July 12, 2026

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

Re: Regulation for Federal Financial Assistance, Docket Number: OMB-2026-0034-0001

Submitted via regulations.gov

Dear Director Vought:

Research!America submits this comment on the Office of Management and Budget's Proposed Regulation for Federal Financial Assistance (OMB-2026-0034-0001) (the proposed rule), which is supplemented by a second attachment focused on the lack of information needed to evaluate the proposed rule. Research!America is a nonprofit, nonpartisan alliance dedicated to making research and innovation a higher national priority and accelerating medical progress. Our members include patient advocacy organizations, academic medical centers, universities, research institutes, scientific societies, public health organizations, philanthropies, and private-sector innovators across the United States.

Research!America supports the federal government's stated commitment to administering federal financial assistance programs with integrity, transparency, accountability, the reduction of administrative burden, and responsible stewardship of taxpayer resources. Those commitments have long been jointly advanced by the federal government and the research community. They have helped make the federal research enterprise both successful and worthy of the public's trust. No system of this scale is perfect, and thoughtful efforts to strengthen its effectiveness should be welcomed.

Based on logic and the input of individuals with extensive, hands-on experience interacting with federal financial assistance programs, the proposed rule would contravene the very objectives OMB hopes to advance. Further, the proposed rule is likely to have a staggering, adverse impact on our economy, our national health, and our national security—undoing through regulation the clear intent of Congress as expressed in hundreds of laws enacted over decades. Finally, the proposed rule is not supported by meaningful analysis of costs,

benefits, and alternatives. Therefore, the proposed rule should be withdrawn and reworked with input from the community.

For more than half a century, federally supported research has been the seed corn that has led to the United States' global leadership in science and technology. Through a research ecosystem that includes patients and healthy volunteers, universities, academic medical centers, nonprofit research institutions, federal laboratories, entrepreneurs, and private industry, it has generated discoveries and innovations that have saved and transformed lives, strengthened the economy, and advanced national security.

That success has depended on federal policy that supports the stability needed to pursue a wide range of scientific questions. Scientific progress is cumulative. Each discovery expands the knowledge that makes future breakthroughs possible, often over years and decades. Preserving the conditions that allow this process to unfold has been crucial to the nation's scientific, technological, economic, and national security leadership.

This proposed rule would undercut stability, undermine progress, and fundamentally alter characteristics of federally supported research in ways that are counterproductive and counter-strategic to U.S. interests. Again, the impacts are so vast and the analysis so lacking that the only solution is for the rule to be withdrawn and reworked.

Through authorizing statutes and annual appropriations, year after year Congress has made clear that it values our system of scientific and medical discovery and innovation. This proposed regulation is so sweeping in its scope that in a single regulation, with only a 45-day comment period, OMB could undermine decades of legislation. Improvement in our system of discovery is always possible, but when the lives of patients, our national security, local jobs and businesses, and our global economic competitiveness are at stake, change should be grounded in a thorough risk-benefit analysis, a complete exploration of options, and a robust engagement with stakeholders. None of that was done here.

In our detailed comments below, we address specific provisions that would 1) undercut the rigor of grant and cooperative agreement decision-making; 2) generate stultifying uncertainty and establish a host of new bureaucratic requirements that can only shrink our nation’s footprint in life-saving science; 3) undermine research that has led improved health outcomes across the nation; and 4) isolate U.S. science and technology from the rest of the world, ceding leadership to other countries. In these ways, the proposed rule not only runs counter to OMB’s stated objectives for the proposed rule but jeopardizes scientific and medical progress at the expense of us all.

In a second attachment, we elaborate on the basis for our strong concern that the proposed rule is not supported by sufficient evidence to evaluate whether it achieves its stated objectives or whether the benefits OMB ascribes to the proposed rule would outweigh its costs.

Merit-Based Review [200.205]

For decades, merit-based review has served as the foundation of federal research funding decisions. The proposed rule would require federal agency heads to assign senior political appointees to conduct pre-issuance reviews of all discretionary awards and to treat peer review recommendations as no more than advisory. In fact, political appointees must ensure that scientific peer review recommendations are not "routinely deferred to."

The proposed rule does not require the political appointees to have any relevant experience or expertise upon which to base funding decisions. This change would arbitrarily separate funding decisions from merit decisions, eliminating the core mechanism that ensures that tax dollars are applied to the projects most likely to yield medical and scientific progress. Other nations have copied the US peer-review system because it yields a high return on investment. At a time when our national competitiveness is under threat, the government should be working to bolster our research and innovation output, not derail it.

Additionally, the proposal to elevate political-appointee review risks destabilization and delay, as the President's policy priorities and the appointees who interpret them will change with some frequency. Scientific projects that were deemed politically acceptable to one political appointee could be deemed unacceptable to the next, likely causing a large administrative and paperwork burden as proposals are thrown out or reworked, bottlenecks in the review, and uncertainty.

Termination Authority [200.340–343]

The proposed rule would significantly expand agency authority to suspend and terminate awards based on changing agency priorities, subjective determinations regarding whether previously approved proposals serve the national interest. No specificity is provided. As noted above, changes in priorities and determinations could happen not only with each change in administration, but also within any given administration's term of office.

The proposed rule would also create a new temporary suspension authority [see 200.340(e)], allowing agencies to issue stop-work orders pausing an award for up to 90 days whenever suspension is determined to be "in the interest of the agency." Unlike the termination standard, which at least requires agencies to provide a brief stated rationale, the suspension standard is undefined and does not require agencies to explain their reasoning. Even if an award is ultimately permitted to resume, a 90-day suspension can disrupt time-sensitive research activities, including clinical trials with fixed enrollment windows or treatment protocols, and longitudinal studies that depend on uninterrupted data collection.

