ASPET
Transforming Discoveries into Therapies

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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 American Society of Pharmacology and Experimental Therapeutics on the Proposed Rule, Regulation for Federal Financial Assistance (Docket No. OMB-2026-0034)

The American Society of Pharmacology and Experimental Therapeutics (ASPET) submits this comment to express strong concerns and objections to the Office of Management and Budget's (OMB) proposed revisions to 2 CFR 200 (Docket OMB-2026-0034).

Introduction

ASPET is a 4,000-member scientific professional society whose members conduct basic, translational, and clinical pharmacology research dedicated to improving Americans' health. Members represent all sectors, working in academic, government, industry, and non-profit organizations. ASPET members have made major contributions to the development of lifesaving new medicines to fight existing and emerging diseases, communicate with the US public about biomedical innovations and discoveries, and improve health outcomes for all US citizens. ASPET is an American-led global leader in pharmacology, a field that advances the science of medicines and therapeutics to accelerate the discovery of life-saving cures for common diseases that affect all Americans, including heart disease, obesity, cancer, Alzheimer's disease, and diabetes.

To support life-saving research, the majority of ASPET members receive federal funding in the form of grants and contracts from many federal agencies, including HHS/NIH, DoD and NSF to support this life-saving research. The link between NIH funding and medicines Americans depend on is direct. Dr. Kathleen M. Giacomini, an ASPET member, conducted NIH-funded research leading to findings that directly inform FDA labeling, dosing, and safety guidance for metformin, the most widely prescribed treatment for Type 2 diabetes, and allopurinol, a standard treatment for gout. These medicines are used daily by millions of Americans. This is not an isolated example. Eighty-three percent of the of NIH investments that supported basic science research on biological targets have contributed to 354 of the 356 medicines approved by the FDA between 2010 and 2019.

ASPET strongly objects to the proposed OMB revisions to 2 CFR 200 and calls for an immediate removal of this proposal. If implemented, this rule will slow the development of new medicines, erode US leadership in scientific innovation, jeopardize economic growth, and ultimately harm the health of all Americans. ASPET is deeply concerned about the content and scale of the changes proposed in this rule.

The rule as proposed is not a reformation of grant management. It is an attempt to remove decision making authority from federal agencies and vest that authority in OMB. OMB's statutory mission lies in financial management and budget coordination, not prescription of government-wide grant administration that severely reduces the ability of federal agencies to administer grants. The proposed rule would place political oversight over more than $1.2 trillion in annual federal grants (5.4% of current US GDP) across every grant making agency, substituting OMB judgement over the expertise of the grant making agencies authorized by Congress to administer those funds.

If enacted the rule would endanger the post-WWII scientific excellence and competitive position that America has built and gained over the rest of the world. NIH's grant administration process has earned international recognition precisely because it insulates funding decisions from political influence. The proposed rule would dismantle that insulation, transforming a merit-based system into one where political alignment, not scientific quality, determines research funding. Reducing the ability of agencies to exercise programmatic oversight to detect and prevent waste, fraud, and abuse problems, and instead depending on directives from an agency that lacks such expertise, is more likely to increase risk than reduce it.

ASPET strongly recommends that OMB withdraw the proposed revision of the Guidance for Federal Financial Assistance in its entirety and consider a different approach to address issues it claims to improve.

Below, we highlight a few areas within the proposed rule that are most impactful to our members. We address how the proposed specific regulations would dismantle the scientific enterprise and highlight how, in many cases, the consequences of the changes are in direct conflict with the intended purpose of increasing transparency, accountability and oversight of federally funded programs.

Summary of Specific Recommendations

ASPET respectfully recommends that OMB:

- Retain the current 2 CFR as guidance, rather than reclassifying it as a government-wide regulation.
- Retain the current § 200.205 to maintain peer review as the basis for award decisions.
- Retain the current § 200.340 to maintain the criteria for termination to those outlined in the grant agreement and remove the undefined "national interest" as a criterion.
- Retain the current § 200.432 to maintain the allowable usage of grant funds to attend conferences to disseminate research findings.
- Retain the current § 200.454 to maintain the allowable usage of grant funds to pay for scientific society dues to further advance workforce development.
- Retain the current § 200.461 to maintain the allowable usage of grant funds to pay for publishing costs to make findings publicly accessible.

