



July 13, 2026

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

Comments submitted electronically via www.regulations.gov.

RE: Regulation for Financial Assistance (OMB–2026–0034)

Dear Director Vought:

The Society for Women's Health Research (SWHR) writes in response to the proposed rule, Regulation for Federal Financial Assistance.

If finalized, the wide-sweeping provisions of the proposed rule will impact all recipients of federal financial assistance, including individual researchers, research institutions, states and local communities, and public health organizations. In analyzing the rule, SWHR is concerned that it will destabilize the integrity and quality of medical science, especially as it pertains to federally funded biomedical and public health research, including grants supported by the National Institutes of Health (NIH). Therefore, we recommend that the Office of Management and Budget (OMB) withdraw this proposed rule.

Founded in 1990, SWHR is a national nonprofit dedicated to advancing women's health through science, policy, and education while promoting research on sex differences to optimize women's health. For more than three decades, SWHR has played a leading role in advancing evidence-based policies at the NIH and the Food and Drug Administration (FDA). SWHR is a nonpartisan organization whose work is grounded in the best available scientific evidence. The nature of our work leads us to be an invested stakeholder in the proposed rule and its implications for the American scientific enterprise.

The proposed rule is published with the intent to "improve transparency, accountability, and oversight for how Federal taxpayer dollars are used in the context of Federal grantmaking." SWHR agrees that mechanisms for ensuring that tax-payer dollars and federally-supported initiatives serve a broader public interest – especially when it comes to medical research and health care – are necessary. However, we do not believe that the provisions of this rule would achieve that intent – and could potentially do the opposite – as the proposal would codify scientific peer review as advisory that will inevitably compromise the kind of science and innovation that receives federal support and, in doing so, create an opaque process in how scientific merit is evaluated. Provisions with respect to the posting of funding

opportunities, terminations of grants, multi-year awards, and diversity, equity, and inclusion (DEI) also raise concern.

In this comment letter, SWHR provides feedback on specific provisions of the rule and additional context as to how the proposed rule would specifically impact women's health research.

Given its broadly applied provisions, the unprecedented impact it would have on scientific integrity and quality, and the insufficient time allotted for the comment period of such an extensive rule – and in alignment with the broader patient advocacy and medical research community – SWHR again urges the OMB to withdraw the proposed rule.

Section 200.204—Notices of Funding Opportunities

SWHR supports the proposed requirement that Notices of Funding Opportunity (NOFOs) be written in plain language. Clear, accessible funding announcements promote transparency, reduce barriers to participation, and help ensure that eligible applicants can effectively identify and compete for federal funding opportunities.

However, SWHR has significant concerns regarding the proposed provision permitting agency heads to waive the public posting of NOFOs based on undefined considerations in the "national interest". As drafted, this authority is overly broad and lacks sufficient standards to guide its implementation. The proposed language would vest substantial discretion in agency leadership, including political appointees, to determine when competitive funding opportunities may be exempted from public notice without establishing objective criteria or transparency requirements.

If the intent is to align funding opportunities with the Administration or agency priorities, the regulation should establish a defined and transparent process for identifying those priorities. At a minimum, the final rule should specify: (1) the criteria that may justify a waiver of public notice; (2) the officials responsible for establishing or approving such priorities; (3) the process by which these determinations will be documented and communicated to the public; and (4) whether, and through what mechanism, stakeholders will have an opportunity to provide input regarding agency funding priorities.

Absent these safeguards, the proposed provision would create substantial uncertainty for researchers regarding the availability of federal funding opportunities and the basis on which they are awarded, undermining the predictability and transparency that are fundamental to competitive basic and applied science and biomedical and health assistance programs. Moreover, providing broad discretionary authority without clear implementation standards is likely to increase administrative burden on agencies by requiring ad hoc determinations and may result in inconsistent application across agencies and programs.

Section 200.205 – Federal Agency Review of Merit of Proposals

SWHR shares the goal of ensuring that federally funded research meets the highest standards of scientific rigor. However, Sections 200.205 of the proposed rule would undermine the existing process, which includes mechanisms for ensuring that research is evaluated primarily on its scientific merit.

With respect to federal review of proposals' merit, the NIH employs a well-established, expert peer review process in which grant applicants are evaluated by independent scientific experts using standardized criteria, including the significance of the proposed research, the rigor and feasibility of the study design, and the expertise and resources of the investigative team. This process is intentionally designed to ensure that funding decisions are based on scientific quality and public health impact rather than being based on external influences.

