July 10, 2026

The Honorable Russell T. Vought
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Submitted electronically via www.regulations.gov
Re: Docket No. OMB–2026–0034 — Guidance for Federal Financial Assistance (2 CFR Part 200 and related parts)

Dear Director Vought:

The Association of Independent Research Institutes (AIRI) submits the following comments on the Office of Management and Budget's (OMB) Proposed Rule, Guidance for Federal Financial Assistance, published in the May 29, 2026 Federal Register (91 FR 32198), which proposes government-wide revisions to 2 CFR part 200 (the "Uniform Guidance") and related agency adopting regulations. We appreciate the opportunity to comment and welcome the opportunity for further discussion if permitted.

AIRI is a national association of more than 80 independent, not-for-profit research institutes conducting basic, translational, and clinical research across the biomedical, behavioral, and life sciences. Our member institutes vary widely in size and scientific focus but share a research-intensive mission and a single-purpose organizational structure. Many of our institutions have no teaching mission, patient services, or other lines of business and that leaves them nimble enough to pivot quickly to emerging scientific opportunities, but also leaves Federal grants and cooperative agreements as their primary, and often sole, source of operating revenue. Collectively, our member institutes receive a significant share of National Institutes of Health (NIH) peer-reviewed, competitively awarded extramural grants, with success rates that consistently meet or exceed the overall NIH average.

Beyond their research output, AIRI member institutes train and employ a meaningful share of the nation's biomedical and life science workforce, including graduate students, postdoctoral fellows, early-career investigators, and technical staff. Many of our institutes are located in small and less-populated states, where they are often the primary point of access to NIH-funded research training and infrastructure for communities that do not have a major academic research institution nearby. The combination of having single-purpose research missions, near-total reliance on Federal award revenue, and a workforce and infrastructure role that extends well beyond any individual grant means that our member institutes are especially sensitive to changes in Federal grants

administration policy that affect funding stability, administrative workload, or the predictability of the award process.

Over the past year, AIRI member institutes have experienced significant delays in grant awards, including year-long gaps for applications with fundable scores, forcing some labs to lay off skilled staff, pause or stop experiments, and scale back planned research programs. Early career investigators have been particularly affected, as gaps in support delay their development and contribute to retention challenges, including some choosing to pursue opportunities abroad where funding stability is perceived as more secure. It is against this backdrop of real operational strain that we offer the comments below, with a particular focus on provisions of the proposed rule that would add further administrative burden or funding uncertainty for small, grant-dependent research institutions. Not only is there significant concern regarding the provisions but the timeline which they are intending to implement would prove nearly impossible for our institutes that operate with lean staff.

AIRI notes that we requested an extension of the comment period, due to the sweeping significance of these changes and the complexity of developing thoughtful feedback on the proposed Rule. We remain concerned that the timeline for comments is inadequate, that the proposal will result in significant harm to our research institutions as described below, and believe that the proposal does not achieve OMB's stated objectives to improve accountability, transparency, or reduction of burden on the regulated community.

As such, AIRI respectfully requests that OMB consider withdrawing this proposal in its entirety and undertaking a more rigorous review of the impact before moving forward. We organize our comments by topic below, grouping related provisions where they raise a common concern. In summary, our principal concerns are as follows:

- Reclassifying 2 CFR subtitle A as a binding OMB regulation, rather than guidance, would eliminate the agency-level adoption step that gives the research community a second opportunity to comment on implementation; we recommend OMB retain subtitle A as guidance.
- Several merit review and risk review changes (§§200.202–200.206) tie funding decisions to undefined, politically contingent terms and an indirect-cost-rate preference that disadvantages independent research institutions, creating instability unrelated to scientific merit.
- Expanded termination authority, elimination of fixed amount awards, and new per-payment verification and justification requirements (§§200.340–343, 200.201, 200.333, 200.305) create unpredictable financial shocks and recurring administrative burden that independent research institutions, with no other revenue base, are poorly positioned to absorb.
- The prohibition on disparate-impact liability (§200.218) is broad enough to risk chilling NIH-funded research on diseases that disproportionately affect specific racial and ethnic populations; we recommend OMB clarify that disease disparities research is not "support" for a disparate-impact liability theory under this section.
- The proposed unallowable costs for publication, periodical subscription, and conference participation costs (§§200.432, 200.454, 200.461) would fall on independent research institutions with no alternative revenue base to absorb them; we recommend these presumptively unallowable costs be struck, and we ask OMB to define "primary purpose" in

§200.454(d) so it does not sweep in advocacy undertaken to advance the scientific enterprise and Federal research funding.

