July 13, 2026

Office of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503

Re: Docket No. OMB-2026-0034

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Office of Management and Budget (OMB) for the opportunity to submit comments on the proposed rule *Regulation for Federal Financial Assistance*.[1]

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives.

BIO acknowledges the Administration's efforts to improve accountability and effectiveness in federal financial assistance. However, as drafted, the proposed rule would introduce significant uncertainty and impose constraints that are fundamentally misaligned with the needs of the national biomedical research ecosystem. If finalized, this rule would risk disrupting critical research, weakening U.S. competitiveness, and slowing the pace of innovation – ultimately harming patients.

BIO highlights six major areas of concern with the proposed rule and opportunities for narrowing its scope to reduce the negative impact it would have on U.S. biopharmaceutical leadership and innovation:

- **The proposed rule will destabilize the biomedical research ecosystem and delay patient access to novel medicines.**
- **The proposed rule will weaken merit-based funding decisions and redirect resources away from high-impact biomedical research.**
- **The proposed rule will restrict vital international research collaboration and weaken U.S. competitiveness.**
- **The proposed rule will undermine emergency preparedness and U.S. health security.**
- **The proposed rule will impede scientific communication and slow the translation of research into medical innovation.**

[1] 91 Fed. Reg. 32189 (May 29, 2026).

- **The proposed rule raises several legal concerns about agency authority, particularly as to proposals that conflict with the statutory purposes of National Institutes of Health (NIH) research grants and other key discretionary programs.**

Federal funding plays a critical role in enabling innovation across the biomedical research ecosystem, supporting the foundational scientific work that underpins private-sector drug development and helping to de-risk early-stage research. Disruptions to this funding model – including increased uncertainty, administrative complexity, or constraints on participation – would not only affect academic researchers but also have direct implications for private-sector investment, partnership formation, and the advancement of new therapies. These effects would be particularly acute for small and emerging biotechnology companies, which play a central role in driving innovation but operate with limited capital and depend on predictable funding environments to advance high-risk programs and attract investment.

For these reasons, BIO strongly opposes the proposed rule and urges OMB to pursue alternative approaches that advance accountability without undermining scientific progress. We outline the key role of federal financial assistance in supporting America's innovation and healthcare ecosystem, as well as our specific concerns regarding how the proposed rule would disrupt that, below.

I. Background: The role of federal financial assistance in supporting America's innovation ecosystem

Federal assistance plays a key role in supporting America's innovation ecosystem, with a particularly important contribution to biotechnology innovation. Support from across the federal government helps sustain the ability of American companies to bring innovations from the earliest stages of basic scientific research through long, costly development processes, all the way to serving American patients and making the U.S. the world leader in biotechnology innovation. Sources of federal financial support that help drive American competitiveness and innovation in biotechnology include:

- Grants and cooperative agreements from the National Institutes of Health (NIH), the world's largest public funder of biomedical research, which provides foundational scientific support for drug discovery and development.
- Grants and cooperative agreements from the Advanced Research Projects Agency for Health (ARPA-H), which was established to accelerate novel, high-impact research in priority areas of biomedical innovation.
- Grants and cooperative agreements from the Centers for Disease Control and Prevention (CDC), which support public health research across a range of disease areas and strengthen the surveillance systems, data infrastructure, and implementation capabilities needed to evaluate and deploy medical innovations in real-world settings.
- Support from the Biomedical Advanced Research and Development Authority (BARDA), which has been highly successful in partnering with the private sector to bring forward pharmaceutical innovations that protect Americans from natural and man-made chemical, biological, nuclear and radiological threats to market.
- Grants by the Department of War, including from Congressionally Directed Research Programs and the Defense Threat Reduction Agency, which support research on potential pharmaceutical innovations to address high-priority public health challenges and national security threats, including those that affect the American warfighter.

- Support from the Small Business Innovation Research (SBIR) program, which provides important non-dilutive funding to early-stage biotechnology companies and helps catalyze private-sector investment in high-risk research and development.

These forms of federal financial support have contributed to countless successful pharmaceutical innovations that are improving and saving the lives of American patients today and are essential to continuing U.S. biotechnology leadership.

Federally funded biomedical research provides the foundational scientific insights that enable private-sector drug development. NIH-funded research contributed to 354 of 356 (99.4%) drugs approved by FDA between 2010 and 2019.[2] Another study examining more than 200 new molecular entities (or their targets) approved by FDA between 2010 and 2016 found that roughly 30% percent of the relevant scientific literature benefited from NIH support, most of which was dedicated to basic research regarding biological targets.[3]

Federal funding for biomedical research provides direct fuel for private sector innovation that advances science and delivers innovations for American patients By supporting high-risk, early-stage research and generating validated biological targets, federal funding stimulates private sector investment, enabling companies to pursue costly clinical development programs and mobilize the substantial capital required to bring new therapies to patients. Investments in the most cutting-edge innovations often may not be feasible without federal support for early-stage research, meaning that new restrictions on such support may mean innovations may never reach the market and deliver results for American patients. Increasing regulations and complexity for recipients of federal assistance will hinder this successful model, imposing new regulatory burdens on public-private cooperation and slowing private-sector innovation.

II. The proposed rule will undermine U.S. biopharmaceutical leadership and innovation by weakening the research ecosystem that supports it.

1. The proposed rule will destabilize the biomedical research ecosystem and delay patient access to novel medicines.

Biomedical research depends on sustained, predictable funding. The proposed expansion of "at will" termination authority for grant-making agencies (§ 200.340(a)(2)) and the introduction of new temporary suspension authority (§ 200.340(e)) threaten the continuity of clinical research that is essential for developing medicines that patients urgently need. OMB's existing regulations provide ample authority for agencies to suspend or terminate grants based on recipient noncompliance with program requirements or concerns about program integrity (§§ 200.339–200.340).

