June 24, 2026

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

Re: Regulation for Federal Financial Assistance; Docket No. OMB-2026-0034

Dear Director Vought:

The Association for Diagnostics & Laboratory Medicine (ADLM) appreciates the opportunity to comment on the Office of Management and Budget's (OMB's) proposed rule, *Regulation for Federal Financial Assistance*. ADLM is concerned that several provisions in the proposed rule could have significant and unintended consequences for federally supported scientific and medical research, including clinical laboratory research that informs patient care, diagnosis, disease prevention, and public health.

ADLM is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. ADLM brings together clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, microbiology, translational medicine, lab management, and other areas of clinical laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

ADLM supports appropriate stewardship, transparency, and accountability in the use of federal funds. However, federal research policy must also preserve scientific integrity, expert review, and the ability of researchers to share findings with clinicians, laboratories, patients, and the public. As drafted, the proposed rule could create uncertainty in the grantmaking process, limit the dissemination of federally funded research, and increase administrative barriers for researchers and institutions.

I. Senior Appointee Review and Involvement -- Proposed §§ 200.202 and 200.205: Program Design, Merit Review, and Pre Issuance Review

Proposed § 200.202 would revise requirements for federal program planning and design by directing agencies to ensure that program goals and objectives are consistent with the public purpose of the authorizing statute and aligned with administration policies and priorities.

Proposed § 200.205 would revise the federal agency merit review process and establish a new pre-issuance review process for discretionary awards. Under the proposal, senior appointees would review proposals selected for funding to ensure consistency with applicable law, federal agency priorities, and the national interest. The proposed rule also states that agencies should ensure discretionary awards advance the President's policy priorities and stipulates that peer review remains advisory.

The existing federal research funding framework, grounded in independent expert peer review, has been extraordinarily successful in advancing medical knowledge, improving patient care, and supporting the development of life-saving diagnostics, treatments, and public health interventions. For decades, this system has helped ensure that scientific and medical research proposals are evaluated based on rigor, feasibility, innovation, and potential benefit to patients and the public.

OMB has not clearly identified what deficiency in the existing merit review system these proposed changes are intended to solve, particularly with respect to federally supported scientific and medical research. Without such justification, ADLM is concerned that the proposed pre-issuance review requirements could introduce uncertainty and political considerations into a system that has historically served the public well by prioritizing scientific merit and expert evaluation.

ADLM is concerned that these changes could shift federal research funding decisions away from independent, merit-based scientific review and toward policy or political considerations that may change over time. While agencies must retain responsibility for final award decisions and compliance with applicable law, scientific peer review is essential to ensuring that research proposals are evaluated based on expertise, rigor, feasibility, reproducibility, and potential impact.

This is especially important for clinical laboratory research. Federal grants support work that informs diagnostic testing, reference intervals, biomarker development, laboratory quality, public health surveillance, and the evidence base used by clinicians and laboratories. If the role of independent scientific review is weakened or if award decisions become less predictable, valuable research that would benefit the American public may be delayed, redirected, or discouraged.

OMB should revise proposed §§ 200.202 and 200.205 to make clear that scientific merit, as assessed through independent expert review, remains the primary basis for research funding decisions. Any departure from peer review recommendations should be documented, transparent, and based on scientific, programmatic, or legal considerations. OMB should avoid finalizing language that could permit research awards to be approved, denied, delayed, or redirected based primarily on shifting policy priorities rather than scientific merit and public health need.

II. Expanded Authority to Terminate Grants - - Proposed §§ 200.340 and 200.341: Suspension, Termination, and Remedies for Federal Awards

Proposed § 200.340 would revise federal award termination and suspension provisions. The proposal would allow a federal agency or pass-through entity to terminate an award in whole or in part if it determines that termination is in the interest of the federal agency or pass-through entity, including when the award no longer effectuates program goals, federal agency priorities, or the national interest as they exist at the time of termination. Proposed § 200.341 would address notification requirements for termination.

ADLM is concerned that this proposed termination authority is too broad and could create significant uncertainty for federally funded research. Scientific and medical research often requires long-term planning, hiring, sample collection, data generation, laboratory validation, technology development, and collaboration across institutions. Researchers and institutions make commitments based on awarded funds and approved research plans. Interrupting this work midstream can reduce the value of completed work, compromise study integrity, and delay translation of findings into clinical practice.

