WashU

WASHINGTON UNIVERSITY IN ST. LOUIS

Comments on OMB Proposed Rule: Revisions to the Uniform Guidance

I. INTRODUCTION AND INSTITUTIONAL INTEREST

Washington University in St. Louis ("WashU" or "the University") respectfully submits these comments in response to the Office of Management and Budget's ("OMB") proposed revisions to the Uniform Guidance at 2 CFR, published May 29, 2026.

WashU is among the nation's leading research universities and academic medical centers. The University enrolls nearly 16,000 students and employs more than 23,000 people, including approximately 4,500 faculty members. As the St. Louis region's second-largest employer, WashU advances discovery and innovation across the biomedical, physical, social, and behavioral sciences and addresses scientific, economic, and public health challenges locally, nationally, and globally. Twenty-six Nobel laureates have been associated with the University, reflecting its longstanding commitment to excellence in research, education, and scholarship.

WashU Medicine is consistently recognized among the nation's premier academic medical centers. Its more than 2,000 faculty physicians provide care at over 130 locations and exclusively staff Barnes-Jewish Hospital and St. Louis Children's Hospital, the academic hospitals of BJC HealthCare. Through its partnership with BJC HealthCare, WashU Medicine also serves as a leader in cancer research and care through Siteman Cancer Center, the only National Cancer Institute-designated Comprehensive Cancer Center in Missouri. WashU Medicine supports more than 2,500 active clinical trials and is internationally recognized for translating discoveries from basic science and engineering into improved patient care and health outcomes.

The University receives more than $800 million annually in federal awards, primarily from the National Institutes of Health, National Science Foundation, Department of Energy, and Department of Defense. These investments support research that advances scientific knowledge, strengthens U.S. competitiveness, improves public health, drives innovation, and contributes to economic growth. As one of the nation's largest recipients of federal research funding, WashU has extensive experience administering federally sponsored research and a substantial interest in ensuring that revisions to the Uniform Guidance strengthen accountability and stewardship while preserving the stability, predictability, and collaborative environment necessary for scientific progress.

The stakes are not primarily institutional. Federally funded research has helped Americans live longer, recover from illnesses that were once fatal, farm more productively, and benefit from technologies that began as government-supported science. When a research grant succeeds, the return does not accrue primarily to the university; it accrues to patients who receive a new treatment, industries that commercialize a discovery, communities that benefit from innovation,

and the country that maintains its scientific and economic leadership. WashU's concern with the proposed rule is that several provisions would weaken this engine of national benefit in the name of reforms that do not advance the national interest as they purport to do.

WashU also recognizes the importance of reducing unnecessary administrative burden in federal research administration. In partnership with Vanderbilt University, WashU developed the white paper *Easing the Burden: A Framework for Federal Regulatory Reform in Higher Education*, which examined the administrative and financial costs of federal compliance across both institutions. That analysis estimated WashU's federal compliance burden at approximately $369 million annually, representing roughly 12% of nonclinical expenditures. This experience informs the University's comments. WashU does not oppose regulatory reform; rather, it supports reforms that reduce unnecessary burden, strengthen stewardship, and preserve accountability without destabilizing active research or shifting unbounded financial and operational risk to recipients.

The Vanderbilt-WashU analysis also underscores that regulatory reform is both necessary and achievable. Federal regulations play an important role in ensuring accountability, integrity, and stewardship across the research enterprise. At the same time, reform efforts are most effective when they reduce duplication, clarify inconsistent requirements, and allow institutions to focus resources on mission-critical research, education, and innovation. WashU therefore supports reforms that streamline compliance processes, improve consistency across agencies, and reduce low-value administrative work while preserving appropriate oversight and accountability.

The proposed rule would substantially rewrite the regulatory framework governing the administration of these awards. The University appreciates OMB's stated objectives of strengthening stewardship of taxpayer funds, increasing accountability, and reducing administrative burden, and offers the following comments regarding provisions that raise significant practical, operational, and scientific concerns, together with recommended modifications.

Several of the proposed revisions would not merely adjust administrative processes; they would alter the conditions under which federally funded research can be selected, continued, suspended, or terminated. WashU supports reforms that improve accountability, transparency, stewardship, and efficiency. However, OMB should not adopt provisions that replace clear standards with broad discretionary authority, introduce non-merit-based criteria into scientific decision-making, or impose operational requirements without adequate justification, transition time, or consideration of less burdensome alternatives. In those respects, several provisions would fall short of the requirements for reasoned agency decision making if adopted as proposed.

In particular, OMB should explain why existing oversight mechanisms, including agency-specific award conditions, noncompliance-based termination, recipient internal controls, Single Audit review, performance reporting, and targeted risk-based monitoring, are insufficient to address the concerns identified in the proposed rule. OMB should also consider less burdensome alternatives before adopting government-wide requirements that would materially alter award selection, suspension, termination, payment, cost allowability, and recipient compliance obligations. Without that analysis, several provisions would not only be problematic as a matter of policy, but would also fall short of the standards for reasoned agency decision-making.

These concerns are heightened because application of the proposed rule is tied substantially to current Administration policy priorities. If adopted unchanged, future administrations would be able to use the rule's provisions and broad, subjective terms to summarily terminate projects funded under prior administrations, imposing many of the costs and hardships identified in this comment. More importantly, the possibility that grants could be terminated based on shifting policy preferences poses a serious long-term threat to investment in research in the United States and risks wasting taxpayer funds already committed to supporting that work. Scientists, institutions, and other research partners may be less willing to invest time, personnel, infrastructure, and matching resources in federally funded research if they cannot have reasonable confidence that meritorious work will be allowed to proceed absent noncompliance or another objective basis for termination.

II. THRESHOLD CONCERN — COMMENT PERIOD AND EFFECTIVE DATE

The 45-day comment period is insufficient given the breadth of the proposed rule, which rewrites dozens of sections spanning termination, merit review, cost principles, foreign-collaboration rules, and employment verification, areas that involve distinct offices within a single institution, including Research Administration, the Office of General Counsel, Human Resources, the Health System, the Library, Sponsored Programs, and other affected offices. The current rulemaking structure has historically allowed an ample comment period for grant recipients and agency input; the compressed timeline here, paired with a proposed October 1, 2026, effective date, does not give recipients adequate time to prepare for and operationalize substantial changes before they bind FY2027 awards. The University urges OMB to extend the comment period and to phase in the effective date for major operational provisions.

DISCUSSION: The challenge is not merely the amount of time available to prepare comments, but the ability to obtain meaningful input from the wide variety of stakeholders affected by the proposed changes. Large research institutions must often coordinate review among faculty investigators, clinical research programs, research administration offices, compliance offices, legal counsel, financial administrators, and institutional leadership. A compressed comment period limits the ability of agencies to receive fully informed feedback regarding the practical implications of complex regulatory changes and therefore reduce the effectiveness of the rulemaking process itself.

The proposed October 1, 2026 effective date is infeasible. Many of the proposed changes would require institutions to revise internal policies, update financial and research-administration systems, modify subaward templates, retrain faculty and staff, coordinate with human resources and payroll systems, and develop new compliance workflows. These changes cannot be implemented responsibly on a compressed timeline without increasing the risk of inconsistent application, administrative error, delayed awards, and disruption to active research. If OMB proceeds with any operationally significant provisions, it should provide a delayed and phased effective date that allows recipients and federal agencies to implement effective compliance measures.

A compliance deadline that does not allow sufficient time for recipients and agencies to implement new requirements reliably also undermines the reasonableness of the rulemaking, particularly where OMB has not explained how recipients are expected to operationalize the changes by the proposed effective date.

RECOMMENDATION: WashU recommends that OMB provide a minimum 60-day comment period for future government-wide revisions of comparable scope and complexity. For this proposed rule, WashU recommends that OMB delay and phase in the effective date for any operationally significant changes that require modifications to institutional systems, policies, or compliance processes consistent with prior implementation timelines for Uniform Guidance revisions.

III. FUNDING STABILITY, TERMINATION, AND SUSPENSION

(§ 200.340(a)) Discretionary Termination Authority

SUMMARY: The proposed rule would require every new discretionary award to include a provision allowing the awarding agency to terminate or suspend it, in whole or in part, whenever the agency determines termination is in the federal interest — including when an award no longer effectuates the agency's program goals, priorities, or the national interest as they exist at the time of termination. The provision is modeled on the termination-for-convenience authority used in federal procurement under the Federal Acquisition Regulation (FAR), applying a procurement-law concept to grants for the first time on a government-wide basis.