Both clinical and non-clinical research require stable long-term investments in infrastructure and highly specialized personnel. Clinical research requires standing up research sites, recruiting patients, and following up with those patients to ensure standardized data collection to track patient outcomes. Non-clinical research similarly depends on sustained

[2] Cleary et al., Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019, JAMA Health Forum, 2023 Apr 7;4(4):e230511.

[3] Cleary et al., Contribution of NIH Funding to New Drug Approvals 2010-2016, PNAS (2018).

investment in validating biological targets, maintaining specialized research platforms and datasets, and retaining highly specialized scientific expertise, all of which can be difficult to rebuild if disrupted.

While grant-making priorities can and should shift across administrations and in response to new policy priorities, predictability in funding support is essential in biomedical research because of the long timeframes inherent in bringing an idea from basic research all the way to an approved product that can serve patients. Typical estimates suggest that the time from identification of a potential drug target to the approval of a new drug for patients can take 10 to 15 years or more.[4] Identification of promising targets before that timeframe even begins can take years longer, making stable and predictable funding streams essential to delivering successful innovation. Many of the most significant steps forward in pharmaceutical innovation have taken decades of research before they reach patients: development of imatinib, for instance, began with the identification of a key chromosome in 1960, with decades of NIH-funded research work advancing toward a product that was eventually approved in 2001.[5] Disruptions in early-stage and investigator-initiated clinical studies can delay or prevent programs from progressing, with downstream effects on larger, privately funded clinical trials and the overall pace of therapeutic innovation.

Mid-award termination or suspension could cause irreversible disruptions to ongoing studies, including the loss of trained research staff, closure of study sites or research facilities, and interruption of patient enrollment, patient care, and follow-up. In many cases, these impacts cannot be easily reversed, resulting in incomplete datasets that may jeopardize the study's methodological rigor, delayed completion—and, therefore, delays in updated practice guidelines or regulatory submissions for any related therapies—or the abandonment of promising therapies. The ultimate consequence is that patients may face delays in access to innovative products or lose access to investigational therapies altogether.

While this rule explicitly states that agencies should use multi-year awards where possible to reduce administrative burden and simplify the application process (§ 200.202), the introduction of broad termination and suspension authorities undermine this objective. Multi-year awards are an important tool to promote stability, efficiency, and long-term planning, but if recipients must account for the possibility that funding could be halted before project completion, the value of multi-year funding commitments is significantly diminished. This uncertainty may discourage institutions from pursuing complex, high-impact research that requires sustained investment over time.

In particular, the proposed framework introduces uncertainty around multi-year awards that span multiple administrations, recognizing that policy priorities often shift from one administration to the next. The proposed rule would make it far too easy for an incoming administration to terminate or suspend grants en masse based on reasons unrelated to scientific merit or patient need, with minimal explanation, and with no appeal rights for the researchers, leaving patients in the lurch (§ 200.341).

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[4] Biotechnology Innovation Organization, *Drug Development, Review & Lifecycle Management*, BIO, https://www.bio.org/policy/human-health/drug-development-review-lifecycle-management

[5] Nat'l Cancer Inst., How Gleevec Transformed Leukemia Treatment, *Cancer.gov* (Apr. 11, 2018), https://www.cancer.gov/research/progress/discovery/gleevec

Truly transformational research also requires taking on the most challenging questions, which may be impeded by uncertainty around grant terminations. Scientific innovation requires a willingness to take risks by asking questions that involve significant uncertainties and may require long timelines to advance. The risk of an abrupt termination of funding will incentivize scientists "playing it safe"—focusing their applications and research on areas that are less controversial, lower risk, and more incremental in nature. In the world of biotechnology, this sort of self-censorship may have the unintended consequence of reducing the likelihood of true scientific breakthroughs and instead focusing federal support on small refinements of known science. This would directly undermine the Trump Administration's efforts to channel federal funding away from "incremental science" and toward transformative developments.[6]

Together, these provisions will destabilize the biomedical workforce and weaken the U.S. research pipeline. Federally funded research supports a highly skilled workforce of investigators, clinicians, and technical experts. Funding instability disrupts hiring and retention, discourages early-career scientists, and creates disincentives for institutions to invest in the most innovative research, which is often inherently higher risk. Over time, this erosion of workforce stability and institutional confidence would weaken U.S. leadership in biomedical innovation and reduce the overall productivity of the research enterprise.

Additional burdens and unpredictability in funding will disproportionately affect research institutions, early-stage investigators, and small biotechnology companies with limited resources. Because these entities often rely on federal assistance to support ongoing research activities, disruptions such as payment delays, cost disallowances, or award suspension could quickly trigger cash-flow crises that halt lab work, delay milestones, and disrupt critical partnerships. Over time, increased uncertainty surrounding federal support may also deter investors and collaborators, making it more difficult for these companies to raise the needed capital, hire the best experts, and advance promising programs. To manage these risks, small firms would need to devote more resources to administrative, accounting, and compliance systems – diverting limited funds and personnel away from research and development.

Uncertainty around expanded termination and suspension authorities also discourage long-term investments in areas critical to national security. Small and mid-size companies endure significant risk in developing medical countermeasures in a space that has little to no commercial market. Predictability and certainty are the two drivers for keeping smaller innovators in this space; this proposed rule impedes both.

These changes undermine the Administration's stated priorities of ensuring that federal research funding is more broadly distributed.[7] President Trump's August 2025 Executive Order on improving federal grant making rightly notes that "[w]riting effective grant applications is notoriously complex, and grant applicants that can afford legal and technical experts are more likely to receive funds," yet increasing the unpredictability and compliance risks for grant

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[6] Jay Bhattacharya, *Advancing Gold Standard Science to Address America's Chronic Disease Crisis*, Council of Councils Director (May 14, 2026), available at: https://dpcpsi.nih.gov/sites/g/files/mnhszr346/files/2026-05/2PM-May14-2026-Councils-of-Councils-Director%20Update.pdf.

