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July 10, 2026

The Honorable Russell Vought
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Regulation for Federal Financial Assistance, Docket Number: OMB–2026–0034

Submitted via regulations.gov

Dear Director Vought:

The AAMC appreciates the opportunity to comment on the proposed rule from the Office of Management and Budget (OMB) "Regulation for Federal Financial Assistance." This proposal would make significant changes to 2 CFR Part 200, currently known as the "Uniform Guidance," the primary framework for awarding and overseeing federal research grants and other forms of assistance. The AAMC is concerned that many of the proposed changes would destabilize the productive and effective relationship between the federal government and the academic biomedical research communities. Before making changes of this magnitude it is essential that OMB work with federal research agencies, grant recipients, and the scientific community to fully understand the impact of these proposed changes and to ensure that these changes do not introduce requirements that: 1) hinder agencies' ability to fund lifesaving research, 2) disincentivize researchers from proposing ground-breaking science for fear that research could be abruptly halted, endangering human participants and wasting years of U.S. investment, and 3) disrupt existing and future valuable collaborations between researchers across the globe and among institutions within the U.S. that keep the nation globally competitive. As this engagement has not been demonstrated in the rush to finalize this rule and for the substantive reasons set forth in this letter, the AAMC urges OMB to withdraw this proposed rule.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 163 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers

International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

The AAMC's member institutions receive the majority of extramural funds awarded by the National Institutes of Health (NIH) and grants from many other federal agencies to conduct scientific research and explore innovations in health care delivery. As a result, the AAMC represents a community that has substantial experience in the proposal and management of federal financial assistance. We share OMB's obligation to ensure the responsible stewardship of federal taxpayer dollars in advancing science, understanding disease, and improving health. To accomplish these ambitious goals and remain internationally recognized as a leader in science and health, the nation's academic research enterprise requires predictable, stable funding supported by Congress and administered by agencies with deep expertise in scientific process and management of federal awards. The foundation of this national commitment is a well-developed and effective system to identify the most promising ideas, invest in their exploration, and collect data to determine their impact, processes that can take many years of sustained investment.

In the preamble to this proposed rule, OMB asserts that the reasons to revise 2 CFR are to "(1) improve transparency, accountability, and oversight for use of Federal taxpayer dollars; (2) clarify the status of OMB's policies and requirements set forth in the 2 CFR regulatory text as an OMB regulation; and (3) reduce recipient burden."[1] The AAMC appreciates and supports these goals. However, the AAMC does not agree that the proposed revisions will achieve these goals. In fact in many cases these proposed changes would have the opposite impact from what OMB seeks to accomplish. Politically-driven decision making about the funding or abrupt termination of scientific grants and other forms of assistance would reduce accountability for the use of federal taxpayer dollars to advance science, improve health, and maintain the United States as a global leader in research, with all its benefits for the nation, including economic. Far from reducing recipient burden, the proposed regulations would substantially increase the burden on recipient institutions, researchers, and on each federal agency asked to implement a rigid set of regulations regardless of that agency's existing policies and Congressional mandates. Finally, the proposal contains vague language and undefined terms throughout that would make uniform and predictable implementation by agencies, a key component of transparency, impossible.

The AAMC provides herein comments and recommendations with respect to many of the proposed provisions. While the AAMC recognizes the broad impact of the proposal across many agencies and nearly every form of federal financial assistance, as representatives of the biomedical research and academic health system communities we focus our comments primarily on the impact of these changes on the federally-funded scientific enterprise.

As a whole, the preamble and text of the proposed rule fail to demonstrate how the revisions would meaningfully improve the current system for the awarding, oversight, and management of federal financial assistance, and in fact, would introduce ambiguity and instability into processes on which recipients and the American public currently rely. **Therefore, the AAMC urges OMB to rescind this proposal in its entirety.**

[1] 91 F.R. 31299.

I. Transformation of the Uniform Guidance into "Uniform Grant Regulations": 2 CFR Part 200

One of the purposes of this proposed revision is to change the existing Uniform Guidance into a set of regulations to be known as the Uniform Grant Regulations. Harmonization of federal regulations and processes can serve to decrease burden and increase consistency across agencies, but the existing Uniform Guidance has already accomplished this goal while taking into account the necessary differences among the agencies. This proposed change would not increase beneficial additional harmonization, but would instead serve to substantially curtail necessary agency discretion and treat the federal government as a monolith. Currently, each agency adopts the Uniform Guidance through a rulemaking process, allowing the public to engage with the agencies and better understand how each agency will implement the guidance consistent with existing policies or agency-specific direction from Congress through enabling legislation. In this proposed rule, not only will the Uniform Guidance be re-cast as a single set of agency-wide regulations, future revisions to these regulations would take place immediately without a process for each agency to seek public comment before adopting it (200.101(d)), further decreasing opportunities for input and clarifications between recipients of federal awards and agencies that will implement the changes. Since its establishment in 2013, the Uniform Guidance has been periodically revised through the rulemaking process to meet the needs of the federal agencies and recipient communities while serving the research enterprise as a whole. **The Uniform Guidance has already proven effective in harmonizing agency grant management efforts, and OMB should not transform it into the proposed Uniform Grant Regulations.**

II. Selection of Proposals for Federal Assistance: §200.205(b) Pre-issuance review, §200.205(c) Procedure for pre-issuance review; §200.205(d) Use of peer review

