July 13, 2026

The Honorable Russell Vought, J.D.
Director
Office of Management and Budget
725 17th St., NW
Washington, DC 20503

**RE: OMB Proposed Rule Revising Federal Grant Administration and Uniform Guidance (Docket No. OMB-2026-0034)**

Dear Director Vought:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group established 20 years ago and comprising more than 150 institutions from across the health care spectrum to promote the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system, appreciates the opportunity to comment on the Office of Management and Budget's (OMB's) proposed rule Revising Federal Grant Administration and Uniform Guidance.[i] PMC supports accountability, transparency, and responsible stewardship of federal funds, however, we are concerned that the proposed rule in its current form would substantially alter federal grant administration requirements and undermine the ability of academic institutions or other grant recipients to advance research, innovation, education that benefits patients. The proposed changes included in the rule will likely increase administrative burden, constrain scientific collaboration, create institutional uncertainty, and reduce the overall effectiveness of federal investments in health research that underpins personalized medicine. Therefore, we urge OMB to withdraw the proposed rule and engage stakeholders more fully in substantial revisions before proceeding with final implementation.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and error toward a more streamlined process for making clinical decisions, which leads to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing

evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

**Statement of Neutrality**

Many of PMC's members will present their own responses to OMB's proposed rule Revising Federal Grant Administration and Uniform Guidance and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule.

**Importance of Predictability for Innovation in Personalized Medicine**

Federal grants are a critical component of the nation's innovation ecosystem. Decades of federally funded research on the genetic and biological underpinnings of disease have contributed to the development of personalized treatments benefiting patients today. To date, more than 300 personalized treatments and over 140,000 diagnostic products have been made available to patients.[ii] These numbers continue to grow, with personalized medicines accounting for more than a quarter of all new drugs approved by the U.S. Food and Drug Administration (FDA) since 2015.[iii] In 2025 alone, the FDA approved 16 personalized medicines representing approximately 36 percent of all newly approved therapeutic molecular entities last year. These new approvals and expanded uses of already approved drugs, biologics, and diagnostics are helping transform care for subsets of patients with cancer as well as rare, common, and infectious diseases.

Since 2015 personalized treatments have driven declines in mortality for some cancers and are now improving treatment of a growing number of diseases outside of oncology. Addressing common, chronic, and rare disease burdens requires sustained investment and institutional capacity. Changes that increase uncertainty for research institutions, like those in the proposed rule, reduce flexibility, weaken capacity, and may significantly harm the research enterprise that has been the foundation of medical breakthroughs. Predictability also supports participation across the innovation ecosystem, including universities, research institutions, startups, and established companies whose complementary capabilities are necessary to translate research into patient benefit. We are concerned that diminished research productivity and slower response to future health needs could ultimately lead to poorer patient outcomes.

**Reducing U.S. Leadership in Health Research and Discovery [Proposed 2 CFR §§ 200.205]**

A stable, predictable, and globally competitive research environment is essential to attracting scientific talent, investment, and partnerships, advancing discovery and commercialization, and maintaining U.S. leadership in emerging technologies, advanced manufacturing, and economic growth. The federal grants and contracts system has enabled the U.S. to lead the world in scientific discovery and biomedical innovation. The success of this system has rested upon a careful balance between accountability and flexibility. Federal grants were designed to support discovery, innovation, and collaboration, while federal contracts were designed to procure specific deliverables. Scientific discovery is creative, iterative, and often requires continued investment over many years before breakthroughs occur. Policies included in the proposed rule that make grants function more like procurement contracts increase uncertainty regarding long-term research support and risk undermining the environment that has fostered U.S. leadership.

PMC is also concerned that several provisions of the proposed rule could shift greater authority over funding decisions away from processes based on scientific merit toward political appointees and agency leadership. The U.S. research enterprise is built on the foundation of merit-based review that evaluates proposals according to

scientific excellence, innovation, feasibility, and public benefit. PMC is concerned that greater executive review of research awards could introduce uncertainty for innovative, high-risk research areas such as genomics, artificial intelligence, gene editing, and emerging therapeutic technologies. We understand the Administration's desire to improve stewardship of federal funding and that it does not believe the current peer review systems provide sufficient oversight. Because merit-based review has been central to the nation's leadership in scientific discovery, PMC proposes that the Administration engage the scientific community in developing alternative proposals that evolve, reform and strengthen the structures for independent expert evaluation already in place.

**Increasing Administrative Burden and Institutional Costs [Proposed 2 CFR §§ 200.113, 200.205, 200.300, 200.329, and 200.332]**

OMB states in the proposed rule that it seeks to improve efficiency and reduce burden. While PMC shares these goals, we believe the proposal is likely to have the opposite effect. The proposed elimination or restriction of mechanisms that currently streamline federal grant administration will require institutions to devote additional time, personnel, and financial resources to compliance activities.

Institutions already face significant administrative demands associated with federal grants and contracts. Additional documentation, monitoring, reporting, approval, and oversight requirements would divert resources away from research. Institutions rely on federal support not only to conduct individual projects, but also to maintain the systems, labs, personnel, compliance functions, data management capabilities, and collaborative infrastructure. Several changes to allowable costs in the proposed rule could shift a greater share of research infrastructure expenses like these onto institutions.