[7] *Implementing a Unified NIH Funding Strategy to Guide Consistent and Clearer Award Decisions*, NIH Grants & Funding (Nov. 21, 2025), https://grants.nih.gov/news-events/nih-extramural-nexus-news/2025/11/implementing-a-unified-nih-funding-strategy-to-guide-consistent-and-clearer-award-decisions.

applicants may well increase the advantage of institutions with the most resources in seeking federal assistance.[8]

Further, these changes would risk disruption to ongoing research on key public health priorities and vulnerable populations. Abrupt funding disruptions could create ethical and operational risks for program participants, weaken infectious disease prevention efforts, and reduce the ability of health systems to identify and respond to emerging threats. Stable federal funding is essential to making progress on long-term priorities, such as federally supported research on highly impactful areas like cancer and HIV. To ensure continued progress on these issues, OMB should preserve transparent, evidence-based, and program-specific grantmaking standards to support long-term planning, reliable service delivery, and effective stewardship of federal resources.

Ultimately, this rule would introduce structural uncertainty into the funding environment that could redirect resources away from the most scientifically promising research and slow the development of life-saving medicines. BIO therefore urges OMB to withdraw the proposed authorities for at-will termination and suspension.

2. The proposed rule will weaken merit-based funding decisions and redirect resources away from high-impact biomedical research.

The Administration has emphasized that federally supported research should meet the standards of "Gold Standard Science," including ensuring that scientific work is subject to unbiased peer review and evaluated based on rigorous, objective criteria.[9] Independent expert review has long served as the primary mechanism by which federal agencies identify research proposals with the greatest scientific merit, technical feasibility, and potential to advance human health.

This proposed rule introduces new pre-award requirements and evaluation criteria that directly conflict with the Administration's tenets of gold standard science. The proposed changes would diminish the central role of expert peer review, undermine transparency in funding decisions, and risk chilling legitimate, important, and legally permissible research activities. This shift undermines the Administration's own goals of evaluating federally supported science in a manner that is free from undue influence and conflicts of interest. The result of these changes

[8] Exec. Order No. 14,332; 90 Fed. Reg. 38,929 (Aug. 12, 2025).

[9] Exec. Order No. 14,303, Restoring Gold Standard Science, 90 Fed. Reg. 22,601 (May 23, 2025) (establishing the Administration's "Gold Standard Science" policy and directing the Office of Science and Technology Policy to issue implementing guidance for federal agencies). See also Off. of Sci. & Tech. Pol'y, Exec. Off. of the President, Agency Guidance for Implementing Gold Standard Science in the Conduct & Management of Scientific Activities (June 23, 2025), https://www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf (providing OSTP guidance to federal departments and agencies on implementing the Executive Order's Gold Standard Science principles); U.S. Dep't of Health & Hum. Servs., Implementing Gold Standard Science: Report to the White House Office of Science and Technology Policy (Aug. 22, 2025), https://www.hhs.gov/sites/default/files/hhs-gold-standard-science-report-2025.pdf (describing HHS's department-wide implementation of the Gold Standard Science tenets); Nat'l Insts. of Health, Leading in Gold Standard Science: An NIH Implementation Plan (Aug. 22, 2025), https://www.nih.gov/sites/default/files/2025-08/2025-gss.pdf (setting out NIH's implementation plan for applying the Gold Standard Science principles to NIH-supported and -conducted research).

will be a redirection of federal funding away from research with the greatest potential to advance scientific knowledge and improve patient outcomes and the opportunity to leverage partnerships across the U.S. research enterprise.

Peer review is a foundational—and statutorily mandated—mechanism for identifying high-impact research projects. Peer review has been widely used since the post-World War II domestic research boom by nearly every U.S. science agency and relies on independent panels of experts in their fields to evaluate proposals based on scientific merit. By drawing on subject-matter experts with deep technical knowledge, peer review evaluates proposals based on rigor, feasibility, and potential impact, helping to ensure that limited federal resources are directed toward the most promising and innovative research. This process also provides a critical safeguard against bias and conflicts of interest by applying consistent, transparent criteria and relying on independent reviewers without a stake in the outcome.

It is thus no surprise that Congress expressly mandated peer review for NIH research grants.[10] NIH's gold standard science implementation plan confirms that the current two-level peer review process— initial peer review for scientific and technical merit and subsequent review by National Advisory Councils or Boards—promotes "the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to NIH."[11]

In contrast, the pre-issuance review requirement (§ 200.205(b)) and the mandate that program goals align with Administration priorities (§ 200.202) introduce ambiguity and shift decision-making authority away from consistent, expert-driven criteria. Weakening this framework could result in funding decisions that are inconsistent, less transparent, and less effective at advancing the high-quality scientific research that underpins U.S. leadership in biomedical innovation.

The proposed rule would undermine review based on scientific merit in favor of more subjective considerations. At every step in the process for discretionary grants, from program design through selection, the proposed rule would require federal grant-making agencies to emphasize "administration policies and priorities," as well as certain priorities of the current administration that would be factored into the funding process. The pre-issuance review requirement (§ 200.205(b)), the mandate that program goals align with Administration priorities (§ 200.202) shifts the focus away from objective merits review by scientific experts and toward more subjective considerations that could vary from administration to administration. This may lead to decisions that undermine transparency and accountability—two of OMB's stated goals for this proposed rule. For instance, medical countermeasures research often addresses emerging or uncertain threats that may not have been anticipated in current policy priorities but are critical for preparedness. Given the rapidly evolving environment for these threats, it is vital that companies undertaking research leveraging medical countermeasure technologies do not face additional uncertainty. The risk of sudden changes in priorities will impact America's ability to rapidly respond to both known and unknown threats when they arise. The proposed rule adds additional risk to an already risky investment environment.