DISCUSSION: Historically, federal grant terminations were rare and tied to material noncompliance. The proposed revision would convert a grant into an effectively "at-will" instrument that can be canceled mid-performance based on a vague and shifting "national interest" standard, destroying the reliability on which multi-year research depends. The breadth of the standard is underscored by the rule's own example: even a minor administrative tracking delay - such as "the failure of the recipient to report subawards on SAM.gov" - is made an explicit basis for termination, confirming that the trigger is not limited to substantive performance failures. The procurement analogy is imperfect: a federal contract purchases a defined deliverable, while a research grant supports a time-limited but evolving program of scientific inquiry in which the recipient incurs substantial up-front, non-recoverable commitments, including multi-year graduate-student support, postdoctoral appointments, faculty effort, specialized equipment, and clinical-trial enrollment, well before any termination decision.

That distinction is not merely practical; it is statutory. The Federal Grant and Cooperative Agreement Act directs agencies to use procurement contracts when the principal purpose is to acquire property or services for the direct benefit or use of the federal government, and to use grant agreements when the principal purpose is to transfer a thing of value to a recipient to carry out a public purpose authorized by federal law. Importing FAR-style termination-for-convenience concepts into the Uniform Guidance would blur this statutory distinction and risk treating research grants as though they were procurement contracts, even though grants are designed to support independent scientific inquiry in furtherance of a public purpose rather than to purchase a defined deliverable for the government's direct use.

In clinical research, an at-will funding mechanism raises ethical and humanitarian concerns. Institutions conducting human-subjects research have continuing obligations to protect participant safety and ensure an orderly study closeout, including adverse event monitoring, participant notification, data management, regulatory reporting, investigational product accountability, and other activities required by approved protocols, Institutional Review Boards, and federal regulations. These obligations often continue long after enrollment has ceased and cannot simply be discontinued upon termination of funding. As a result, institutions may remain legally, ethically, and financially responsible for activities necessary to protect participants and preserve data integrity even when the federal funding supporting those activities has been withdrawn.

Furthermore, when combined with the proposed changes to merit review in §200.205, the expanded termination authority creates a risk that awards approved under one administration could be terminated under another based on changing policy priorities rather than project performance or scientific merit. Research projects often require years of sustained investment before meaningful results emerge. A framework that permits funding decisions to shift with changing administrations introduces instability for recipients and increases the likelihood that taxpayer investments will be abandoned before the scientific objectives of the award can be realized. The problem is not only a practical one. OMB has not explained what is problematic with the current approach, which ties termination to noncompliance, and it says nothing about the reliance interests that build up around a multi-year award or the more measured tools it could use instead. For those reasons, the University does not believe a discretionary termination authority of this kind could meet the standard for reasoned agency decision-making.

Illustrative Example: Consider a five-year, $1.9 million NIH R01 supporting research on pediatric neurodevelopmental disorders. The award funds a doctoral student's stipend and tuition, 40% of a postdoctoral fellow's salary, a full-time research technician, and a longitudinal patient cohort specific for the study. In year three – after the University and the federal government have together invested more than $1 million – the award is terminated mid-stream on a discretionary "national interest" basis, with no finding of noncompliance. The doctoral student, then two years into a dissertation built around the funded aims, would be left without a realistic path to completing the degree, and the University would have to cover the remaining salary and tuition or leave the student stranded. The postdoctoral fellow and technician would face layoffs on short notice. The patient cohort, which took three years to assemble and cannot be rebuilt, would simply be lost. It is difficult to see what the government gains from this outcome. It would have paid for most of a project only to abandon it before any results emerged, wasting the taxpayer dollars the rule is supposed to protect.

RECOMMENDATION: WashU recommends that OMB not adopt the proposed discretionary termination authority for federal research awards. The existing termination framework should continue to focus on objective criteria, including material noncompliance, rather than a capricious and undefined "national interest" standard. If OMB nevertheless adopts a discretionary termination authority, it should: (1) define "national interest"; (2) limit discretionary termination to clearly identified circumstances and, absent extraordinary circumstances, to budget-period boundaries rather than mid-project termination; (3) guarantee recovery of orderly wind-down and non-cancellable commitment costs, including the costs of participant safety, animal welfare,

trainee support, and other close-out obligations that continue after funding ends; (4) preserve administrative hearing rights; and (5) remove administrative reporting lapses, such as SAM.gov reporting delays, as termination triggers. OMB should also clarify that any new discretionary termination authority will apply prospectively and should not be applied to active awards that were issued under the existing termination framework, absent material noncompliance or another objective basis for termination.

(§ 200.340(d)) Temporary Suspension / Stop-Work Orders

SUMMARY: OMB proposes a new paragraph (d) authorizing agencies and pass-through entities to issue written stop-work orders, modeled on the FAR.

DISCUSSION: Stop-work authority does not belong in the grant funding mechanism at all. It is borrowed from procurement, where the government pauses work on a defined deliverable it has purchased, and it does not translate to research, where the recipient has already committed personnel, participants, animals, and specimens to a research program that cannot simply be switched off and back on. Importing stop-work authority introduces the same instability as discretionary termination and it is particularly hazardous for active human-subjects research, where work cannot be paused without compromising participant safety and data integrity. Stop-work orders are particularly difficult to implement in ongoing human-subjects research because many study activities cannot simply be paused pending further agency direction. Participant safety monitoring, adverse event reporting, investigational product accountability, protocol-required follow-up visits, and other regulatory obligations often continue regardless of funding status. Other research activities cannot be interrupted without permanently compromising scientific value, including longitudinal studies, animal breeding colonies, seasonal field studies, and continuous environmental monitoring efforts. Unlike a procurement contract, these projects involve time-sensitive scientific activities and ongoing participant or animal-care obligations that do not pause simply because the funding does.

Instability also falls directly on the people who carry out the work. Discretionary awards routinely fund graduate student stipends and tuition, postdoctoral salaries, and the wages of research staff and technicians, often committed years in advance. A stop-work order can leave these individuals without compensation on short notice and with no comparable funding to support them, which jeopardizes graduate students' progress toward their degrees and forces institutions to lay off skilled project staff whose specialized training is difficult and costly to replace.

WashU-Specific Example: WashU Medicine investigators lead and participate in long-running federally funded Alzheimer's disease research, including longitudinal studies that depend on repeated participant visits, biospecimen collection, imaging, cognitive assessments, and sustained participant engagement over many years. A stop-work order issued mid-project could cause missed visits, participant attrition, interruptions in data collection, and loss of continuity that cannot simply be restored once the suspension is lifted. In longitudinal Alzheimer's research, the value of the study depends on continuity over time; once critical observation windows are missed or participants disengage, years of prior federal investment may be permanently diminished.

RECOMMENDATION: WashU recommends that OMB not adopt the proposed stop-work authority for federal financial assistance awards. The proposed authority is ill-suited to research grants, where work often involves ongoing participant-safety obligations, animal welfare responsibilities, longitudinal data collection, or time-sensitive scientific activities that cannot be paused without causing permanent harm. If OMB nevertheless retains stop-work authority, it should at minimum exempt ongoing human-subjects research, animal research, and other projects involving continuing safety, welfare, or other scientific-continuity obligations, or require agencies to provide explicit direction regarding allowable activities necessary to satisfy those obligations during the stop-work period.

(§ 200.341) Termination Notification and Recipient Procedural Protections

SUMMARY: OMB proposes that discretionary termination notices must include a brief summary of the reasons for termination (rather than merely citing the regulatory provision), must direct the recipient to stop work and prohibit new obligations, and must provide the recipient with an opportunity to submit a statement regarding termination costs.

DISCUSSION: WashU supports the baseline procedural protections in § 200.341, including a stated rationale and an opportunity to submit a statement on termination costs - as a necessary, if insufficient, check on the expanded discretionary-termination authority in § 200.340. The critical structural concern is that the proposed rule bifurcates recipients' procedural rights: for terminations based on noncompliance, existing rights to object and to pursue a hearing and appeal would be preserved, but for discretionary terminations the rule would expressly withhold those objection, hearing, and appeal rights. In their place, the recipient would receive only written notice with "a brief summary of the reason or reasons" for termination - reasons that may apply to an entire class of awards rather than the specific award, and as to which the agency "is not required to provide a detailed or exhaustive analysis" - together with stop-work instructions and an opportunity to submit a statement of termination costs within a reasonable time. A recipient's only avenue to contest an unlawful discretionary termination would be an action in the U.S. Court of Federal Claims. These protections do not cure the core concerns identified above: a non-exhaustive "summary of reasons" tied to a vague and shifting "national interest" standard provides little basis for meaningful review, and litigation in the Court of Federal Claims is not a practical remedy for most recipients or downstream subawardees.

Illustrative Example: Suppose a five-year NIH R01 studying a novel biomarker for early Alzheimer's detection receives a discretionary termination notice in year three. The notice states only that the award "no longer effectuates agency priorities" and gives no rationale specific to the project. The University is left to guess whether the problem is the science, some institutional policy, or a decision applied across a whole class of awards. Without a specific explanation, the University cannot meaningfully respond, address the concern, or plan an orderly wind-down. Because the only recourse is an action in the Court of Federal Claims, most recipients will have no practical remedy.