Currently, agency leaders, including political appointees, have the authority to determine the topics and priorities when calling for applications. The proposed rule shifts political input from the initiation of the application process to the end by providing political appointees authority to make grant determinations and direct funding decisions to align with administration priorities. While agencies rightly have the authority to establish broad research priorities, scientific review and funding decisions must be grounded in objective, expert evaluation. The rule also introduces ambiguous concepts such as "gold standard science" without clearly defining the term or explaining how it would be applied consistently across funding decisions. Without clear, objective standards, the proposal creates uncertainty for applicants, risks discouraging innovative and high-impact research, and adds unnecessary administrative burden. These reasons lead to concerns as to whether scientific merit will remain the primary basis for funding.

Additionally, and in conflict with its stated intent, the proposed rule would compromise transparency in the grant-making process. Funding decisions made by undefined criteria will only make it more difficult for researchers and the public to understand how and why grants are awarded, whether decisions are being made consistently, and whether federally funded research remains responsive to the nation's most pressing evidence-based health needs.

SWHR support efforts to ensure that federally funded science is of the highest caliber. This goal is best achieved by strengthening the existing expert peer review system and federal research infrastructure. Scientific excellence depends on rigorous, transparent, and independent evaluation, and those principles – not political influence – should remain the foundation of the federal research enterprise.

Section 200.340 – Termination and Suspension; 200.341 – Notification of Termination Requirement; 200.342

The proposed rule would afford agencies broad discretion to terminate federal grants and other forms of financial assistance; it also removes the appeals process. Although agencies should retain the ability to terminate awards for recipient noncompliance, poor performance, or other legitimate statutory or regulatory reasons, a final rule must more clearly define and limit discretionary termination authority to promote predictability and ensure continuity in the delivery of federally supported programs.

Broad discretionary termination authority is especially concerning in the context of biomedical and public health research. Many federally funded research projects – including clinical trials, longitudinal cohort studies, and prevention research – require continuous support over multiple years to produce scientifically valid results. Terminating awards because a particular research area is no longer an agency priority may

interrupt ongoing studies, compromise data integrity, diminish the value of prior federal investments, and delay the development of evidence needed to improve public health.

These concerns are particularly acute for women's health research, which often depends on long-term studies to address historical gaps in scientific knowledge. Abrupt termination of such awards may disproportionately undermine research that requires sustained observation and follow-up to generate meaningful findings.

Similarly, prevention-focused research examining strategies to reduce the incidence of chronic diseases – including heart disease, Alzheimer's disease, osteoporosis, and other conditions that disproportionately or differently impact women – depends on long-term continuity. Discretionary termination of these projects could significantly impede the development of evidence necessary to advance preventive care and improve health outcomes.

SWHR suggests that any final rule provide additional procedural safeguards governing discretionary terminations, including retention of the appeals process, and ensure that agencies consider the broader programmatic and public impacts of terminating awards for reasons unrelated to recipient performance or compliance.

Section 200.202 – Program Planning and Design

The proposed rule encourages the use of multi-year awards to reduce the frequency of application and award cycles and to provide recipients with greater funding stability. It is true that – when appropriately applied – multi-year awards can improve administrative efficiency for both agencies and recipients and facilitate long-term project planning. However, these benefits are contingent upon recipients having reasonable assurance that awarded funds will remain available throughout the approved project period. The final rule should retain and strengthen the provisions authorizing multi-year awards by expressly cross-referencing the standards governing termination and suspension. Specifically, OMB should clarify that a multi-year award should not be terminated or suspended for reasons unrelated to recipient performance or compliance without consideration of the recipient's reliance interests and the impact on research beneficiaries.

OMB should also consider the practical effects that expanded use of multi-year awards may have on the distribution of federal financial assistance under fixed appropriations. Although committing funding for the full project period at the time of award provides greater certainty for individual recipients, it also reduces the total amount of funding available for new awards during a given fiscal year. Experience at the NIH beginning in 2025 illustrates this concern. As NIH expanded the use of upfront multi-year funding, Institutes and Centers were required to commit larger portions of their annual appropriations to existing awards, resulting in fewer competing awards¹. Any final rule should therefore preserve agency discretion to employ multi-year awards in a manner that advances programmatic objectives without unnecessarily reducing the number of competitive funding opportunities or impeding broader participation in federal financial assistance programs.

