Appeals [Section 200.342]
- Elimination of Fixed Amount Awards [Section 200.201]
- Conferences [Section 200.432] and Publication and Printing Costs [Section 200.461]
- Prohibition of Using Federal Funds for Covered Foreign Collaborations [Section 200.220]

Binding Authority of Proposals on All Departments and Agencies

If implemented, this proposed rule converts the Uniform Guidance from a guidance document to a regulation, binding all agencies that award federal grants. It would establish uniform administrative requirements, cost principles, and audit requirements for all federal awards. This represents a significant shift in governance of federal financial assistance. The Uniform Guidance has provided a flexible framework that federal agencies have implemented in a manner specific to their individual statutory missions, portfolios, and grant programs. By codifying these provisions as binding regulation, OMB is centralizing authority and reducing agencies' ability to exercise their own scientific and programmatic judgement. This revised approach replaces a framework that has successfully balanced accountability with flexibility for one that is more prescriptive.

If the OMB proposal is implemented, Agencies will no longer have the authority to update their own policies. Medical research evolves rapidly and often requires the NIH to adapt its administrative requirements to respond to emerging scientific opportunities, public health needs, and advances in research practices; however, NIH will lose that discretion under this proposed framework. This rigid structure is poorly suited to the diverse nature of federally funded research and risks creating unintended barriers to innovation, collaboration, and efficient grants management.

Federal Agency Review of Merit of Proposals [Section 200.205]

OMB proposes to require federal awards to "demonstrably advance the President's policy priorities" and make scientific merit review advisory. This is a fundamental departure from the process that has governed federal research for decades and has made the United States the world leader in medical research. ASH strongly opposes this change because it risks not only the United States' leadership position but also the health of Americans who depend on the cures developed with this federal investment.

NIH statute (42 U.S.C. § 289a, 282(b)(16) and 284(c)(3)) addresses peer review to ensure that federal research funding is prioritized based on scientific merit and that funded projects are scientifically rigorous and consistent with public health needs. Current guidance states that NIH grants shall be reviewed by relevant study sections and then reviewed by institute and center councils before being signed off by an institute and center director. This mechanism provides consistent evaluation of research grants and ensures they are grounded in evidence and expertise consistent with long-term research goals. NIH guidance has already established that medical research must achieve meaningful results to advance human health.

Under current policy, the Administration has the authority from the onset to set priorities for research that are consistent with their goals (e.g., through notices of funding opportunities, and requests for applications). The proposed change in procedure would move political influence from the beginning of the grant cycle when determining what grant applications are solicited to the back end, 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 provide guidance. ASH believes this change would undermine the US scientific enterprise, particularly because in most instances political appointees do not have the expertise necessary to properly evaluate scientific merit in the highly complex, rapidly changing scientific arena. This proposal also creates extra layers of review delaying the time between grant submission and potential approval. Therefore, we urge continuation of the process by which decision-making authority over awards remains guided by peer-review panels with subject matter expertise and accountability.

This section also would require grant recipients to comply 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. ASH believes this requirement is substantively flawed and will undermine medical research, including hematologic diseases and conditions.

The proposed rule does not define “Gold Standard Science” or establish the criteria by which compliance would be assessed. The Administration has released Executive Order (EO) 14303 titled “Restoring Gold Standard Science” and NIH’s Implementation plan for "Gold Standard Science" that outlines the Administration’s thinking on this topic. However, there is still no clear mechanism for implementing it in practice or understanding its operational implications for researchers. The research community also has not had an opportunity to provide feedback, including on how the underlying goals may sound in principle but difficult to operationalize.

EO 14303 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.”

ASH agrees with the Administration that federal research should be conducted in a manner consistent with these concepts. However, there are research projects where applying these concepts does not make sense. For instance, there are instances where privacy rules would conflict with the tenet of transparency. For small populations, it may be difficult to reproduce all results because of how a research project may be structured. The proposed rule does not contemplate these circumstances. As such, ASH does not believe it is possible to apply one standard across all federal grantmaking agencies based on the information currently available to researchers and the public.

