July 13, 2026

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

Re: Comment on Proposed Rule, Regulation for Federal Financial Assistance (Docket OMB-2026-0034) (May 29, 2026)

Dear Director Vought:

The Alzheimer's Association and the Alzheimer's Impact Movement appreciate the opportunity to comment on the proposed rule on Federal Financial Assistance and the impact it will have on the Alzheimer's and dementia community.

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support, and research. The Alzheimer's Impact Movement (AIM), a separately incorporated advocacy affiliate, is a nonpartisan, nonprofit organization and works to make Alzheimer's a national priority.

Today, there are nearly 7 million Americans living with clinical Alzheimer's disease and the population of Americans aged 65 and older is projected to grow from 58 million in 2022 to 82 million by 2050. There are multiple treatments approved by the Food and Drug Administration (FDA) to slow the progression of Alzheimer's disease, recently FDA-cleared Alzheimer's disease blood tests, and continuing innovation around brain health and lifestyle modification to benefit cognition. We work together with the people living with Alzheimer's disease and other diseases that cause cognitive impairment and dementia, their family members who care for them, and the global community of scientists and clinicians working to prevent, treat, and ultimately cure this disease. These tremendous steps forward would not be possible without the continued leadership and investment of the United States government.

Alzheimer's is a leading cause of death in the United States and is projected to affect nearly 13 million Americans by 2050; care for people living with dementia is estimated to cost the nation $409 billion in 2026 alone. Progress against a disease of this scale depends on a federal research system that funds the best science and public health research, shares results openly, collaborates across borders, and provides the multi-year stability that long studies and clinical trials require. While we understand the goals behind this rule, we are concerned that, as currently proposed, it may unintentionally weaken these foundations and could affect the United States' standing as the leader in biomedical research. We respectfully urge the Office of Management and Budget (OMB) not to finalize the rule in its current form.

Federal Agency Review of Merit of Proposals (§200.205)

In the proposed rule, §200.205 establishes a pre-issuance review process under which senior agency appointees would determine that proposals selected for funding are consistent with applicable law, Federal agency priorities, and the national interest. It specifically states that senior appointees would ensure that discretionary awards advance the President's policy priorities, prohibit the use of funds for discriminatory or otherwise impermissible purposes, and emphasize ensuring compliance with applicable law. The proposed rule states that scientific peer

review remains advisory and does not replace agency discretion. It also directs agencies to incorporate benchmarks for measuring performance against “Gold Standard Science” and to weigh institutional commitment to research integrity in award decisions.

The Association and AIM have concerns about this proposal and respectfully urge OMB not to move forward with finalizing it, given the potential long-term impacts on the scientific community and on the United States' continued role as the worldwide leader in biomedical research. We appreciate OMB's intent to ensure funding decisions are consistent with applicable law. At the same time, we caution that allowing senior appointees to direct awards toward the President's priorities could inhibit the long-term research and programs recommended by scientific peer review committees.

Expert peer review by qualified scientists is a mechanism that has made the United States the world leader in biomedical research. It is how the nation ensures that Federal research dollars support the most meritorious, rigorous, and reproducible work and it protects taxpayers and patients from funding decisions not aligned with scientific merit.

In a field as complex and rapidly evolving as Alzheimer’s disease and other dementia, the disciplined evaluation of scientific merit, rationale, and methodology should remain with scientists and researchers otherwise there can be real impact on the people who are counting on this research. Peer review is what adjudicates the merit, the scientific rationale, and the methodology of a proposal. And when a scientific finding is reproduced through different methods and by different teams, that convergence does not duplicate effort; it strengthens confidence in the result and propels the field toward the next discovery. Research, especially research looking at complex diseases like Alzheimer’s disease, often requires sustained investment across multiple administrations and funding cycles. Maintaining stable, merit-based review processes is therefore particularly important for preserving continuity in research that may take years or decades to yield breakthroughs for patients and families.