Diversity, Equity, and Inclusion (DEI)

¹ <https://reporter.nih.gov/>

Throughout the proposed rule, OMB repeatedly references efforts to address or eliminate "unlawful DEI practices." While SWHR supports compliance with applicable federal civil rights laws and opposes unlawful discrimination in any form, we are concerned that the proposed language may be interpreted too broadly. Such an interpretation could create uncertainty and have unintended consequences by discouraging organizations from engaging in lawful and beneficial activities designed to improve access and reduce barriers, including initiatives that promote women's health, geographic access (e.g., rural health initiatives), disability access, language access, and other legally permissible accommodations and outreach efforts. The most effective, efficient, and impactful research is reflective of the population that it is intended to treat. Therefore, SWHR encourages OMB to clarify that the rule is intended to address only conduct that is unlawful under existing federal civil rights laws and does not restrict or discourage lawful activities that expand access, promote representation, or improve unbiased participation in federally supported programs.

Comment Period

SWHR joined a broad coalition in requesting that the OMB extend the public comment period by 45 days, to August 27, 2026, before proceeding with any final rule. We reiterate that request here.

The proposed 45-day comment period is insufficient given the breadth of the proposed changes and the number of affected entities. Likewise, the proposed four-month implementation period does not provide adequate time for agencies and grant recipients to understand the final requirements, update policies and procedures, train personnel, and implement necessary operational changes.

Because this proposal represents a sweeping policy change with significant consequences across the federal financial assistance landscape, SWHR is concerned that the current timeline does not provide OMB with sufficient opportunity to adequately evaluate the substantial volume and complexity of comments that will be submitted.

The scope, complexity, and far-reaching implications of this proposal for virtually every federal grant recipient and federal agency warrant additional time for stakeholders to prepare comprehensive comments and for OMB to meaningfully review and consider the feedback it receives. Extending both the comment period and the implementation timeline would promote a more transparent, deliberative, and effective rulemaking process and will allow sufficient time for evaluating material impacts of the rule, including economic and public health forecasts.

Conclusion and Recommendations

The United States' scientific and biomedical research enterprise is one of our nation's greatest strengths. It has produced groundbreaking discoveries, improved the lives of millions of patients, and established the United States as the global leader in scientific and medical innovation. Any changes to the federal research funding process should strengthen – not undermine – the scientific rigor, independence, transparency, and accountability that have made this system the best model in the world.

SWHR supports efforts to ensure that federally funded research is of the highest quality. At the same time, we are deeply concerned that this proposed rule would have significant unintended consequences, including the slowing of innovation, discouraging high-quality research, and reducing public confidence in the federal research enterprise. The expedited comment period and proposed implementation timeline

of the rule also does not adequately address the resources and implementation costs that would be required to operationalize these changes, raising additional concerns about efficiency and taxpayer value.

These concerns are particularly significant for women's health research. Progress in understanding biological sex differences, improving the inclusion of women in clinical research, and addressing longstanding gaps in evidence has depended on a stable, transparent, and scientifically rigorous funding process. Policies that introduce uncertainty or diminish confidence in merit-based scientific review risk slowing advances in the prevention, diagnosis, and treatment of conditions that disproportionately affect women or present differently between the male and female sexes and, to remain competitive in global competition, the federal research enterprise should be positioned to expand scientific discovery in this area.

We also encourage OMB to engage meaningfully with the scientific community, including patient advocacy organizations and other stakeholders to better understand the practical implications of these proposed changes and to develop policies that strengthen scientific excellence without compromising the integrity of the peer review process.

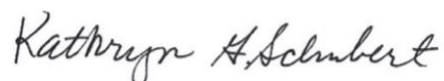
In summary, SWHR urges the OMB to withdraw this proposed rule.

Should the rule be finalized, SWHR strongly urges that OMB:

- 1) Safeguard the role of scientific peer review and ensure any political oversight is consistent with the state of the science when it comes to publishing NOFOs, evaluating applications for basic and translational science and medical research funding, and in the potential termination of existing grants;
- 2) Ensure that population needs remain central to program implementation and that the final rule more clearly distinguishes between unlawful discrimination and lawful activities designed to improve access to research participation, health care, and necessary accommodations for underserved populations;
- 3) Provide an extension on the existing comment period to allow for meaningful input from all impacted stakeholders and industries and sufficient time for evaluating the rule's impacts, especially from in terms of the rule's economic soundness, its impacts to public health, and its impacts to federally supported medical research.

SWHR remains committed to working with federal partners to promote a research enterprise that is rigorous, transparent, accountable, and driven by scientific merit. We look forward to your response and can be contacted as a resource as OMB continues to explore ways to streamline and improve federal grantmaking. Please feel free to contact me directly at Kathryn@swhr.org with any questions.

Sincerely,



Kathryn G. Schubert, MPP
President and Chief Executive Officer
Society for Women's Health Research