[2 CFR Part 1] - Uniform Guidance Reclassification
2 CFR Part 1 explicitly states, “Publicization of the OMB guidance in the CFR does not change its nature – it is guidance, not regulation.” The proposed rule would replace “guidance” with “regulation” across the entirety of 2 CFR all at once, changing flexibility for rigidity, binding regulation without procedural protections.

OMB ignores the “potential impact on the public” portion of 2 CFR 1.230, which states that “any portion of the guidance that has a potential impact on the public is published with an opportunity for public comment. Given the scope and breadth of the proposed changes, OMB should have given more time to the research community and other stakeholders to engage with the proposed revisions. ASPET requested an extension to the 45-day comment period which was denied. It is inconceivable that OMB would consider that the “potential impact on the public” would be minimal given that it is changing guidance to regulation over the entirety of the federal grantmaking process.

Due to the conversion to a regulation, which creates a more stringent following and enforcement, OMB and its proposed rule ignore the Administrative Procedure Act, which requires independent notice and comment rulemaking for each substantive change being made. One single notice and comment rulemaking changing the entirety of the federal grantmaking process certainly ignores the public impact and the substantial changes that are to be made.

Typically, when a regulation of this size and magnitude is proposed, the agency has been authorized to do so in language passed by Congress. Congress affords the agency the ability to make the regulation to enact legislation by Congress. In this case, there is no authorization legislation, merely Executive Orders and press statements. OMB does not have the power to make sweeping changes. Under *West Virginia v. EPA*, the Major Questions Doctrine requires that agencies have clear congressional authorization for decisions of vast political and economic significance. “Vast political and economic significance” is the key determining factor as to whether the Major Questions Doctrine is applied. In the proposed rule, OMB is proposing to place political appointees as final arbiters deciding who receives a grant. OMB is proposing that grants can unilaterally be cancelled without cause due to “national interests” determined by the presidential administration in power at that time. OMB proposed this rule without an economic impact statement, asking respondents to reply with their own economic impact. OMB has access to federal government-provided data that would show the economic impacts of the proposed rule, directly affecting $1.2 trillion in federal grants, not including the downstream effects of those grants. For example, every grant dollar invested in the NIH returns $2.57, or over $94 billion, in economic output. This is equivalent to 0.29% of the US GDP, or the economy of the state of Delaware, as measured by the United for Medical Research and available economic data. For the above examples, congressional authorization is required, and there is no such authorization for this action.

The proposed rule section 200.101(d)(2) establishes a pseudo-supremacy clause, whereby the new OMB rule would take precedence over any existing agency regulation that conflicts with the new regulation. The resulting rule would therefore have overarching supremacy over a range of congressional authorizations and court decisions, something no agency has the power to promulgate without specific congressional authorization. This section would also remove the abilities of agencies to effectively operate and enact their missions and objectives, centralizing all decisions into OMB. OMB’s ability within the grantmaking process is limited to financial management and grant administration, 2 CFR 1.300.

Congress has had multiple opportunities since the creation of the “Uniform Guidance” to grant OMB the authorization for supremacy over the entire grant making enterprise, let

alone the entire regulatory structure, as this proposed rule would seek to establish. It clearly has not. Without such authorization, courts have found that the scope of authority held by an agency is determined by the agency's organic statute and, without explicit authorization from Congress, any attempt to regulate outside the organic statute is impermissible (*FDA v. Brown & Williamson Tobacco Corp*.). In this instance, Congress has established separate schemes with the creation of the NIH and other science agencies thus preventing this type of regulation from occurring.

Federal agencies are required to engage in "reasoned decision-making" and take a "hard look at the evidence before issuing, changing, or rolling back regulations." Under the *Motor Vehicle Manufacturers Association v. State Farm* "arbitrary and capricious" test, a regulation can be struck down if the agency failed to consider an important aspect of the problem, offered an explanation that runs counter to the evidence, relied on factors Congress did not intend it to consider, and overlooked entirely obvious alternatives. The preamble offers multiple examples of political and partisan sources of evidence for the rulemaking, thus ignoring the necessity to remain neutral. There is no rational connection between the facts and the choices OMB made.

The proposed rule is not logically sound nor properly justified. The record does not reflect the serious impact of the proposed rule, nor does it show how the agency arrived at its decision. The proposed rule does not address the economic impact of its changes.