We are also concerned that the term “Gold Standard Science” standard remains undefined and that the proposed appointee criteria create unpredictability. Applied subjectively, such standards could disadvantage the innovative and early-stage approaches that are common, and essential, in dementia research, and could place final funding authority with individuals who do not have subject-matter expertise in the relevant science. These concerns extend beyond research grants to program awards, such as public health and caregiver support cooperative agreements, where funding decisions should rest on demonstrated public health value rather than changing political priorities.

If OMB moves forward with the proposal, the final rule should establish a clear standard that scientific merit, as determined by qualified peer reviewers, is the primary factor in award decisions, and should preserve a determinative, not merely advisory, role for scientific peer review. Any “Gold Standard Science” benchmark should be defined transparently and consistently with established norms of scientific integrity, and qualified scientific experts should retain a central role in evaluating scientific merit.

Prohibition of using Federal awards to promote or support theories of disparate-impact liability, Prohibition of discriminatory event services, and Statutory and national policy requirements (§200.218, §200.219, §200.300)

In these sections, OMB proposes to prevent awards from being used to promote or support theories of disparate-impact liability, or diversity, equity, and inclusion policies or practices and seeks to ensure that Federal funds are not used in a discriminatory manner generally.

If finalized, the Association and AIM urge OMB to distinguish between ideology and health disparities in applying this rule. Black older Americans are approximately twice as likely and Hispanic Americans are about 1.5 times as likely to develop Alzheimer’s or other dementias. The disease also disproportionately affects women and

individuals in rural communities, and veterans living with post-traumatic stress disorder or traumatic brain injury have a higher risk of developing cognitive decline and dementia[1]. These are disparities in the health and well-being of Americans.

Research that seeks to understand the causes, prevalence, progression, and outcomes of Alzheimer's disease and other dementia among different populations should not be construed as promoting a particular ideology. Rather, such work is fundamental to understanding disease burden, improving prevention and treatment strategies, and ensuring that Federal health programs effectively serve the populations Congress intended to benefit. Addressing gaps in research and care, including through the use of Federal dollars, is a scientific imperative and avoids increased costs to payers, including Medicare and Medicaid. We urge OMB to explicitly affirm that research, data collection, program evaluation, patient outreach, and other evidence-based activities designed to identify, understand, or address health equity and disparities remain fully eligible for Federal funding when conducted pursuant to statutory program purposes and rigorous scientific or public health methodologies.

Prohibition of Using Federal Funds for Covered Foreign Collaborations (§200.220)

Under the proposed rule, the "Domestic-First" framework and the prohibitions on collaborative research involving "covered foreign countries" would require case-by-case approval for international collaborations that are today standard scientific practice, and could broadly restrict travel, technical assistance, research activities, and indirect costs associated with that work.

Alzheimer's disease and other dementia impact millions of Americans and impose enormous costs on U.S. families, employers, Medicare, and Medicaid. Advancing treatments, prevention strategies, and diagnostics for Americans requires access to global data, diverse study populations, and international scientific collaboration. In the dementia field, international partnerships are essential to achieving outcomes that directly benefit the American people.

Some of the most important questions in the field cannot be answered within any single country. The complexity of these brain diseases requires massive data sets and collaboration across numerous teams. For instance, the genetic heterogeneity of the disease tells us that while there may be individual genes that contribute to a person's risk or resilience, there are also important aspects of genetic ancestry that may influence the role of those genes. For example, populations affected by rare, dominantly inherited, and early-onset forms of Alzheimer's are too few in any one part of the world to support robust study in isolation, and it is only through international networks that bring together enough families and individuals with these mutations that we can understand the genetic contributors to risk and the underlying biology of the disease. This is knowledge that ultimately benefits all Americans. Restricting these collaborations would not protect American interests; it would slow the very discoveries that serve them.

