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Association for the Advancement of Blood & Biotherapies

July 10, 2026

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

Re: Regulation for Federal Financial Assistance: Proposed Rule (OMB-2026-0034)

Dear Mr. Vought,

The Association for the Advancement of Blood & Biotherapies (AABB) respectfully submits these comments in response to the Office of Management and Budget's (OMB) proposed rule, "Regulation for Federal Financial Assistance," published in the Federal Register on May 29, 2026.

AABB is an international, not-for-profit organization representing institutions and individuals involved in transfusion medicine and biotherapies. The association is committed to “improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.” For decades, AABB has been working toward this mission by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, hospital and blood center administrators, medical technologists, and other health care providers.

Federally supported research in transfusion medicine, blood, and biotherapies underpins the safety, efficacy, and availability of lifesaving therapies relied on by millions of Americans every day. Approximately 4.5 million patients receive blood transfusions annually in the United States, representing more than 14 million blood components transfused each year to support trauma care, major surgery, cancer treatment, organ transplantation, obstetric hemorrhage, and other lifesaving interventions. Unlike most medical therapies, blood has no manufactured substitute and depends entirely on the generosity of volunteer donors, making a safe, stable, and resilient blood supply a unique national resource.

Federal investments in research have been essential to improving blood safety, strengthening emergency preparedness, advancing trauma resuscitation, and accelerating innovations in cell and gene therapies. Sustaining this research enterprise is therefore critical not only to improving patient outcomes but also to enhancing national security, military readiness, and the nation's ability to respond to disasters, emerging infectious diseases, and mass casualty events. For example,

- National Institutes of Health (NIH) funded research has driven landmark advances in blood safety, pathogen reduction technologies, transfusion practices, and the development of CAR T-cell therapies and other innovative technologies.
- The Department of Defense funded the development of transportable blood treatment systems for operational use.
- Biomedical Advanced Research and Development Authority (BARDA) provided support for research related to pathogen reduction technology, innovative blood products, and next-generation biomanufacturing platforms for cellular therapies.
- Defense Advanced Research Projects Agency (DARPA) funded research to develop a field-deployable, shelf-stable whole blood equivalent.
- Health Resources and Services Administration (HRSA) supports cord blood banks that provide treatment options for patients with over 75 diseases.

These investments illustrate the extraordinary return that federal biomedical research has provided to taxpayers. They have improved patient outcomes, strengthened military readiness, enhanced national preparedness for emerging infectious diseases and mass casualty events, and supported an internationally competitive biotechnology sector. Preserving these benefits requires a research enterprise that is stable, predictable, and grounded in independent scientific excellence.

AABB shares the administration's commitment to responsible stewardship of taxpayer funds, transparency in grant administration, and ensuring that federal investments deliver measurable results for the American people. However, we are concerned that OMB's proposed rule falls short of these objectives. AABB offers the following comments in the hope that they will inform policies that better advance these shared goals while preserving the scientific rigor and operational stability that is critical for therapies to progress from the bench to the bedside with direct impact on patient care.

We respectfully request that OMB withdraw the proposed rule in its entirety and engage with the biomedical research community in developing policies that enhance accountability while preserving the scientific rigor, operational stability, and collaborative partnerships necessary to translate discoveries into lifesaving therapies.

Executive Summary

AABB understands OMB's interest in improving the efficiency, transparency, and accountability of federal financial assistance. The integrity of federal grantmaking is a shared priority, and we are committed to working constructively with the administration to explore a framework that protects taxpayer resources while enabling the scientific and clinical work that serves all Americans. However, the proposed rule raises significant concerns that warrant careful reconsideration.

While the 45-day comment window was far too short to develop a response that addresses all relevant aspects of the proposed rule, AABB highlights the following proposals as being particularly problematic:

- Demoting peer review from a binding determination to advisory input and introducing mandatory political appointee review as a condition of award issuance will result in

loss of independent scientific peer review as the determinative basis for award decisions.

- Providing federal agencies with vague termination authority without clearly defined procedural safeguards will produce an arbitrary and unpredictable awards framework - with significant economic and strategic consequences for the United States.
- Unduly restricting international collaborations has the potential to interfere with critical scientific research that ensures the United States has a resilient blood supply and state-of-the art blood products and biotherapies.
- Restricting funds from being used for costs associated with publication, conferences, professional memberships, and journal subscriptions will limit the dissemination and adoption of research findings.