[10] 42 USC §§ 241(a), 289a, 289a-1(a)(2).

[11] NIH, Leading In Gold Standard Science: An NIH Implementation Plan (Aug. 22, 2025), https://www.nih.gov/sites/default/files/2025-08/2025-gss.pdf.

Compounding this concern, the proposed rule introduces broad and, in some cases, undefined evaluative criteria that could further distort funding allocation. Concepts such as “gold standard science,” if not clearly operationalized, create uncertainty regarding how such standards would be interpreted or applied in practice. Scientific research relies on diverse methodologies that may be inconsistently interpreted under ambiguously defined “gold standard science.” For example, research methods for an ultra-rare disease may use small-n trials and rely on natural history as a control, while the approach for a novel vaccine may rely on randomized trials, observational, real-world evidence, and immuno-bridging. Each of these are gold standard methodologies but may not fit into “gold standard” if defined in a way that does not align with the most efficient, feasible, and fit-for-purpose method for conducting research. In rare disease research, for instance, trained reviewers are well-positioned to evaluate the technical nuance inherent in clinical trial designs for a given disease or area of research. In contrast, the application of inadequately defined criteria by administrators unfamiliar with the sub-specialization under study may inappropriately disadvantage novel designs aimed at addressing the challenges of those rare disease populations. Similarly, provisions that prioritize institutions with alignment to these undefined standards could shift competitive advantage toward entities whose research portfolios conform to current policy perspectives on issues unrelated to their proposed research projects, rather than those best positioned to conduct high-quality, innovative research that addresses unmet patient needs and advances scientific knowledge.

The proposal also raises significant concerns regarding institutional eligibility and the potential exclusion of high-performing research organizations for reasons unrelated to scientific capability. Broad criteria tied to institutional characteristics or activities could be used to deny funding to research organizations that otherwise possess world-class expertise and infrastructure. These types of arbitrary restrictions risk excluding some of the nation’s most capable research institutions, discouraging investment in high-risk, high-reward research, and ultimately weakening the U.S. position as a global leader in biomedical innovation.

More broadly, any revised framework should be grounded in clear objectives, transparent processes, and evidence-based decision-making. Research institutions and industry partners can adapt to new requirements when standards are clear, lawful, consistent, and workable; uncertainty arises when broad discretion is paired with ambiguous implementation criteria.

The proposed provisions could constrain scientifically necessary research practices and weaken the quality of biomedical evidence. Finally, BIO notes with concern the increased scrutiny on funded activities that seek to identify or address differences across patient populations by characteristics such as race. Relevant language appears in the proposals for pre-issuance review process for award selection (§ 200.205(b)(2)) and for prohibiting the use of federal funds to “promote or support theories of disparate-impact liability” (§ 200.218) or to “fund, promote, encourage, subsidize, or facilitate ‘diversity, equity, and inclusion’” (§ 200.300(b)).

To the extent these proposals go beyond existing federal requirements, they may create uncertainty regarding the allowability of research practices that are widely recognized as scientifically appropriate. In biomedical research, evaluating variation across patient populations is not ancillary – it is fundamental to understanding disease biology, informing clinical trial design, and ensuring that therapies are safe and effective in real-world use. These analyses are routinely incorporated into study design, statistical methodology, and regulatory submissions. Introducing ambiguity or perceived compliance risk in this area may lead researchers, institutions, and sponsors to avoid scientifically appropriate study designs or analytical

approaches. Over time, this could result in datasets that are less representative of the U.S. population, limiting the generalizability and reliability of evidence used by regulators, clinicians, and patients.

Constraints or uncertainty surrounding these practices may also discourage investment in areas of research involving complex or heterogeneous patient populations, where scientifically rigorous approaches often require more sophisticated study designs. This could reduce private-sector engagement in high-risk, high-need areas and slow innovation in fields where unmet medical need remains significant.

These considerations are also important in terms of reaching the specific patient populations most affected by particular public health threats, such as HIV. Federal HIV programs are designed to reach populations with substantial need for prevention, care, treatment, and support services. Restrictions that limit services to certain populations or undermine prioritization of services based on legitimate programmatic objectives could create compliance uncertainty and reduce access to essential HIV services.

In sum, this rule would shift the federal research funding landscape in ways that will disadvantage scientifically meritorious, high-impact, and patient-centered research. By introducing ambiguity, reducing reliance on peer review, constraining institutional participation, and altering incentive structures, the proposed rule will redirect resources away from the areas of science most likely to deliver meaningful advances in medical innovation. Over time, these effects could reduce the efficiency with which federal research dollars translate into high-quality scientific outputs, discourage private-sector investment in high-risk research, and weaken the foundation that underpins U.S. leadership in biomedical innovation.

BIO therefore urges OMB remove the pre-issuance review requirement and ensure that eligibility, selection, and compliance requirements are clearly defined, consistently applied, and grounded in independent scientific evaluation, appropriate population characteristics, and research integrity. OMB should preserve the integrity of evidence-based grantmaking by ensuring that expert review remains the primary basis for federal funding decisions, and clarify that political review may not displace statutory, scientific, or programmatic criteria established by Congress and implementing agencies.