RECOMMENDATION: WashU recommends that OMB not eliminate existing objection, hearing, and appeal rights for discretionary terminations. If OMB retains a discretionary termination mechanism, recipients should have a meaningful administrative process to contest the

termination, supported by a specific statement of reasons sufficient to allow the recipient to respond. OMB should not limit recipients to litigation in the Court of Federal Claims, which is not a practical remedy for many recipients or downstream subrecipients. OMB should also pair the opportunity to submit a statement of termination costs with a corresponding obligation to reimburse reasonable and necessary costs, consistent with WashU's recommendation under § 200.343.

(§ 200.343) Allowability of Costs During Suspension / After Termination

SUMMARY: OMB's preamble states that costs incurred after a discretionary termination would be unallowable unless expressly authorized by the agency or pass-through entity. However, this does not fully align with the operative regulatory text, which does not declare such costs unallowable but instead leaves their allowance to agency discretion. For discretionary terminations, agencies are not required to authorize additional costs incurred after award termination but have the discretion to do so based on information provided by the recipient. In making such determinations, agencies would be permitted to weigh payment of additional termination costs against competing policy concerns such as responsible stewardship of federal funds, program goals, agency priorities, or the national interest.

DISCUSSION: Coupled with discretionary termination and stop-work authority, this provision leaves the University responsible for non-cancellable obligations and close-out costs it cannot recover, shifting financial risk to recipients. The proposed rule makes cost recovery wholly discretionary. The result is that the very same shifting "national interest" rationale that can justify a discretionary termination can also be invoked to deny recovery of the unavoidable wind-down costs. This discretionary, unbounded standard provides no reliable basis on which the University can budget for the risk of non-cancellable commitments (e.g., multi-year personnel appointments, subject-safety obligations, and equipment leases).

WashU-Specific Example: A WashU-led implementation study had completed the infrastructure-building phase and began data collection across three institutions when subsequent funding was not received. Because recruitment timing was built into the study design, the project could not be paused without compromising scientific validity. The lapse created unreimbursed staffing and recruitment pressures across the participating sites, including staff loss and reassignment. Under the proposed § 200.343 framework, similar necessary continuation, closeout, or wind-down costs could be left to agency discretion, shifting unavoidable costs to the recipient even where those costs are necessary to preserve the scientific integrity of the project.

RECOMMENDATION: WashU recommends that OMB replace the proposed discretionary balancing test with a binding obligation to pay all reasonable and necessary costs the recipient incurs in connection with the suspension or termination, including non-cancellable obligations and close-out and wind-down costs. If OMB retains agency discretion regarding termination-cost reimbursement, it should require: (1) objective standards governing the exercise of that discretion; (2) written findings explaining the basis for any denial or reduction of requested costs; and (3) reimbursement of costs necessary to satisfy legal, regulatory, ethical, or participant-protection obligations that continue following a suspension or termination.

IV. INTERNATIONAL COLLABORATION AND RESEARCH SECURITY

(§ 200.202(e)) Domestic-First Eligibility for R&D Awards

SUMMARY: Direct awards to foreign entities would be prohibited unless expressly authorized by statute or where a senior agency appointee determines a "compelling interest" exists. “International elements” may be included when designing research and development programs only if the agency determines they are justified, consistent with the program objectives, and in the U.S. national interest. Agencies must consider factors such as whether the international element is necessary to achieve scientific objectives, provide access to unique expertise or resources unavailable domestically, enhances the scientific enterprise of the U.S., and whether the foreign collaborator has sufficient capacity.

DISCUSSION: This change would negatively impact research in areas where international collaboration is scientifically necessary because faculty will stop proposing projects that rely on foreign data streams, unique repositories, or populations that exist only outside the U.S. The "domestic-first" requirement would isolate U.S. scientists from global innovation necessary for major breakthroughs, and for an institution conducting global clinical trials it would eliminate the ability to recruit adequate patient cohorts for many diseases, causing studies to fail to capture diverse genetic variations. Some scientific questions are inherently international because the relevant population, disease prevalence, environmental exposure, biological resource, or dataset does not exist in sufficient quantity within the United States. International collaboration in these circumstances is not a discretionary preference but a scientific necessity.

Many diseases studied by American researchers do not occur with sufficient frequency in the United States alone to support adequately powered clinical trials or natural-history studies. International collaboration allows U.S. investigators to answer scientific questions more rapidly, accelerate therapeutic development, and bring new treatments to American patients sooner. The point bears emphasis: these partnerships are not favors to foreign institutions. They are how the United States imports knowledge it cannot generate on its own, and the ultimate beneficiaries are American patients, American industry, and the American public. Restricting such collaborations would directly diminish the scientific opportunities available to U.S. researchers and the health benefits ultimately realized here at home.

International collaboration often advances, rather than undermines, the U.S. national interest. In many fields, the facilities, populations, environmental conditions, datasets, or biological resources necessary to answer a scientific question are located outside the United States. U.S. researchers may need access to major international research infrastructure, unique clinical populations, specialized animal models, or environmental conditions that do not exist domestically. Restricting those collaborations would not make the United States more secure or more competitive; it would make it more likely that important discoveries occur elsewhere without U.S. participation, leadership, or benefit.

The Dominantly Inherited Alzheimer Network (DIAN), the NIH-funded international study pioneered by WashU Medicine investigators, aggregates more than 200 families across more than 40 sites in 18 countries because the genetic mutations studied are exceedingly rare and no single country holds enough affected families to power the research. Under domestic-first, each

international element would require case-by-case "necessary"/"national interest" justification subject to senior-appointee approval, introducing approval risk and delay into a network whose international structure is a scientific necessity, not a discretionary preference.

WashU-Specific Example: WashU researchers are developing a gene therapy for CLN1 disease, also known as infantile Batten disease, a rapidly progressing genetic disorder that is fatal in childhood. The therapy has shown real promise in mice but translating that success to the far more complex human brain requires testing in a large animal model before the team can responsibly move forward toward a clinical trial in children. That model exists only in Scotland, where collaborators developed genetically engineered sheep carrying the CLN1 mutation. These sheep are unique and do not exist at any U.S. institution, so late-stage work of this kind can be carried out only through the foreign collaboration. Under a domestic-first default, a collaboration of this kind could be restricted or denied even though the work is funded primarily to benefit American children who will otherwise die of the disease. Cutting off the foreign collaboration would not only waste the substantial federal investment already made, it would also stall a therapy that is close to reaching the children who need it.

RECOMMENDATION: WashU recommends that OMB not adopt a blanket domestic-first default for research and development awards. The better approach is a disclosure-and-mitigation framework that manages the real risks of international engagement, while reserving complete prohibitions for narrowly defined circumstances. If OMB nevertheless retains a domestic-first framework, the University recommends that it: (1) establish objective, publicly available criteria governing when international elements satisfy the "necessary" and "national interest" standards; (2) require decisions on international collaboration requests within a defined timeframe to avoid research delays; (3) create an expedited review process for collaborations involving unique populations, datasets, facilities, biological resources, or scientific expertise unavailable within the United States; and (4) grandfather existing awards and research networks so that projects approved under prior rules may continue without disruption for the remainder of their approved project periods.

(§ 200.220) Prohibition on Collaboration with Covered Foreign Countries/Entities

SUMMARY: OMB proposes a government-wide prohibition on using federal funds — direct or indirect — to support collaborations with covered foreign countries or entities. “Covered foreign countries” include countries designated as foreign adversaries, countries of particular concern, and countries subject to sanctions or national security restrictions. “Covered foreign entities” include entities owned or controlled by such countries, entities on federal concern lists, and entities affiliated with military, intelligence, or security services of a covered foreign country.

DISCUSSION: This provision takes a narrow, agency-specific statutory restriction - the "Wolf Amendment," which to date has prohibited only NASA from using appropriated funds to support bilateral or multilateral collaboration with covered foreign countries or entities - and extends it government-wide across all federal agencies by regulation rather than by statute. Because many foreign universities have some degree of state affiliation, the breadth of "covered foreign entity" - which reaches entities "affiliated with" a covered country's military, intelligence, or security services - is difficult to apply in practice. An institution would have to investigate every entity it

does business with to determine whether that entity is “affiliated with” a country of concern, an extraordinary undertaking. The express extension to "indirect costs allocable to such collaborations" reaches furthest of all: read broadly, it could implicate the University's negotiated F&A treatment wherever a covered collaboration exists anywhere in its portfolio. Existing multi-year consortia could likewise be disrupted mid-stream if a partner is later designated as covered.