The proposed rule would also narrow recipients' procedural rights when termination decisions are made. Under current regulations, recipients have the right to object, request a hearing, and pursue an appeal when an agency initiates a remedy for noncompliance, including termination. The proposed rule would preserve these procedural rights only for terminations based on noncompliance, with no requirement that agencies provide appeal rights for discretionary terminations and suspensions.

In practice, this means recipients facing termination or suspension based on shifting agency priorities, rather than their own conduct, would have no agency-level avenue to challenge the action, leaving litigation as the only recourse. Pairing expanded discretionary termination authority with reduced procedural protections would dramatically compound the uncertainty recipients face, creating higher barriers to entry and reducing the ability of small businesses and research institutions to sustain research operations.

This change also has particular significance for activities that depend on continuity, including clinical trials, longitudinal studies, multi-year cooperative agreements, public health initiatives, and long-term research projects. These activities are designed to generate benefits over extended periods of time and often cannot be interrupted without undermining their intended purpose.

Research!America is particularly concerned about the implications for patients and families who participate in federally funded research. Many of these patients participate in clinical research precisely because they have no other option. Beyond that, research participants rightly expect that studies will proceed as approved and that their participation will contribute to improving future care. Mid-study terminations unrelated to misconduct or noncompliance undermine that expectation, erode patient and community trust, and diminish the value of contributions made by research participants.

Regardless of which Administration is in office, federal financial assistance programs should operate with the expectation that awards will proceed uninterrupted as approved unless recipients fail to meet established requirements or engage in misconduct. Research!America urges OMB to maintain long-standing protections that provide recipients with reasonable assurance that awards will continue absent fraud, waste, abuse, material noncompliance, or recipient misconduct.

Taken individually and as a whole, the termination authorities proposed could disrupt lives and progress in science. The existence of these authorities in such a sweeping regulation is disruptive enough to cause economic, health, and national-security consequences.

Oversight Requirements [200.208]

Research!America supports strong oversight and responsible stewardship of taxpayer resources. However, several provisions of the proposal would introduce substantial costs and delays caused by new reporting requirements, monitoring obligations, payment-related requirements, review processes, and administrative responsibilities without demonstrating that existing safeguards are insufficient or that the proposed changes would meaningfully improve accountability.

The federal research enterprise already operates within an extensive framework of audits, financial controls, reporting requirements, conflict-of-interest disclosures, research integrity policies, agency oversight mechanisms, and merit review processes.

Additional oversight requirements may be warranted where specific risks have been identified. However, oversight mechanisms should be narrowly tailored, evidence-based, and designed to improve accountability without unnecessarily increasing administrative burden, delaying funding, or diverting resources from research, education, public health, and other federally supported activities [see 200.208].

Among Research!America's concerns, the proposed rule would expand agencies' ability to impose new conditions, reporting obligations, restrictions, or oversight requirements after awards have already been issued. Such provisions would make long-term planning more difficult and could divert resources away from the activities federal grant and cooperative agreement programs are intended to support.

Research!America shares OMB's interest in protecting the integrity of federal research investments, and we support agency efforts to identify genuine risk. However, we are

concerned that several of the new risk factors in [200.206] are defined too broadly to reliably distinguish actual risk from mere reputational or associational proxies. A "history of questionable practices" does not specify what a threshold of verification, adjudication, or due process applies before an allegation can factor into a funding decision. The research enterprise already has well-established mechanisms for addressing scientific misconduct and questionable practices, including institutional research integrity offices, journal correction and retraction processes, and federal bodies such as the Office of Research Integrity, and these mechanisms apply rigorous, expert-driven standards of evidence.

These mechanisms exist because the stakes of getting it wrong are high. Allowing risk determination to hinge on unadjudicated allegations or organizational affiliation, rather than on a grant recipient's actual record of administering federal awards, could easily lead to funding decisions inconsistent and disconnected from the central goal of ensuring the best science is funded and federal investments deliver tangible public value. We urge OMB to tie risk criteria to verifiable standards developed with input from the research community and other affected stakeholders so that program integrity and scientific excellence can work in tandem.

Research!America is also concerned about the new authority [under 200.208] that would allow agencies to add or remove specific award conditions at any point during the period of performance, with changes required to take effect within 15 calendar days of the agency's determination. We recognize agencies need tools to respond to legitimate, emerging risk, and recipients understand that accepting an award means accepting oversight. Our concern is practical. This compressed timeline gives recipients little ability to adjust staffing, procurement, subaward structures, or research activities to come into compliance with new conditions, particularly for institutions managing large award portfolios or multi-site research.

A 15-day implementation window is poorly matched to the operational realities of federally funded research and risks penalizing recipients for delays driven by the arbitrary timeline itself, rather than noncompliance. We recommend OMB adopt a more flexible implementation period, set in consultation with impacted agencies and other stakeholders, which allows good-faith recipients adequate time to comply while preserving agencies' ability to act on genuine risk.

Use of cost-reimbursement contracts [200.320]

The proposal to discourage cost reimbursement contracts would force small firms, such as those receiving Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) awards, to absorb inherently unpredictable R&D and manufacturing costs. Because many SBIR/STTR projects involve technical uncertainty, this added financial risk could lead to scope reductions, delays, or cancellations. Stricter limits or additional approvals for cost recovery would reduce funding for labs, quality systems, and compliance—core capabilities needed to meet NIH milestones. This could push small companies toward lower-risk, incremental projects that are easier to budget, rather than high-impact research with greater scientific uncertainty, undermining American competitiveness in innovative areas.

Scientific Collaboration, Dissemination, and Training [200.220, 200.432, 200.454, and 200.461]

Scientific progress depends not only on the conduct of research, but also on the conditions that enable research to succeed. These include the ability to collaborate, communicate findings, train future researchers, and pursue scientific questions wherever the relevant expertise, data, or patient populations exist.