3. The proposed rule will restrict vital international research collaboration and weaken U.S. competitiveness.

The proposed § 200.220 would introduce a new government-wide prohibition on using federal funds to support certain collaborations with covered foreign countries or entities unless an exception is granted. Under proposed § 200.220(b), the restriction would apply "regardless of whether Federal funds are used for direct programmatic activities, research, technical assistance, travel, or indirect costs allocable to such collaborations." Along similar lines, proposed § 200.202(e) would introduce limitations and complexities associated with "international elements," including "performance of activities under the Federal award outside of the United States or by a foreign entity." Because these restrictions would apply broadly to activities conducted under federal awards, it could affect not only direct research conducted abroad but also collaborative components embedded within domestic awards. As a result, the provision may have significant implications for biomedical research, which often relies on multinational collaborations.

These restrictions could significantly disrupt multi-site international clinical trials and longstanding research partnerships that are critical to advancing medical innovation for American patients. Many life-saving therapies are developed through global collaboration, where researchers draw on distinct patient populations, shared infrastructure, and complementary expertise across countries. Many trials for medicines affecting large populations, such as those for chronic and infectious diseases, depend on enrollment across multiple countries to achieve sample sizes necessary to capture diverse epidemiological contexts. International trials often enable faster patient enrollment, generate more generalizable data, and facilitate simultaneous regulatory engagement across jurisdictions. These trials can also be particularly helpful for diseases that are rare or seasonal in the U.S. (e.g., rare genetic conditions, pediatric cancers, influenza). Limiting participation in these collaborations could delay development timelines, reduce data quality, and ultimately slow American patient access to new treatments.

Relatedly, the proposed rule may harm the American biopharmaceutical industry's ability to compete in the global marketplace. U.S. leadership in biomedical innovation is reinforced by engagement with global regulatory counterparts and harmonization initiatives. Constraints on collaboration could reduce opportunities for alignment on regulatory science, thereby increasing fragmentation and inefficiencies in global development pathways. With the United States as the world leader in global biomedical innovation and regulatory science, international coordination efforts are an important mechanism for maintaining U.S. influence and advancing high-quality shared standards. Constraints on collaboration could reduce opportunities for alignment and diminish this strategic advantage. Further, international coordination efforts help harmonize regulatory environments in order to support the broadest possible markets for U.S. innovators by reducing regulatory barriers.

BIO recognizes and supports the Administration's goal of strengthening U.S. competitiveness in the global biotechnology landscape, including in relation to China. However, restricting access to international scientific collaboration will not advance this objective. Biomedical innovation is increasingly driven by global knowledge exchange, and policies that limit U.S. researchers' ability to engage with and learn from international partners may, in fact, place the U.S. at a competitive disadvantage.

These resources are particularly important for small companies, who may rely on foreign contract research organizations (CROs), laboratories, clinical sites, subcontractors, or suppliers to achieve the operations needed for American companies to bring innovative medicines to American patients. BIO supports ensuring appropriate safeguards for national security, but blanket restrictions on international engagement do not accomplish this objective and add to unnecessary cumulative regulatory burden while blocking partnerships necessary to bring innovative new medicines to patients, disproportionately affecting small biopharma companies. Such safeguards should be carefully calibrated so as not to unnecessarily impede beneficial and low-risk scientific collaboration.

Finally, the breadth of the proposed restriction could create significant compliance uncertainty and administrative burden. Institutions may find it difficult to assess whether routine research interactions, data sharing, or subcontracting arrangements trigger restrictions under the rule. This uncertainty could lead to overly cautious behavior, discouraging participation in otherwise permissible and scientifically valuable collaborations, and raise costs for U.S. research institutions and smaller biotech companies at a time when they are in fierce competition with

other nations for attracting research projects, talent and private capital. Federal financial assistance policies should preserve participation across the innovation ecosystem, including universities, research institutions, startups, and established companies whose complementary capabilities are necessary to translate research into real-world products and public health benefits.

The proposed rule could limit access to data and weaken critical partnerships essential for tracking and responding to emerging diseases, and so impede domestic preparedness for emerging threats, both naturally occurring and manmade. The monkeypox and Ebola outbreaks provide important examples of the critical nature of our collaboration with trusted allies and partners during regional and global emergencies. The 2024 monkeypox outbreak and the current Ebola outbreak required rapid coordination among public health agencies, academic researchers, and industry to characterize the emerging strains, support diagnostic development, and generate clinical evidence for the use of vaccines and therapeutics in affected populations.

These activities depended on flexible federal funding mechanisms that allow researchers to move quickly. For pathogens such as Bundibugyo ebolavirus, where no approved vaccines or therapeutics currently exist, response efforts often rely on quickly repurposing existing platforms and advancing novel candidates into clinical evaluation. Interruptions to grants, cooperative agreements, or international research partnerships could delay patient enrollment, disrupt clinical trial networks, and impede the collection of data necessary for regulatory decision-making. Responses to any threat from bioterrorism would also rely on these kinds of international cooperation, including work by HHS agencies with partners in other nations to prepare for the possibility of biological threats that result from accidental releases or deliberately designed bioweapons.

Taken together, these provisions risk isolating U.S. researchers from the global scientific community, slowing the pace of discovery, and limiting patient access to breakthroughs that depend on international cooperation. BIO strongly recommends that OMB eliminate or significantly narrow the scope of §§ 200.220 and 200.202(e) and ensure that any restrictions are targeted, risk-based, and designed to preserve the collaborative frameworks that underpin modern biomedical research and innovation.

4. The proposed rule will undermine emergency preparedness and U.S. health security.

Effective emergency preparedness depends on a combination of steady, long-term preparations and, when the need arises, an assertive response characterized by speed, flexibility, and coordination across a highly interconnected research ecosystem. Federal support for this work is often provided through cooperative agreements and other flexible funding mechanisms specifically designed to facilitate a nimble response during evolving public health threats, in addition to sustained baseline funding. The proposed rule, however, introduces additional procedural requirements, expanded oversight authorities, and potential funding uncertainties that could hinder the rapid initiation and modification of outbreak-related research, compromising our ability to rapidly respond to emerging pathogens.