WashU supports appropriate restrictions that prevent federal research funds from benefiting sanctioned entities, foreign adversaries, or entities that present genuine national-security risks. The proposed rule extends a broad covered-entity framework across all federal awards without sufficiently clear definitions, public lists, transition rules, or limits on the treatment of indirect costs. Without objective criteria and a reliable federal source of truth, recipients may be unable to determine with confidence whether a foreign collaborator, parent entity, affiliate, or downstream partner is covered, particularly where designations change during an active award.

Illustrative Example: A multi-site oncology clinical trial of a promising investigational therapy is sponsored by a U.S. pharmaceutical company that is a subsidiary of a parent company with manufacturing operations in a covered country. Midway through enrollment, the parent is designated a “covered foreign entity.” Because the prohibition reaches “indirect costs allocable to such collaborations,” the University faces uncertainty over whether it must halt enrollment of patients already receiving the investigational therapy – patients who may have no alternative treatment – and whether its negotiated F&A treatment is jeopardized across its broader portfolio. A mid-stream designation of this kind could disrupt an active trial in ways that directly harm participants.

RECOMMENDATION: WashU recommends that OMB limit the prohibition to clearly identified entities appearing on publicly available federal restricted-party or covered-entity lists and provide objective criteria for determining when an entity is considered "affiliated with" a covered foreign country. OMB should also clarify that indirect costs allocable to otherwise permissible federally funded activities are not rendered unallowable solely because a recipient maintains unrelated collaborations with a covered entity.

If OMB retains the proposed prohibition, it should establish transition and grandfathering provisions for existing awards, clinical trials, and research collaborations that were permissible when initiated. Recipients should be provided with a reasonable period to wind down, transfer, or restructure affected activities following any new designation. OMB should further clarify that active human-subjects research may continue to the extent necessary to protect participant safety and satisfy ethical and regulatory obligations.

V. MERIT REVIEW, APPLICANT RISK, AND POLITICIZATION OF SCIENCE

(§ 200.205(b)) Pre-Issuance Review and Merit Review Reform

SUMMARY: As part of the merit review process, each Federal agency head would be required to designate one or more senior appointees to conduct a pre-issuance review of every discretionary award to ensure consistency with applicable law, agency priorities, and the national interest. In

doing so, the appointee must apply enumerated principles, including that an award: (1) demonstrably advance the President's policy priorities; (2) not fund, promote, or facilitate racial preferences or the use of race or intentional proxies for race, "denial of the sex binary in humans," illegal immigration, or any initiative that "compromise[s] public safety or promote[s] anti-American values"; (3) should all else being equal, give preference to institutions with lower indirect cost rates; (4) should be distributed across a "broad range of recipients," balancing those likely to produce "immediately demonstrable results" against those with "longer-term, breakthrough" potential; and (5) reflect a commitment to "Gold Standard Science," with agencies prioritizing an institution's commitment to "rigorous, reproducible scholarship" over its historical reputation or perceived prestige." The appointee must exercise independent judgment and may not "ministerially ratify or routinely defer to" the recommendations of others. Peer review is expressly preserved, but only as advisory. Finally, an agency is not required to issue any award under a NOFO and may repost the opportunity if doing so would fund low-quality proposals or be inconsistent with these principles.

DISCUSSION: The nation's research enterprise has historically derived its strength, and its return on taxpayer investment, from awarding funds on the basis of scientific and technical merit assessed by subject-matter experts. Inserting senior political appointees into the funding decision for every discretionary award politicizes science, making funding turn on alignment with the sitting administration's priorities rather than on technical merit. Substituting the policy priorities of whichever party holds power makes ideology a selection criterion and risks directing public funds toward politically favored work rather than the best science.

Requiring a senior appointee to conduct independent, non-ministerial review of every discretionary award also creates a structural bottleneck. NIH alone makes on the order of tens of thousands of competing awards annually; a small number of appointees cannot meaningfully assess the technical merit of thousands of highly specialized proposals - the precise problem subject-matter peer review evolved to solve. The likely effects include longer and less predictable times-to-award, higher reversal rates of peer-recommended proposals, and greater difficulty planning hiring, recruitment, and facilities investments.

The proposed rule would also damage the peer-review system itself. Peer review is not a ministerial step. It requires experienced scientists to spend substantial time evaluating the technical rigor, feasibility, significance, and methodological soundness of complex proposals. Actively practicing scientists who serve on study sections and federal review panels are the experts best positioned to assess whether a proposal reflects rigorous, reproducible, and technically sound science. They are also best positioned to distinguish between research that is appropriately high-risk and potentially high-impact, and research that appears promising but contains conceptual or methodological flaws that make the proposed work unlikely to succeed. That judgment requires years of experience in the relevant field and cannot be replicated through generalized political or administrative review.

Researchers devote time to this labor-intensive work despite competing obligations to conduct their own research, mentor students and trainees, treat patients, and fulfill institutional responsibilities because they understand peer review to be central to ensuring that federal research dollars are awarded to the most scientifically promising and technically sound projects.

That willingness to participate depends on trust. If reviewers come to believe that their scientific judgments will be routinely displaced after the fact by nontechnical or political review, they will have less reason to devote scarce time to the process. Experienced WashU faculty with senior academic leadership experience and extensive service on NIH study sections and other federal review panels have expressed concern that relegating peer review to an advisory role would discourage high-quality reviewers from participating or from investing the same level of effort in preparing rigorous, complete, and useful critiques. Over time, that would weaken the pool of expert reviewers, reduce the quality of review, diminish the feedback available to investigators seeking to improve their proposals, and make federal funding decisions less scientifically reliable.

The harm would not stop with reviewers. If investigators come to believe that funding decisions will turn primarily on alignment with political priorities rather than scientific merit, they may be less willing to invest their careers, laboratories, trainees, and institutional resources in federally funded research. That would undermine the competitiveness of American science and weaken the very system that has allowed federally funded research to produce world-class results.

Weighing "the President's policy priorities" injects criteria that shift across administrations into research that often takes five to ten years to mature, raising the prospect that a project approved under one administration is disfavored or, combined with the new § 200.340 authority, terminated under the next. Relegating expert peer review to a purely advisory role and encouraging agencies to "broaden the range of recipients" further dilutes the value of merit-based selection.

Administrations have legitimate authority, consistent with statutory requirements, to establish programmatic priorities through the design of funding opportunities. If an agency wishes to prioritize a particular area of research, the appropriate place to do so is in the NOFO itself, where the criteria are public, prospective, and known to all applicants. It is far more problematic to introduce shifting policy priorities after applications have been submitted and peer reviewed, because doing so permits selection among otherwise eligible applicants based on non-merit criteria that were not the basis on which proposals were developed or evaluated.

The provision is also internally inconsistent. It purports to demand a commitment to "Gold Standard Science," which depends on rigor, reproducibility, transparency, and evaluation by those with the relevant expertise. Yet it simultaneously strips peer-review panels of decisional authority and empowers political appointees to reject proposals they judge to be misaligned with presidential priorities.

A selection process driven by political alignment rather than technical merit does not meet Gold Standard Science. It undermines it. It also reduces transparency because applicants and recipients would not know which senior appointees are conducting the review, what criteria they are applying, or how those criteria are being weighed against the scientific and technical merit assessed through peer review.

Compounding these concerns, the provision adds review criteria that are both undefined and ideologically charged - most notably the direction that funding decisions account for whether an applicant or project advances, or does not undermine, "anti-American values." That criterion is entirely subjective, invites viewpoint- and ideology-based selection, and cannot be reliably applied by reviewers or anticipated by recipients. OMB should remove it. Any consideration of this

kind that is retained should at least be defined precisely and limited to conduct that is already unlawful.

The proposed framework also works against the rule's stated commitment to rigorous, reproducible, and breakthrough science. Replication and reproducibility studies may not always appear novel or immediately demonstrable, but they are essential to validating findings, improving research quality, and ensuring that taxpayer-supported science produces reliable results. Similarly, breakthrough research often requires investigators to pursue ambitious questions whose significance may not be fully apparent for years. A review framework that favors shifting policy priorities or short-term outcomes may disincentivize investigators from pursuing ambitious or confirmatory work. The result would be less of the rigorous, reproducible, and breakthrough science the rule says it wants to encourage.

Instructing reviewers to prefer institutions with lower indirect cost rates may steer federal research away from the institutions best equipped to perform it. Indirect cost rates are not a measure of efficiency – they reflect the actual audited cost of the facilities and administrative infrastructure an institution has built to support research. The institutions most capable of carrying out complex, high-risk studies are frequently the ones with higher rates because they have invested in the specialized facilities and equipment that such work requires. A preference of this kind also discourages future investment, since an institution that builds new specialized capacity raises its rate and, under this criterion, harms its competitiveness for awards.