The Association's own work illustrates how integral, not incidental, international collaboration is to progress. For example, the Association coordinates the Worldwide FINGERS (WW-FINGERS) network bringing together multidomain approaches in numerous cultural settings to inform solutions of behavioral interventions for all communities and populations across the United States; supports global brain health efforts and related cross-border scientific efforts through the Global Biomarker Standardization Consortium (GBSC) to develop quality control processes and methodology that applies to emerging fluid biomarkers; and, through its International Research Grant Program (IRGP), which funds investigators across the globe. These long-standing programs reflect the scientific consensus that the fight against dementia requires a worldwide research community.

The proposed rule also provides no clear standard by which agencies would evaluate when international participation by a foreign entity crosses into a prohibited collaboration. That ambiguity creates significant

[1] Alzheimer's Association. (2026). *2026 Alzheimer's Disease Facts and Figures.*

practical challenges for recipients trying to design and sustain compliant research programs. In the field of Alzheimer's disease and dementia, structured international collaboration is not contrary to American interests, but instead it is often indispensable to developing the evidence, treatments, diagnostics, and prevention strategies wanted and needed by Americans.

The Association and AIM urge OMB to reconsider making these sections final. The final rule should not adopt a blanket Domestic-First framework. If any international restrictions are retained, they should be narrow and risk-based, tied to specific, identified national security concerns, with a clear, published standard, an efficient approval pathway, and explicit protection for established scientific collaborations and clinical-trial networks.

Termination and Suspension, Notification of Termination Requirement, Opportunities to Object, Hearings, and Appeals (§200.340, §200.341, §200.342)

The proposed revisions would permit an agency to suspend or terminate an active award for discretionary reasons, including when the agency determines that the award "no longer advances agency priorities or the national interest" as those exist at the time of the termination, so long as the agency offers a brief written rationale, with "agency priorities" defined as those of the politically accountable agency. In practice, this could significantly weaken meaningful protection against arbitrary or politically motivated terminations and would undermine researchers' ability to engage in the long-term scientific planning that scientific progress requires.

Discretionary termination of federal awards causes tangible and lasting harm to researchers, patients, and taxpayers, a harm that is not limited to research alone. The same funding instability can also interrupt implementation grants, workforce development programs, and public health initiatives that translate scientific advances into clinical practice. Longitudinal data sets lose their scientific value when studies end early. Clinical-trial participants lose any benefit when they are forced to stop mid-protocol. Many participants enroll in Alzheimer's disease and dementia studies because they have few other opportunities to access cutting-edge interventions or contribute to research that may benefit future generations. Abrupt termination of studies can undermine participant trust, discourage future enrollment in clinical research, and delay progress toward urgently needed treatments. Graduate students and early-career scientists must abandon their training. Community organizations and health systems implementing evidence-based dementia care models lose the capacity they've built to deliver diagnostics and treatment. And the taxpayer dollars already invested at the outset of a study, trial, or program are wasted. Significant administrative and financial costs are incurred at the outset of any award; terminating midstream wastes that up-front investment and disrupts the financial and administrative flow on which these efforts depend, and ultimately delays not just research, but patients' access to evidence-based care, diagnostics and treatments.

The Association and AIM recognize the need to guard against bad actors who may misuse federal funds. We urge OMB to consider, however, that Federally funded research and programmatic awards are not the same as construction contracts that can be paused and resumed at will. A clinical trial or longitudinal study, once interrupted, often cannot be restarted as participants are lost, data integrity is compromised, and years of work can be undone; and restarting may require significant additional resources to implement. A stop-work order raises immediate questions about the safety and welfare of trial participants, the loss of irreplaceable measurement timepoints and data, and whether a study could ever be reconstituted, which is often impossible. The proposed standards may compound this risk: terms such as "agency priorities," "the national interest," and "no longer in the public interest" are open to broad interpretation. Agencies already have authority to terminate awards, and the proposed language could make terminations on political grounds considerably easier in the future.