The federal system for funding scientific proposals that have the potential to accelerate American technology, develop new treatments for patients, or decrease the burden of disease rests on a key foundational principle: recognizing scientific merit requires scientific expertise. Since 1946, the NIH has relied on independent panels of subject matter experts to evaluate scientific proposals before funding decisions are made, a system described by NIH in 2025 as one established "to ensure independent, expert review free from inappropriate influence."[2] That explicit commitment remains active: in announcing its most recent peer review reforms, the agency reaffirmed that "centralized peer review will mitigate the potential bias by entirely separating the peer review and funding components of NIH."[3] Congress has also codified this principle by making peer review a legal precondition for funding: the NIH "may not approve or fund any proposal that is subject to technical and scientific peer review […] unless the proposal has undergone such review […] and has been recommended for approval by a majority of the members […] conducting such review."[4] This system is the internationally recognized standard for evaluating proposed research and a model for other nations' scientific enterprises.[5]

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[2] National Institutes of Health, *NIH Centralizes Peer Review to Improve Efficiency and Strengthen Integrity* (March 6, 2025), https://www.nih.gov/news-events/news-releases/nih-centralizes-peer-review-improve-efficiency-strengthen-integrity.
[3] *Id*.
[4] 42 U.S.C. § 289a–1(a)).
[5] See, e.g., the Canadian Institutes of Health Research, the federal research investment agency established in 2000 and modeled after the NIH. https://cihr-irsc.gc.ca/e/37792.html.

The AAMC's longstanding recognition of this effective process was most recently reiterated in a letter to the NIH this year regarding its proposed agency-wide strategic plan:

> "Merit-based peer review remains the bedrock of the NIH's process to ensure the agency is funding the highest-quality and most impactful scientific research. Experienced reviewers who are content experts in the relevant field of study are needed to ensure that the most meritorious research projects are funded. NIH should ensure that expert individuals are identified and appointed to serve on study sections and other advisory bodies and that the organization of the review process ensures a smooth review process that facilitates the identification of research projects that will advance discoveries."[6]

Despite a record of federally-funded scientific achievement sustained by a merit-based review process, the proposed rule would undermine the very system that has established the United States as a global leader in science and technology. The proposed rule does so by establishing a new "pre-issuance review" as an additional step of the merit review process. While the proposal asserts that "nothing in this part must be construed to create any rights to any particular level of review,"[7] the proposed language signals that federal agencies should be applying these criteria and principles to proposals "selected for funding." This indicates that the intended new review process would begin with selecting proposals through a scientific merit review and that those proposals recommended to be funded are then subjected to this "pre-issuance review," a political litmus test. Without regard to the already-determined scientific merit, these new factors would be applied and "may form the basis of a decision not to select an applicant to receive a Federal award."[8] The intent of the proposal to prioritize the political review of research over its scientific merit is underscored by the proposed addition that peer review recommendations "remain advisory, and are not ministerially ratified, routinely deferred to, or otherwise treated as de facto binding by senior appointees or their designees."[9]

Merit-based peer review, the anchor of the federal grant review process, has always been advisory. In the case of the NIH, committed scientists are asked to serve on study sections where they review, analyze, and discuss details of proposals, and make scientific recommendations to federal agencies with essential information about the proposals under review. The leaders of NIH institutes and centers, who are the designees of the NIH Director, a Presidential appointee, are already accountable for ensuring that all grants awarded meet the agency's funding priorities. The AAMC believes that incorporating the proposed pre-issuance review under the existing Uniform Guidance provision entitled "Federal agency merit review of proposals" suggests that OMB believes the merit of a grant application should be based primarily on its alignment with a single administration's priorities, not on the science it proposes. In expanding the length of the existing §200.205 by nearly five times to detail the pre-issuance review, the proposal serves to codify the executive orders and specific priorities of the current administration while minimizing the effectiveness of the current system for merit review, the system which has resulted in Nobel prize winning discoveries, life-saving treatments, and advances in foundational science.

The current provision §200.205 provides sufficient direction to federal agencies to establish an effective, merit-based system through which to evaluate scientific proposals. **The AAMC strongly urges OMB to**

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[6] See AAMC, *Re: Request for Information Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031* (May 12, 2026), https://www.aamc.org/media/89881/download?attachment.
[7] 91 F.R. 32249, Proposed 200.205(d).
[8] 91 F.R. 32249, Proposed 200.205(a).
[9] 91 F.R. 32212.

withdraw §200.205(b), §200.205(c), and §200.205(d), and to retain the existing §200.205, which reads in its entirety:

> Unless prohibited by Federal statute, the Federal agency must design and execute a merit review process of applications for discretionary Federal awards. The objective of a merit review process is to select recipients most likely to be successful in delivering results based on the program objectives as outlined in section § 200.202. A merit review is an objective process of evaluating Federal award applications in accordance with the written standards of the Federal agency. These standards should identify the number of people the agency requires to participate in the merit review process and provide opportunities for a diverse group of participants, including those representing underserved communities. The merit review process explained in this section must be described or incorporated by reference in the applicable funding opportunity. See appendix I to this part. See also § 200.204. The Federal agency must also periodically review its merit review process.