- AIRI opposes the government-wide extension of international research collaboration restrictions (§200.220, §200.329, §200.331–332), which risks reducing scientific collegiality and weakening U.S. competitiveness against China and other nations investing heavily in biomedical research.

Retain 2 CFR Subtitle A as Guidance, Not a Binding Regulation

Before turning to specific provisions, AIRI objects to the structural change that affects how all of the provisions discussed below will take effect and how they may be revised in the future. Since 2013, 2 CFR part 200 has had the status of OMB guidance, which becomes binding on a given Federal agency's awards only once that agency completes its own notice-and-comment rulemaking to adopt the guidance into its agency-specific regulations in 2 CFR subtitle B. The proposed rule would eliminate that intermediate step. The proposal to remove the statement that subtitle A is "guidance, not regulation," to redesignate 2 CFR subtitle A (to be renamed the "Uniform Grants Regulation") as a binding OMB regulation in its own right, and to provide that future OMB amendments take effect government-wide on OMB's own effective date, without requiring each grantmaking agency to separately propose, take comment on, and finalize its own implementing rule would be transformative and is inadequately justified.

Under the current two-step structure, the agency-level adoption process provides a second, agency-specific opportunity for the grantee community to comment on how a new OMB policy will actually be implemented for a particular program, and a natural interval during which agencies and recipients can identify and resolve implementation problems before a requirement becomes binding. Collapsing this into a single, OMB-level rulemaking removes that second checkpoint and will cause angst not only for grant recipients but for agency officials. The loss of an agency-specific comment opportunity is a meaningful reduction in the public's ability to shape how these requirements will operate in practice, and will fail to reduce administrative burden and uniformity.

We recommend that OMB withdraw the proposed reclassification and retain 2 CFR subtitle A as guidance, preserving the existing requirement that each Federal agency adopt subtitle A, and any future substantive amendments to it, through its own notice-and-comment rulemaking before that text becomes binding on the agency's awards.

Changes to Merit Review in Funding Decisions

[§§200.202–200.206] Strike Undefined, Politically Contingent Merit and Risk Review Criteria
The proposed rule places substantially greater emphasis on agency priorities and policy considerations in discretionary funding decisions, including a pre-issuance review requirement at §200.205(b) under which political senior appointees must independently evaluate whether proposals "demonstrably advance the President's policy priorities." Proposed §200.205(b)(2)(iv) further directs that discretionary awards must not be used to fund, promote, or facilitate "any other initiatives that compromise public safety or promote anti-American values," §200.205(b)(7) directs agencies to weigh an institution's perceived "commitment to rigorous, reproducible scholarship" and progress toward "Gold Standard Science" in discretionary funding decisions, and §200.206 directs scrutiny of an applicant's history of "questionable practices." Throughout these provisions, eligibility and funding decisions are repeatedly tied to whether a proposal advances "agency priorities," the "President's policy priorities," or "the national interest."

AIRI's central concern with this provision is that none of these terms, "agency priorities," "the President's policy priorities," "the national interest," "questionable practices," or "anti-American values", is defined in the proposed rule, and none of the terms are tied to scientific merit, reproducibility, or the quality of the proposed research. By their nature, these terms describe the priorities of whichever administration is in office at a given time, rather than a fixed, scientifically grounded standard. A multi-year R01 or program project grant may be reviewed for renewal, supplementation, or continued funding under an entirely different set of "priorities" or a different understanding of "the national interest" than existed when the award was first made, with no change in the underlying science. For our independent research institutions that plan staffing, facilities, and multi-year research programs around the expectation of continued grant funding, based on competitive merit, tying funding eligibility to politically contingent and undefined terms introduces a level of instability in the research enterprise that is unrelated to scientific merit and that our member institutions, with no other lines of business to fall back on, are poorly positioned to absorb.