The Association and AIM respectfully offer the following recommendations for the final rule: (1) provide that terminations of research awards be grounded in documented scientific, compliance, or financial reasons rather than changes in political priority; (2) prohibit discretionary termination of ongoing clinical trials, longitudinal studies, and other human-subject research absent documented concerns regarding safety, compliance, fraud,

waste, abuse, or failure to perform; (3) include a documented rationale and due process for any termination other than for noncompliance; (4) define key terms, including "agency priorities," "the national interest," and "pass-through entity"; and (5) require agencies to evaluate and document the impacts of any proposed termination on research participants, patient safety, ongoing clinical activities, and previously expended Federal funds before a termination becomes effective.

Indirect Costs (§200.414)

While OMB does not explicitly propose capping indirect cost rates in research, it instructs agencies to favor institutions with lower rates. Federal agencies require substantial documentation for scientific progress, compliance, and financial reporting, requiring expert teams to support these efforts and provide clear direction and oversight of federal resources. These administrative and compliance functions are supported by indirect rates. Indirect costs also support the research infrastructure necessary to conduct safe, compliant, and high-quality biomedical research, including research laboratories, data security systems, participant protections, regulatory oversight, and specialized scientific facilities. Without these investments, many Federally funded research projects could not proceed.

Indirect cost rates are negotiated with the Federal Government and reflect the actual costs of supporting research activities. Favoring institutions solely because they have lower indirect rates may not reduce overall costs to taxpayers and could inadvertently disadvantage institutions with the infrastructure, expertise, and capabilities required to conduct complex biomedical research efficiently at scale.

Larger research institutions, such as academic medical centers, often have higher indirect rates due to the necessity of maintaining expensive core facilities (e.g., tissue culture environments, advanced microscopy, and other specialized equipment) and a concentration of expert personnel. These shared, sophisticated resources can ultimately decrease overall research costs by serving a large number of researchers across disease areas and preventing duplication or redundancy. This existing capital infrastructure allows for economies of scale that enable scientific discoveries and breakthrough therapies. The neurodegeneration research ecosystem depends on investments in sophisticated research infrastructure that support discovery, clinical trials, biomarker development, data management, patient recruitment, and regulatory compliance. These capabilities are frequently housed within academic medical centers and major research institutions that have negotiated indirect cost rates reflecting the true costs of maintaining such infrastructure. Policies that penalize institutions for these legitimate costs may ultimately reduce research capacity, slow scientific progress, and delay the development of treatments and interventions needed by patients and families.

The Alzheimer's Association and AIM urge OMB to reconsider this policy and continue supporting the research infrastructure that has made the United States the global leader in biomedical innovation, consistent with the recently announced initiative at the Department of Health and Human Services, Operation TrialBlazer.

Conferences (§200.432)

Under the proposed rule, the cost of attending a conference would be allowable only if participation is expressly approved by the agency and written into the terms and conditions of the award before work begins. This reverses the longstanding and well-founded presumption that attendance at scientific conferences is an allowable cost of conducting research.

Scientific conferences are not ancillary to research but are a critical component of the scientific process itself. Researchers use these forums to evaluate emerging evidence, receive expert feedback, form new collaborations, identify methodological improvements, and disseminate findings to the broader scientific community. These opportunities are where you often identify new techniques to apply to answer a confounding question, learn a piece of a puzzle that may not yet be in the published literature and identify cross discipline opportunities for

collaboration and shared learnings. This is also a key part of the scientific leadership for the individual -- presenting their findings and receiving real time feedback on their protocol, their findings and their conclusions to elevate the work and drive forward discovery.

Moreover, it is often impossible at the outset of a multi-year award to identify every conference attendance opportunity that may become scientifically relevant during the life of a project. Requiring attendance to be specified in advance within award terms could create unnecessary administrative burdens for both agencies and recipients while limiting researchers' ability to respond to emerging scientific developments. Requiring case-by-case advance approval and requiring that each instance of attendance be pre-specified in award terms would reduce participation by Federally funded researchers, slow scientific exchange, and ultimately stall science. Over time, these effects will weaken American leadership in scientific innovation and delay the discoveries that improve the lives of the American people.