Pre-issuance review proposed principles - §200.205(b)

The AAMC is concerned that the proposed principles enumerated for pre-issuance review, would require senior political appointees to apply criteria that have no relationship to scientific merit to proposals already deemed meritorious by expert reviewers. The proposed rule would therefore result in the opposite of what OMB intends; it severs the connection between scientific merit and funding decisions that makes federal research investment productive. It would also result in significant delays in the grant award process, given that the proposed rule does not address how agencies will staff these new functions, how timelines would shift, the interaction of merit review with existing review cycles. When combined with the additional review criteria proposed in §200.206 (*Federal agency review of risk posed by applicants*), which could add a lengthy and intrusive inquiry into the personal affiliations of individual applicants, institutions would be left with a limited basis for planning or anticipating when awards will be issued. Further, the proposed rule fails to include a requirement that agencies document how the senior appointees "use their independent judgment" as required by the proposed pre-issuance review, an omission that is in direct opposition to the intended goal of increasing transparency. At minimum, any funding decision that departs from merit review-based recommendations should require a written, grant-specific explanation available to both the agency and the applicant that provides an explanation for why a senior appointee determined that a grant recommended for funding by scientific experts was not funded because of the pre-issuance review.

The proposed principles[10] that senior political appointees "must" apply in the review of each grant illustrate what could be used to replace expert scientific judgment. Through the application of these political standards, senior political appointees could essentially negate merit review, creating a system in which the scientific enterprise is constantly beholden to the shifting focus during and between administrations. Scientific progress requires long-term investment in research so that scientists can conduct thorough investigations, which often take years to complete. The AAMC is concerned that a political review of grant proposals would destabilize the American research enterprise, especially if political review were combined with the proposed termination provision, which would allow grant termination based on the "national interest" at the time of termination, not at the time of the grant award or connected to a Notice of Funding Opportunity. (See below, proposed §200.340.) Codifying the use of the U.S. scientific enterprise as a means to accomplish political outcomes would make it routine for each new administration to terminate any grants funded during a previous administration, regardless of impact

[10] Proposed as §200.205(b).

on the research or scientific progress. These proposed changes threaten U.S. competitiveness, scientific progress, advancements in medical care, and the economic growth resulting from a healthy research enterprise.

Proposed pre-issuance review principle 1: Advancing the President's policy priorities—The proposed rule requires that senior appointees or their designee apply the "principle" that every discretionary award "must, where applicable, demonstrably advance the President's policy priorities."

Federal science agencies fund a broad spectrum of research. In the case of biomedical research this spectrum runs from basic molecular biology to clinical trials to population health studies. The majority of the research the federal government funds is not tied to any President's stated policies, but rather operates in service of the long-standing goal for the government to fund science which improves the health of all Americans. While Presidents have historically set certain scientific priorities for which a finite portion of federal research funds are directed, the remainder of the federal science budget is administered by the leadership at federal agencies. These leaders work diligently to advance scientific progress and invest federal resources as effectively as possible, based on years of assessment and evaluation of how to optimally structure a research portfolio which both explores new areas for discovery and expands critical ongoing work.

Tying all new awards to "advanc[ing] the President's policy priorities" is unsustainable. When a President *has* identified scientific priorities, the existing process for funding research that demonstrably advances those priorities is effectuated through the agency's Notice of Funding Opportunity. Using this mechanism, an agency can set forth specific criteria by which a proposal can be assessed at the merit review stage, without the need for a second, "pre-issuance" review. When a President's policy priorities are not specifically scientific priorities, it is not appropriate to require a political review process by which a senior appointee evaluates a meritorious scientific proposal against a host of unrelated policy positions.

This pre-issuance review principle (200.205(b)(1)) should not be included in a final rule. The provision is 1) overbroad, suggesting that this review should seek to advance all policy priorities, not just scientific priorities, 2) redundant, given existing processes for advancing an administration's scientific priorities through Notices of Funding Opportunity and 3) difficult to administer absent specific delineation of any President's scientific priorities.

Proposed pre-issuance review principle 2: Defined categorical prohibitions—The proposed rule would prohibit the use of federal funds for activities tied to specific issues the administration has designated as contrary to its domestic policy priorities—priorities that have no bearing on scientific merit or research quality. Codifying a single administration's policy prohibitions in this proposed government-wide regulation is legally and scientifically unsound and internally inconsistent within the proposed rule. Proposed Principle 1, which requires political appointees to ensure that awards demonstrably advance "the President's policy priorities" ties funding criteria to whichever administration is in power; Principle 2 locks in the current administration's ideological prohibitions permanently regardless of what a future President's priorities may be. Several of the proposed criteria that senior appointees would be required to apply have no standard or fixed meaning. Terms like "anti-American values" and "intentional proxies for race" are undefined and would be impossible to use in evaluating grant applications. Because these terms

would be subject to the interpretation of the political appointee undertaking the review, their application will inevitably vary across agencies, reviewers, and administrations, directly undermining OMB's stated goals of consistency and transparency.