We are also concerned about the specific mechanism through which these undefined criteria would be applied. Proposed §200.205(b) requires that senior appointees, rather than the scientists who conduct peer and merit review, make an independent, non-ministerial judgment as to whether a proposal typically selected through a meritorious process nonetheless fails to "demonstrably advance the President's policy priorities" or otherwise satisfy these undefined criteria. This inserts an additional layer of review, conducted by political appointees with no additional criteria to ensure such appointees are qualified to evaluate either scientific merit, public need, or strategic value. This creates a realistic risk of reduced funding success for reasons unrelated to scientific quality, and a corresponding reduction in our institutions' ability to forecast and rely on Federal research funding from one funding cycle to the next.

These provisions are also difficult to reconcile with the administration's own Executive Order 14303, "Restoring Gold Standard Science" (May 23, 2025), which defines Gold Standard Science to require that federally supported research be "subject to unbiased peer review" and conducted "without conflicts of interest." Proposed §200.206 states that "peer review remains advisory and does not replace agency discretion," undermining the judgment of scientific peer reviewers to the undefined political criteria discussed above which moves federal grantmaking further from Gold Standard Science.

We recommend that OMB strike §200.205(b)(1), (b)(2)(iv), and the related "agency priorities" and "national interest" language throughout §§200.202–200.206 and instead limit pre-issuance review to verifying consistency with applicable law and the specific, objective criteria already published in the notice of funding opportunity.

[§200.205(b)(3)] Remove the Indirect-Cost-Rate Merit Review Preference

Proposed §200.205(b)(3) directs that, all else being equal, preference for discretionary awards should be given to institutions with lower indirect cost rates. AIRI is concerned that this provision, if implemented, would systematically disadvantage independent research institutions relative to larger, more diversified institutions, without regard to the underlying reasons for rate variation.

Indirect cost rates among independent research institutions vary for reasons that have nothing to do with efficiency or stewardship of federal funds. Because our member institutions are single-purpose entities with no teaching mission, auxiliary enterprises, or other activities across which to

spread administrative costs, their negotiated rates are an unavoidable feature of the research-only business model, not a discretionary cost choice.

We recommend that OMB either remove proposed §200.205(b)(3) or clarify that a lower indirect cost rate, standing alone, is not a permissible factor in merit review. As written, agencies implementing this provision could create a structural disadvantage for small, independent research institutions that have no relationship to the quality of the science being funded or the integrity of the institution's financial management.

[§200.206(b)(2)(viii)] Define Undefined Terms in the Memberships and Affiliations Risk Factor
Proposed §200.206(b)(2)(viii) would permit a Federal agency, based on publicly available and verifiable information, to consider an applicant's "membership in or affiliation with organizations engaged in activities that violate Federal law, undermine public safety or national security, or advocate for the overthrow of the United States Government" as a factor in pre-award risk review.

Terms such as "undermine public safety or national security" are not defined in the proposed rule, and the provision does not specify what process, if any, an applicant would have to learn that a particular membership or affiliation has been flagged as relevant to its risk assessment, or to respond before a funding decision is made. In addition to being members of AIRI, our member institutes are themselves members of numerous scientific, professional, and trade associations as an ordinary part of conducting research. Without clearer definitions and a notice-and-response mechanism, this criterion risks being applied inconsistently across applicants and reviewers, in a manner unrelated to an applicant's actual conduct or the integrity of its research. We ask OMB to define the operative terms in this provision and to specify a process by which an applicant is notified of, and may respond to, an affiliation-based risk determination before it affects a funding decision.

Funding and Financial Instability for Research Institutions

Three separate provisions of the proposed rule would each, independently, expose independent research institutions to sudden, unpredictable financial shocks that an organization with no alternative revenue base is poorly positioned to absorb.