For the reasons above, ASPET strongly recommends that OMB withdraw this rulemaking in its entirety.

[§ 200.205] - Political Appointee Review

ASPET strongly opposes the proposed rule to mandate political appointee involvement in grant review. It is capricious and distinctly separated from the established scientific process that is based on rigorous and reproducible scientific evidence.

Peer review has been an established process for federally funded research. Peer review has long provided a measure of quality control for scientific literature that is based on scientific merit. Trusted results enable readers and the public to gain knowledge, help funders see the impact of their investments, and allow the scientific community to build on reliable work and drive the next wave of innovation.

Proposed section 200.205 would require senior political appointees to conduct a mandatory pre-issuance review of every discretionary grant before it is awarded. These appointees are explicitly forbidden from deferring to peer reviewers or routinely ratifying their recommendations. Further, proposed Section 200.205(d) would explicitly state that peer review recommendations "remain advisory and are not ministerially ratified, routinely deferred to, or otherwise treated as *de facto* binding."

Taken together, the two sections would replace the merit-based peer review system with a political appointee review process that is undefined, unappealable, and insulated from the scientific expertise Congress required when it established the NIH peer review framework.

Inserting senior political appointees into the merit review process would create additional administrative and bureaucratic burdens, adding an unaccountable actor. This actor would be applying vague and undefined review criteria that would be instrumental in determining the trajectory of American research with no requirement for adequate training or standards of scientific evidence. The current system, while imperfect, offers a fair and credible review of all research using the rigorous and unbiased peer review process. The current system relies on peer review conducted by field experts, with years of experience, who operate through an independent process free from outside influence.

The subjugating of peer review to just “advisory” status creates a conflict of law: OMB does not have the authorization to promulgate rules that supersede congressional authorization. This proposal would violate the laws that mandate scientific peer review to inform grant making decisions at NIH. 42 USC 289a, 282(b)(16) and 284(c)(3) provide the structure for the NIH peer review process that allows for a reliable and predictable process for evaluating proposals for scientific merit. This structure exists to ensure that research funding is grounded in factual evidence, expertise, and provide for long-term national interests without the influence of political gain. Scientific peer review prevents waste, fraud, and abuse due to its focus on evidence, expertise, and independence; replacing it with a political process would instead exacerbate waste, fraud, and abuse.

Finally, within this section, there is portion that directs agencies to prioritize institutions that “demonstrate success in implementing Gold Standard Science” while deprioritizing institutional prestige and historical reputation. The proposed rule does not provide a definition of the nebulous “Gold Standard Science” and builds a system in which political appointees have unlimited power to prioritize or disfavor institutions based solely on the present political climate. This creates dangerous circumstances in which there are vague, undefined criteria that cannot be met, challenged, or reviewed. The proposed rule, if implemented, will also undermine public confidence in the scientific community and the results they publish.

For the reasons above, ASPET strongly recommends that OMB withdraws the revisions to § 200.205.

[§ 200.340] - Allowable Termination

Proposed section 200.340 would allow any grant to be terminated if doing so is in the interest of the agency, or if the grant “does not effectuate program goals.” Further, termination is allowed if the grant does not align with “federal agency priorities, or national interests as they exist at the time of termination.” OMB frames this as analogous to “termination for convenience” in federal contracting.

The proposed termination authorization grants unilateral power to a political appointee. The proposed rule also creates a contractual doctrine where none exists, nor does OMB have the congressional authorization to create one.

The current rule is that grants are subject to termination only under defined circumstances: failure to comply with terms, both parts mutually agree to end, or when the program loses legal basis. These are explicitly defined criteria, with due process afforded (including in findings of noncompliance that could include fraud, abuse, or misconduct) and an appeal process is provided. The current conditions consider the longitudinal processes of planning and executing complex scientific research.

Basic discovery science does not operate on contractual terms that can easily be defined. Some scientific research takes years, if not decades, to bear results, let alone the results as initially defined. Scientists follow the science and thus research grants follow along. The idea that science can be contorted to fit within “the four corners” of a contract is antithetical to scientific practice.

This rule would directly constrain scientific decision making. How can a long-term decision be made if the constant fear of termination is present? Student training, staff hiring, equipment purchases, and other institutional investments would become a gamble even under multi-year awards, all of which could be canceled at any time with merely the assertion of non-alignment with "national interests." This is fundamentally incompatible with basic contract law, which requires that all terms and conditions be defined and understood

by all parties. "National interests" is undefined, unconstrained, and provides no basis for a grantee to know what is required to remain in compliance.