Unfortunately, the proposed rule contains limited analysis regarding implementation costs and administrative impacts on grant recipients. Given the breadth of the proposed revisions, stakeholders should have a clearer understanding of anticipated costs, operational impacts, and unintended consequences. Before finalizing the rule, OMB should provide additional analysis that can inform evidence-based policymaking.

**Introducing Institutional Risk and Reducing Stability [Proposed 2 CFR §§ 200.340 and 200.332]**

Several provisions would increase uncertainty for grant recipients by expanding termination authorities and creating new compliance obligations without corresponding procedural safeguards. Currently, federal grants may be terminated only under limited, defined circumstances: when a recipient fails to comply with the terms of the award, when both parties mutually agree to end it, or when the program loses its legal basis. These protections exist to give researchers, institutions, and communities the certainty they need to make long-term commitments based on awarded grants.

Under the proposed rule, any active federal grant could be terminated because a political appointee determines it no longer serves "the national interest as they exist at the time of the termination." No finding of noncompliance, fraud, or misconduct is required. Successful research and workforce development programs require long-term planning, recruitment of faculty and staff, investment in infrastructure, and sustained partnerships with communities and government agencies. Greater uncertainty regarding award continuation and grant administration could discourage institutional investment and undermine the stability necessary for successful program implementation. The proposed changes could make it more difficult for institutions to engage in long-range planning, retain highly qualified personnel, and maintain the infrastructure necessary to support federally funded activities.

**Limiting Scientific Exchange [Proposed 2 CFR §§ 200.432, 200.454, and 200.461]**

Scientific conference participation, journal subscriptions, and publication costs have been standard allowable costs under federal science grants, recognized as essential to conducting research. The proposed rule limits these scientific exchanges, would deprive researchers of access to the literature, and make it financially prohibitive for researchers to disseminate their findings. If finalized, the rule would make conference attendance allowable only if expressly pre-approved by the agency and written in the original grant award terms. The proposed rule would also reverse a provision that has explicitly permitted journal subscriptions as allowable research costs for more than 50 years with no justification for the reversal beyond a reference to "stewardship." Finally, the proposed rule would make publication costs categorically unallowable, directly contradicting a prior open access mandate which requires that federally funded research be made publicly available.

Professional meetings, scientific journals, and other publications are where scientists present findings, receive peer critique, identify new approaches, and build the collaborations that drive discovery. They are essential for sharing learnings, developing best practices, and fostering collaborations that foster innovation. These revisions would limit opportunities to translate research into practice, hinder industry collaboration, and could also have significant financial implications for institutions that rely on conferences or professional meetings to support educational programming, professional development, and year-round activities that advance evidence-based patient care.

**Threats to International Collaboration and Health Care Innovation [Proposed 2 CFR §§ 200.202 and 200.220]**

PMC is particularly concerned about provisions in the proposed rule that would impose new restrictions on international collaboration and additional approval requirements for research partnerships. Global investment in precision medicine is expected to grow substantially, reflecting its increasing impact on clinical innovation, biotechnology, and public health.[iv] Health care challenges like those that are increasingly benefiting from personalized medicine approaches are inherently global and require collaboration across institutions, disciplines, and national borders. While security considerations must be addressed appropriately, broad restrictions on international engagement risk impeding scientific progress and reducing the ability of U.S. researchers to lead global health initiatives.

A government-wide prohibition would bar the use of federal funds for collaborations with countries or entities designated as foreign adversaries or subject to national security sanctions, covering research, travel, and indirect costs. However, the proposed rule does not clearly define how agencies will operationalize eligibility determinations, leaving significant uncertainty about how international participation is evaluated. These provisions may introduce complications for institutions evaluating existing or prospective partnerships, especially in the rare disease space where small patient populations are often located globally.

**Conclusion**

PMC urges OMB to withdraw the proposed rule and engage stakeholders more fully before proceeding with final implementation. We believe OMB, the federal agencies, and Congress should identify alternative approaches that could strengthen accountability while preserving the flexibility, partnership, and scientific excellence that have long characterized the federal grant system and contributed to the increasing applications of personalized medicine in patient care. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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[i] Office of Management and Budget. *Proposed Rule Revising Federal Grant Administration and Uniform Guidance (Docket No. OMB-2026-0034)*. May 29, 2026. https://www.govinfo.gov/content/pkg/FR-2026-05-29/pdf/2026-10817.pdf. (accessed July 7, 2026)

[ii] Hooker, G.W. *Building and Infrastructure to Enable the Delivery of Genomic Medicine*. January 7, 2021. https://doi.org/10.1002/ajmg.c.31881. (accessed July 7, 2026)

[iii] Personalized Medicine Coalition. Personalized Medicine at the FDA: The Scope and Significance of Progress in 2025. May 14, 2026. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/02/report-3.pdf. (accessed July 7, 2026)

[iv] Grand View Horizon Databooks. *Global Precision Medicine Market Size and Outlook 2023-2030*. https://www.grandviewresearch.com/horizon/outlook/precision-medicine-diagnostics-therapeutics-market-size/global?__cf_chl_f_tk=Gkb2m9b0ttgRmN5gRrhVQQg6syNF6WqceWKgaLa07s4-1783446542-1.0.1.1-dDpyoF1IwBT27nHSkEbraywxiGEYnuVkaBwQCXRED64. (accessed July 7, 2026)