[§§200.340–200.343] Withdraw Expanded Suspension and Discretionary Termination Authority
The proposed rule would let agencies terminate any discretionary award, in whole or in part, whenever doing so serves agency priorities or the national interest as they exist at the time. A discretionary termination under this provision requires only a brief written summary of the agency's reasoning, does not require the administrative hearing rights that apply to compliance-based terminations under §200.342, and is not subject to the SAM.gov reporting that applies to terminations for noncompliance. This removes meaningful due process for grant recipients and deprives institutions of a real opportunity to contest the basis for losing a multi-year award before the funding is gone and the work has stopped. A clinical study, longitudinal cohort, or animal research protocol cannot simply be paused and resumed without scientific and financial loss.

Because our research institutions are single-purpose organizations with Federal awards as their primary or sole revenue source, and many carry multi-year staffing and facility commitments appropriately determined by the awards they hold, the loss of one or more major awards without warning or recourse can quickly outpace an institution's financial reserves. The resulting financial instability falls first on the research workforce including graduate students, postdoctoral fellows, early-career investigators, and technical staff whose positions are tied to the terminated award.

Then in the most severe cases, a small, independent research institution that loses a sufficiently large share of its award portfolio may have no path to remain financially viable at all, which could result in the closure of the institution and the halt of critical scientific progress. Even short of an actual termination, this risk affects our members' ability to attract and retain talent and financially plan for operations in the coming years. We recommend that OMB retain a more defined, performance-linked standard for mid-project terminations of multi-year research awards, or at minimum extend administrative hearing rights to discretionary terminations affecting awards already in their performance period.

It is worth nothing that the proposed pre-issuance review requirements in §200.205(b) and the expanded termination authority in §200.340, taken together, could disadvantage investigator-initiated and long-term foundational research whose value may not be immediately apparent from currently stated agency or Presidential priorities. The history of the American research enterprise demonstrates that many of the nation's most transformative scientific advances, originated from curiosity-driven, investigator-initiated work that preceded, and ultimately enabled, major Federal initiatives such as the Human Genome Project and the BRAIN Initiative. AIRI's concern is not that agencies should be prohibited from establishing research priorities, but that funding decisions tied to undefined or politically contingent standards may inadvertently suppress precisely the exploratory research that has historically generated breakthroughs for that launched Federal priority programs.

[§200.201, §200.333] Withdraw the Elimination of fixed amount awards
The proposed rule would eliminate the use of fixed amount awards and subawards unless specifically authorized by Federal statute, reversing the approach adopted in 2014 and refined in 2024. Eliminating this mechanism government-wide, rather than addressing the specific transparency concerns OMB has identified with its implementation, replaces a comparatively low-burden funding mechanism with the full cost-reimbursement monitoring and documentation requirements that apply to standard grants which will ultimately add administrative costs across an institution's entire award portfolio without a corresponding increase in research output. This is in direct opposition to this administration’s intention to provide more funding to research studies versus administrative costs at research institutions.

We recommend OMB withdraw this change and retain current authority to use fixed amount awards and subawards; if transparency concerns remain, OMB should adopt defined minimum standards for their use rather than eliminating the mechanism altogether.

[§200.305] Strike the New per-payment verification and justification requirements
The proposed rule would require Federal agencies to verify recipient eligibility through Treasury's Do Not Pay system before disbursing any Federal payment, and would separately require recipients and subrecipients other than States to submit a brief written justification, tied to project milestones or activities, with every payment request, whether the request is for an advance or a reimbursement.

OMB identifies related procurement changes elsewhere in the proposed rule as implementing Executive Order 14222, the administration's “Department of Government Efficiency” Cost Efficiency Initiative; the Do Not Pay verification and per-payment justification requirements in §200.305 are, in substance, the codification into the Uniform Guidance of that same initiative, commonly known as “Defend the Spend.” AIRI shares OMB's interest in preventing improper payments, but this new layer of documentation imposed on every routine drawdown versus one-

time or periodic reporting is a significant increase in administrative burden for our institutions. For institutions like ours that depend on frequent, predictable drawdowns to meet payroll and operating expenses, adding a justification requirement to each individual payment request introduces a recurring administrative burden and a new source of potential delay in the timing of fund disbursement, compounding financial instability for research institutions. We recommend OMB strike the proposed per-payment justification requirement in §200.305.