If the analogy to “termination for convenience” is correct, the only remedy for a grantee with a terminated grant is to argue that the termination was in “bad faith” or a “clear abuse of discretion” of the contracting officer. Under the proposal, the contracting officer is undefined. For a grantee facing a termination due to perceived misalignment with “national interests,” the proposal creates an unreasonable expectation that a grantee would be expected to prove “bad faith” or “clear abuse of discretion” but this is not possible because “national interest” is a term so ill-defined that it cannot be reasonably challenged. This allows for a singular political appointee to act as jury, judge, and executioner, something that does not exist within American jurisprudence, regulation, or legation.

Another issue is that the proposed rule would apply retroactively to all existing grants. Awards made under prior regulatory frameworks would immediately become subject to potential termination under a standard that did not exist when the grants were awarded. Institutions that have hired staff, purchased equipment, and built research infrastructure on the basis of multi-year federal commitments would have no protected expectation that those commitments will be honored.

This retroactive application raises serious legal problems. First, when the government seeks to terminate a benefit it has already granted, due process requires that the recipient receive notice and a meaningful opportunity to be heard before termination. Termination on "national interest" grounds requires no finding, no hearing, and no appeal. Because "national interests" is undefined in the proposed rule, this termination standard gives grantees no meaningful basis to comply, respond, or appeal. This is a deficiency that courts have found constitutionally impermissible under the vagueness doctrine.

For the reasons above, ASPET strongly recommends that OMB withdraws the revisions to § 200.340.

[§ 200.432] - Conference Attendance

For decades, conferences have served as key platforms for collaborative exchange of scientific knowledge. Scientists attend conferences to connect with others in their fields and share their research findings, collaborate, and learn from one another. Scientific conferences are essential to the science enterprise and propel innovation.

One notable example of how scientific conference connections have led to groundbreaking therapies is the discovery of CRISPR/Cas9, the gene editing tool that has been developed into an FDA-approved therapeutic treatment for sickle cell disease and promises hope for treating other genetic disorders and cancers. The two 2020 Nobel Prize in Chemistry winners who discovered this powerful tool, Dr. Emmanuelle Charpentier and Dr. Jennifer Doudna, met at a scientific conference in 2011, established a meaningful collaboration, and published their partnership research findings in a seminal paper showing that it was possible to use an enzyme called Cas9 to precisely edit genes. This is just one story wherein collaborations that lead to groundbreaking discoveries were facilitated by scientific conference attendance.

Conference attendance reduces research redundancy. It allows scientists to share negative results and work in progress, serving to reduce waste. Conferences serve as a space for networking and career development, which greatly benefits early career scientists who will lead American scientific innovation in the years ahead.

The proposed changes make attending conferences an unallowable cost by default, requiring agency pre-approval for conference attendance. This greatly increases

administrative burden on researchers and funding agencies. It is also deeply impractical: the content focus of a scientific conference is usually not shared until the year of the conference. In funding applications, scientists cannot reasonably predict years in advance which conferences will be most beneficial to share their findings, especially before they have generated the results of the experiments and clinical trials they are proposing to conduct in federal research grant applications.

The proposed rulemaking is silent on how agencies are to determine whether to approve a conference attendance request. There are no criteria nor appeals processes within the rule, and therefore inadequate information for conference organizers to plan OMB-conforming conferences. With the additional administrative burdens on the attendee, this is a negative economic cost for compliance with an undefined rule.

Conferences are an essential functional component of many science societies and organizations, including ASPET. If the proposed changes are implemented, ASPET will not be able to support and host our annual conference. The proposed changes have broader economic implications as the proposed changes would impact the entire ecosystem that supports scientific conferences. This includes professional organizations that organize conferences, hospitality staff associated with conference venues, and all the economic benefits that accrue to cities that host scientific conferences. An economic analysis would show that this proposed rule would have major negative economic impacts across all these sectors. OMB should have already conducted these required analyses and should instead not rely solely on public comments.

For the reasons above, ASPET strongly recommends that OMB withdraws the revisions to § 200.432.