Collectively, these policies will undermine the stability of federal research funding, which will slow scientific progress, delay patient access to lifesaving care, compromise national security, weaken national preparedness, and jeopardize the United States' standing as a global leader in biomedical research. These policies may delay funding decisions, potentially postponing multicenter clinical trials by months, driving up costs, and delaying patient access to new therapies. Additionally, they may interrupt longitudinal studies, invalidating years of accumulated data and requiring those studies to restart.

For these reasons, AABB respectfully urges OMB to withdraw the proposed rule and engage stakeholders in developing reforms that strengthen accountability while preserving the scientific excellence, operational stability, and public trust that have made the United States the world leader in biomedical innovation.

I. The Proposed Rule's comment period should be extended.

AABB urges OMB to extend the public comment period for this proposed rule from 45 days to at least 90 days. OMB's proposed rule is among the most consequential revisions to the federal financial assistance framework since the original Uniform Guidance was established in 2013. The proposed rule spans more than 100 pages in the *Federal Register* and proposes substantive changes to administrative requirements, cost principles, award design, oversight structures, and termination authorities that affect virtually every federally funded research and health care institution in the United States.

The current 45-day comment window is insufficient for affected individuals and organizations to fully assess the operational, financial, and programmatic impacts of the proposed changes and provide meaningful, substantive input. A 90-day comment period would better serve the administration's goals of transparency and stakeholder engagement by enabling a more complete public record.

II. Scientific peer review must remain the foundation of research award decisions.

Independent, merit-based scientific peer review is the cornerstone of the federal biomedical research enterprise. It ensures that taxpayer dollars are invested in the most scientifically rigorous, innovative, and impactful research while maintaining public confidence that funding decisions are based on scientific merit rather than political considerations.

We urge OMB to vacate the proposed approach in 2 CFR §200.205, which would reframe peer review as advisory and require pre-issuance review of discretionary awards by one or more senior political appointees to ensure alignment with administration priorities. Federal agencies appropriately establish research priorities through strategic plans, congressional appropriations, and funding opportunity announcements. Independent scientific peer review should then determine which proposals best address those priorities based on scientific merit, feasibility, and potential impact.

The consequences extend beyond academic research. Federally supported biomedical research directly strengthens military medicine, national preparedness, and emergency response capabilities. Research supported through this system has advanced hemorrhage control, battlefield transfusion practices, freeze-dried plasma, blood supply resilience, emerging infectious disease surveillance, and novel cell therapies for radiation injury. Delays or uncertainty in funding decisions could slow progress in each of these strategically important areas.

America's leadership in biomedical innovation depends on a research enterprise that attracts and retains the world's most talented scientists, fosters long-term collaboration, and translates discoveries from the laboratory to improved patient care. For decades, this enterprise has been built on independent competitive, peer review that has earned broad bipartisan support across administrations. This model has generated innovations that benefit military and civilian patients while strengthening the nation's scientific and economic competitiveness.

Introducing a mandatory political appointee review as a final checkpoint before award issuance would:

- Delay time-sensitive research, including studies supporting battlefield medicine, blood supply resilience, and emerging infectious disease preparedness.
- Delay the initiation of clinical trials and patient enrollment, slowing the development of new blood products, transfusion practices, and cell and gene therapies for patients with serious or life-threatening conditions.
- Reduce the predictability needed for researchers, institutions, and industry partners to invest in multi-year programs.
- Discourage leading scientists from pursuing careers in the United States, as they may choose to work in countries where research funding is insulated from political review.

- Create a precedent that future administrations, regardless of political affiliation, could use to alter or influence federal awards.
- Erode public confidence in the objectivity and integrity of federally funded research, which ultimately serves all Americans.

Independent scientific peer review is more than an administrative requirement. It is the foundation of public trust in federally funded research. Merit-based review ensures that taxpayer resources are invested in the highest-quality science through a transparent and objective process that evaluates scientific rigor, feasibility, innovation, and potential public benefit. Preserving this system protects the integrity of federal research funding, promotes scientific excellence, and ensures continuity across changes in political leadership.

Thus, AABB urges OMB to preserve independent scientific peer review as the primary and determinative basis for discretionary research award decisions. While political appointees may continue to contribute broad policy priorities, funding decisions should remain grounded in objective scientific evaluation conducted by independent subject matter experts. This longstanding framework has enabled the United States to become the world's leader in biomedical innovation and should remain the cornerstone of federal research funding.