Outbreak response research relies on the ability to act quickly to protect Americans' health—whether through issuing supplemental funding, adding clinical trial sites, or pivoting

research objectives as new data emerge. Burdensome compliance and pre-award requirements could cause delays at critical early stages of an outbreak, the most important window of opportunity to protect Americans' health by identifying and containing the threat. Similarly, clinical research during emergencies often requires real-time protocol modifications, such as expanding patient cohorts or updating endpoints. If these changes trigger additional review or introduce compliance risk under revised criteria, researchers may be slower to adapt studies in ways that are essential to generating timely and actionable evidence.

The proposed rule could also weaken the collaborative frameworks that underpin effective outbreak response. As infectious diseases do not respect international borders, public health preparedness requires global collaboration for American protection and coordination among diverse domestic and international entities, as described in the preceding section. Effective response requires tight integration between surveillance, antigen discovery, and vaccine design. Barriers to collaboration and funding flexibility at any step would disrupt this pipeline. Since withdrawing from the World Health Organization (WHO) in January 2026, the U.S. has prioritized bilateral partnerships to support global health security—which makes the flexibility and responsiveness of federal assistance mechanisms even more critical. Limitations or increased administrative complexity could discourage participation in international collaborations, particularly among smaller or less-resourced institutions. This, in turn, could limit participation in global pathogen surveillance networks, reduce access to critical data and biological samples, and delay the identification of and response to emerging threats before they reach the United States.

While rapid responses to new outbreaks are essential, long-term investments in preparedness are also essential. Since outbreaks of emerging infectious diseases, like Ebola, are sporadic and commercial incentives are very limited, long-term public investment is often the primary mechanism sustaining the scientific infrastructure needed to respond. Under the proposed rule, additional pre-award review requirements, expanded suspension authorities, and increased administrative uncertainty could have delayed critical research activities needed to assess transmission dynamics, evaluate medical countermeasures, and inform public health decision-making. The increased uncertainty surrounding federal assistance created by the proposed rule would undermine preparedness for future outbreaks by discouraging continued investment in high-risk pathogens that pose significant public health and national security concerns for America.

The proposed rule may also disrupt state and local funding flows that are central to U.S. health security. Many of these efforts rely on federally funded cooperative agreements to maintain continuity in immunization programs, disease surveillance, and real-time data systems. Funding instability could affect vaccine ordering, distribution, and coverage tracking, as well as weaken surveillance systems that monitor safety and population-level risk. These capabilities are essential not only for routine public health functions, but also for detecting emerging threats, coordinating rapid responses, and supporting the deployment and monitoring of medical countermeasures during outbreaks. Disruptions to these systems would therefore reduce the speed, reliability, and effectiveness of the nation's public health response infrastructure.

This proposed rule would reduce speed, flexibility, and coordination in grants and cooperative agreements. In the context of pandemics and other biological threats, even small delays or barriers in research, collaboration, or information-sharing can have significant consequences. BIO therefore urges OMB to ensure that the final rule preserves the ability to rapidly initiate, modify, and sustain awards in response to

emerging threats to the U.S., and maintains the flexibility and collaborative capacity necessary to support strong U.S. leadership in global health security and protect Americans' health.

5. The proposed rule will impede scientific communication and slow the translation of research into medical innovation.

Restrictions on publication costs (§ 200.461), conference attendance (§ 200.432), and advertising and public relations costs (§ 200.421) will limit the ability of researchers to share results, collaborate, and engage with the broader scientific and medical community. Historically, these dissemination-related costs have been appropriately supported through grants because they are integral to the conduct and impact of research and often cannot be predicted with precision at the time of award.

Open cooperation among scientists across the U.S. and partner nations is a central element of sustaining the dominant U.S. leadership role in the global research ecosystem. Requiring advance identification, review, or approval of such costs is unrealistic in fast-moving research environments and risks delaying timely communication of important scientific findings. Scientific progress depends not only on conducting research, but also on communicating findings to other researchers, clinicians, investors, and patients. Conferences, peer-reviewed publications, and related communications activities are essential mechanisms through which gold standard science is validated, refined, and translated into follow-on innovation. As stated in NIH's gold standard science implementation plan, "NIH continues to encourage scientists to freely communicate their scientific findings to the public and through scientific journal publications, reports, and conferences."[12]

Moreover, the proposed approach appears to undermine separate federal efforts to promote transparency and public access to research results – a core tenet of gold standard science.[13] Federal agencies have increasingly emphasized the importance of publishing in open access journals and making data widely available. NIH's current Public Access Policy "recognizes and understands that publishing itself is not free" and so offers guidance for "institutions and authors when budgeting for and paying allowable and reasonable publication costs."[14] However, open access publication often requires significant article processing charges and related expenses. Restricting the allowability of publication and communication costs may make it more difficult for researchers to comply with these expectations, effectively undermining the government's own transparency objectives.

Impeding these efforts and placing new burdens on scientists in the U.S. is especially concerning at a time when the U.S. is in fierce competition with the rising competitiveness of China's biotechnology industry. Slowing cooperation among researchers will reduce the appeal of working within the U.S. and increase the relative attractiveness of working with countries that the U.S. government has identified as concerning, such as China, as well as other nations that are trying to build emerging biotechnology innovation hubs of their own. Imposing new barriers

[12] NIH, Leading In Gold Standard Science: An NIH Implementation Plan (Aug. 22, 2025), https://www.nih.gov/sites/default/files/2025-08/2025-gss.pdf.

[13] Exec. Order No. 14,303, Restoring Gold Standard Science, 90 Fed. Reg. 22,601 (May 23, 2025).