[§ 200.454] - Professional Society Dues

Scientists pay membership dues to scientific societies and professional organizations like ASPET for a variety of reasons. Their reasons include sharing their research, establishing and building a professional community, career development opportunities, and promoting advancements to the general public. Scientific societies contribute to efforts to shape scientific policy, advocate for scientific literacy, and educate future scientists (including K-12). The proposed changes will prohibit the use of funds to pay membership dues to a professional society, including societies for which membership may be necessary to fulfill grant award requirements.

Scientific research areas in alignment with award requirements change over time, as well as the focus area of research for a scientist. Following the science may take a scientist across many different fields and societies from broad focused societies to specialty societies, scientists need the flexibility to move between societies. The usage of award funds for maintaining membership in scientific societies that add reputation and community service opportunities to recipients should not be hindered.

Professional scientific societies like ASPET reinvest the dues received into the research community by sponsoring the peer review infrastructure, providing career development opportunities for scientists across all career stages, and building the infrastructure for scientists to connect, collaborate, and share their findings. These societies are beneficial to the scientific enterprise as they supplement and de-risk these investments using non-federal dollars. Science societies also invest in the future workforce through a variety of experiences by sponsoring mentorship programs that allow experienced scientists to guide and support early career scientists. Societies fund grants that support undergraduate, graduate, and postdoctoral trainees to attend professional meetings to expand their understanding of the field and create a community. Science societies ensure that there is a well-trained workforce within the biomedical research enterprise.

For the reasons above, ASPET strongly recommends that OMB withdraws the revisions to § 200.454.

[§ 200.461] - Allowable Publication Costs

Federally funded researchers have an obligation to communicate their research findings to the public; many federal agencies that fund ASPET members' research (such as the NIH) *require* that scientists publish their work in publicly accessible forums. These publications are vital for progress, and drive discovery and innovation. Such work should be disseminated in forums that are trusted by the community, and peer-reviewed journals are the gold standard due to their rigorous expert review. Preprint servers, such as bioRxiv, are not peer-reviewed and are not an adequate substitute for peer-reviewed journals.

The proposed changes make publication costs (including open access fees) unallowable unless required by statute or if preapproved by an agency. This is in direct conflict with NIH (and other agencies) public access policies found in the CHIPS and Science Act of 2022. It is also in direct conflict with the intended purpose of the proposed changes of increasing transparency and accountability. The immense amount of unnecessary administrative burden that will transpire from requiring agency preapproval will cause significant delays to disseminating research findings and will diminish the public's trust in science. Given the various science agencies' requirements to make published findings publicly accessible, the proposed rule will be very cumbersome for OMB to implement and is in direct conflict with the intended purpose of reducing recipient burden. NIH alone funds tens of thousands of active grants, all of which are subject to its public access policy. Requiring agency pre-approval for publication costs across that volume of awards would generate an administrative burden of enormous scale and directly contradict the proposed rule's stated goal of reducing recipient burden.

Scientific societies that publish peer-reviewed research journals, like ASPET, depend on revenue from publication charges. The loss of this funding will destabilize the business model we rely on to invest in the research community, supporting the long-standing integrity of the peer review process, rigorous publishing, and the broad dissemination of high-quality research. This ecosystem must thrive to maintain the pillars intended in the proposed changes of transparency and accountability.

For the reasons above, ASPET strongly recommends that OMB withdraws the revisions to § 200.461.

Conclusion

ASPET acknowledges and shares OMB's stated goals of transparency, accountability, oversight, and reduced burdens. While the current system is imperfect, ASPET does not agree with the Proposed Rule as stated. The backbone of American science is the rigorous, unbiased, merit-based systems for which science grants are approved, discussions are held at convenings, findings are published, and information is disseminated to the public. The Proposed Rule does not meet its stated goals of transparency, accountability, oversight, and reduced burdens. Instead, the Proposed Rule creates an opaque, politically motivated system that lacks the necessary oversight and accountability, while increasing administrative burdens on grant recipients and the agencies who are responsible for carrying out Congressionally mandated missions and directives. For the reasons stated above, ASPET strongly recommends OMB withdraw the proposed rulemaking in its entirety. In its place, OMB should inform the grant making agencies of its goals and let those agencies work with their respective communities to achieve those aims, not through wholesale edict, but meaningful public comment periods and engagement.

Respectfully submitted.