Unlike executive orders and other actions used to implement an administration's priorities while in office, these proposed regulations seek to commit future administrations to specific policy priorities, absent future amendment through notice-and-comment rulemaking, a time-consuming activity for the executive branch and for the American public. **Assuming that the intention of these proposed regulations is to bind future administrations to the same requirement to advance its own policy priorities through the scientific grant awarding process, the principle (200.205(b)(2)) should not be included in a final rule as it requires a political review to advance specific policy priorities rather than providing direction on how to identify the policy priorities in place at the time of the review.**

Proposed pre-issuance review principle 3: Reward lower indirect costs [200.205(b)(3)] The proposal seeks to codify a requirement that federal agencies apply the following: "All else being equal, preference for discretionary awards should be given to institutions with lower indirect cost rates." These indirect, or facilities and administrative,[11] cost rates assigned to institutions that receive federal funds are developed by the U.S. government through engagement with each institution and follow specific instructions and considerations. The rates are routinely audited, periodically reassessed, and represent a only a portion of the actual costs that an institutions incurs when conducting federally-funded research. The indirect cost rate for an institution is based on documented historical costs and cost analysis studies, and reflects the resources and facilities at that particular institution. Indirect cost rates do not reflect how expertly, efficiently, or effectively a research project will be carried out. Further, the qualifier "all else being equal" does not ameliorate the core flaws of this provision. Scientific research is complex, as are the proposals requesting funding for this work; in no situation could it be objectively determined that "all things" are equal between two proposals. As a result, this provision will either never be applicable or will be interpreted as implied direction from OMB that agencies should always find a way to direct federal awards towards those institutions with lower indirect cost rates. Directing federal agencies to award grants based on the government-developed indirect cost rate is both scientifically and procedurally inappropriate. **The proposed provision (200.205(b)(3)) should be eliminated and not included in a final rule because it would add a criterion to funding decisions that is unrelated to the scientific merit of a proposal, is largely out of the control of the applicant institution, and undermines the very process that OMB has established to set indirect costs.**

Proposed pre-issuance review principle 4: Assessments of recipients' likely scientific outcomes—The proposed rule asserts that political appointees should issue awards to a "broad range of recipients" without further instruction and then directs the appointee to award research grants to "a mix of recipients likely to produce immediately demonstrable results and recipients with the potential for potentially longer-term, breakthrough results." Federal agencies routinely balance their portfolio of awards to fund institutions and investigators across the U.S. conducting a wide variety of research projects.. For a regulation that seeks to provide binding rules applicable to all agencies, the term "broad range of

[11] AAMC, *Facilities & Administrative Costs* (accessed on July 7, 2026), https://www.aamc.org/about-us/mission-areas/biomedical-research/facilities-administrative-costs.

recipients" is vague and difficult to implement or enforce. This ambiguous language could be used by a political appointee to overturn a decision to award a research grant on the basis that the recipient institution wouldn't contribute to a "broad range of recipients." Without defined criteria, vesting this discretion in a political appointee further removes the grantmaking process from merit-based review.

The decision to award grants based on whether the senior political appointee believes that the research will "produce immediately demonstrable results" is equally problematic. Science does not operate on pre-determined timelines or outcomes, and it would be impossible to categorize research proposals based on desired results and when those results would be available. In broad terms, clinical trials with planned enrollment and testing over a period of years will be of longer duration than a planned rapid analysis of an existing data set, but most research would be expected to fall between these extremes. The most consequential biomedical advances of the past century emerged from years of basic research with no "immediately demonstrable" application. Novel discoveries often require advances in experimentation and the development and optimization of protocols and reagents, all of which take significant time and effort. The mRNA vaccine technology that enabled the development of COVID-19 vaccines through Operation Warpspeed, one of the most consequential public health achievements of the past several decades, originated from basic research that began in the 1970s.[12] Similarly, research on the GLP-1 molecule, now the primary component of weight-loss and diabetes drugs including Ozempic and Wegovy, began decades before anyone imagined the research would result in a treatment for obesity.[13] Under a pre-issuance review standard assessing whether proposals would lead to "immediately demonstrable results," the fundamental research underlying these advancements might not be considered.

Proposed pre-issuance review principles 5, 6, & 7: Scientific Standards and Institutional Conduct

The proposed rule would also direct political appointees to prioritize funding to institutions which have demonstrated a commitment to "Gold Standard Science" and a "commitment to rigorous reproducible scholarship." Neither standard in the proposed rule is measurable or definable, nor is there any indication as to how a senior political appointee would begin to assess an institution's commitments to these vague terms. "Gold Standard Science" is not only undefined in any regulation, proposed or existing, it has no concrete definition that could be used to assess an institution or a grant proposal. Even the preamble to this proposed regulation puts the term "Gold Standard Science" in quotes, in an acknowledgement that this is a term first used in a May 23, 2025 executive order[14] without connection to any objective, recognized standard. Without any guidance to the senior appointees, these proposed "principles" could be used arbitrarily to exclude any institution from receiving a federal research grant, regardless of the scientific merit of the proposal or type of research.

Federal agency review of risk - §200.206 (b)(vii) & (b)(viii)

Protecting the integrity of federal research programs is essential to maintaining public trust and the credibility of science, and AAMC has consistently supported that goal. The proposed rule expands the

[12] Johns Hopkins Bloomberg School of Public Health, *The Long History of mRNA Vaccines* (Oct. 7, 2021), https://publichealth.jhu.edu/2021/the-long-history-of-mrna-vaccines.
[13] "GLP-1 drugs are transforming diabetes, obesity and more. Could a Nobel be next?" STAT (Sept. 30, 2023) https://www.statnews.com/2023/09/30/weight-loss-ozempic-nobel-prize-science/.
[14] Exec. Order No. 14303, 90 F.R. 22601 (May 23, 2025).

risk factors federal agencies already consider when assessing applicants, proposing four new items, each of which raises substantial concerns.