[14] NIH, 2024 NIH Public Access Policy, Notice Number: NOT-OD-25-047 (Dec. 17, 2024), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html.

and new restrictions for researchers in the U.S. will inevitably lead to more of the most talented American scientists considering seeking support elsewhere and reduce the ability of the U.S. to attract world-leading researchers who can maintain and extend U.S. leadership.

These constraints will also have direct implications for Americans' ability to access the most cutting-edge research and care. Health care providers rely on up-to-date clinical and scientific information to make informed treatment decisions, and patients benefit when new evidence is disseminated quickly and broadly. Delays in publication or reduced engagement with scientific forums could slow the incorporation of new therapies, diagnostics, and best practices into clinical settings, ultimately limiting patient access to the benefits of federally funded research. Restrictions on conference participation are similarly harmful as conferences are a prime source of data sharing and learning among researchers in real time. Restrictions create bottlenecks for sharing findings and forming collaborations for additional research.

This shift toward fixed-price contracting and away from cost reimbursement would force small firms to absorb unpredictable R&D and manufacturing costs. Because many SBIR projects involve technical uncertainty, this added financial risk could lead to scope reductions, delays, or cancellations. Meanwhile, stricter limits or additional approvals for recovering indirect costs would reduce funding for labs, quality systems, and compliance—core capabilities needed to meet NIH milestones. Reduced overhead recovery and greater fixed-price risk would 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. These shifts would place significant burdens on American innovators at a time when the U.S. is facing increasing competition from our adversaries.

Taken together, this rule will create barriers to the effective dissemination of scientific knowledge, thereby slowing innovation and limiting the public health impact of federal research funding. OMB should preserve flexibility for reasonable dissemination-related costs and recognize that communication, publication, and scientific exchange continue to be essential components of the American research enterprise.

6. The proposed rule raises several legal concerns about agency authority, particularly as to proposals that conflict with the statutory purposes of NIH research grants and other key discretionary programs.

The proposed rule raises a number of legal concerns under the Administrative Procedure Act (APA), including the potential conflicts between the proposed rule and program-specific statutes; the challenges of commenting on so broad a rule that would affect so many different programs, particularly in light of the many unanswered questions described in the preceding sections concerning the rule's scope; and the likelihood that the rule will not achieve OMB's professed goals of increasing transparency and reducing burdens for federal funding applicants and recipients.

This section uses the example of NIH's extramural research grants—the federal government's largest source of discretionary grant funding—to illustrate these points. As noted at the outset, however, NIH grants are only one of many grant programs that support crucial biomedical research for BIO members and our partners.

The large volume of significant proposed changes creates substantial uncertainty regarding whether and how various proposed policies can be implemented without contradicting program-specific statutes. Acknowledging that OMB lacks authority to override substantive statutes that govern specific federal programs, OMB maintains existing regulation at 2 C.F.R. § 200.101(d) that federal statutes govern in the event of any conflict with OMB's uniform regulations.[15] However, OMB's substantial new proposed requirements and restrictions will make this policy much more difficult to implement in practice. Where such conflict exists, agencies lack authority to override congressional direction, set forth in statute, notwithstanding OMB's goal of making federal grants more immediately responsive to shifting political priorities in the White House.

To provide one example particularly salient to BIO members, when establishing the NIH extramural research program, Congress directed HHS to "encourage, cooperate with, and render assistance" to researchers conducting "studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments."[16] Congress further directed HHS to "promote the coordination of" this research.[17] To achieve these aims, Congress authorized NIH to make grants "for such research projects as are recommended by the [applicable] advisory council" through the peer-review process.[18] These statutes present significant tension with aspects of OMB's proposed rule, including the following:

- OMB has proposed vague restrictions on research and recruitment activities that take into account race, sex, and other demographic traits. If these proposals were interpreted to prohibit balanced clinical trial recruitment and stratified research findings, that policy would seriously undermine efforts to study the "causes, diagnosis, treatment, control, and prevention" of disease. Some medications have different effects for women than for men, for example; some medical devices have different levels of efficacy based on skin color. Moreover, Congress expressly directed NIH to "ensure" that women and "members of minority groups are included as subjects" in funded research projects, and that studies are designed to "provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial."[19] Gold standard science aims to capture the truth, including biological or social differences in the causes, diagnosis, treatment, control, and prevention of disease across demographic groups. Moreover, Congress directed NIH to ensure that.

- At-will terminations and suspensions, untethered from any consideration of program compliance or scientific merit, impairs Congress's goal of funding research to support human health and flourishing. In the preamble to the proposed rule, OMB asserts that "the authority to make discretionary awards . necessarily includes the ability to revisit

[15] Further, to the extent OMB's proposed policies conflict with existing agency regulations, OMB asserts that "the Federal agency should apply the Government-wide policies in this part to the greatest extent permitted by law"—introducing a new, highly general regulatory directive without providing direction for how agencies should manage cases where the new government-wide policies conflict with agency- or program-specific regulations.

[16] 42 U.S.C. § 241(a).

[17] *Id.*

[18] *Id.* § 241(a)(3).

[19] 42 U.S.C. § 289a-2(a) & (c).

earlier decisions."[20] Because these at-will provisions will be clearly advertised upfront, OMB argues, applicants can "make informed decisions regarding acceptance of Federal awards," thereby mitigating any concerns about recipients implementing their funded projects in good-faith reliance on the award. However, in light of the time and complexity required for major research projects, applicants have no reasonable risk-mitigation strategies. Should they be expected to secure back-up funding in the event their federal award is unexpectedly terminated, through no fault of their own? Should they scale back their ambitions and seek federal funding only for smaller-scale projects that can be more easily sustained if funding is revoked? These outcomes are flatly inconsistent with Congress's directive for HHS to "encourage, cooperate with, and render assistance" to researchers seeking to heal the sick.