Several provisions of the proposed rule would undermine these conditions. Restrictions on publication and dissemination activities would impede the communication of scientific findings and reduce the public value generated by federally funded research. Publication is not a peripheral activity. It is the primary mechanism through which discoveries are scrutinized, validated, replicated, and translated into practical benefit [see 200.432, 200.454, and 200.461].

The proposed rule would also prohibit the use of federal funds for certain activities characterized as "issue advocacy or public messaging" [200.450(c)(iv)]. As drafted, this provision creates uncertainty about whether researchers and research institutions may communicate scientific findings to policymakers, testify before Congress, participate in public discussions, or otherwise share evidence developed through federally supported research.

The value of federal research extends beyond the generation of new knowledge; it depends on that knowledge informing public policy, clinical practice, and other decisions that improve the health, safety, and well-being of the American people. A provision that discourages or limits the communication of research findings to policymakers and the

public would diminish the return taxpayers receive from their investment in research and weaken evidence-based policymaking.

Preserve Beneficial International Collaboration [200.220]

Research security is critically important, and Research!America supports targeted approaches to protecting sensitive research, intellectual property, and national security interests.

However, the proposed restrictions on international collaborations are sufficiently broad that they would impede legitimate scientific partnerships that advance U.S. interests and benefit the American people. Many important advances in biomedical research, particularly in areas such as rare diseases, clinical trials, artificial intelligence, and other emerging technologies, depend on carefully managed international collaboration [see 200.202].

America's leadership in science and technology has been built not only on strong domestic support for research, but also on its ability to attract talent, foster collaboration, and serve as a global hub for scientific discovery. International collaboration is particularly important in areas where critical expertise, patient populations, data, or scientific capabilities are dispersed across borders. These partnerships accelerate the development of new diagnostics, treatments, vaccines, and prevention strategies that directly benefit American patients. Restricting these collaborations would slow discovery, delay medical progress, and weaken America's scientific and technological leadership.

For many of the most pressing scientific and public health challenges, international collaboration is not optional; it is a scientific necessity. The beneficiaries are American patients, families, and communities. Clinical trials for rare diseases frequently cannot enroll enough participants within the United States alone. International recruitment makes those trials possible and accelerates the development of treatments for American patients who often have few or no therapeutic options. More broadly, the United States cannot fully address emerging health threats, antimicrobial resistance, or other challenges that transcend national borders without scientific partnerships that provide access to expertise, data, and real-world conditions beyond our own. Restricting the collaborations that generate this knowledge would delay the discoveries, treatments, and preventive strategies needed to protect and improve American health.

Broad restrictions on international scientific collaboration would also reduce the return taxpayers receive from federally funded research. Scientific progress increasingly depends on access to global expertise, data, infrastructure, and patient populations. When

promising collaborations are delayed, restricted, or abandoned, research takes longer, discoveries reach patients more slowly, and the public receives fewer benefits from federal research funding.

Health Disparities Research [200.218, 200.300]

Research!America is also concerned that the proposed rule would create uncertainty around the continued eligibility of health disparities research. Research aimed at understanding why some groups experience higher rates of disease or poorer health outcomes benefits everyone. Faced with uncertainty about what activities remain allowable, institutions and researchers are likely to scale back or avoid health disparities research, including studies examining and addressing differences in health outcomes affecting rural communities, veterans, racial and ethnic minorities, sexual and gender minority groups, people with disabilities, older adults, children, tribal communities, and patients with rare or chronic diseases.

No disease affects everyone equally. Every medical advance begins by asking why one person develops a disease while another does not, why one treatment works for some patients but not others, or why some populations experience worse outcomes. Understanding and addressing those differences is the foundation of preventing, diagnosing, treating, and curing disease.

Health disparities research complements that effort by examining differences in health outcomes across populations and identifying strategies to improve health outcomes at that scale. It is not separate from medical progress; it is an essential component of it. Restricting research on certain health disparities would impede scientific discovery, limit progress against disease, and undermine the goal of achieving better health for all Americans.

Conclusion

The concerns above are representative, not exhaustive. A second attachment delineates analytical and data gaps that prevent a dispassionate assessment of the positive and negative impacts of the rule against its stated objectives and the most important metric: the wellbeing of the American people.

Again, we appreciate OMB's interest in improving the administration and oversight of federal grant and cooperative agreement activities. While we urge the agency to withdraw this rule, please call on Research!America if we can assist in forging a new path forward with the goal of strengthening US S&T in the interests of the United States and the American people.

Respectfully submitted,

Russ Paulsen, President & CEO
Research!America

Attachment 2: Evaluation of the Evidentiary Basis for Proposed Regulation for Federal Financial Assistance (OMB-2026-0034-0001), as delineated in the Regulatory Impact Analysis Accompanying the Proposed Revisions to 2 CFR Part 200

Research!America submits this evaluation of the evidence base for the Office of Management and Budget's Regulation for Federal Financial Assistance (OMB-2026-0034-0001).

Research!America is a nonprofit, nonpartisan alliance dedicated to making research and innovation a higher national priority and accelerating medical progress. Our members include patient advocacy organizations, academic medical centers, universities, research institutes, scientific societies, public health organizations, philanthropies, and private-sector innovators across the United States.

Introduction

OMB acknowledges that the proposal requires a Regulatory Impact Analysis but argues that the Regulatory Flexibility Act does not apply because small entities would be affected only indirectly through agency implementation. That distinction is difficult to reconcile with the fact that Executive Branch agencies would no longer be implementing OMB's requirements based on guidance, but on regulation, making the proposed rule's effects on small entities direct, not indirect.