Peer review has worked for decades, and OMB now proposes to push it aside in favor of political pre-issuance review without explaining why the change is needed or why a less drastic option, such as setting its priorities in the funding opportunity itself, would not serve just as well. A provision that contradicts itself on its own terms (i.e., invoking "Gold Standard Science" while displacing the expert peer review that standard depends on), and that is adopted without grappling with alternatives, does not meet the standard for reasoned agency decision-making.

The proposal also does not justify the need for expanded authority to decline to issue awards or repost a funding opportunity where peer review has identified meritorious applications. Federal research agencies routinely receive more scientifically meritorious proposals than they can fund. In that environment, it is unlikely that expert review panels would be unable to identify fundable proposals in ordinary review cycles. OMB should therefore explain why existing agency authority to design NOFOs, establish program priorities, and make funding decisions within appropriated amounts is insufficient before adopting a new framework that permits agencies to set aside peer-reviewed proposals based on broad and subjective criteria.

Illustrative Example: A highly specialized R01 proposing single-cell sequencing methods to map immune-cell populations in pediatric leukemia depends on technical assessment by reviewers with expertise in computational immunology and genomics. A small number of senior agency appointees, however capable generally, cannot meaningfully evaluate the rigor or feasibility of such a proposal, which is the reason subject-matter peer review developed in the first place. Sending every discretionary award through such review would add months to the time it takes to issue an award, which in turn disrupts postdoctoral hiring and the collection of patient samples.

RECOMMENDATION: WashU recommends that expert peer review remain the controlling determinant of scientific and technical merit, with any pre-issuance review limited to confirming legal eligibility and compliance. Political criteria should not displace merit-based selection, and any override of a peer-review recommendation should require a specific, written, and reviewable justification. WashU further recommends that OMB remove the instruction to prefer, all else being equal, institutions with lower indirect cost rates. OMB should also preserve the central role of expert peer review to maintain confidence among reviewers and applicants that technical merit remains the operative measure for evaluating scientific quality. Any consideration of administration policy priorities should occur through the design of funding opportunities, where criteria are public, prospective, and known to all applicants, rather than through post-application selection among otherwise eligible proposals based on non-merit criteria.

(§ 200.206) Expanded Applicant Risk Assessment

SUMMARY: The proposed changes expand the risk assessment factors that an agency can consider when determining whether an institution is able to fulfill the terms and conditions of an award. OMB proposes to add subjective criteria, including an applicant's history of "questionable practices" such as plagiarism, publication of non-replicable studies, or engaging in activities or initiatives that are inconsistent with federal civil rights laws or religious liberty laws. Agencies may also consider the applicant's membership or "affiliation" with organizations engaged in activities that "undermine public safety or national security." An applicant's compliance with Section 117 reporting may also be considered.

DISCUSSION: The current Uniform Guidance focuses on objective metrics - financial stability, audit reports, and internal controls. The proposed changes expand the risk assessment to allow agencies to consider highly subjective criteria with no clear definition of what constitutes an "affiliation" or an activity that "undermines public safety." At a large research institution, thousands of faculty members hold professional memberships and participate in international coalitions; without definitions, institutions cannot monitor every external "affiliation" of their workforce. Section 117 enforcement already falls under the statutory authority of the Department of Education, which has audit and correction processes; allowing individual grantmaking agencies to independently determine compliance histories will produce conflicting assessments across the federal government.

Unlike financial controls, audit findings, or institutional compliance systems, the proposed affiliation-based factors frequently involve conduct that is outside the institution's ability to monitor or control. Universities cannot reasonably investigate, monitor, and continuously assess the external activities, memberships, editorial-board service, advisory-board participation, and professional affiliations of thousands of individual researchers. A risk-assessment framework should focus on factors that institutions can objectively measure and meaningfully address.

Illustrative Example: A faculty cardiologist serves on the editorial board of an international medical society and the scientific advisory board of a global health coalition. Under the expanded and undefined "affiliation" factor, the University would have to identify, monitor, and continuously assess thousands of such external memberships across its faculty in order to anticipate agency

risk determinations – an undertaking with no objective standard and no realistic compliance pathway.

RECOMMENDATION: WashU recommends that OMB revise § 200.206 to: (1) retain objective, financially grounded risk factors - financial stability, audit findings, internal controls, and demonstrated performance - as the basis for applicant risk assessment; (2) remove, or at minimum precisely define and narrow "affiliation" and conduct that "undermines public safety or national security," so that an institution can reasonably determine what is required and is not held accountable for the unmonitorable external affiliations of thousands of individual faculty; and (3) defer assessment of Section 117 compliance to the Department of Education to avoid inconsistent and duplicative compliance determinations across grantmaking agencies. These revisions would preserve appropriate risk-based oversight while ensuring that recipients are evaluated on objective, administrable factors within the institution's ability to monitor and address.

VI. OMB AUTHORITY AND REGULATORY RESTRUCTURING

(§§ 200.110, 2 CFR subtitle A) Reclassification of 2 CFR as OMB Regulation and Streamlined Future Amendments

SUMMARY: OMB proposes to reclassify 2 CFR 200 from guidance to a binding OMB regulation (a "Uniform Grant Regulation"), so that future OMB amendments take effect government-wide through a single Federal Register notice-and-comment document rather than individual agency rulemakings.

DISCUSSION: Consolidating amendment authority in a single OMB document would bypass the specialized knowledge of each individual federal agency and its specific research communities, and the swift proposed timeline demonstrates that recipients are not being given ample time to prepare for implementation. The current agency-by-agency structure provides important opportunities for tailored input. Although OMB frames centralization as promoting predictability and uniformity, much of the practical predictability institutions currently rely on comes precisely from agency-level implementation that accounts for program-specific timelines and existing agency regimes. A single effective date applied government-wide — here, October 1, 2026, with no transition period — can in fact reduce predictability by binding FY2027 awards before recipients can operationalize the changes. Going forward, consolidating amendment authority in a single OMB notice-and-comment vehicle would compress the opportunities for program-specific, research-community input that individual agency rulemakings have historically provided, making it harder for affected stakeholders to surface operational problems before changes take binding effect government-wide.

Federal agencies that support research do not operate under identical statutory authorities, program structures, or scientific missions. NIH, NSF, DOE, DOD, NASA, and other agencies fund different kinds of research, use different application and review processes, and administer awards through distinct programmatic and legal frameworks. A single OMB rulemaking may promote consistency in some areas, but a one-size-fits-all approach will override agency-specific

requirements and eliminate the tailored implementation that makes federal research administration workable across different scientific fields and funding models.

At the same time, WashU supports efforts by OMB and federal agencies to test evidence-based approaches that reduce administrative burden and improve stewardship of federal funds. The concern is not with innovation in grant administration, but with government-wide changes that have binding effect without sufficient agency-specific input, transition time, or evaluation. OMB should preserve flexibility for agencies to pilot new approaches, assess their effectiveness, and scale reforms that demonstrably improve efficiency without disrupting active research programs.

Illustrative Example: A government-wide amendment issued with a single effective date could require simultaneous revisions to financial systems, subaward templates, training materials, institutional policies, and sponsor-specific guidance across thousands of active awards, creating implementation challenges that would previously have been phased through agency-specific rulemaking.

RECOMMENDATION: WashU recommends that OMB preserve meaningful opportunities for agency-specific implementation and stakeholder input when adopting future government-wide revisions to the Uniform Guidance. Major regulatory changes should include reasonable implementation periods, phased effective dates where appropriate, and mechanisms for agencies to address program-specific operational considerations. OMB should also provide sufficient advance notice and transition guidance to allow recipients to update policies, systems, training materials, and subaward structures before new requirements become effective.

For revisions that substantially alter award administration, compliance obligations, or cost principles, OMB should provide a minimum 12-month implementation period unless a shorter timeline is required by statute. OMB should also preserve agency authority to pilot burden-reduction and efficiency initiatives, provided those pilots include clear evaluation criteria, stakeholder input, and appropriate transition protections for active awards.

VII. NATIONAL POLICY RESTRICTIONS ON AWARD USE

(§ 200.300(b)) Codification of DEI and Gender Ideology Prohibitions

SUMMARY: OMB proposes to amend § 200.300 to require that, to the maximum extent permitted by law, agencies and pass-through entities ensure a Federal award is not used to fund, promote, encourage, subsidize, or facilitate: (1) "diversity, equity, and inclusion" (DEI) or "diversity, equity, inclusion, and accessibility" (DEIA) policies, principles, or practices that violate applicable Federal anti-discrimination laws — including racial preferences or the use of race or intentional proxies for race; (2) "gender ideology" as defined in E.O. 14168; and (3) the sex "transition" of a child under 19. OMB warns that recipients “should not assume that practices previously viewed as consistent with prior Executive Branch guidance will necessarily satisfy applicable Federal anti-discrimination requirements as applied to Federal awards.”

