NATIONAL ACADEMY OF MEDICINE

MONICA M. BERTAGNOLLI, MD
President

July 10, 2026

Submitted electronically via www.regulations.gov

The Honorable Russell T. Vought
Director, Office of Management and Budget
Executive Office of the President
725 17th Street NW
Washington, DC 20503

Re: Comments of the National Academy of Medicine on the Proposed Rule, *Regulation for Federal Financial Assistance*
Docket No. OMB-2026-0034; RIN 0348-AB81 (lead)
91 Fed. Reg. 32198 (proposed May 29, 2026); Comment Deadline: July 13, 2026
Proposed Effective Date: October 1, 2026

Dear Director Vought:

Introduction. The National Academy of Medicine (NAM) appreciates the opportunity to comment on the Office of Management and Budget's (OMB's) proposed rule, Regulation for Federal Financial Assistance, revising 2 CFR Part 200. The NAM is an honorary society of more than 2,400 members elected in recognition of their distinguished professional achievements across biomedical science, public health, and medicine. The NAM is part of the National Academy of Sciences, Engineering, and Medicine (NASEM), which provides nonpartisan, evidence-based advice to policy makers and the nation overall. We endorse the comment on the proposed rule submitted by the NASEM and hereby submit additional comments reflecting the unique perspectives of the NAM's members and our mission to improve health for all.

As leaders of health centers and academic institutions, industry and biotechnology companies, nonprofit research organizations, disease-focused foundations, and public health organizations, the NAM's members are major contributors to the nation's biomedical, clinical, and public health research enterprise. Through this lens, we are particularly concerned about how the proposed rule stands to impact the quality of care and health outcomes for patients, families, and communities whose health depends on the continued productivity and excellence of American science. We are equally concerned about the likely impacts on early-career investigators, who depend on stable, merit-based funding to sustain their careers, and who represent the future of the scientific enterprise.

NATIONAL ACADEMIES Sciences Engineering Medicine

mbertagnolli@nas.edu
202-334-3300

500 Fifth Street, NW
Washington, DC 20001

For more than 70 years, federal investment in biomedical and clinical research has relied on a straightforward operating premise: individual awards are selected on scientific merit, determined through rigorous, independent, competitive peer review, within priorities that elected leaders set through statute, appropriations, and agency mission. That premise, which has endured across diverse administrations and has received consistent bipartisan support, has delivered an astonishing return on investment: dramatic reductions in deaths from cancer, cardiovascular disease, and infection; life-enhancing advances in organ transplantation; strengthened maternal and fetal health; improved treatment of genetic, neurological, and musculoskeletal disorders; and the promise of new disease cures through immune- and gene-based therapies, to name just a few examples. This research infrastructure underpins modern medicine, drives economic growth, has sustained decades of U.S. world leadership in science and innovation, and continuously delivers life-changing results to the American people. It is not a bureaucratic formality. The record of the last seven decades shows there is no reason to fundamentally alter this enterprise, particularly by instituting changes that may undermine its effectiveness.

Preserve the primacy of independent merit review [200.205]. The required pre-issuance review by senior appointees proposed by OMB would insert a layer of non-technical, discretionary judgment between expert peer review and final funding decisions, with peer-review recommendations rendered explicitly advisory. We take seriously OMB's assurance that this does not discourage peer review, and we appreciate that agency officials, nominated by the President and confirmed by the Senate, have authority over funding decisions and that the process must respect the Federal Advisory Committee Act of 1972.

However, the ambiguity of the proposed structure creates potential for harm. Unpredictable or non-technical revision of funding criteria may inhibit exactly the ambitious, rigorous, long-range research that has produced the greatest gains in public health. Any pre-issuance review should be confined strictly to legal and administrative considerations and clearly defined in the rule itself. It should be stated explicitly and bindingly that scientific and technical merit determinations reached through peer review will not be overridden on non-technical or political grounds without strong justification showing that the decision advances public health goals. In addition, OMB should explain in the final rule, (1) the specific statutory authority under which it may direct agencies to subordinate statutorily required peer review to appointee review; (2) how the proposed § 200.205 can be reconciled with 42 U.S.C. § 289a and comparable agency statutes; and (3) how a wholesale conversion of guidance into regulation, with government-wide preemption of individual agencies' implementing flexibility, is consistent with the Administrative Procedure Act. These are significant legal paradigms on which affected institutions have relied for decades in structuring research programs, employment, and clinical commitments, and they warrant a comprehensive response.

Protect multi-year awards from discretionary termination [200.340]. The advancement and excellence of American medicine rely on stable, long-term investments and generation-spanning research, particularly in critical areas of national need, including chronic disease, nutrition, and environmental, mental, and behavioral health. Clinical and translational research is defined by years-long commitments to trial participants, cohorts, and laboratory infrastructure that cannot be paused and resumed without harm. The proposed expansion of termination and suspension

authority (e.g., permitting an award to be ended with only a brief, non-exhaustive statement of reasons), introduces instability that research cannot absorb. A substantive, documented basis should be required for any discretionary termination of an active award. Grantees should be given a meaningful opportunity to respond before termination takes effect, and any processes must allow for ethical unwinding of research studies that involve human or animal subjects.