A standard that will govern eligibility for federal financial assistance across all federal agencies must be clearly defined. 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. Any standard of this nature must be subject to notice and comment rulemaking to ensure it is properly defined and operationally feasible.

Additionally, ASH is concerned about the application of this standard to research on hematologic diseases and conditions like SCD, hemophilia, and blood cancers. Different research questions require different methodologies. A narrow interpretation of “gold standard science” could unintentionally exclude valuable and necessary research, particularly on rare diseases. As a field matures, what is considered “gold standard science” will evolve; this proposal provides no room for that evolution.

Termination and Suspension [Section 200.340] and Opportunities to Object, Hearings, and Appeals [Section 200.342]

Federal agencies, including NIH, already have authority to terminate awards for noncompliance, mutual agreement, recipient withdrawal, or instances where an award no longer advances program goals or agency priorities. The proposed rule expands this authority to permit termination when funded projects no longer advance "current program goals, agency priorities, or the national interest." Additionally, the proposal eliminates existing requirements to provide administrative hearing or appeal rights for discretionary terminations. ASH strongly opposes these proposed changes.

As discussed, federal research grants are awarded after the completion of rigorous scientific and technical peer review. In many instances, research, including in hematopoietic cell-transplantation, requires years of sustained investment before meaningful discoveries are made, or new cures are available to patients. Allowing grants to be terminated based on evolving priorities and the undefined "national interest" rather than scientific merit or programmatic performance fundamentally changes the nature of the federal research enterprise. Many of the most transformative advances in hematology, including immunotherapies, gene therapies, and stem cell transplantation, were built upon decades of sustained research whose ultimate impact could not have been predicted when the work began.

ASH members consistently expressed concern that this provision would create a pervasive climate of uncertainty that extends well beyond the grants ultimately terminated. Investigators would be discouraged from pursuing innovative, high-risk, or long-term research if funding could be withdrawn after years of successful scientific progress solely because administrative priorities have changed. Rather than encouraging bold scientific inquiry, the proposal would encourage researchers to pursue only projects perceived to align with current administration priorities, restricting the influx of new scientific knowledge, narrowing the scope of scientific discovery, and limiting future breakthroughs.

The proposed authority would also have significant consequences for the medical research enterprise and workforce. Federal research grant awards support graduate students, postdoctoral fellows, physician-scientists, laboratory technicians, research nurses, data analysts, and clinical research coordinators whose employment depends upon stable funding. Abrupt grant termination would disrupt ongoing experiments, reduce recruitment into research, and discourage early-stage investigators from pursuing research careers. ASH also anticipates that, if implemented, research institutions will reduce their investment in the research infrastructure necessary to conduct transformative research because the uncertainty will affect their ability to set budgets and perform long-term planning.

The risks are particularly acute for clinical research involving patients with hematologic disorders. Clinical trials frequently require years to enroll participants, administer investigational therapies, and collect long-term safety and efficacy data. Premature termination of these studies could interrupt patient care, impact patient safety, compromise participant follow-up, invalidate years of data collection, and undermine public trust in clinical research. Participants enroll in federally funded studies with the expectation that investigators will complete the research responsibly and generate knowledge that benefits future patients.

Finally, ASH is deeply concerned that the proposal would eliminate existing administrative hearing and appeal rights for discretionary terminations. Existing mechanisms for oversight already permit agencies to terminate awards under certain circumstances. Expanding termination authority without establishing objective criteria, procedural safeguards, or an opportunity for independent review creates substantial uncertainty for institutions and investigators while increasing the risk of inconsistent decision-making.