The RIA accompanying the proposed revisions to 2 CFR Part 200 provides an insufficient basis to assess:

- The nature and scope of the specific concerns the proposed rule purports to address;
- Whether the proposed rule would fulfil its stated objectives;
- Whether alternative approaches could achieve the stated objectives with fewer burdens; and fundamentally,
- Whether the widespread, disruptive effects of the proposed rule on our economy, our health, and our national security are justified by any positive outcomes the proposed rule could achieve.

Throughout the RIA, OMB appropriately acknowledges that important information is unavailable, uncertain, or cannot be quantified.

1. Evidence Supporting the Need for Regulatory Change

Relevant RIA Sections: Section 2 (Need for Regulation); Section 6 (Benefits); Section 9 (Comparison of Discounted Benefits, Costs and Transfers)

RIA Conclusion

The RIA concludes that the proposed rule is expected to improve transparency, accountability, oversight, stewardship of federal funds, payment integrity, consistency across federal grant and cooperative agreement programs, and overall program integrity. These anticipated benefits provide the principal justification for the proposed revisions.

Information Necessary to Evaluate the Conclusion

The RIA clearly identifies the objectives the proposed rule is intended to achieve. However, it provides limited information regarding the magnitude of the problems the proposal is intended to address. It also provides insufficient information to gauge the extent to which the proposed revisions are expected to improve existing outcomes.

For example, the RIA does not quantify or otherwise characterize:

- Improper payments attributable to existing grant administration practices.
- Fraud, waste, or abuse associated with current use of fixed amount awards or fixed amount subawards.
- Instances in which existing agency authorities proved insufficient to suspend or terminate awards.
- Costs associated with current publication and printing practices.
- Risks or losses attributable to existing foreign collaboration policies; or
- The frequency or severity of the oversight deficiencies the proposal is intended to address.

Similarly, while the RIA repeatedly concludes that expanded oversight, additional compliance requirements, and enhanced monitoring will improve accountability and stewardship, it provides little information regarding the current magnitude of those problems or the extent to which the proposed changes are expected to reduce them.

As a result, the RIA does not provide sufficient information to assess whether the scope of the proposed revisions is proportionate to the problems they are intended to address or whether less burdensome approaches might reasonably achieve comparable objectives.

Why This Matters

An important purpose of a Regulatory Impact Analysis is to help policymakers and the public understand both the nature of the problem a regulation is intended to address and the evidentiary basis for concluding that the proposed regulatory approach is likely to improve current outcomes.

The issue is not that every anticipated benefit is not precisely quantified. Rather, the RIA provides limited information regarding the scale of the underlying problems or the expected magnitude of improvement associated with the proposal. Without that information, policymakers and the public cannot meaningfully evaluate whether the proposal is likely to advance its stated objectives or whether its anticipated benefits are proportionate to its anticipated costs and implementation burdens.

This analytical gap is a recurring theme throughout the RIA. In multiple sections, the analysis acknowledges that important information is unavailable, uncertain, or cannot be quantified, yet nevertheless reaches affirmative conclusions regarding the proposal's anticipated effects. The following sections identify additional examples of this pattern.

2. Establishing an Appropriate Baseline

Relevant RIA Sections: Section 4 (Baseline); Section 7 (Costs); Section 9 (Comparison of Discounted Benefits, Costs and Transfers)

RIA Conclusion

The RIA establishes the current regulatory and operational environment as the baseline against which the anticipated effects of the proposed rule are evaluated. It concludes that the proposed revisions are expected to improve accountability, oversight, payment integrity, and stewardship of federal funds while reducing administrative burden for recipients and federal agencies.

Information Necessary to Evaluate the Conclusion

An appropriate baseline is essential to evaluating the effects of any proposed regulation because it provides the point of comparison for estimating anticipated costs, benefits, and implementation impacts. While the RIA provides descriptive information regarding categories of recipients, federal awards, and selected existing policies, it provides limited baseline information for many of the activities directly affected by the proposed rule.

For example, the RIA does not provide baseline information regarding:

- The current use of fixed amount awards or fixed amount subawards sufficient to estimate the practical significance of eliminating those mechanisms.
- The number or characteristics of awards currently terminated or suspended each year.
- The frequency with which agencies rely on existing termination authorities.
- The extent to which publication and printing costs are charged to federal awards.
- The prevalence of foreign research collaborations that may be affected by the proposed restrictions.
- The volume of payments that would be subject to the proposed payment verification requirements; or
- The current administrative burden associated with the practices the proposal would modify.

Without this information, it is difficult to determine whether the proposed revisions would affect a relatively limited portion of federal grant and cooperative agreements or substantially alter long-standing administrative practices across a broad range of recipients. Research!America members expect these changes would have enormous, disruptive consequences.

Why This Matters

A Regulatory Impact Analysis relies on an accurate and sufficiently detailed baseline to evaluate the practical significance of proposed regulatory changes. Without an understanding of current practice, policymakers and the public cannot meaningfully assess the magnitude of anticipated improvements, estimate implementation costs, or determine which provisions are likely to have the greatest operational significance.

The RIA provides limited baseline information for many of the activities most directly affected by the proposal. As a result, the analysis does not provide a sufficient foundation for evaluating the scale of the proposal's anticipated effects or determining whether those effects are likely to justify the associated implementation burdens.

This analytical limitation also affects subsequent portions of the RIA. Estimates of anticipated benefits, costs, and distributional effects necessarily depend upon an understanding of existing conditions. Where the baseline is incomplete, the ability to evaluate those later conclusions is correspondingly limited.

3. Assessment of Distributional Effects

Relevant RIA Sections: Section 4 (Baseline); Section 7 (Costs); Section 10 (Factors Influencing Cost Estimates and RIA Outcomes)

RIA Conclusion

The RIA identifies a broad range of entities that may be affected by the proposed rule, including institutions of higher education, hospitals, nonprofit organizations, state, local, and tribal governments, researchers, sponsored programs offices, and other recipients of federal grants and cooperative agreements. It acknowledges that implementation costs may vary across organizations while concluding that the proposal is expected to improve accountability, oversight, stewardship of federal funds, and administrative efficiency.