III. The proposed rule's award termination authority is vague and unpredictable.

The proposed rule would substantially expand federal agencies' authority to suspend or terminate awards while providing few objective standards or procedural safeguards to guide that authority. The proposed rule would permit a federal agency to terminate an award whenever it determines that the termination is "in the interest of the Federal agency," or that the award "does not effectuate program goals, Federal agency priorities, or the national interest." *See* 2 CFR §200.340. These terms are undefined and would create a framework that is arbitrary, introduces significant uncertainty into federal research awards, and invites inconsistent application across agencies, administrations, and award recipients.

AABB is concerned that this broad termination authority has the potential to disrupt ongoing research and clinical programs that cannot be discontinued once underway without jeopardizing patient safety or wasting years of prior federal investment. In fields such as blood safety and availability, transfusion medicine, and biotherapies, clinical trials and longitudinal studies frequently span years. Abrupt termination of clinical trials or longitudinal studies without clear cause, adequate notice, or an opportunity to address agency concerns could undermine the very taxpayer investment the administration seeks to protect while delaying improvements in patient care.

Examples of unintended consequences could include the premature termination of ongoing Phase II and Phase III clinical trials, cord blood banking programs, multicenter observational studies, long-term gene therapy follow-up, and emerging pathogen surveillance programs. Rather than improving stewardship of taxpayer resources,

premature termination of scientifically sound research often increases long-term federal costs by wasting prior investments, requiring studies to be repeated, delaying the translation of discoveries into clinical practice, and reducing the return on decades of federal investment in biomedical research.

Research programs involving transfusion medicine and biotherapies require sustained institutional investment, specialized personnel, sophisticated laboratory infrastructure, and long-term collaborations among academic medical centers, blood collection organizations, hospitals, biotechnology companies, and federal partners. The uncertainty created by broad termination authority threatens not only individual awards but also the collaborative research ecosystem that supports innovation. As institutions become less willing to invest in long-term federally funded research, opportunities for scientific discovery, technology transfer, workforce development, and public-private partnerships will likewise diminish.

For clinical research, award termination has consequences that extend beyond investigators and institutions. Patients who volunteer to participate in federally funded clinical trials do so with the expectation that scientifically and ethically conducted studies will be completed whenever possible. Abrupt termination of funding may interrupt treatment, compromise long-term safety monitoring, and diminish public confidence in clinical research. These consequences are particularly significant for studies involving rare diseases, transfusion-dependent conditions, and novel cell and gene therapies, where alternative research opportunities may be limited.

Therefore, AABB urges OMB to work with the research community on a framework that includes safeguards, such as: (1) clear, objective criteria for suspending or terminating awards, (2) providing recipients with advance notice and an opportunity to address identified concerns, and (3) ensuring that termination decisions are based on transparent and consistently applied standards. These guardrails would strengthen accountability while preserving the stability, predictability, and public trust that are essential to the nation's biomedical research enterprise.

IV. The proposed rule's award termination authority will have significant economic and strategic consequences for the United States.

The proposed expansion of federal agencies' authority to terminate awards would have consequences extending far beyond individual research projects. By introducing uncertainty into the federal funding process, the proposed rule risks weakening the research ecosystem that has made the United States the global leader in biotechnology and biomedical innovation. This ecosystem depends on stable, predictable, and merit-based federal investments that encourage long-term commitments by academic institutions, health systems, nonprofit organizations, biotechnology companies, and private investors.

Biomedical innovation depends upon sustained investment over many years, as exemplified by the development of blood stem cell transplantation and CAR-T cell

therapies. Research grants support not only individual scientific discoveries, but also the laboratories, specialized equipment, highly skilled workforce, and collaborative networks that ultimately generate new diagnostics, medical devices, biologics, blood products, cell and gene therapies, and advanced manufacturing technologies. These long-term investments cannot be developed or sustained in an environment where funding may be terminated based on broad or undefined concepts such as "agency priorities" or the "national interest," without clear standards or procedural safeguards.

The strength of the U.S. biomedical research enterprise lies in its ability to catalyze complementary investments from universities, health systems, philanthropic organizations, and private industry. Federal funding frequently serves as the foundation upon which additional public and private investment is built, accelerating scientific discovery, technology transfer, domestic manufacturing, and commercialization. Policies that reduce confidence in the stability of federal research funding therefore have consequences that extend well beyond individual grants, affecting the broader innovation ecosystem that drives economic growth and improves public health.