- §200.206(b)(ii) would define awards "that are in excess of awards the applicant typically implements." It is already part of the evaluation of NIH to consider the ability of an institution or applicant to effectively manage the requested federal funds,[15] adding this as a risk factor may disincentivize institutions from seeking to expand smaller or new research programs by applying for grants that exceed the size of their past federal awards.
- §200.206(b)(vii) would add a review of the applicants' "history of questionable practices" which would include plagiarism, and "discredited or non-replicable studies published by the applicant or its staff," intimating that a study that has not been replicated or for which an attempted replication study was unsuccessful or arrived at different result is a "questionable practice." It suggests that the publication of a study that was "discredited" (an undefined term) or not replicated is equal to scientific misconduct, akin to plagiarism.
- §200.206(b)(viii) would add ask a risk assessment factor "memberships and affiliations with organizations engaged in activities that violate Federal law, undermine public safety or national security, advocate for the overthrow of the United States Government." Every element of this provision is overly broad, vague, and subject to interpretation so could not be implemented in a consistent and fair manner. Further, the inquiries and activities required by this provision raise concerns about potential violations of individual investigators' privacy and rights under the First Amendment of the U.S. Constitution.
- §200.206(b)(ix) would add compliance with section 117 of the Higher Education Act, which describes receipt of foreign gifts and contract disclosures. Inclusion of this element exceeds the authority of OMB and would be impossible for individual federal agencies to implement. Agencies are not in a position to assess applicants' compliance with a federal statute that already includes compliance and enforcement mechanisms.

We strongly recommend OMB take the following action with respect to these four proposed additions:

- §200.206(b)(ii): Remove.
- §200.206(b)(vii): Remove entirely or: Define a limited lookback period for the "history of questionable practices" factor; clarify that the provision applies only to the applicant investigator, not to the entirety of the applicant institution.; replace "plagiarism" with "debarred from receiving federal awards as a result of a finding of research misconduct made in accordance with the Public Health Service Policies on Research Misconduct"[16] and; eliminate subsection (B) to eliminate the undefined and non-objective terms "discredited or non-replicable."
- §200.206(b)(viii): Remove.
- §200.206(b)(ix): Remove.

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[15] "Factor 3: Expertise and Resources (Investigator, Environment), to be evaluated as either sufficient for the proposed research or not (in which case reviewers must provide an explanation)" https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review/framework

[16] 42 C.F.R. § 93.234 (defining "research misconduct" as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results").

- Consistent with OMB's stated goals of transparency and accountability, require agencies to identify the specific information relied upon and provide applicants an opportunity to respond before any adverse determination is made as a result of any elements of §200.206.

III. Termination and Suspension of Grants: §200.340

The AAMC shares OMB's commitment to transparency, accountability, and the integrity of federal research investment. Federal agencies should have meaningful authority to terminate awards that are not meeting their scientific or programmatic objectives, to address noncompliance that materially impacts the scientific progress or the safety of human participants in the research, and to ensure that federal funds are not supporting institutions with inadequate research integrity. The Uniform Guidance already provides that authority in its current form.[17] The proposed rule would expand that authority permitting agencies to terminate awards at any time based on a determination that the project no longer reflects shifting agency priorities or "the national interests as it exists at the time of termination."
Research is not an activity that can be paused and resumed at a whim. When a grant is terminated after initiation, research teams dissolve, animal studies cannot be continued, and patients enrolled in clinical trials are left without a path forward with potentially no alternative care pathway.

As the nation learned from the unprecedented sudden terminations of thousands of NIH grants in early 2025,[18] the disruption from a single termination can have widespread, negative, and lasting impact on scientific fields. The 2025 terminations halted mid-stream projects that had already generated over 14,000 publications and 608,000 citations,[19] and terminated long-term studies in ways that "undermine[] the infrastructure that was being built to map long-term trends that would have generated meaningful insights about health outcomes over time."[20]

As AAMC documented in the recent brief, *Navigating a Shifting Federal Research Landscape*: *Perspectives on Recent Changes in Research Compliance and Policy*, our member institutions have direct experience with the consequences of grant terminations—halted clinical trials, reductions in staff, and interrupted training programs.[21] Shifting political priorities are not a legitimate basis for ending a research award that is otherwise performing as intended. This proposed rule, if finalized as drafted, would allow routine termination of scientifically sound, productive research studies. In addition to the destabilizing impact this would have on ongoing research, the prospect of sudden termination could have a detrimental effect on researchers' willingness to proposing ground-breaking ideas in response to federal Notices of Funding Opportunity. Additionally, it could reduce enrollment in clinical trials as people learn that research they are considering participating in could be halted and abandoned at any time, rendering meaningless the risks that they took and the time they invested.

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[17] 2 C.F.R. § 200.340.
[18] AAMC, *Tracking NIH Funding* (Updated July 6, 2026), https://www.aamc.org/about-us/biomedical-research/publication/tracking-nih-funding.
[19] *How the 2025 NIH Grant Terminations Varied by Researchers' Demographic Groups*, 122 PNAS e2527755123 (2026), https://www.pnas.org/doi/10.1073/pnas.2527755123.
[20] AcademyHealth, *Situation Report: NIH Grant Terminations and Senate Funding Bill Tensions* (Mar. 13, 2025), https://academyhealth.org/blog/2025-03/academyhealths-situation-report-nih-grant-terminations-and-senate-funding-bill-tensions.
[21] AAMC, *Navigating a Shifting Federal Research Landscape* (June 2026), https://www.aamc.org/media/90506/download; see also AAMC, *Impact of NIH Grant Terminations: Clinical Trials* (May 2025), https://www.aamc.org/about-us/mission-areas/biomedical-research/publication/impact-nih-grant-terminations.