OMB should not finalize proposed §§ 200.340 and 200.341 as drafted. At a minimum, any discretionary termination authority should be narrowly tailored, limited to clearly defined circumstances, and accompanied by due process protections, including notice, a meaningful opportunity to respond, and reimbursement of allowable costs incurred in good faith. OMB should also clarify that termination authority should not be used to disrupt scientifically sound research solely because agency priorities change after an award has been made.

III. Diverse Data - Proposed §§ 200.205, 200.218, and 200.300: Nondiscrimination Requirements, Disparate Impact, and Representative Data

Proposed § 200.218 would establish a government-wide prohibition on using federal award funds to promote or support theories of disparate impact liability, except where required by law. Proposed § 200.300 would revise statutory and national policy requirements for federal awards, including provisions related to nondiscrimination and unlawful Diversity, Equity, & Inclusion (DEI) activities. Proposed § 200.205 would also require pre-issuance review to ensure that discretionary awards do not use funds for discriminatory or otherwise impermissible purposes.

ADLM supports compliance with federal nondiscrimination laws and agrees that federal award funds must be administered consistent with applicable law. However, OMB should ensure that the final rule does not restrict or discourage lawful activities that are essential to sound scientific and medical research, including the collection, analysis, reporting, and use of demographic, clinical, and population-level data.

Representative data is critical to clinical laboratory science. Laboratory tests, diagnostic algorithms, biomarkers, and AI-enabled tools must be developed, validated, and evaluated using data that reflect the intended use population. This is not a political consideration. It is a scientific requirement. Without representative data, researchers, laboratories, clinicians, and regulators may not be able to determine whether a test or tool performs reliably across relevant patient populations, including differences related to age, sex, pregnancy status, comorbidities, geography, ancestry, and other clinically meaningful variables.

This issue is particularly important as healthcare increasingly incorporates AI and data-driven tools. AI systems can reflect and amplify limitations in the data on which they are trained or validated. For that reason, federally supported research must be able to evaluate whether datasets are representative, whether results are generalizable, and whether diagnostic or predictive tools perform appropriately across the patients they are intended to serve.

As drafted, proposed §§ 200.205, 200.218, and 200.300 could be read broadly by agencies, recipients, or subrecipients in a way that hinders lawful and scientifically necessary activities, such as representative study design, demographic data collection, subgroup analysis, assessment of diagnostic performance across populations, and evaluation of potential bias in AI-enabled tools. These activities do not inherently constitute unlawful discrimination or preferential treatment. Rather, when conducted consistent with applicable law and ethical research standards, they are necessary to ensure that federally supported research produces accurate, valid, and clinically useful results.

OMB should revise the final rule to make clear that nothing in §§ 200.205, 200.218, or 200.300 prohibits or discourages lawful collection, analysis, reporting, or use of demographic and population-level data for scientific, clinical, regulatory, quality improvement, or public health purposes. OMB should also clarify that federally funded researchers may continue to conduct representative recruitment, subgroup analyses, reference interval development, diagnostic validation, and AI performance evaluation when those activities are reasonable, scientifically justified, and conducted in compliance with applicable nondiscrimination laws.

IV. Foreign Restrictions - Proposed §§ 200.202 and 200.220: Domestic First Framework and Covered Foreign Collaborations

Proposed § 200.202 would require agencies to apply a domestic-first framework to research and development awards. Proposed § 200.220 would prohibit recipients and subrecipients from obligating or expending federal funds to support certain bilateral or multilateral collaborations, agreements, programs, or activities with covered foreign countries or covered foreign entities, unless an exception applies.

ADLM supports safeguards to protect research security, national security, and the integrity of federal funds. However, clinical laboratory science is inherently global. Diagnostic standards, reference intervals, infectious disease surveillance, assay harmonization, and public health preparedness often depend on collaboration across borders. International collaboration can provide access to unique expertise, study populations, specimens, datasets, technologies, and public health information that may not be available domestically.

A broad or unclear restriction on foreign collaborations could discourage appropriate scientific partnerships that advance United States (US) public health interests. This could be particularly harmful in areas such as infectious disease surveillance, laboratory harmonization, rare disease diagnostics, pediatric reference intervals, and evaluation of diagnostic technologies across diverse populations and settings.