Elimination of Fixed Amount Awards [Section 200.201]

ASH strongly opposes the proposed elimination of fixed amount awards and subawards. This change would significantly increase the administrative burden while reducing flexibility, predictability, and efficiency. Our members consistently identified fixed amount awards as one of the most effective mechanisms for reducing administrative burden. These awards allow investigators and federal agencies to focus on scientific performance rather than transaction-level financial management.

Their elimination would necessitate substantially greater budget preparation, financial tracking, documentation, and post-award reconciliation. Rather than improving stewardship of taxpayer dollars, these requirements would divert valuable time and resources away from scientific research while increasing administrative costs for recipients and federal agencies.

The proposal would be particularly harmful to NIH training grants, fellowships, and other standardized funding mechanisms. Training awards rely on predictable funding levels to support trainee stipends, tuition, institutional allowances, and educational activities over multiple years. Investigators and institutions use these fixed awards to recruit trainees, develop research programs, and ensure continuity of training. Eliminating fixed amount awards would introduce uncertainty into these programs, increase administrative complexity, and ultimately reduce the number of opportunities available to train the next generation of hematologists and other physician-scientists. At a time when the medical workforce already faces significant shortages, policies that discourage investment in research training are unwise and counterproductive.

Similarly, fixed amount awards are widely used to support data coordinating centers, multicenter clinical trials, and collaborative research networks. These mechanisms provide predictable funding that enables participating institutions to establish infrastructure, initiate studies, and coordinate activities efficiently across multiple sites. Requiring cost-reimbursable subawards would substantially increase administrative requirements for both coordinating centers and participating institutions, creating unnecessary barriers to scientific collaboration. Smaller institutions and community-based research sites, which often have limited grants management infrastructure, would be disproportionately affected.

When asked about the impact of the proposed rule, ASH members emphasized that medical research requires flexibility to respond to changing scientific opportunities and economic conditions. Investigators cannot accurately predict every experimental outcome, staffing need, or supply cost over the course of a multi-year award. Inflation, supply chain disruptions, and changing research priorities frequently require investigators to reallocate resources while remaining within an overall funding limit. Fixed amount awards appropriately balance fiscal accountability with the flexibility needed to achieve the scientific objectives for which federal funding was awarded.

Existing oversight, audit, and financial reporting requirements already provide substantial accountability for federal research investments. The proposed changes would simply shift emphasis away from scientific outcomes toward increasingly burdensome financial administration. Accordingly, ASH urges OMB to retain fixed amount awards and subawards as an available funding mechanism. Rather than eliminating these awards, OMB should preserve agencies' discretion to use the funding approach most appropriate for the activity being supported.

Conferences [Section 200.432] and Publication and Printing Costs [Section 200.461]

OMB proposes to expand the current scope of unallowable costs under federal grants to include conference registration fees unless pre-approved as well as publication and printing costs. ASH strongly opposes these restrictions and is concerned that these changes would increase grant recipient burden and introduce unnecessary barriers in disseminating results from federally funded research.

Scientific dissemination is not an optional activity that occurs after research is complete; it is an essential component of the research process through which federally funded discoveries are evaluated, replicated, and translated into improved patient care. Restricting investigators' ability to present their work at scientific meetings or publish their findings will diminish the scientific and public health return on the federal government's investment in medical research.

Scientific conferences, like the ASH Annual Meeting, which convenes approximately 30,000 clinicians and researchers, provide opportunities to present findings, obtain peer feedback, and establish collaborations for advancing research objectives. The proposed requirement that conference attendance receive specific agency approval and be identified in advance is both impractical and unnecessarily burdensome. Conference schedules, abstract acceptances, invited presentations, and emerging scientific opportunities cannot be anticipated years in advance of when grants are awarded.

Requiring repeated agency approval would delay dissemination, increase administrative costs for investigators and agencies, and reduce participation in scientific meetings without improving accountability.

The proposal would be particularly harmful to trainees and early-career investigators who often rely exclusively on grant support to present research and establish scientific collaborations. Many institutions lack discretionary funds to replace federal support for conference attendance, disproportionately affecting the next generation of biomedical researchers.