DISCUSSION: While the University fully supports compliance with all applicable federal anti-discrimination laws, the sweeping, undefined, and politically charged language introduced in this revision creates significant regulatory uncertainty that could disrupt core university operations,

accredited educational programs, and vital biomedical research. The principal concern is that the rule's key terms are broadly and ambiguously defined, yet violations carry the most severe consequence available: termination of the entire award. Under a more targeted enforcement structure, a disputed cost item would result in a disallowance of that item alone, whereas under this framework, the same dispute could jeopardize the whole project. The gender-ideology provision, read broadly, could reach legitimate biomedical research on sex differences, intersex conditions, or endocrinology. The challenge is not merely compliance but predictability. Institutions can comply with clear rules. They cannot reliably comply with standards that depend on undefined terms and evolving interpretations. When potential noncompliance carries the risk of award termination, uncertainty itself becomes a significant operational burden, encouraging recipients to avoid otherwise lawful activities simply because the regulatory boundaries are unclear.

These concerns are heightened because the proposed restrictions would be imposed as government-wide award conditions through an omnibus grants-administration rule, rather than through a dedicated proceeding focused on the specific policy questions at issue. Whatever the underlying policy objectives, contested and undefined terms should not be incorporated into every federal award without clear definitions, a developed administrative record, proportionate remedies, and safe harbors for good-faith compliance. A framework that allows ambiguous terminology to trigger whole-award termination risks chilling lawful research, education, clinical, and public-health activities that federal agencies have historically supported.

Illustrative Example: An NIH-funded endocrinology study examining sex-based differences in cardiovascular disease risk involves legitimate biomedical inquiry into biological differences that may affect disease risk, diagnosis, treatment, and outcomes. Under the broadly worded "gender ideology" prohibition, the University cannot determine whether these protocols involve prohibited content. Because the penalty is termination of the entire award rather than disallowance of a single cost, investigators may avoid such inquiry altogether, chilling research that is squarely within the scientific mainstream and critical to the health of the American public.

RECOMMENDATION: WashU recommends that OMB not finalize § 200.300(b) in its current form as part of this omnibus grants-administration rule. If OMB proceeds with this framework, it should revise § 200.300(b) to provide clear, objective, and administrable standards tied to existing statutory and regulatory requirements rather than undefined or subjective terminology. Any restrictions on the use of federal funds should be narrowly tailored to unlawful conduct and should not create uncertainty regarding otherwise permissible scientific, educational, clinical, or public-health activities.

OMB should further clarify that federally funded research involving health disparities, demographic characteristics, sex-based biological differences, environmental exposures, epidemiology, or other scientifically relevant population variables does not constitute prohibited activity solely because such research examines differences in outcomes among populations. Compliance standards should be sufficiently specific so that recipients can reasonably determine their obligations and avoid unnecessary restrictions on lawful research, education, and patient-care activities.

If OMB retains the proposed framework, it should establish a formal process through which recipients may request written agency guidance or safe-harbor determinations regarding specific activities before those activities become the basis for enforcement action, award suspension, or termination.

(§ 200.218) Prohibition on Disparate Impact Theories

SUMMARY: OMB proposes a new § 200.218 barring agencies, pass-through entities, recipients, and subrecipients from using federal financial assistance to promote or support theories of disparate-impact liability based on federally protected characteristics such as race, sex, or age — directing that agencies "eliminate the use of disparate-impact liability in all contexts relevant to Federal awards." "Disparate-impact liability" is defined as a theory under which a facially neutral policy or practice gives rise to an automatic or near-insurmountable presumption of unlawful discrimination wherever there are differences or disparities in outcomes among groups, even absent any proven discriminatory intent. The prohibition reportedly extends not only to supporting disparate-impact studies and litigation but also to award activity driven by assumed disparate-impact risk, unless expressly required by law, and would be enforceable as an award term and condition. A narrow exception preserves internal statistical or demographic analysis for program evaluation, research, or similar purposes — but only where federal award funds are not used for the analysis and the results are not applied to activities under the award.

DISCUSSION: The disparate-impact provision is especially consequential for science because examining why a disease, environmental exposure, or educational outcome differs across populations is foundational to health-disparities research, environmental epidemiology, and education research. A study documenting higher maternal mortality in a particular population could be characterized as "promoting" disparate-impact theory even where no liability claim is involved. The same problem extends to environmental epidemiology: a study showing that a hazard concentrates in certain communities uses the very analytical frameworks the provision targets and could be characterized in the same way. The breadth of "promote or support" is magnified by the lack of definitions for the rule's key terms. The proposed internal analysis exception does not cure this problem. By its terms it applies only where federal award funds are not used for the analysis and the results are not applied to award activities; but where a research grant's funded purpose is to study outcome disparities, the analysis is the award itself. The carve-out therefore shields only incidental internal analysis and offers no meaningful protection for the funded research.

Illustrative Example: One federally funded study documents higher maternal mortality among rural Missouri populations and another is an environmental epidemiology study showing that a particular airborne hazard concentrates in specific communities. Both rely on the kind of analysis that the proposed UG revision would prohibit. Because the funded purpose of each award is the disparity analysis itself, the "internal analysis" carve-out does not help.

RECOMMENDATION: WashU recommends that OMB not finalize § 200.218 in its current form. If OMB proceeds, it should clarify that scientific research examining differences in outcomes among populations does not constitute promotion of disparate-impact liability theories. At a minimum, the rule should expressly exempt federally funded research activities designed to understand

disease burden, treatment outcomes, environmental exposures, educational outcomes, or other scientific questions involving population-level differences.

VIII. ADMINISTRATIVE BURDEN AND COST PRINCIPLES

WashU supports efforts to reduce unnecessary administrative burden and improve the efficiency of federal award administration. Several provisions in the proposed rule, however, would increase transactional review, create duplicative approval processes, or shift costs to recipients without a corresponding improvement in stewardship or accountability.

(§ 200.204) Notices of Funding Opportunities and Grants.gov Submission Requirements

SUMMARY: OMB proposes to revise § 200.204 to require federal agencies to post Notices of Funding Opportunities (NOFOs) on Grants.gov and to require applicants to apply using Grants.gov unless an exception applies. OMB also encourages plain-language NOFOs and Statements of Interest (SOIs) when high application volume or lengthy proposals are expected.

DISCUSSION: WashU supports OMB's goal of improving transparency and reducing burden in the funding opportunity process. A single, searchable location for NOFOs can help applicants identify federal funding opportunities more efficiently, and plain-language NOFOs and appropriately designed SOIs may reduce unnecessary application burden.

However, OMB should clarify that the requirement to apply using Grants.gov is not intended to eliminate or displace agency-specific research application systems that are already integrated into federal grants administration and tailored to the needs of scientific research. Research-intensive agencies rely on specialized systems, including NSF's Research.gov environment, to support agency-specific application requirements, proposal validation, institutional routing, submission tracking, and post-submission interactions. These systems are not merely duplicative platforms; in many cases, they are the tools that make complex research submissions workable.

A rigid requirement that all applications be prepared and submitted through a single generic Grants.gov interface could unintentionally increase burden by forcing institutions to abandon established workflows, retrain faculty and research administrators, reconfigure internal systems, and duplicate information across platforms. It could also disrupt agency-specific validation checks that help applicants identify errors before submission. This would be inconsistent with OMB's stated goal of reducing recipient burden and with the Vanderbilt-WashU white paper's recommendation to streamline federal grant processes in ways that reduce duplication and preserve efficient award-management tools.

Illustrative Example: A WashU investigator preparing an NSF proposal may use Research.gov to develop the proposal, complete agency-specific forms, run compliance checks, route the application through institutional review, and submit the final proposal. If § 200.204 were interpreted to require submission only through a generic Grants.gov interface, WashU would need to rework established proposal-development workflows and train investigators and administrators to use a different process, even where agency-specific systems already support accurate, timely, and compliant submission.

RECOMMENDATION: WashU recommends that OMB retain Grants.gov as the government-wide public posting location for NOFOs, while clarifying that agency-specific research application systems, system-to-system submissions, and other integrated platforms may satisfy the Grants.gov application requirement when authorized by the federal agency. OMB should preserve agency flexibility to use systems such as Research.gov and other established platforms where those systems reduce burden, improve application quality, or are necessary to support complex scientific submissions.

WashU also recommends that OMB retain the Statement of Interest concept as an optional, pre-application mechanism for funding opportunities expected to generate high application volume or lengthy, complex proposals. When structured with clear criteria, reasonable timelines, and transparent agency feedback, a Statement of Interest process can reduce burden by allowing applicants and agencies to assess programmatic fit before institutions invest substantial time and resources in preparing full proposals. OMB should clarify, however, that the process should not become an additional mandatory review layer, should not delay otherwise eligible applications, and should not be used to screen applications based on undefined or non-merit-based criteria.

