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LEONARD DAVIS INSTITUTE of HEALTH ECONOMICS

Rachel M. Werner, MD, PhD
Executive Director, Leonard Davis Institute of Health Economics
Robert D. Eilers Memorial – William Maul Measey Professor in Health Care Management
Professor of Medicine
University of Pennsylvania

June 10, 2026

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

Dear Madam or Sir:

Thank you for the opportunity to comment on proposed rule OMB-2026-0034, "Regulation for Federal Financial Assistance," Regulatory Information Number (RIN) 0348-AB88.

I am a Professor of Medicine and a researcher at the University of Pennsylvania, where I have been on the faculty for 22 years. During that time, I have led 20 grants funded by federal agencies, including the NIH and the AHRQ. My research focuses on improving the quality and value of care that older adults receive, particularly in nursing homes and at the end of their lives.

I am concerned about the effect that the proposed rule, "Regulation for Federal Financial Assistance" would have on my research and, ultimately, on improving patient care. I am particularly concerned about the following provisions:

§200.205 — Pre-issuance review by political appointees, with peer review demoted to advisory

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. This

In my field of health economics, reviewers assess whether a study can credibly identify the effects of programs affecting older adults and other vulnerable populations, including payment, the organization of health care, and new delivery innovations in health care. Reviewers are skilled at evaluating whether a quasi-experimental design can support causal inference, whether risk adjustment is adequate, whether administrative and claims data are being used appropriately, whether sources of bias and confounding have been addressed, and whether the proposed analyses are sufficient to answer the proposed research question. These judgments require specialized methodological expertise. and political appointees are not positioned to judge the rigor or appropriateness of the proposed science.

The post-war American research system has long relied on peer-review to ensure funding of rigorous research, making the U.S. research enterprise one of the most productive in the world. Scientific progress is made because we defer to the independent technical judgment rather than to the preferences of whoever held office. That principle is especially important for observational research, where findings may ultimately support, refine, or challenge the way we deliver health care and improve patient lives in the U.S. A political review that is explicitly forbidden from deferring to expert scientific judgment does not add a safeguard atop merit review; it substitutes political preference for scientific expertise.

The government's legitimate accountability interests can be met without subordinating peer review. Agencies already ensure statutory compliance, verify responsible stewardship of public funds, and may decline proposals that fail to meet established standards. I therefore urge OMB to strike the subsections that diminish the role of expert peer review and replace independent scientific assessment with political review.

§200.340 — Mid-award termination for shifting "priorities"

The proposal expands the authority to terminate active awards on the basis of "agency priorities," requiring no finding of noncompliance and only a brief written rationale, and analogizes this authority to the termination-for-convenience clause used in federal procurement. However, and importantly, research grants are not contracts for the delivery of a predefined product; they support the generation of new knowledge through projects that often unfold over many years and require substantial investments in infrastructure, personnel, and data resources.

My research frequently involves the assembly of longitudinal datasets, the development of partnerships with health care organizations, and the recruitment and training of research staff with specialized expertise. These commitments are difficult to unwind once a study is underway.

Allowing awards to be terminated based on changing agency priorities, absent concerns about performance or compliance, introduces uncertainty into the research enterprise. Investigators and institutions may become less willing to undertake projects that require long-term investment or that address questions whose answers will emerge only over several years. Yet many of the most important questions in my field, including the effects of payment reforms, delivery-system innovations, and programs serving older adults, can only be studied through sustained, longitudinal research.

Federal agencies already possess mechanisms to address noncompliance, poor performance, or other legitimate concerns regarding grant administration. I therefore urge OMB to strike this provision permitting termination of active awards solely on the basis of changing agency priorities and to retore termination only for cause.

§200.432, §200.461 — Cost prohibitions

These changes would effectively eliminate the use federal funds to support the most important ways to disseminate new research findings that are funded by federal grants:

- **Conferences (§200.432)** The proposal would allow conference travel only if pre-approved and explicitly written into an award at the time it is issued. In practice, this approach is difficult to implement in research fields where the most relevant opportunities for scientific exchange often emerge years after a project begins.

  In health economics research, conferences are a primary venue for presenting preliminary findings and receiving methodological and substantive feedback to strengthen the research.

  At the time an award is made, investigators cannot reasonably anticipate which conference, workshop, or scientific meeting will be most relevant several years later. New

findings emerge, timelines shift, research priorities evolve, and opportunities for collaboration arise throughout the life of a project. Requiring advance specification or case-by-case approval of conference participation adds administrative burden while limiting researchers' ability to engage with the scientific community in a timely manner.

- **Publication costs and open-access fees (§200.461)** The proposal would make publication costs presumptively unallowable, despite existing federal policies requiring that the results of federally funded research be made publicly accessible. In health economics research, publication is not simply a means of dissemination; it is a core part of the scientific process through which findings are evaluated, validated, and incorporated into the broader evidence base.

  Peer-reviewed publication allows other researchers to assess methods, replicate analyses, and build on prior work, key priorities of the NIH and Director. It is also the primary mechanism through which evidence reaches policymakers, health care organizations, clinicians, and the public. It is also essential for credibility and trust.

Taken together, these provisions would shift key decisions throughout the funding lifecycle away from expert scientific judgment and toward discretionary administrative review. They would also restrict activities that are integral to the research process, including participation in scientific conferences, publication of findings, and the long-term planning required for sustained research programs.

Federal research funding should be both accountable and scientifically rigorous. Existing mechanisms already provide accountability, with substantial oversight of federal awards, while preserving rigor through the role of expert peer review and the flexibility needed to conduct high-quality research. In my field of health economics, these safeguards help ensure that studies addressing health care delivery, financing, and outcomes generate reliable evidence that can inform health care delivery and improve patient care.

I respectfully urge OMB to withdraw or substantially revise the provisions named above. Doing so would preserve accountability while maintaining the scientific standards that have long underpinned federally funded research.

Sincerely,

Rachel M. Werner, MD, PhD