Information Necessary to Evaluate the Conclusion

A government-wide regulation affecting diverse recipients is unlikely to affect all organizations equally. Evaluating distributional effects is therefore an important component of determining both the practical implications of a proposed rule and whether particular categories of recipients are likely to experience disproportionate implementation burdens.

While the RIA identifies the categories of entities that may be affected, it provides limited analysis regarding how anticipated costs, benefits, and administrative burdens are likely to be distributed across those recipients.

For example, the RIA does not evaluate:

- Which categories of recipients are most likely to incur significant implementation costs.
- Whether smaller organizations with limited administrative capacity are likely to experience disproportionately greater burdens.
- Whether research-intensive institutions are likely to experience different operational impacts than recipients whose activities do not depend upon long-term research programs.
- Whether organizations engaged in multi-institution or international collaborations are likely to experience greater compliance burdens than recipients without such partnerships.
- Whether hospitals, institutions of higher education, nonprofit organizations, and governmental recipients are likely to experience different implementation challenges; or

- Whether the anticipated benefits of the proposal are expected to accrue similarly across affected recipient categories.

Without this information, the RIA does not provide a basis for evaluating how the proposal's practical effects may differ across the wide range of organizations subject to the rule.

Why This Matters

Understanding distributional effects is an important element of regulatory analysis because aggregate estimates of anticipated costs and benefits may obscure significant differences among affected entities. A rule that imposes modest burdens on average may nevertheless create substantial implementation challenges for particular categories of recipients.

The analytical question is not whether every category of recipient will experience different impacts. Rather, the RIA provides limited analysis of whether such differences are likely to exist despite recognizing the diversity of organizations subject to the proposed rule.

As a result, policymakers and the public cannot meaningfully evaluate whether the proposal's implementation burdens are likely to fall evenly across recipients or whether certain sectors may experience disproportionately greater operational, administrative, or financial impacts. This uncertainty also limits the ability to assess the proposal's overall costs and benefits and whether alternative approaches could achieve comparable objectives while reducing burdens on those recipients most affected.

4. Evaluation of Regulatory Alternatives

Relevant RIA Sections: Section 5 (Regulatory Alternatives)

RIA Conclusion

The RIA briefly discusses alternatives considered for several major provisions of the proposed rule, including subrecipient oversight, payment accountability, termination and suspension authorities, domestic preference requirements, and program integrity reforms. It concludes that the selected approaches are preferable because they are expected to better achieve the proposal's objectives.

Information Necessary to Evaluate the Conclusion

Evaluating regulatory alternatives is a central purpose of a Regulatory Impact Analysis because it enables policymakers and the public to assess whether the selected approach is likely to achieve the stated objectives more effectively or efficiently than other reasonable options.

The RIA identifies alternatives that were considered for several major provisions. However, it provides limited comparative analysis explaining why the selected approaches are expected to produce better outcomes than the alternatives discussed.

For example, the RIA provides limited information regarding:

- The anticipated costs and benefits of the alternatives considered.
- The extent to which alternative approaches might achieve comparable improvements in accountability, oversight, or payment integrity.
- Whether less burdensome alternatives were considered for provisions expected to increase administrative or compliance costs.
- The expected implementation challenges associated with competing approaches; or
- The basis for concluding that the selected approaches are likely to produce superior outcomes across the diverse federal financial assistance programs subject to the rule.

In many instances, the RIA identifies an alternative, states that it was considered, and explains why it was not selected in general terms. However, it provides limited comparative analysis of the relative costs, anticipated benefits, implementation challenges, or operational tradeoffs associated with the competing approaches.

Why This Matters

A Regulatory Impact Analysis serves not only to explain why a particular regulatory approach was selected, but also to demonstrate why reasonable alternatives were not. Comparative analysis provides policymakers and the public with a framework for evaluating whether the selected approach is likely to produce greater public benefit than other available options.

The RIA provides limited comparative analysis supporting its conclusion that the selected approaches are preferable to the alternatives considered.

As a result, policymakers and the public cannot meaningfully assess whether the proposal reflects the most effective or least burdensome means of achieving OMB's stated objectives. This limitation is particularly significant for a government-wide rule affecting a broad and diverse population of recipients, where different regulatory approaches may reasonably be expected to achieve similar objectives while producing materially different implementation costs and operational impacts.

5. Assessment of Anticipated Benefits

Relevant RIA Sections: Section 6 (Benefits); Section 9 (Comparison of Discounted Benefits, Costs and Transfers)

RIA Conclusion

The RIA concludes that the proposed rule is expected to improve transparency, accountability, oversight, stewardship of federal funds, payment integrity, program integrity, consistency across federal financial assistance programs, and national security. These anticipated benefits provide the principal rationale for the proposed revisions.

Information Necessary to Evaluate the Conclusion

Many of the benefits identified in the RIA are inherently difficult to quantify with precision. Nevertheless, a Regulatory Impact Analysis should provide sufficient information to evaluate the anticipated magnitude of those benefits and the extent to which they are expected to result from the proposed regulatory changes.

While the RIA identifies numerous anticipated benefits, it provides limited information regarding their expected magnitude or the basis for concluding that the proposal is likely to achieve them.

For example, the RIA does not estimate or otherwise characterize:

- The anticipated reduction in improper payments.
- The expected improvement in accountability or program integrity.
- The anticipated reduction in fraud, waste, or abuse.
- The expected improvement in payment integrity.
- The anticipated benefits associated with expanded oversight authorities.
- The expected effect of the domestic preference requirements.
- The anticipated reduction in risks associated with the proposed foreign collaboration restrictions; or
- The extent to which the proposal is expected to improve administrative efficiency or reduce recipient burden.