We recommend that OMB eliminate the proposed changes to §200.340 and retain termination as a remedy reserved only for circumstances in which the research is not progressing in accordance with the award, where continuation poses a risk of harm to research participants,[22] or where the recipient has materially failed to comply with the terms and conditions of the award.[23]

We urge OMB to consider the following:

- ***National Interest.*** Remove "national interest as it exists at the time of termination" as an independent basis for discretionary termination. Because the assertion of what constitutes a national interest may change suddenly during an administration or with each new administration, a researcher would be reluctant to propose a complex, multi-year project knowing that the research could be halted without notice at any time.
- ***Written Explanation.*** Require a detailed, individualized written explanation for any termination which would be sufficient to permit meaningful review, with administrative errors addressed through corrective action rather than termination. A fact-specific explanation requirement would also ensure that technical or administrative noncompliance is *not* used as a basis for terminating an otherwise meritorious award;
- ***Administrative Appeal***. Restore the right of administrative appeal, which would allow institutions to seek a timely review of a termination before a decision becomes final. The profound, deleterious impact of a grant termination on scientific progress, on the individuals involved in human subjects research, and on the research workforce connected with the grant, warrants careful consideration before such an extreme action is taken. It is in the interest of the federal government to seek other remedies prior to terminating a grant, an action which could result in wasting years of investment of federal funds from taxpayers.
- ***Human Subjects Protection.*** Require agencies to provide for the timely and orderly discontinuation of human subjects research, including continued funding sufficient to protect enrolled participants before any termination takes effect. The proposed rule contains no provision which addresses termination of active clinical trials and could compromise institutions' obligations to protect human subjects under the Common Rule, 45 CFR Part 46.

IV. Foreign Collaborations: § 200.202(e) Eligibility of Entities for Research; §200.220 Prohibition of Using Federal Funds for Foreign Collaborations

The proposed rule requires that all research and development awards go to U.S. entities, with foreign awards permitted only where an authorized or agency head determines a "compelling interest" exists, a term the rule does not define. The preamble for the proposed rule states that the "domestic-first" framework seeks to "strengthen alignment between Federal research and development funding and national priorities."[24] A "domestic-first" framework, if interpreted by agencies as "domestic-only" research funding, is incompatible with the inherent interconnected nature of emerging health threats and critical biomedical research. The AAMC submits that maintaining the U.S. as a global leader in biomedical research is itself a national priority, one the proposed rule would directly undermine.

[22] 45 C.F.R. Part 46.
[23] 2 C.F.R. § 200.340.
[24] 91 F.R. 32,211.

The diseases that have the potential to threaten American lives (e.g., pandemic pathogens, drug resistant bacteria, emerging infectious threats), cannot be studied solely within the confines of the U.S. As the National Academies of Sciences, Engineering, and Medicine have stated, "[a]n effective surveillance system is critical to detect and monitor infectious disease both within the U.S. and globally."[25] Further, a 2025 *Nature Medicine* analysis confirms that withdrawing U.S. funding from international programs directly reduces the quantity and quality of global health knowledge produced—knowledge that protects American lives and sustains the nation's scientific leadership.[26] That finding cuts to the heart of the matter: America's global health leadership is inseparable from the global research relationships that make it possible.

Finally, OMB asserts that this provision advances "national priorities," but the national priority that is truly at stake is America's standing as the world's preeminent leader in science, including but not limited to biomedical research. Withdrawing from long-standing global partnerships does not strengthen alignment between federal research funding and national priorities. Instead, it jeopardizes the very goals and interests this provision purports to serve. The AAMC made this case to Congress in its 2021 Pandemic Preparedness Recommendations, urging sustained investment in international research infrastructure as essential to U.S. health security. [27] We also reiterated this point in the AAMC's recent comments to NIH, urging recognition that "[r]esearch is also inherently global. NIH policies and resources should allow for and facilitate productive international collaboration on scientific issues and recognize the essential contributions of our international partners and collaborators."[28]

The AAMC urges OMB to withdraw § 200.202(e). If OMB retains this approach, we strongly recommend at minimum the establishment of a streamlined, program-level determination for compelling interests in international programs, particularly in global health, infectious disease, and pandemic preparedness, rather than requiring award-by-award justification. We also encourage OMB to define all key terms including "compelling interest," "national interest," and "justified" so that institutions can reliably know whether their programs qualify.

§200.220 Prohibition of Using Federal Funds for Foreign Collaborations

The AAMC fully supports robust research security measures and shares OMB's commitment to protecting federally funded research from genuine foreign threats. AAMC, along with many other organizations and academic institutions, has worked in collaboration with the federal government for many years to inform the development of policies and regulations which balance threats to security with the need for open science and international collaboration to advance discovery and spur innovation. The proposed rule's government-wide prohibition on collaborations with "covered foreign countries" or "covered foreign entities," however, moves in the wrong direction. A country-level prohibition cannot distinguish between institutions that present genuine security risks and those that do not, and a broad prohibition that

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[25] Institute of Medicine, *Informing the Future: Critical Issues in Health* (National Academies Press, 2d ed. 2003), https://www.ncbi.nlm.nih.gov/books/NBK216159/.
[26] *Global Distribution of Research Efforts, Disease Burden, and Impact of U.S. Public Funding Withdrawal*, Nature Medicine (Aug. 2025), https://www.nature.com/articles/s41591-025-03923-0.
[27] AAMC Washington Highlights, *AAMC Submits Pandemic Preparedness Recommendations* (July 2021), https://www.aamc.org/advocacy-policy/washington-highlights/aamc-submits-pandemic-preparedness-recommendations.
[28] AAMC, *Re: Request for Information Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031* (May 12, 2026), https://www.aamc.org/media/89881/download?attachment.

forecloses legitimate and collaborative relationships is incompatible with the inherent global nature of biomedical research nor does it support the government's "domestic-first" leadership goals.