ASH is equally concerned by the proposal to make publication costs unallowable. Publication is the primary mechanism through which federally funded discoveries enter the scientific record, inform clinical practice, and become accessible to other investigators, clinicians, and patients. The proposed rule creates a conflict by expecting researchers to disseminate their research findings while restricting their ability to use grant funds for the reasonable costs necessary to accomplish that objective. Article processing charges, page charges, and other publication expenses represent a small fraction of overall research costs but are essential to ensuring that research findings are broadly disseminated and publicly accessible.

ASH publishes the Blood Journals portfolio, the premier scholarly resource for basic, translational, and clinical research regarding blood disorders. Society publishers, like ASH, play a critical role in safeguarding the scientific process and patient safety. They oversee rigorous peer review, ensuring that research is properly vetted so that only valid, trustworthy science enters the record. Through expert editorial oversight, they evaluate manuscripts to confirm that methods, analyses, and conclusions are sound and accurate. Additionally, they provide editorial services like copyediting and assistance with graphs and illustrations. Society publishers also provide the infrastructure to disseminate this vetted knowledge to the global community, while protecting authors' rights and managing copyright. These functions -- validation, quality control, distribution, and protection of intellectual property—are essential services, and each carries real costs that must be supported to maintain the integrity and reliability of the scientific enterprise.

ASH urges OMB to retain conference attendance and reasonable publication costs as allowable research expenses when they directly support the objectives of a federally funded award. Scientific dissemination is fundamental to the research enterprise, and preserving investigators' ability to communicate federally funded discoveries is essential to advancing biomedical science and improving outcomes for patients with hematologic diseases.

Prohibition of Using Federal Funds for Covered Foreign Collaborations [Section 200.220]

ASH supports appropriate safeguards to protect national security, intellectual property, and federally funded research. However, we are concerned that the proposed restrictions on collaborations involving designated foreign countries are overly broad and could unnecessarily impede legitimate medical research that poses little or no national security risk. Diseases do not know international boundaries and insights in other areas of the world directly benefit patients in the United States.

Modern medical research is inherently collaborative and increasingly international. Scientific advances frequently depend on access to specialized expertise, unique technologies, biological specimens, and large datasets and patient populations, all of which are distributed across the global research community. These collaborations are particularly important in hematology where rare diseases often require multinational research networks to generate meaningful and statistically significant scientific evidence. The proposed restrictions risk limiting scientific exchange and progress. One ASH member highlighted how his work on HIV-associated malignancies, hematologic cancers, and immunologic disorders would be negatively impacted if restrictions were placed on collaboration with China and certain countries in Africa.

ASH members also expressed concern that broad restrictions would diminish the United States' scientific leadership. Countries such as China have become major contributors to medical research, producing important discoveries, technologies, and clinical evidence that benefit patients worldwide. Preventing United States investigators from engaging in appropriate scientific collaborations risks isolating them from significant advances while encouraging international partnerships that exclude the United States.

Rather than strengthening American competitiveness, broad prohibitions will reduce innovation and slow the pace of medical discovery.

At the same time, ASH recognizes that collaborations involving sensitive technologies or controlled information that present legitimate national security concerns warrant enhanced scrutiny. Existing disclosure requirements, conflict-of-interest policies, and agency oversight provide important mechanisms to identify and manage these risks. OMB should build upon these targeted safeguards rather than adopt categorical restrictions that apply regardless of the nature of the research or the actual level of risk. Therefore, ASH urges OMB to revise the proposed provisions to preserve legitimate international scientific collaboration while maintaining robust protections for national security.

For the reasons outlined, ASH urges OMB to rescind this proposal immediately to protect the medical research enterprise and public health. Should you have any questions or require further information, please contact ASH's Chief Policy Officer Suzanne Leous at 202-776-0544 or *sleous@hematology.org*.

Sincerely,

Robert Negrin, MD

President