- The proposed prohibition on using federal funds for publications or conferences conflicts with Congress's directive for NIH to "promote the coordination" of research on human disease. This conflict is evident in NIH's current policies that "*encourage* scientists to freely communicate their scientific findings to the public and through scientific journal publications, reports, and conferences."[21]

In light of these statutory conflicts, OMB and HHS should, at a minimum, expressly confirm that these proposed provisions would not apply to NIH extramural grants issued under 42 U.S.C. § 241(a). Because any attempt to impose these conditions on NIH grants would defy Congress's intent, any such attempt could be struck down under the APA in court as in excess of HHS and OMB's authority.[22] But stepping back, the existence of such serious statutory tensions with the largest discretionary grant program counsels against finalizing these provisions at all, given the likelihood of similar statutory tensions under other grant programs.

Due to these many ambiguities and uncertainties, the proposed rule does not provide a meaningful opportunity for public comment. The APA generally requires agencies to issue a notice of proposed rule-making before issue a final rule, thereby providing the public a meaningful opportunity to comment on the proposed rule's implications.[23] In this case, however, it is challenging for interested parties to provide informed comments on the proposed rule because of the complex ways it interacts with innumerable existing agency statutes and regulations. Under the proposed rule, agencies will now be bound by a number of new regulatory directives and policies—e.g., to "demonstrably advance the President's policy priorities" and "prioritize institutions that have demonstrated success in implementing Gold Standard Science"—without sufficient explanation as to how these directives will be interpreted and applied, nor how they will interact with existing requirements across the constellation of federal financial assistance programs.

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[20] OMB asserts that the proposed at-will termination policy would be "generally applicable to discretionary awards, but not to Federal awards made under programs where legislation establishes an entitlement to the funds on the part of the recipient, such as block grants, those awarded based on a statutory formula, or disaster recovery grants." Proposed 2 C.F.R. § 200.340(b)(2).

[21] NIH, Leading In Gold Standard Science: An NIH Implementation Plan (Aug. 22, 2025) (emphasis added), https://www.nih.gov/sites/default/files/2025-08/2025-gss.pdf.

[22] 5 U.S.C. § 706(2)(A) & (C).

[23] 5 U.S.C. § 553(c); *see, e.g., Connecticut Light & Power Co. v. Nuclear Regulatory Com.*, 673 F.2d 525 (D.C. Cir. 1982) (noting that the APA requires "the opportunity for interested parties to participate in a meaningful way in the discussion").

Although all major federal grant-making agencies are participating in the rule-making, the preamble does not discuss any of the major grant programs affected by OMB's proposals. This puts the onus on stakeholders to rapidly analyze the rule's implications and develop arguments as to why this or that provision should not apply to this or that grant program.

The proposed rule will likely fail to achieve OMB's stated aims of transparency and reduced burden. The Administrative Procedure Act (APA) directs courts to set aside any agency action that is "arbitrary and capricious."[24] The Supreme Court has held that the APA requires an agency to provide a reasoned basis for its decision, including by considering relevant factors, addressing important aspects of the problem, and explaining why the evidence supports the policy choice made.[25]

In this instance, the preamble identifies various goals for OMB's proposed rule, including goals to "improve transparency" and "reduce recipient burden."[26] As described above, however, this proposed rule is likely to generate significant uncertainty and confusion among applicants and recipients, and will therefore increase recipient burdens associated with interpreting the rule's impacts and discerning its implications in various programs, in addition to the added administrative burdens of complying with the various new restrictions on federal funding and developing contingency plans for unexpected terminations or suspensions. For each program, recipients and administering agencies will need to consider how the new regulatory structure relates to existing regulatory obligations and, ultimately, statutory mandates—creating confusion and increasing compliance burdens.

Because OMB's proposed rule is likely antithetical to the aims OMB purports to pursue, a final rule risks being struck down as arbitrary and capricious under the APA.

The proposed rule introduces numerous potential conflicts with existing statutes, fails to provide a meaningful opportunity for comment, and imposes numerous new policies that would accomplish the opposite of OMB's justifications for the rule. BIO therefore urges OMB to withdraw the proposed rule or, at a minimum, issue a new proposed rule that provides sufficient clarity to support meaningful public comment, including expressly confirming that NIH extramural grants are not subject to any of the provisions discussed in this letter.

III. Conclusion

As outlined in our detailed comments above, BIO strongly opposes the proposed rule. While we recognize the Administration's goal of improving accountability in federal financial assistance, the rule as drafted would introduce significant uncertainty, reduce flexibility, and impose constraints that will hinder and increase costs for the biomedical research ecosystem.

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[24] *Id.* § 706(2)(A).

[25] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that an agency action is arbitrary and capricious when, among other basis, the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise").

[26] 91 Fed. Reg. 32198, 32200.

As detailed above, these provisions would destabilize critical research, undermine merit-based funding, restrict international collaboration, weaken emergency preparedness capabilities, and impede the dissemination of scientific knowledge—ultimately harming patients and eroding U.S. leadership in biomedical innovation. At a time when global competition is intensifying and public health challenges are increasingly complex, federal policy must support, not hinder, the systems that drive discovery and deliver life-saving therapies.

BIO therefore urges the agencies to substantially revise or withdraw the proposal and work with stakeholders to develop a framework that preserves scientific integrity, promotes collaboration, and ensures continued progress for patients. In addition to specific recommendations made above, any final rule should establish well-defined implementation criteria, avoid vague standards that may be interpreted inconsistently across agencies, provide meaningful opportunities for stakeholder engagement, and allow a reasonable implementation period that supports continuity of high-quality federally funded research.

Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/s/

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/s/

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