Consistent with our recommendation on §200.202 (e) above, we urge OMB to withdraw this provision as potentially duplicative or conflicting with existing export control and foreign influence policies, including existing Export Administration regulations,[29] NIH's Foreign Influence Policy,[30] and the National Science Foundation (NSF) Research Security Program.[31]

If OMB retains this provision, we recommend that it establish a clear, expedited process—with defined timelines and transparent criteria— through which institutions can obtain national-interest determinations for federally-funded research across all agencies. The application of §200.220 to overhead costs as it relates to covered collaborations would significantly impact how institutions account for and report their federally funded research portfolio. Rather than reducing administrative burden, a stated goal of this rulemaking, this expansion would impose extraordinary compliance costs, including time and resources spent inventorying all international collaborations and agreements, implementing due diligence processes for vetting foreign partnerships, and determining which overhead costs are attributed to each. The research security goals this provision pursues are legitimate, but a categorical country-level prohibition imposes extraordinary compliance burdens without advancing the intended goals of §200.220, and at the cost of the international partnerships necessary for American research, safety, and security.

V. Allowable Costs: §200.432 Conference Costs; §200.454 Memberships, Subscriptions, and Professional Activity Costs; §200.461 Publication Costs and Open Access Fees

In a substantial change that would negatively impact the ability of American scientists to discuss and disseminate the results of federally-funded research, the proposal would prohibit the use of federal award funds for a host of essential activities which are necessary for the field of science and for development of the scientific workforce.

The NIH has recently engaged the research community in a thoughtful process for considering the extent to which publication fees should be allowable costs in research awards.[32] Finalizing the proposed rule as drafted would entirely negate the NIH's work to find the right balance between responsible stewardship of federal research funds and the ability to effectively disseminate the results of federally-funded research.

It is not possible nor reasonable to assume that all institutional recipients of federal research funding will be able to absorb these costs. The result of these proposals will not be a cost shifting from federal funds to institutional funds. It will be a shift from participation in these essential activities to grant-by-grant decisions about which investigators will be able to participate in scientific conferences, which research will be published in journals seen by key scientists, and which research groups have the advantage of broader access to subscriptions and professional activities. This change will not have a uniform impact across the research community and threatens to disproportionately disadvantage early career researchers, smaller or less well-resourced institutions, and organizations without additional state or philanthropic funding to cover these costs. **We urge OMB not to include these provisions in a final rule, instead**

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[29] 5 C.F.R. Parts 730–774.
[30] National Institutes of Health, *Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021* (NOT-OD-21-073).
[31] 42 U.S.C. § 6605.
[32] National Institutes of Health, *Request for Information on Maximizing Research Funds by Limiting Allowable Publishing Costs* (NOT-OD-25-138).

allowing agencies to retain discretion over the allowability of costs that are essential to the dissemination of scientific results and the development of scientific collaborations.

VI. Health Disparities Research §200.218 (Prohibition of using Federal awards to promote or support theories of disparate-impact liability)

The AAMC strongly recommends the withdrawal of §200.218. This proposed provision directing agencies, to ensure federal that awards are administered in a matter that does not "promote or support theories of disparate-impact liability" is unnecessary, potentially conflicts with statutes that obligate agencies to address the activities it seeks to prohibit, and could be misinterpreted by agencies and by potential applicants to imply that the fields of health disparities and health equity research should not and will not be supported by the federal government.

The Minority Health and Health Disparities Research and Education Act of 2000,[33] established the NIH center later elevated to the National Institute on Minority Health and Health Disparities for the express purpose of conducting and supporting "research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities" and requires NIH to maintain a comprehensive plan and budget for health disparities research across its institutes and centers.[34]

Health disparities research follows a well-established three phase progression: detecting differences in health outcome across population groups, understanding the determinants that produce those differences, and designing interventions that reduce or eliminate them. [35] Statements from the NIH's current leadership has recognized this same trajectory, stating that the agency will prioritize research that "goes beyond measuring health disparities to focusing on solution-oriented approaches"—including evaluation science, implementation science, health policy research, and dissemination science aimed at testing, scaling, and implementing interventions that improve poor outcomes.[36] Achieving those ambitious federal goals requires methodological breadth through both qualitative and quantitative research approaches, including intersectional frameworks that capture how race, sex, geography, and other factors shape health outcomes. The proposed provision §200.218 threatens to halt this progression by codifying in federal regulation a confluence of vague terms and misconstrued doctrine, the result of which could have federal agencies prohibit the very solutions-focused research that NIH has identified as the field's priority.