In many instances, the RIA identifies anticipated benefits qualitatively while acknowledging that they cannot be quantified. However, it provides limited information regarding the

expected scale of those benefits or the evidence supporting the conclusion that they are likely to result from the proposed revisions.

Why This Matters

A Regulatory Impact Analysis need not assign a precise dollar value to every anticipated benefit. However, it should provide policymakers and the public with sufficient information to evaluate whether the anticipated benefits are likely to be substantial enough to justify the costs and implementation burdens associated with the proposal.

The RIA provides limited information regarding the expected magnitude of those benefits, or the evidence supporting the conclusion that the proposed revisions are likely to achieve them.

As a result, policymakers and the public cannot meaningfully evaluate whether the proposal's anticipated benefits are likely to justify its anticipated costs, whether the selected regulatory approach is proportionate to the problems it seeks to address, or whether alternative approaches might achieve comparable public benefits with fewer implementation burdens.

This analytical limitation becomes particularly significant when considered together with the issues identified in the preceding sections. Where the need for regulatory change, the baseline, the distribution of impacts, and the comparative performance of alternatives remain uncertain, the ability to evaluate the proposal's anticipated benefits is correspondingly limited.

6. Assessment of Anticipated Costs

Relevant RIA Sections: Section 7 (Costs); Section 9 (Comparison of Discounted Benefits, Costs and Transfers); Section 10 (Factors Influencing Cost Estimates and RIA Outcomes)

RIA Conclusion

The RIA acknowledges that many implementation costs associated with the proposed rule cannot be quantified and requests public comment regarding those costs. At the same time, it concludes that the proposal is expected to produce important public benefits and characterizes most implementation costs as minimal to modest, while recognizing that some recipient costs may be substantial.

Information Necessary to Evaluate the Conclusion

The RIA appropriately acknowledges that significant uncertainty exists regarding the proposal's implementation costs. However, it provides limited information regarding the magnitude, distribution, and principal drivers of those costs.

For example, the RIA does not estimate or otherwise characterize:

- The anticipated compliance costs associated with expanded oversight and reporting requirements.
- The administrative costs associated with new payment verification and justification requirements.
- The costs associated with enhanced subrecipient monitoring.
- The costs associated with implementing the proposed restrictions on foreign collaborations.
- The costs associated with changes to publication and printing requirements.
- The aggregate implementation costs across affected recipient categories; or
- Which provisions are expected to account for the largest share of implementation costs.

The RIA also states that recipient costs may range from minimal to substantial but provides limited information regarding which provisions are expected to produce those outcomes, which categories of recipients are most likely to experience substantial impacts, or the circumstances under which implementation costs would be expected to fall toward either end of that range.

Why This Matters

Regulatory analyses frequently involve some degree of uncertainty, particularly for proposals affecting diverse organizations and activities. In this respect, the RIA appropriately recognizes that important cost information is unavailable and seeks additional public input.

The analytical question is whether the information presented is sufficient to support the RIA's overall conclusions regarding the proposal's anticipated effects. Where implementation costs may range from “minimal to substantial”, understanding the principal cost drivers, the recipients most likely to be affected, and the relative magnitude of anticipated costs becomes central to evaluating whether the proposal's anticipated benefits are likely to justify its implementation burdens.

As a result, policymakers and the public cannot meaningfully assess the proposal's expected costs, compare those costs with its anticipated benefits, or determine whether alternative approaches might achieve similar public objectives with fewer administrative and operational burdens. This section also illustrates a recurring theme throughout the RIA: uncertainty is acknowledged, but the information necessary to evaluate the proposal's overall conclusions remains incomplete.

7. Assessment of Effects on Research Institutions and Research Activities

Relevant RIA Sections: Section 3 (Description of the Rule); Section 6 (Benefits); Section 7 (Costs).

RIA Conclusion

The RIA identifies institutions of higher education, hospitals, researchers, graduate students, and other research-related entities among the categories of recipients that may be affected by the proposal. The analysis concludes that the proposed revisions are expected to improve accountability, oversight, stewardship of federal funds, and program integrity across federal financial assistance programs.

Information Necessary to Evaluate the Conclusion

Research institutions are identified throughout the RIA as an important category of affected recipients. However, evaluating whether the proposal is likely to achieve the RIA's stated objectives within the research ecosystem requires understanding not only which institutions are affected, but how the proposed revisions would affect the conduct of federally supported research.

The RIA's conclusions regarding accountability, oversight, stewardship of federal funds, and program integrity necessarily depend on how the proposal changes the administration and conduct of research activities. Those effects are also essential to evaluating the proposal's implementation costs, operational consequences, and whether any resulting burdens are justified by the anticipated benefits.

While the RIA identifies research institutions as affected entities, it provides limited analysis regarding how the proposed revisions may affect research activities, including:

- Clinical trials.
- Longitudinal studies.
- Multi-institution research collaborations.

- International scientific collaborations.
- Graduate research training.
- Research publication and dissemination.
- Management of complex research portfolios.
- Long-term research planning.

Similarly, the RIA provides limited analysis regarding how provisions such as expanded oversight requirements, restrictions on foreign collaborations, publication cost limitations, expanded termination authorities, and additional administrative requirements may affect the conduct of federally supported research.

The RIA also does not evaluate whether these effects may differ from those experienced by other categories of recipients or whether they may influence the conduct, administration, continuity, or outcomes of federally supported research.

Why This Matters

Research differs from many other forms of federal financial assistance because it often involves long planning horizons, multi-year projects, collaborations among numerous institutions, highly specialized personnel, and activities that build upon prior scientific progress. Changes to the administration of research awards therefore may have operational consequences that differ from those associated with other categories of federal financial assistance.