[§200.218] Clarify That the Disparate-Impact Prohibition Does Not Reach Health Disparities Research

Proposed §200.218 directs agencies to eliminate the use of disparate-impact liability in Federal awards, including ensuring awards are not used to support "disparate-impact studies" or activities based on the assumed risk of such liability in which differences in outcomes among races, sexes, or similar groups give rise to a presumption of discrimination.

The definition proposed is written broadly enough to reach a substantial and scientifically essential body of biomedical and behavioral research documenting and addressing diseases that disproportionately affect specific racial and ethnic populations, such as sickle cell disease, certain cancers, hypertension, diabetes, and maternal mortality. Such research necessarily involves measuring and reporting differences in outcomes among different races or ethnic groups, the same fact pattern the proposed definition uses to describe disparate-impact liability, even though the research in question concerns biological and epidemiological outcomes rather than a presumption of unlawful discrimination.

Because the proposed rule does not distinguish between disparate-impact liability theories used in civil-rights or employment contexts and the ordinary scientific practice of stratifying disease research by race or ethnicity to understand and address documented health disparities, our principal concern is the chilling effect this ambiguity would create for our researchers. Investigators and grants offices, uncertain whether a given study could be characterized as "supporting" disparate-impact-related findings, may decline to propose, fund, or continue such research rather than risk a compliance finding, even where there is no liability. This risk falls particularly hard on small, independent research institutions that lack dedicated legal staff to assess where a given line of disease disparities research falls relative to this provision.

We recommend OMB clarify that the prohibition does not apply to biomedical, behavioral, or public health research documenting differences in disease prevalence, progression, or outcomes among racial or ethnic populations, and that such research is not "support" for a disparate-impact liability theory within the meaning of this section. Absent this clarification, we are concerned that this provision will discourage exactly the kind of health disparities research that is necessary to improve health outcomes for the specific populations affected, without advancing the civil-rights objectives the provision is intended to serve.

[§§200.432, 200.454, 200.461] Strike the Disallowances of Publication, Subscription, and Conference Costs

AIRI opposes the proposed disallowance of several cost categories that are necessary to the conduct and dissemination of federally funded research. Proposed §200.461 would make publication costs unallowable under Federal awards except where specifically required by statute or separately approved by the Federal agency on a case-by-case basis. Proposed §200.454(b) would make subscriptions to business, professional, academic, and technical periodicals

unallowable with no exception, and §200.432(b) would permit conference attendance costs only where the agency has expressly approved participation and included it in the award's terms and conditions.

AIRI supports OMB's stated objective of promoting rigorous, reproducible, and trustworthy scientific research. However, AIRI is concerned that the proposed disallowance of publication costs, subscription costs, and conference participation costs under §§200.432, 200.454, and 200.461 is inconsistent with that objective and may undermine the very mechanisms by which scientific quality is evaluated, validated, and disseminated.

These are not discretionary or peripheral costs for our member institutions. Publication in peer-reviewed journals, including open-access placement, is the primary mechanism by which the results of federally funded biomedical and behavioral research reach other scientists, clinicians, patients, and the public; disallowing article processing charges does not eliminate the cost of publishing, it simply shifts that cost from the Federal award onto an institution's already thin operating margins, or pressures investigators toward outlets without open-access fees regardless of audience reach. Likewise, current subscriptions to technical and scientific periodicals and active participation in scientific conferences are how our investigators stay current within the field, present their own findings, and recruit and train the next generation of scientists. These are activities that directly serve, rather than detract from, the objectives of the underlying Federal award and are integral components of the scientific process. A case-by-case, agency-approval model for these costs, with no agency-level standard for how or when approval will be granted, replaces a predictable, budgetable cost category with an unpredictable one.

This inconsistency extends to the administration’s own Executive Order 14303, “Restoring Gold Standard Science,” which directs agencies to make the data, analyses, and conclusions of influential federally funded research publicly available and defines Gold Standard Science as reproducible and subject to peer review which are outcomes that depend on publication. Making publication costs presumptively unallowable works against the very transparency and peer-review mandate EO 14303 sets for federally funded science.