For Alzheimer's disease and dementia research, scientific conferences are particularly important because the field is advancing rapidly in areas such as biomarkers, diagnostics, prevention strategies, and therapeutic development. Delays in sharing findings and integrating new evidence into ongoing research efforts can slow progress toward treatments and improved care for patients and families. Restricting researchers' ability to participate in scientific conferences would not strengthen stewardship of Federal funds; it would impede the exchange of knowledge that allows Federal research investments to generate the greatest possible return for the American public.

The Association and AIM respectfully urge OMB to allow attendance at peer-reviewed scientific conferences within an investigator's funded area of research to remain a presumptively allowable cost, without a requirement for case-by-case advance agency approval.

Fundraising and investment management costs, Lobbying, and Memberships, subscriptions, and professional activity costs (§200.442, §200.450, §200.454)

In these sections, OMB proposes to require prior written approval for costs related to fundraising and investment activities and memberships, subscriptions, or similar professional activities, as well as prohibiting the use of Federal funds to engage in issue advocacy or public messaging of political or policy positions. "Fundraising" and "issue advocacy," however, are undefined in this proposed rule, creating potential harmful ambiguity.

The Association and AIM support appropriate limitations on the use of Federal funds for lobbying and partisan political activities. However, evidence-based public health education, scientific dissemination, caregiver outreach, patient navigation, community awareness initiatives, and other activities designed to improve health outcomes should not be considered "issue advocacy" simply because they address matters of public concern.

For example, public health education and community awareness activities (e.g., brain health educational campaign, caregiver support outreach) are apolitical and exist for the benefit of all Americans. Similarly, memberships and participation in professional organizations often play an important role in the dissemination of scientific knowledge, professional development of future clinical and scientific leadership, and collaboration among researchers, healthcare professionals, and service providers working to improve patient outcomes.

The Association and AIM respectfully request that OMB define these and related terms and protect activities important to the health and well-being of the country.

Publication and Printing Costs (§200.461)

The proposed rule would make publication costs, including page charges, article processing charges (APCs), and open-access fees, unallowable unless expressly required by statute or approved in advance by the agency,

reasoning that a general requirement to make results publicly available should not be construed as authorizing publication costs.

Dissemination should not be considered an add-on to research; it is core to scientific progress. Federal investments in research generate the greatest public benefit when findings are made available to other researchers, clinicians, policymakers, and the public. Publication is the primary mechanism through which taxpayer-funded discoveries are translated into broader scientific progress and public benefit. If researchers are not presenting their findings or publishing their work, then the potential impact on reproducibility and redundancy will expand. These are opportunities for identifying synergies and shared approaches, for identifying when a common answer from different paths has been identified further solidifying that scientific discovery or answer -- this enables the next step or question to be targeted, and this is the scientific method. Alzheimer's and dementia research advances depend on the rapid, open sharing of results across the global scientific community. Journals and subscriptions give researchers access to new, cutting-edge discoveries in their fields at relatively minimal cost. They compile novel scientific insights, document which ideas have been and are being tested, and generate questions that drive the next round of discovery. Making publication unallowable would slow the spread of taxpayer-funded findings and weaken the feedback loop on which the entire enterprise depends.

These restrictions would also deepen existing imbalances. Researchers at small, rural, and less well-resourced institutions would be least able to absorb publication costs on their own, widening the gap between them and investigators at large urban centers. It is difficult for the Federal government to meaningfully encourage scientific innovation while also limiting the dissemination that turns innovation into shared knowledge. The Association and AIM urge OMB to continue to allow publication costs, including APCs and open-access fees, as a standard and routine research expense.

We appreciate OMB's consideration of our comments on the proposed rule. We are happy to be a resource as you continue your work. Please do not hesitate to contact Laura Thornhill, Director of Regulatory Affairs at lthornhill@alz-aim.org if we can be of additional assistance.

Sincerely,

Joanne Pike, DrPH
President & CEO, Alzheimer's Association
CEO, Alzheimer's Impact Movement