The analytical question is not whether research institutions should be subject to appropriate oversight or accountability requirements. Rather, it is whether the RIA provides sufficient information to evaluate its conclusion that the proposal will improve accountability, oversight, stewardship of federal funds, and program integrity within one of the principal sectors governed by the regulation.

Without evaluating how the proposal may affect research administration and research activities, policymakers and the public cannot meaningfully determine whether the proposal's anticipated benefits are likely to be achieved within the nation's research ecosystem or whether implementation effects may differ materially from those anticipated elsewhere in the federal financial assistance system. This limitation is particularly significant given the central role federally supported research plays in advancing medical progress, scientific discovery, economic competitiveness, and national security.

8. Assessment of Termination and Suspension Provisions

Relevant RIA Sections: Section 3 (Description of the Rule); Section 5 (Regulatory Alternatives); Section 6 (Benefits); Section 7 (Costs); Section 8 (Transfers).

RIA Conclusion

The RIA concludes that the proposed revisions to the termination and suspension provisions largely clarify existing authorities, are not expected to substantially alter current implementation practices, and will improve accountability, oversight, and stewardship of federal funds by ensuring agencies retain appropriate tools throughout the award lifecycle.

Information Necessary to Evaluate the Conclusion

The RIA concludes that the proposed revisions are unlikely to materially change current practice. Evaluating that conclusion requires information regarding how existing authorities are currently used, the extent to which they have proven insufficient, and the basis for concluding that the proposed revisions will not materially affect recipient or agency behavior.

While the RIA discusses the policy rationale for clarifying and expanding these authorities, it provides limited information regarding:

- The number and characteristics of awards currently terminated or suspended each year.
- The frequency with which existing authorities have proven insufficient to address programmatic concerns.
- The anticipated effect of the proposed revisions on agency implementation practices.
- The anticipated effect of the proposed revisions on recipient decision-making and risk management.
- The extent to which expanded authorities may influence the willingness of organizations to undertake long-duration or higher-risk activities; or
- The operational implications for projects that depend on multi-year funding, complex collaborations, or long-term planning.

The RIA also concludes that the proposal is unlikely to substantially change current implementation practices but provides limited information explaining the basis for that conclusion or the evidence supporting it.

Why This Matters

Termination and suspension authorities differ from many other administrative provisions because they influence not only how awards are managed after problems arise, but also how recipients evaluate risk before undertaking federally supported activities. The practical effects of such authorities therefore extend beyond the number of awards ultimately terminated or suspended.

The analytical question is not whether agencies should retain appropriate termination and suspension authorities. Rather, it is whether the RIA provides sufficient information to evaluate the conclusion that the proposed revisions are unlikely to materially alter current practice or produce broader operational effects.

Without evaluating how expanded authorities may influence agency implementation, recipient decision-making, and the management of long-term activities, policymakers and the public cannot meaningfully assess whether the proposal's anticipated benefits are likely to outweigh its broader anticipated effects. This limitation is particularly important for research, public health, infrastructure, and other federally supported activities that depend upon sustained planning, stable collaborations, and predictable administrative expectations.

9. Assessment of Behavioral Responses and Secondary Effects

Relevant RIA Sections: Section 7 (Costs); Section 10 (Factors Influencing Cost Estimates and RIA Outcomes).

RIA Conclusion

The RIA primarily evaluates the proposed rule in terms of its direct administrative and compliance effects. It concludes that the proposal is expected to improve accountability, oversight, stewardship of federal funds, and program integrity while acknowledging uncertainty regarding certain implementation costs.

Information Necessary to Evaluate the Conclusion

The practical effects of a regulation are determined not only by the requirements it imposes, but also by how affected entities respond to those requirements. Evaluating anticipated behavioral responses is therefore an important component of understanding a regulation's real-world effects.

While the RIA analyzes the proposal's direct administrative requirements, it provides limited analysis regarding how applicants, recipients, subrecipients, and other affected organizations may adjust their behavior in response to those requirements.

For example, the RIA does not evaluate whether the proposal may influence:

- Decisions to apply for or accept federal financial assistance.
- The design or scope of federally supported projects.
- Institutional approaches to managing administrative or compliance risk.
- Decisions regarding domestic or international research collaborations.
- Participation by smaller organizations with limited administrative capacity.
- Long-term planning for projects that depend upon stable, multi-year funding; or
- Organizational decisions regarding staffing, partnerships, or investment in federally supported activities.

The RIA also provides limited analysis regarding whether these types of behavioral responses could affect the proposal's anticipated costs, benefits, or overall effectiveness.

Why This Matters

Regulatory effects are often shaped not only by the requirements contained in a rule, but also by the behavioral responses those requirements produce. As a result, anticipated behavioral changes may influence both the costs and the benefits ultimately associated with a regulation.

The analytical question is not whether particular behavioral responses will occur. Rather, it is whether the RIA provides sufficient information to evaluate how affected organizations may reasonably respond to the proposed changes and whether those responses could influence the proposal's anticipated effects.

Without considering these potential behavioral responses, policymakers and the public cannot meaningfully evaluate whether the proposal's practical effects are likely to align with the outcomes anticipated in the RIA. This limitation is particularly significant because behavioral responses may either amplify or diminish the proposal's anticipated benefits and implementation burdens in ways that are not reflected in the current analysis.

10. Assessment of Cumulative Effects

Relevant RIA Sections: Sections 6 (Benefits), 7 (Costs), 8 (Transfers), 9 (Comparison of Discounted Benefits, Costs and Transfers), and 10 (Factors Influencing Cost Estimates and RIA Outcomes).

RIA Conclusion

The RIA evaluates the anticipated effects of the proposal on a provision-by-provision basis and concludes that the proposed revisions are expected, collectively, to improve accountability, oversight, stewardship of federal funds, and program integrity while producing implementation costs that are generally characterized as minimal to modest, although some recipient costs may be substantial.