Preserve the ability to convene independent expert judgment [200.450, 200.454, 200.432, 200.421]. Another important concern is the capacity of scientific and medical organizations, including the NAM, to convene experts, clinicians, patients, and stakeholders in the service of the public interest, free from political influence. Independent consensus studies and advisory activities are especially valuable precisely because they are insulated from short-term political pressure. Independence enables the development of objective advice for policy makers, evidence-based consensus, meaningful engagement with patients and communities, and open public dialogue. Any policy that could be read to condition Federal support on the substantive positions taken by participants in such activities, or that discourages engagement with legitimate but sensitive scientific questions, would undermine the independence that makes these activities valuable, and would be contrary to the Federal Advisory Committee Act of 1972.

Moreover, supporting the dissemination of research through publications, meetings, and public engagement promotes scientific exchange and debate, provides transparency of outcomes, promotes public accountability, and amplifies the economic impact of federally supported research. If access to communications related to federally funded scientific research is restricted, investments made by the American people will be much harder to translate into better patient care, lower costs, and improved health.

Preserve the scientific study of differences in health outcomes [200.218]. The proposed prohibition on Federal support for "disparate-impact liability" theories should not be permitted to reach, or to inhibit, the scientific measurement and analysis of differences in health outcomes across populations. Epidemiology, health services research, and health care quality measurements routinely and necessarily examine why outcomes differ by geography, age, income, occupation, and environmental or clinical exposure, and this is particularly relevant to rural, economically disadvantaged, and chronically ill communities where such differences are most acute. These research types represent a method of scientific inquiry, not a theory of legal liability, and are indispensable to any successful national effort to prevent and treat disease. The final rule should state expressly that § 200.218 does not restrict research that measures, analyzes, or reports differences in health outcomes.

Preserve stable pathways for trainees and the early-career workforce [200.201, 200.218, 200.300, 200.432, 200.454, 200.461]. The future of the biomedical research enterprise depends on the fellows, postdoctoral researchers, and early-career investigators who are trained within it, and several proposed provisions, though not framed as workforce policy, would together destabilize that pipeline. The proposed elimination of fixed-amount awards and subawards, absent specific statutory authorization, would sweep in the stipends, milestone-based payments, and performance-based fellowship mechanisms that many training programs rely on, replacing streamlined support with heavier cost-documentation burdens ill-suited to trainees. There is also a risk that the proposed restrictions on activities addressing disparate impact or promoting

diversity, equity, or inclusion (DEI) will curtail lawful broadening-participation programs—including bridge programs, targeted fellowships, and undergraduate research programs—that provide important career development opportunities and have long been valued as merit-based investments in the nation's scientific workforce. In addition, the proposed prior-approval requirements for conference attendance, professional society membership, and publication costs will fall hardest on trainees, for whom presenting work, building a professional network, and publishing are essential to building scientific careers.

The proposed rules should explicitly demonstrate how they will sustain and advance the size and quality of the nation's current and future human capital across all science, engineering, and medicine disciplines. These fields are essential for advancing our nation's vitality and global competitiveness. Fellowship and traineeship mechanisms should be exempted from the proposed restrictions on fixed-amount awards; established, merit-based workforce and broadening-participation programs should be clarified as outside the scope of the disparate-impact and DEI-related provisions; and reasonable, streamlined support for conference attendance, professional memberships, and publication activities that trainees require to build successful scientific careers should be preserved.

Preserve the ability to collaborate internationally [200.202, 200.220]. Global health threats do not operate neatly within borders, and neither can the science required to address them. Provisions that would generally restrict research and development awards to domestic entities and require senior political approval for international program elements, such as by extending Wolf Amendment–style restrictions government-wide, would isolate American investigators from international collaborations, cohorts, and data-sharing arrangements that are essential for pandemic preparedness, vaccine development, therapeutic innovation, and rare-disease research, among other important national priorities. Streamlined, agency-level pathways for meritorious international scientific collaboration should be preserved, reserving case-by-case restrictions for demonstrated, specific national security concerns.

Conclusion. We acknowledge, fully and without reservation, that federal agencies must ensure awards comply with law, advance authorized missions, and serve the national interest, and that elected leaders properly set funding priorities through statute, appropriations, and agency strategy. Our request is more fundamental: that within those priorities, the selection of specific projects remains a scientific determination made through independent, technical review, not a discretionary decision revisited at each stage of the award lifecycle. The existing approach is what has allowed the United States to lead the world in turning public investment into cures, treatments, and healthier lives, and it is what enables the American people to trust that their tax dollars fund the research most likely to improve their health.

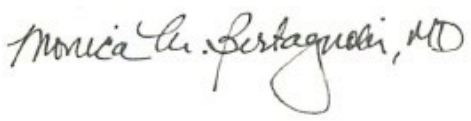
The proposed rule should be revised to make the primacy of independent scientific merit review explicit and binding, not merely aspirational; to require substantive justification before any active award is terminated and allow for ethical unwinding when human or animal subjects are involved; to safeguard the ability of scientific and medical organizations to convene and advise free of political interference; to preserve the scientific study of differences in health outcomes; to protect fellowship, traineeship, and broadening-participation mechanisms from provisions not

intended to reach them; and to preserve streamlined pathways for international scientific collaboration.

The NAM welcomes the opportunity to work with OMB toward a final rule that advances transparency and accountability without compromising the scientific integrity that has made American biomedical research the standard the rest of the world seeks to emulate.

Please direct any questions to Elizabeth Finkelman, MPP, Chief of Staff, at efinkelman@nas.edu.

Respectfully submitted,



Monica M. Bertagnolli, M.D.
President, National Academy of Medicine