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Submitted via www.regulations.gov to:

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

Docket No.: OMB-2026-0034

**RE: Regulation for Federal Financial Assistance**

Dear Director Vought:

The Massachusetts Biotechnology Council ("MassBio") appreciates this opportunity to submit comments on the Regulation for Federal Financial Assistance proposed rule ("proposed rule") from the Office of Management and Budget (OMB).

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,800+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

We acknowledge the Administration's efforts to ensure that recipients of federal financial assistance are compliant with established federal rules and accountable for how funds are used. However, as drafted, this proposed rule would constrain the biomedical research community and disrupt the future development of innovative and life-saving therapies. It is vital to protect and uplift Massachusetts' innovation ecosystem and to foster an environment that helps America maintain global competitiveness. If finalized, the rule would interrupt the critical research pipeline, weaken America's global competitiveness, and slow the pace of innovation, to the detriment of patients.

For the reasons described below, MassBio urges OMB to withdraw the proposed rule.

## I. The Proposed Expansion of At-Will Termination Authority and Suspension Provisions for Grant-Making Agencies Will Destabilize the Biomedical Research Ecosystem.

Biomedical research depends on sustained, predictable funding over extended timeframes. Both the proposed expansion of at-will termination authority and the proposed suspension provisions for grant-making agencies threaten the continuity of clinical research essential for developing medicines patients urgently need. Research—both clinical and non-clinical—requires stable investments in infrastructure and highly specialized personnel that cannot be quickly reconstituted if disrupted. Mid-award terminations could cause irreversible disruptions, including loss of trained staff, closure of study sites,

interruption of patient enrollment and follow-up, and incomplete datasets that jeopardize study rigor. Such consequences delay or prevent program progression, with downstream effects on larger privately funded trials and the overall pace of therapeutic innovation in this country.

The drug development process typically takes 10 to 15 years, or longer, from target identification to approval—a timeline making stable, predictable funding streams essential to successful innovation. Uncertainty around multi-year awards, particularly those spanning administrations, would make it far too easy for incoming administrations to terminate grants based on reasons unrelated to scientific merit or patient need, with minimal explanation and no appeal rights. This uncertainty undermines the rule's stated objective of promoting multi-year awards to reduce administrative burden.

These provisions will destabilize the biomedical workforce, discourage early-career scientists, and dissuade institutions from investing in high-risk, high-reward research. Funding instability imposes disproportionate burdens on small biotechnology companies with limited resources, like many of MassBio's emerging companies. These entities often rely on federal assistance to support ongoing activities, and disruptions such as payment delays or award suspension could trigger cash-flow crises that halt lab work and disrupt partnerships. Over time, increased uncertainty may deter investors and collaborators, making it more difficult for small firms to attract capital and advance promising programs. Paradoxically, increased unpredictability and compliance risks may advantage only the most resource-rich institutions.

***MassBio urges OMB to withdraw the proposed provisions on at-will termination and suspension in order to protect small biotechnical companies from funding instability.***

## II. The Proposed Pre-Issuance Review Requirement and Requirement to Align with Administration Priorities Will Impede Merit-Based Funding Decision-Making and Shift Resources Away from Life-Altering Biomedical Research.

The Administration has emphasized that federally supported research should meet standards of "Gold Standard Science," including unbiased peer review and rigorous, objective evaluation criteria.[1] However, the proposed rule introduces new requirements that directly conflict with these principles. The pre-issuance review requirement and mandate that program goals align with Administration priorities shift decision-making authority away from consistent, expert-driven criteria and toward more subjective considerations that vary with political priorities. Peer review—mandated by statute for NIH grants—has long served as the primary mechanism for identifying research with the greatest scientific merit, technical feasibility, and potential to advance human health. Weakening this framework risks funding decisions that are inconsistent, less transparent, and less effective at advancing high-quality science.

The proposed rule also introduces broad, sometimes undefined evaluative criteria that could distort funding allocation. Provisions prioritizing institutions with alignment to undefined standards could inappropriately disadvantage novel research designs or exclude high-performing institutions for reasons unrelated to scientific capability, ultimately weakening U.S. biomedical leadership.

The proposed restrictions on research examining variation across patient populations also raise concerns. Evaluating variation across patient populations is fundamental to understanding disease biology, designing clinical trials, and ensuring therapies are safe and effective across populations. Congress expressly directed NIH to ensure women and minorities are included as research subjects and that

[1] Executive Order No. 14,303, Restoring Gold Standard Science, 80 Fed. Reg. 22,601 (May 23, 2025).

studies analyze whether variables affect different populations differently.[2] Constraints or uncertainty regarding these practices could discourage research involving complex or heterogeneous patient populations, reducing private-sector engagement in high-risk, high-need areas and slowing innovation.

***MassBio urges OMB to remove the pre-issuance review requirement to maintain unbiased, merit-based decision-making.***

## III. The Proposed Restrictions on Using Federal Funds to Support Collaborations with Covered Foreign Countries or Entities, Together with Proposed Limitations on "International Elements," Will Put the American Biomedical Research Community at a Global Competitive Disadvantage.

The proposed restrictions on using federal funds to support collaborations with covered foreign countries or entities, combined with limitations on "international elements," could significantly disrupt multi-site international clinical trials and partnerships critical to advancing medical innovation. Many life-saving therapies are developed through global collaboration, drawing on distinct patient populations, shared infrastructure, and complementary expertise across countries. Trials for medicines affecting large populations depend on enrollment across multiple countries to achieve necessary sample sizes and capture diverse epidemiological contexts. International trials enable faster patient enrollment, generate more generalizable data, and facilitate simultaneous regulatory engagement across jurisdictions—benefits particularly important for diseases that are rare or seasonal in the U.S. Limiting participation in these collaborations could delay development timelines, reduce data quality, and slow American patient access to new treatments.