Language prohibiting the use of federal funds to "promote or support theories of disparate-impact liability" could be interpreted by various agencies as being broad enough to include a blanket prohibition not only research but activities, programs and services across all the sectors impacted by all federal agencies. Federal law *already requires* institutions to examine outcomes across populations. For example, NIH's clinical research inclusion policy—from the NIH Revitalization Act of 1993[37]— requires that federally funded research include women and minorities as participants and that results are analyzed

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[33] Pub. L. 106-525, codified at 42 U.S.C. § 285t.
[34] *Id*.
[35] Kilbourne AM, Switzer G, Hyman K, Crowley-Matoka M, Fine MJ. *Advancing health disparities research within the health care system: a conceptual framework.* Am J Public Health. 2006 Dec;96(12):2113-21. doi: 10.2105/AJPH.2005.077628.
[36] National Institutes of Health, *Advancing NIH's Mission Through a Unified Strategy* (2025), https://www.nih.gov/about-nih/nih-director/statements/advancing-nihs-mission-through-unified-strategy.
[37] NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (codified in relevant part at 42 U.S.C. § 289a-2).

subgroup.[38] The U.S. Department of Health and Human Services' regulations under the Age Discrimination Act require institutions to avoid policies with disproportionate effects on the basis of age.[39] Beyond these federal obligations, accreditation standards, state anti-discrimination laws, and health care payor contracts routinely require institutions to monitor and support whether their programs are reaching all populations equitably.[40]

The proposed rule provides no guidance on how institutions are to satisfy these independent, yet coexisting obligations, leaving them without a workable path to full compliance. Nor does it specify where permissible internal analysis ends and prohibited "promotion or support" begins, a line that is particularly difficult to draw at research institutions where federal funding is deeply interconnected with institutional operations through indirect costs, shared facilities, and faculty with both federally funded and institutional responsibilities.

The consequences of this provision extends far beyond the biomedical enterprise—to every American who depends on it for their care. Heart disease, cancer, diabetes, maternal mortality do not affect Americans equally; they fall unfairly and disproportionally on specific communities, often for reasons rooted in access, environment, and circumstance rather than biology alone. The NIH Director has stated that the agency wants research that moves beyond measuring these disparities toward solutions that fix them—but the potential prohibition on the very inquiry needed to identify those disparities would make that goal impossible to achieve. **Accordingly, the AAMC urges OMB to eliminate proposed §200.218, a prohibition on "using Federal awards to promote or support theories of disparate-impact liability."**

VII. Effective date

The preamble indicates that OMB intends to finalize this proposed rule with an effective date of October 1, 2026, just 4 months from the publication of the proposed rule. This is a remarkably short period of time in which to undertake the review of comments, deliberate on potential revisions to the proposal, develop and publish the final text and preamble, and implement all requirements by the three dozen agencies that would be bound by the regulations. Not only does an insufficient implementation timeframe lead to uncertainty and inconsistent application of the rule's requirements, it would significantly disrupt existing funding and budget cycles for the recipients of federal assistance, most of whom do not operate on the federal government's fiscal year.

This rushed timeframe for a complex rulemaking process includes an unusually brief comment period of 45 days. Despite many requests, OMB has declined to extend the comment period to allow sufficient time for thoughtful review of the proposed rule. Further, a draft guidance document from the NSF published June 24, 2026 presents a document that fully incorporates the language from this proposed rule without waiting for the final rule to be published.[41] Taken together, these actions signal an intention to move the proposed rule into regulation and implementation without meaningful revision or regard for the many thousands of comments submitted to OMB in response to this proposed rule. Under this timeline,

[38] 2 U.S.C. §289a-2.
[39] 45 C.F.R. §91.12.
[40] *The Journey Toward Health Care Equity: Accredited Hospitals' Alignment with Joint Commission Health Care Equity Standards Preimplementation*, Health Equity (Oct. 23, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11512081/.
[41] NSF, *Guidance on Financial Assistance* (June 24, 2026), https://www.regulations.gov/document/NSF-2026-OTR-0001-0003.

agencies would have a maximum of two months to implement the most substantial changes since the Uniform Guidance was issued, and such an insufficient and impractical two month implementation timeframe would only occur if OMB finalized the rule within days of the comment deadline for the proposed rule.

By way of comparison, when the Uniform Guidance was last revised, OMB first issued a Request for Information on February 9, 2023, asking the public for input on necessary changes to improve the Uniform Guidance.[42] A proposed rule was issued 8 months later,[43] and the final rule was issued April 22, 2024[44] with a requirement that federal agencies adopt and implement the changes by October 1, 2024. The revisions were far less extensive than the sweeping revisions proposed here, and yet required a process of nearly 20 months to complete. **The AAMC again urges OMB rescind the proposed rule in its entirety. If the proposed rule is instead substantially revised to address the thoughtful and significant concerns expressed from across the biomedical research community, we ask that the final rule include an implementation date of no less than 12 months from the date of publication of the final rule, giving agencies sufficient time to amend any policies and procedures with sufficient notice to recipients.**

The United States' global scientific leadership is a direct result of the merit-based, internationally connected, and scientifically rigorous research enterprise that federal investment has supported for decades. The AAMC remains fully committed to constructive engagement with OMB on any of the issues or recommendations in these comments and would be pleased to provide additional information or clarification. For questions, please contact Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel or Daria Grayer, MA, JD, Regulation and Policy Leader.

Sincerely,

Elena Fuentes-Afflick, MD, MPH
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

[42] 88 F.R. 8480.
[43] 88 F.R. 69390.
[44] 89 F.R. 30046.