(§§ 200.201, 200.333) Elimination of Fixed Amount Awards and Subawards

SUMMARY: OMB proposes to eliminate the use of fixed amount awards and subawards unless authorized by federal statute. Under a fixed amount award, the recipient is entitled to a set amount tied to milestones or deliverables rather than actual costs incurred and is therefore not subject to the cost principles. Current § 200.201 permits these awards, and current § 200.333 allows pass-through entities to make fixed amount subawards up to $500,000 with the prior written approval of the federal agency. The proposed rule would permit federal agencies to make fixed amount awards only where a statute expressly authorizes them and would prohibit pass-through entities from issuing fixed amount subawards altogether. OMB's stated rationale is that fixed amount awards limit transparency and hinder oversight because they involve no routine monitoring of actual costs and no financial reporting.

DISCUSSION: The elimination of fixed amount subawards is operationally unworkable and runs directly counter to OMB's stated objective of reducing recipient burden. Fixed amount subawards are widely used to support milestone-driven payments in multi-site clinical trials. Moving all research to a cost-reimbursement model shifts away from a "pay for performance" structure – in which recipients are held accountable for achieving milestones – to one in which the government pays for effort expended even if the project fails to meet its goals, while increasing transactional burden for the University and its subawardees. The effect is most acute in federally funded clinical trials, where prime institutions rely on milestone-driven, per patient capitation subawards. That structure gives the government budget certainty: funds are paid out only on verified completion of a protocol visit, so a trial of 500 patients has a known, enrollment-based cost. Additionally, pass-through entities must already perform an individualized risk assessment of every subrecipient, and the fixed amount subaward has long been the lower-risk option in that toolkit – limiting financial exposure by tying oversight to verified milestones. Eliminating the option would strip pass-through entities of a proven way to manage risk, trading milestone-based oversight for additional administrative process that does nothing to improve how federal funds are protected.

Illustrative Example: In an NIH-funded clinical trial involving 12 sites and a target enrollment of 500 subjects, the prime institution pays each site a fixed per-subject capitation amount (for example, $3,000 per completed protocol visit). The government gets budget certainty under this arrangement, since money only moves once a milestone is verified, and the smaller community sites are not exposed to open-ended financial risk.

RECOMMENDATION: WashU recommends that OMB retain the existing authority for pass-through entities to issue fixed amount subawards, subject to appropriate risk assessment and agency oversight.

At a minimum, OMB should preserve the use of fixed amount subawards for activities where performance can be readily measured against objective milestones or deliverables. This is particularly important in multi-site clinical trials, where per-patient capitation payments provide budget certainty, align reimbursement with verified performance, reduce administrative burden, and facilitate participation by community-based and smaller research sites.

If OMB elects to restrict fixed amount subawards more broadly, it should establish an explicit exception for clinical trials and other milestone-driven research activities and permit agencies to approve their use on a programmatic basis rather than requiring specific statutory authorization.

(§ 200.305(c)) Payment Justification

SUMMARY: OMB proposed to require a "brief written justification" for each payment request. The brief justification must include "information on the activities or aspects of the Federal award that correspond to the payment request." Examples include project milestones, project activities, administrative activities, or other requirements that must be completed under the award.

DISCUSSION: Converting automated drawdowns into a transactional, pre-approval process would cause significant volatility for recipients. Universities would have to decide whether to stall critical scientific projects or absorb millions in unreimbursed costs while waiting for individual agency personnel to manually review justifications. Universities are already subject to single-audit requirements and internal-control assessments; requiring payment justifications at a transactional level is a redundant layer of oversight that runs against the spirit of the Single Audit and is directly contradictory to OMB's stated objective of reducing award-recipient burden.

Additionally, the examples in the proposed change represent programmatic progress justifications that are already captured through annual performance reporting mechanisms, such as the RPPR, and do not necessarily correlate with the rate or timing of expenditures. Scientific progress is inherently nonlinear and often occurs independently of spending patterns. Significant expenditures may be incurred in advance of measurable outcomes, such as equipment purchases, participant recruitment, or data collection activities, while substantial scientific advancements may occur during periods of relatively low spending, such as data analysis and interpretation. Consequently, expenditure patterns are not a reliable proxy for scientific progress or project performance.

OMB has not explained why existing risk-based oversight, periodic financial reporting, recipient internal controls, Single Audit review, or targeted sampling of higher-risk awards would be

insufficient to address the stated concern without imposing a universal justification requirement on every payment request.

WashU-Specific Example: WashU has more than 1,400 federal awards on automated drawdowns; this proposal would generate at least 16,800 payment justifications annually, each requiring preparation by the recipient and review by federal personnel. The proposal effectively converts a cash management process into a transactional programmatic review process without demonstrating a corresponding improvement in stewardship or risk mitigation. The University estimates that it would need several additional FTEs to facilitate this change.

RECOMMENDATION: WashU recommends that OMB withdraw the proposed payment-justification requirement and continue relying on the existing risk-based oversight framework established through the Single Audit process, recipient internal controls, and existing financial and programmatic reporting requirements. If OMB believes additional payment oversight is necessary, it should consider less burdensome alternatives, such as targeted sampling, risk-based review, or enhanced review for recipients or awards with identified financial-management concerns, rather than imposing a universal justification requirement on every drawdown.

(§ 200.303(f)) E-Verify Mandate

SUMMARY: All recipients and subrecipients would be required to participate in DHS's E-Verify program for employees and contractors performing work in the U.S. under a federal award.

DISCUSSION: Extending E-Verify from the federal contractor context to all federal financial assistance represents a significant operational change for research institutions. In FY2026, WashU had approximately 9,750 individuals paid from federal awards, while only approximately 3% of its current federal grant portfolio is subject to an E-Verify requirement under existing federal contractor rules. Expanding E-Verify from this limited population to all federally funded appointments would require substantial modifications to HR, payroll, hiring, onboarding, compliance, and research administration processes.

In addition, the proposed language leaves important questions regarding scope. It is unclear whether the requirement applies to graduate research assistants, postdoctoral fellows, visiting scholars, stipend-supported trainees, or other categories of individuals supported by federal awards who may not fit neatly within traditional employee or contractor classifications. An October 1, 2026 effective date provides insufficient time for institutions to design, test, and implement the necessary operational changes for a population of this size.

Illustrative Example: A federally funded research project requires rapid onboarding of graduate research assistants, postdoctoral fellows, visiting scholars, or stipend-supported trainees to align with an award start date or study enrollment timeline. If the E-Verify requirement applies to some or all of these categories but the scope is unclear, the University would need to pause appointments or create new HR and research-administration review processes before individuals can begin work. Without clear definitions and sufficient implementation time, the requirement could delay project start-up and disrupt research staffing.

RECOMMENDATION: WashU recommends that OMB clearly define the categories of individuals subject to the E-Verify requirement, including the treatment of graduate students, trainees, visiting

scholars, stipend-supported individuals, and others who may contribute to federally funded research without fitting neatly into traditional employee or contractor categories. If OMB retains this requirement, it should provide a phased implementation period, align the requirement with existing federal contractor E-Verify processes where possible, and provide sufficient guidance and transition time for institutions to integrate any new requirements into existing hiring, payroll, onboarding, and research-administration systems.

(§ 200.303(a)) Internal Control Standards

SUMMARY: OMB proposes to revise the internal-control provision in § 200.303(a), including by removing references to recognized internal-control frameworks such as the Standards for Internal Control in the Federal Government and the COSO Internal Control Integrated Framework.

DISCUSSION: Removing references to recognized internal-control frameworks would create uncertainty regarding the standard against which recipient controls will be evaluated. Recipients need clear, objective benchmarks to design, maintain, and test internal controls across complex federal research portfolios. Recognized frameworks provide a common reference point for recipients, auditors, and federal agencies and help support consistent, good-faith compliance.

RECOMMENDATION: WashU recommends that OMB retain references to recognized internal-control frameworks or identify an equivalent safe harbor for recipients that maintain controls consistent with established federal or industry-recognized standards.

(§ 200.461) Publication Costs Unallowable by Default

SUMMARY: Publication costs, including open-access fees, page charges, and article-processing charges, would be unallowable, with exceptions requiring statutory authorization or advance case-by-case agency approval. A general requirement to make results publicly available is not considered agency authorization.