OMB should ensure that any final rule related to foreign collaborations is targeted, risk-based, and clearly limited to collaborations that raise specific security or legal concerns. The final rule should avoid discouraging appropriate international research partnerships that advance US scientific leadership, patient care, and public health. OMB should also provide clear definitions and implementation guidance so recipients can distinguish prohibited collaborations from lawful, scientifically justified international work.

V. Dissemination of Scientific Information - Proposed §§ 200.432, 200.454, and 200.461: Conference, Professional Activity, and Publication Costs

Proposed § 200.432 would make conference attendance costs allowable only if participation is expressly approved by the agency and included in the terms and conditions of the award.

Proposed § 200.454 would limit allowable membership, subscription, and professional activity costs to those necessary to fulfill award requirements and subject those costs to prior agency approval. Proposed § 200.461 would make publication costs, including page charges, article processing charges, open access fees, and similar fees for peer-reviewed publications, generally unallowable unless required by statute or approved in advance by the federal agency on a case-by-case basis.

ADLM is concerned that these provisions would treat scientific dissemination as ancillary to federally funded research when, in fact, dissemination is central to the value of federal research investment. Publication in peer-reviewed journals, presentation at scientific meetings, and engagement with professional societies are core mechanisms through which research findings are evaluated, replicated, challenged, translated, and implemented in clinical practice.

For clinical laboratory science, dissemination is especially important. Laboratory professionals, clinicians, manufacturers, public health officials, regulators, and researchers rely on peer-reviewed publications and scientific meetings to understand new evidence related to diagnostic testing, reference intervals, biomarkers, laboratory quality, emerging pathogens, and new technologies. Limiting the allowability of publication and conference costs could delay or reduce the ability of federally funded researchers to share findings with the communities responsible for applying them in patient care and public health.

The proposal also could create unnecessary administrative burden by requiring case-by-case approval for routine and predictable costs that are directly related to the award. These costs are often modest relative to the overall award but essential to ensuring that research findings reach the scientific and medical communities.

OMB should maintain publication, conference, membership, subscription, and professional activity costs as allowable when they are reasonable, allocable, and directly related to the federal award. OMB should not finalize language that makes publication costs broadly unallowable or that requires case-by-case prior approval for routine dissemination activities. At minimum, OMB should clarify that peer-reviewed publication, open access publication when appropriate, presentation of federally funded findings, and participation in scientific meetings are allowable when they advance the objectives of the award.

VI. Administrative Burden - Proposed Government-Wide Changes to 2 CFR Part 200: Administrative Burden and Implementation Uncertainty

The proposed rule would make broad government-wide revisions to 2 CFR Part 200, affecting the full lifecycle of federal awards, including program design, notices of funding opportunities, merit review, award terms, recipient obligations, termination, cost principles, subrecipient management, and audit requirements.

ADLM is concerned that the proposal could create substantial administrative burden and implementation uncertainty for researchers, institutions, and federal agencies. Clinical laboratory researchers and institutions already operate under extensive federal requirements designed to ensure accountability, research integrity, patient safety, privacy, and appropriate use of funds. Additional prior approval requirements, broad termination authority, unclear standards tied to changing agency priorities, and new compliance obligations could divert time and resources away from research and toward administrative processes that do not meaningfully improve stewardship of federal funds.

The scope of the proposed changes also makes it difficult for affected stakeholders to fully evaluate the implications for federally supported medical and scientific research. Researchers, professional societies, hospitals, academic medical centers, laboratories, public health entities, and other recipients will need sufficient time and clear guidance to understand how these changes would operate in practice.

OMB should not finalize the proposed rule as drafted. OMB should carefully assess the cumulative burden of the proposed changes, provide additional clarity on ambiguous provisions, and ensure that any final rule preserves the ability of federally funded researchers to conduct, complete, and disseminate scientifically valid research. OMB should also consider whether additional stakeholder engagement is necessary before adopting changes of this scope.

For these reasons, ADLM urges OMB to revise the proposal to preserve independent scientific peer review, narrow any award termination authority, protect the lawful use of representative data in scientific and medical research, protect appropriate scientific collaboration, maintain reasonable publication and dissemination costs as allowable, and avoid unnecessary administrative burdens that could slow medical and scientific progress.

Thank you for considering ADLM's comments. If you have any questions, please email Vince Stine, PhD, ADLM's Chief Policy Officer, at vstine@myadlm.org, or Evan Fortman, MPA, ADLM's Manager of Government Affairs, at efortman@myadlm.org.

Sincerely,

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President, ADLM