Information Necessary to Evaluate the Conclusion

Individual provisions of a regulation rarely operate in isolation—and the provisions of this proposed regulation will not. Recipients implement regulatory changes as an integrated set of requirements, and the combined effect of multiple changes may differ from the effect of any single provision considered independently.

While the RIA evaluates many of the proposal's provisions individually, it provides limited analysis regarding how those provisions may interact when implemented simultaneously.

For example, the RIA does not evaluate the cumulative effects of implementing:

- Expanded oversight and reporting requirements.
- New payment verification and justification requirements.
- Enhanced subrecipient monitoring requirements.
- Restrictions on foreign collaborations.
- Domestic preference requirements.
- Publication and printing cost limitations.
- Expanded termination and suspension authorities; and
- Other administrative and compliance requirements introduced by the proposal.

Similarly, while the RIA describes certain existing administrative requirements in its Baseline discussion, it provides limited analysis regarding how the proposed revisions would change those requirements in practice. The analysis generally does not distinguish between existing administrative responsibilities and the incremental burdens associated with new or expanded requirements, nor does it evaluate whether the interaction of multiple changes may produce implementation burdens, operational challenges, or administrative effects that differ from those associated with any individual provision considered independently.

Why This Matters

Evaluating cumulative effects is an important component of regulatory analysis because the combined operation of multiple provisions may produce practical outcomes that are not apparent when each provision is evaluated independently. Similarly, evaluating administrative burden requires an understanding not only of the proposed requirements, but also of the extent to which those requirements expand or alter existing administrative responsibilities.

The analytical question is not whether any individual provision is expected to impose significant burdens. Rather, it is whether the RIA provides sufficient information to evaluate the cumulative effects of the proposal and how they relate to existing administrative requirements.

Without evaluating both the cumulative interaction of the proposal's provisions and the extent to which they expand existing requirements, policymakers and the public cannot meaningfully assess the proposal's overall anticipated effects or determine whether the combined implementation burdens are likely to justify the anticipated benefits. This limitation reinforces the importance of establishing an appropriate baseline, as discussed in Section 2, because without a clear understanding of current practice, the incremental effects of the proposed revisions cannot be reliably evaluated.

11. Assessment of Uncertainty and Its Implications for the RIA's Conclusions

Relevant RIA Sections: Sections 7 (Costs), 9 (Comparison of Discounted Benefits, Costs and Transfers), and 10 (Factors Influencing Cost Estimates and RIA Outcomes).

RIA Conclusion

The RIA acknowledges that important information regarding anticipated costs, implementation effects, and other aspects of the proposal is unavailable, uncertain, or cannot be quantified. It nevertheless concludes that the proposed rule is expected to improve accountability, transparency, stewardship of federal funds, payment integrity, and overall program effectiveness.

Information Necessary to Evaluate the Conclusion

The RIA acknowledges uncertainty in numerous areas and, in several instances, requests additional information from the public regarding anticipated costs and implementation effects. It is worth noting that this proposed regulation gave the public an extraordinarily limited time to produce this information.

At the same time, uncertainty extends beyond implementation costs. As discussed throughout this appendix, important information is also limited regarding:

- The magnitude of the problems the proposal is intended to address.
- The baseline against which anticipated effects should be measured.
- The distribution of anticipated costs and benefits across affected recipients.
- The comparative performance of alternative regulatory approaches.
- The anticipated magnitude of the proposal's benefits.
- The effects of the proposal on research activities and the broader research ecosystem.
- Behavioral responses by applicants, recipients, and subrecipients; and
- The cumulative effects of implementing multiple regulatory changes simultaneously.

Taken together, these uncertainties affect many of the principal analytical components of the RIA.

Why This Matters

Uncertainty is an inherent feature of many regulatory analyses, particularly those involving complex programs and diverse recipients. The analytical question is therefore not whether uncertainty exists. Rather, it is whether the information presented is sufficient to support the conclusions the RIA ultimately reaches.

Throughout the RIA, uncertainty is acknowledged. However, as discussed in the preceding sections of this appendix, many of the uncertainties involve information that is central to evaluating whether the proposal is likely to achieve its stated objectives and whether its anticipated benefits are likely to justify its anticipated costs and implementation burdens. OMB attempts to shift responsibility for alleviating this uncertainty onto affected parties yet gives those parties a remarkably short period in which they can comment and refuses multiple requests for an extension of the comment period.

As a result, policymakers and the public cannot meaningfully determine whether the proposal is likely to produce the outcomes anticipated in the RIA or whether alternative approaches might achieve comparable objectives with fewer burdens. Collectively, the analytical limitations identified throughout this appendix prevent a comprehensive evaluation of whether the proposed rule is supported by sufficient evidence to justify its adoption.

Final Conclusion

Throughout the RIA, OMB acknowledges numerous areas in which important information is unavailable, uncertain, or cannot be quantified. The recurring issue identified throughout this assessment is not the existence of uncertainty. Rather, the recurring issue is that the RIA reaches affirmative conclusions regarding the proposal's anticipated benefits, implementation effects, and overall outcomes despite acknowledging that important information necessary to evaluate those conclusions is unavailable or incomplete.

Collectively, the analytical limitations identified in this assessment leave policymakers and the public without a sufficient basis to determine the nature and scope of the concerns the proposed rule is intended to address, whether the proposed rule would achieve its stated objectives, whether less burdensome alternatives could achieve those same objectives, or whether the proposed rule's disruptive effects on our economy, our health, and our national security are justified by any resulting benefits.

Research!America remains committed to working constructively with OMB, federal agencies, Congress, and other stakeholders to ensure proper stewardship of federal financial assistance while preserving the characteristics that have made the United States the world's leader in science, technology, and medical innovation.