DISCUSSION: Grant recipients are required by federal public-access mandates to disseminate findings, yet the rule expressly forecloses recovering the cost of doing so, creating a new unfunded mandate. Many leading journals are open-access-only or levy article-processing charges of several thousand dollars per article; moving these to unallowable shifts a substantial recurring cost onto the institution or, in the alternative, pressures researchers toward lower-visibility venues that do not charge such fees. The case-by-case approval exception adds an administrative step to every affected publication and provides little budgeting predictability.

The proposed revision creates a direct conflict with longstanding federal policy promoting broad public access to the results of federally funded research. Federal agencies increasingly require investigators to make publications and research outputs publicly available. Eliminating the allowability of publication costs shifts the financial burden of complying with those mandates onto recipients, effectively converting a federal dissemination requirement into an institutional expense.

Publication costs also support the return on the federal government's research investment. Publishing federally funded results in venues that are visible, peer reviewed, indexed, and accessible to the relevant scientific, clinical, industry, and public audiences increases the

likelihood that findings will be scrutinized, reproduced, cited, translated, commercialized, or incorporated into future research and practice. Treating public availability as insufficient authorization for publication costs undervalues the role that effective dissemination plays in ensuring that federally funded research produces public benefit.

Illustrative Example: The University estimates that it would absorb approximately $1.2 million annually across federal awards if this proposed revision were to take effect.

RECOMMENDATION: WashU recommends that OMB retain publication costs, including open-access publication fees, article-processing charges, page charges, and similar dissemination expenses, as allowable costs under federal awards. The dissemination of research findings is not separate from the research process; it is one of the principal means through which the public realizes the benefit of its investment in federally funded research.

If OMB retains the proposed restriction, publication costs incurred to comply with federal public-access requirements should remain automatically allowable without case-by-case agency approval. At a minimum, OMB should establish a streamlined approval process and objective approval criteria for publication expenses that are reasonable, necessary, and directly related to the dissemination of federally funded research results.

If OMB's concern is cost discipline rather than prohibition, it should consider less burdensome alternatives, such as reasonable cost parameters or agency-level guidance for article-processing charges, rather than making publication costs categorically unallowable. A categorical prohibition would create an unfunded mandate where federal policy requires public dissemination, but federal awards cannot pay the reasonable costs of that dissemination.

(§§ 200.432, 200.454) Prior Approval for Conferences and Memberships

SUMMARY: Under revised § 200.432, all conference attendance costs are unallowable unless expressly approved by the federal agency and written directly into the award's terms and conditions. Similarly, under revised § 200.454, all costs for memberships in professional organizations require explicit prior written approval of the federal agency. Costs of the recipient's subscriptions to professional or academic periodicals are unallowable. There is a strict prohibition on funding memberships in any organization whose primary purpose includes "issue advocacy."

DISCUSSION: Requiring award-specific prior approval for each conference adds an approval step onto an activity that is central to how science advances. It also risks missed presentation deadlines and reduced participation by graduate students and postdocs, for whom early-career conference attendance is a primary means of entering the field. For § 200.454, deciding whether a society's primary purpose is "issue advocacy" is an inherently subjective determination that could capture memberships that a project genuinely requires. Scientific conferences and scholarly organizations play a critical role in the dissemination of research findings, scientific collaboration, workforce development, trainee mentoring, and the advancement of knowledge.

WashU-Specific Impact: The proposed treatment of subscriptions and periodicals would also have a measurable institutional impact. Library resources are part of the research infrastructure that allows investigators, trainees, and research staff to access the scientific literature necessary

to design studies, interpret findings, avoid duplication, and disseminate results. Based on WashU's FY2025 draft F&A proposal and results from the FY2024 library study, the proposed treatment would reduce the University's library component from 1.02 to 0.63, resulting in an estimated $1.7 million loss in uncapped facilities cost recovery. This would not reduce the need for library resources; it would simply shift the cost of maintaining access to federally necessary research infrastructure from federal awards to the institution.

Illustrative Example: A graduate student or postdoctoral fellow supported by a federal award is accepted to present project results at a national scientific meeting after the award has already been issued. If conference attendance must be expressly approved in advance and written into the award terms and conditions, the trainee may miss the presentation opportunity, or the institution may have to absorb the cost. This would reduce dissemination of federally funded research findings and limit professional development opportunities for early-career researchers.

RECOMMENDATION: WashU recommends that OMB retain the current treatment of conference participation, professional memberships, academic periodicals, library resources, and related scientific engagement activities as allowable costs when they are necessary to accomplish the objectives of a federal award or support the institutional research infrastructure required to carry out federally funded research.

If OMB proceeds with the proposed prior-approval requirements, approvals should be granted at the award level rather than on a conference-by-conference basis, and agencies should establish objective approval criteria and expedited review processes to avoid unnecessary delays.

To the extent that participation in professional societies, scientific meetings, editorial activities, or similar scholarly activities is necessary to accomplish the objectives of a federally funded project, OMB should ensure that such participation remains generally permissible and is not subject to unnecessary administrative barriers.

OMB should also clarify that communicating, presenting, publishing, or discussing the results of federally funded research does not constitute prohibited "issue advocacy" merely because the research concerns a sensitive scientific, clinical, public-health, or policy-relevant topic.

(§§ 200.329–200.332) Subaward Tracking and Subrecipient "Reputational Harm" and Determination Requirements

SUMMARY: OMB proposes to require pass-through entities to make subrecipient/contractor determinations for all downstream entities (including "related entities" such as affiliates and subsidiaries) and to ensure subrecipients do not take actions that could "significantly damage the reputation" of the pass-through entity, federal agency, or federal government. Recipients must confirm in performance reports that all subawards issued during a reporting period have been reported to SAM.gov, with failure potentially resulting in termination, and must ensure that funds transferred to affiliates/subsidiaries are tracked as subawards.

DISCUSSION: The "damage reputation" standard is extremely broad and undefined, yet violations could result in termination. Requiring determinations for all internal affiliates and related organizations may also reach arrangements not previously treated as subawards. The University generally supports transparency in subaward reporting and already reports subawards over

$30,000 under FFATA. The principal operational concern is the new requirement to report subawards on SAM.gov by the end of the month following issuance, which would require modifying the University's current reporting pull for all subawards. Institutions have not previously been required to report third-tier subrecipients in the ordinary course of award administration. As written, it is unclear which entity has the reporting responsibility.

Illustrative Example: A research university issues hundreds of subawards annually to domestic and international collaborators and already reports first-tier subawards in accordance with existing federal transparency requirements. Under the proposed rule, the institution may also be required to identify, classify, track, and report certain affiliates, subsidiaries, and other related entities that have not historically been treated as subaward recipients. Implementing these requirements would require modifications to institutional systems, development of new data-collection and verification processes, and additional personnel dedicated to compliance monitoring and reporting. Because failure to satisfy the reporting requirements could potentially serve as a basis for enforcement action or termination, institutions would be required to devote substantial resources to ensuring timely and accurate classification of complex organizational relationships that may not be readily apparent.

RECOMMENDATION: WashU recommends that OMB remove the proposed "significant reputational harm" standard or replace it with objective, clearly defined criteria tied to specific legal, compliance, or performance deficiencies. OMB should also clarify reporting obligations for affiliates, subsidiaries, and related entities and provide a phased implementation period for any new reporting requirements. Recipients making good-faith efforts to collect, verify, classify, and report required subaward information should not be subject to suspension or termination based solely on administrative reporting delays or reporting errors.

IX. CONCLUSION

WashU appreciates the opportunity to comment on these proposed revisions and respectfully urges OMB not to finalize the proposed rule in its current form. Collectively, the proposed changes would increase administrative burden, reduce predictability in the management of federal awards, shift significant financial and operational risk to recipients, and introduce broad discretionary standards into federal research administration without sufficient justification, transition time, or consideration of less burdensome alternatives. In several instances, the proposals may also undermine long-term scientific, clinical, and collaborative research activities that depend on stable funding, clear requirements, and sustained partnerships.

These comments are grounded in the same principles reflected in the Vanderbilt-WashU white paper. WashU recognizes the need for thoughtful regulatory reform that reduces redundancy, increases coherence across agencies, and redirects limited resources toward research, innovation, education, and public benefit. The University encourages OMB to prioritize reforms that standardize federal grant processes, reduce duplicative reporting, rely on existing risk-based oversight mechanisms, preserve efficient award-management tools, and evaluate burden-reduction strategies before applying them government-wide.

The University also recognizes the importance of strengthening research security, accountability, transparency, and stewardship of federal funds. Certain objectives reflected in the proposed rule, including efforts to improve transparency in subaward reporting and greater accountability in award administration, are important. However, those objectives are best achieved through clear standards, objective risk-based oversight, meaningful procedural protections, and policies that preserve the stability necessary for research institutions to conduct high-quality research on behalf of the American public.

The University would welcome the opportunity to provide additional analysis, data, or concrete examples on any of the provisions discussed.