Unlike universities and hospitals, which can draw on tuition, clinical revenue, or state appropriations to absorb a newly disallowed cost category, AIRI member institutions rely overwhelmingly on Federal grants and cooperative agreements as their primary or sole source of operating revenue. These new restrictions would create challenges and could impede the public dissemination of federally funded discoveries. Such an outcome would be inconsistent with the goals of transparency, accountability, and scientific excellence that the proposed rule seeks to promote. We also flag proposed §200.454(d), which would disallow membership costs for organizations whose “primary purpose” is lobbying or issue advocacy, a term left undefined in the proposed revision. AIRI itself engages in lobbying and issue advocacy on behalf of its membership, including through comments such as this one, undertaken to advance the American scientific enterprise and promote robust Federal research funding, and many of our member institutes similarly belong to scientific societies that engage in some policy advocacy alongside their primary scientific mission. Because “primary purpose” is undefined, institutes and auditors are left to guess at where a given society falls, creating exactly the kind of unpredictable, case-by-case cost determination that the disallowance provisions elsewhere in this section also raise.

We recommend OMB strike the changes in §§200.461, 200.454(b), and 200.432(b) and revert to current allowability standards; if any version is retained, OMB should specify the approval standard

and timeline and define “primary purpose” in §200.454(d) by reference to an organization's predominant activities and budget allocation.

[§200.220, §§200.329, 200.331–200.332] Withdraw the Government-Wide Extension of International Collaboration Restrictions

The proposed rule extends the NASA-specific restriction on collaboration with certain foreign countries and entities (the Wolf Amendment) to a government-wide baseline rule [§200.220] and separately expands pass-through entity obligations for subrecipient and affiliate reporting [§§200.329, 200.331–332].

AIRI opposes the government-wide extension of this restriction on international research collaboration. Biomedical and behavioral science is, by its nature, a collaborative and international enterprise: progress on cancer, neurodegenerative disease, infectious disease, and rare disorders has historically depended on the free exchange of data, materials, methods, and scientific talent across borders. Extending this restriction beyond its narrower, mission-specific origin at NASA risks reducing the collegiality and openness that has long been a defining strength of the American research enterprise, replacing routine scientific exchange with a compliance-driven calculus of which international collaborations are administratively and legally safe to pursue.

As other nations, including China, make substantial and sustained investments in biomedical and life-sciences research, the United States' continued leadership has depended in significant part on its ability to attract international scientific talent and to engage the best researchers worldwide as collaborators rather than competitors. A government-wide framework that makes international research collaboration administratively burdensome and legally uncertain risks pushing promising international partnerships, and the researchers who would pursue them, toward other countries that impose fewer such restrictions, at the exact moment the United States can least afford to cede ground in the global competition for scientific talent and discovery. Separately, the compliance burden of determining whether a collaborator is a "covered foreign entity" or whether a related-party transfer must be reported as a subaward falls hardest on smaller institutes that lack dedicated compliance and legal staff.

AIRI members are committed to good stewardship of Federal research dollars and take seriously their role in protecting federally funded research from foreign adversaries. Our member institutions have invested significant time and resources in implementing the research security provisions enacted by this administration and Congress in recent years, and we believe research institutions should be given the opportunity to demonstrate the outcomes of those changes before additional restrictions on international collaboration are imposed.

We recommend OMB withdraw the government-wide extension at §200.220 and retain its current, narrower application.

Conclusion

Taken together, the provisions discussed above would, if finalized as proposed, expose AIRI member institutions to a degree of financial and administrative instability that many single-purpose, grant-dependent research institutions would struggle to withstand, with consequences for the research workforce and, in the most severe cases, for the continued existence of the institutions themselves. We do not believe this is the outcome OMB intends, but it is the practical effect the rule would have on our sector as currently drafted.

AIRI appreciates the opportunity to comment on this proposed rule, and we would welcome the opportunity to discuss these comments further with OMB staff.

Sincerely,

David Cabrera
President, Association of Independent Research Institutes