These restrictions could also significantly harm the American biopharmaceutical industry's ability to compete globally. U.S. leadership in biomedical innovation is reinforced by engagement with global regulatory counterparts and harmonization initiatives. Constraints on collaboration would reduce opportunities for alignment on regulatory science, thereby increasing fragmentation and inefficiencies in global development pathways. Because the U.S. plays a leading role in global biomedical innovation, international coordination efforts are important mechanisms for maintaining U.S. influence and advancing shared standards. These resources are particularly important for small companies, which may rely on foreign contract research organizations, laboratories, clinical sites, and suppliers. In fact, 80 percent of MassBio's biopharma member companies have fewer than 50 employees, and these companies have no commercial revenue because they do not yet have an FDA-approved product. These small companies rely on services from overseas Contract Manufacturing Organizations and Contract Development and Manufacturing Organizations for critical R&D expertise and manufacturing capabilities, including raw material sourcing, molecule development and production, cell line development, biomarker testing, and more. Blanket restrictions on international engagement add unnecessary cumulative regulatory burden, disproportionately affecting small biopharma companies while blocking partnerships necessary to bring innovative medicines to patients.

At a time when the U.S. faces intensifying competition from rising biotech competitiveness in other nations, policies that limit U.S. researchers' ability to engage with international partners may place the U.S. at a competitive disadvantage. The breadth of the proposed restriction creates significant compliance uncertainty and administrative burden, potentially leading institutions to discourage participation in otherwise permissible and scientifically valuable collaborations. Moreover, restrictions

[2] 42 U.S.C. § 289a-2(a), (c).

on collaboration with allied nations during public health emergencies—which required rapid coordination among public health agencies, researchers, and industry—could delay patient enrollment, disrupt clinical trial networks, and impede collection of data necessary for regulatory decision-making.

***MassBio strongly recommends eliminating the proposed restrictions on using federal funds to support collaborations with covered foreign countries or entities, as well as the proposed limitations on "international elements," to preserve small biopharmaceutical companies' ability to collaborate with foreign entities.***

## IV. The Proposed Restrictions on Publication Costs, Conference Attendance, Advertising, and Public Relations Costs Will Stall the Translation of Research into Innovation.

Restrictions on publication costs, conference attendance, and advertising and public relations costs will limit researchers' ability to share results, collaborate, and engage with the broader scientific and medical community. Dissemination-related costs have been appropriately supported through grants because they are integral to research conduct and impact, and often cannot be predicted with precision at award time. 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 are essential mechanisms through which science is validated, refined, and translated into follow-on innovation. NIH's gold-standard science implementation plan explicitly states that the agency "encourages scientists to freely communicate their scientific findings to the public and through scientific journal publications, reports, and conferences."[3] In addition, the proposed prohibition on publications or conferences conflicts with Congress's directive for NIH to "promote the coordination" of research, evident in current NIH policies encouraging free communication of findings.

The proposed approach undermines separate federal efforts to promote transparency and public access to research results—core to gold standard science. Federal agencies increasingly emphasize publishing in open access journals and making data widely available. NIH's Public Access Policy recognizes that "publishing itself is not free" and offers guidance for budgeting publication costs.[4] However, open access publication often requires significant article processing charges. Restricting allowability of publication and communication costs may make compliance with transparency expectations more difficult, effectively undermining the government's own transparency objectives. Healthcare providers rely on up-to-date clinical and scientific information to make informed treatment decisions; delays in publication or reduced engagement with scientific forums could slow incorporation of new therapies and best practices into clinical settings, limiting patient access to research benefits.

These constraints will have direct implications for American competitiveness. Impeding scientific cooperation at a time when global competition is intensifying—particularly with rising Chinese biotech competitiveness—will reduce the appeal of working within the U.S. and increase the relative attractiveness of other nations. Restricting conference participation creates bottlenecks for real-time data sharing and collaboration formation. A shift toward fixed-price contracting while restricting dissemination costs would force small firms to absorb unpredictable costs and reduce funding for labs, quality systems, and compliance—core capabilities needed to meet milestones. Reduced overhead recovery and greater financial risk would push small companies toward lower-risk, incremental projects

[3] 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.
[4] 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.

rather than high-impact research with greater scientific uncertainty, undermining American competitiveness in innovative areas.

***OMB should remove provisions that would restrict reasonable costs related to publication, conference attendance, advertising, and public relations.***

**V. Conclusion**

While MassBio recognizes the Administration's goal of improving accountability in federal financial assistance, we oppose this proposed rule. As drafted, it would harm small biotechnical companies by creating funding uncertainty and imposing constraints on international partnerships. These provisions would destabilize the biotech ecosystem, compromise merit-based funding, and impede the dissemination of scientific research—ultimately undermining U.S. leadership in biomedical innovation and coming at the expense of patients. ***We urge OMB to support America's biotech industry and withdraw this proposed rule.***

MassBio thanks CMS for your consideration of our comments. Please don't hesitate to contact me at (617) 6745148 or kendalle.oconnell@massbio.org if you have any questions or would like any additional information to consider our comments.

Sincerely,

Kendalle Burlin O'Connell
CEO & President
Massachusetts Biotechnology Council (MassBio)