The biotechnology sector has become a major driver of the American economy. Federally supported research serves as the foundation for startup companies, intellectual property development, technology transfer, domestic manufacturing, and high-paying jobs across the country. Many transformative therapies — including CAR T-cell therapies, gene-editing technologies, advanced blood safety platforms, and next-generation biomanufacturing approaches — originated through federally funded basic and translational research before being commercialized by the private sector. Weakening the predictability of this research pipeline risks slowing innovation, reducing domestic manufacturing opportunities, postponing patient access to lifesaving therapies, and diminishing the return on decades of taxpayer investment in biomedical research.

Stable federal research funding also supports the education and training pipeline that sustains America's future biomedical workforce. Graduate students, postdoctoral fellows, physician-scientists, laboratory professionals, and early-career investigators rely upon predictable research support to establish careers in science and medicine. Increased uncertainty surrounding federal awards may discourage talented individuals from pursuing biomedical research careers or encourage established investigators, entrepreneurs, and biotechnology companies to seek opportunities in countries that offer more stable research environments, gradually eroding of the United States' scientific workforce and innovation capacity.

The consequences extend beyond economic competitiveness to national security. Biotechnology, advanced biomanufacturing, regenerative medicine, and artificial intelligence-enabled biomedical research and blood supply resilience have become strategic priorities for nations around the world. Competitor nations continue to make sustained investments in these fields as part of long-term national strategies. Maintaining U.S. leadership in these fields requires a research environment that provides confidence to investigators, institutions, and private-sector partners that scientific investments will be evaluated fairly, supported consistently and protected from

unnecessary disruption. Policies that introduce uncertainty into federal research funding risk ceding leadership in strategically important technologies that are essential to healthcare, economic competitiveness, military readiness and national security.

Accordingly, AABB respectfully recommends that OMB work with the biomedical research community to establish clear, objective criteria and transparent safeguards governing award suspension or termination. Such reforms would strengthen accountability while preserving the stability, predictability and public confidence that have enabled the United States to remain the world's leader in biomedical innovation, biotechnology, transfusion medicine, and biotherapies. A predictable federal research enterprise is not only essential to scientific progress; it is fundamental to maximizing the return on taxpayer investment, improving patient care, strengthening national preparedness, and sustaining America's global leadership in biomedical research.

V. The proposed restrictions on international collaboration will interfere with critical research.

AABB is deeply committed to advancing the safety and availability of the U.S. blood supply and the biotherapies ecosystem. While AABB recognizes OMB's concern related to U.S. national security, we believe that the proposed rule's vague restrictions related to international collaboration could impede legitimate and beneficial scientific partnerships needed for scientific advancement and innovation. *See* 2 CFR §200.220.

International scientific collaboration has long been one of the United States' greatest competitive advantages and a cornerstone of biomedical innovation. Carefully managed collaborations with trusted international partners strengthen — not weaken — U.S. scientific leadership, national security, and public health preparedness. They enhance surveillance for emerging infectious diseases, accelerate the development and validation of new technologies, expand access to scientific expertise, and improve preparedness for future public health emergencies.

Transfusion medicine and blood safety are inherently global disciplines. Emerging infectious diseases, blood-borne pathogens, donor eligibility issues, and the development of new blood products frequently require international surveillance, data sharing, and coordinated scientific investigation. Lessons learned in one country often directly improve the safety and availability of the U.S. blood supply. International collaboration has been instrumental in identifying and responding to emerging transfusion-transmitted infectious disease threats. Early sharing of epidemiologic and scientific data enables timely risk assessments, development of donor screening strategies, and implementation of evidence-based safeguards that protect the U.S. blood supply. These collaborations have directly strengthened national preparedness while protecting both blood donors and transfusion recipients in the United States.

Many of AABB's members collaborate with researchers, blood centers, academic institutions and governmental organizations in allied nations on research related to blood safety and pathogen reduction technologies, novel blood products, emerging

infectious disease preparedness, and the development of cell and gene therapies. These collaborations have led to internationally recognized clinical standards, accelerated evaluation of new technologies, improved donor and recipient safety and strengthened the resilience of the U.S. blood supply.

Importantly, international collaboration and national security are not mutually exclusive objectives. Existing federal policies already provide mechanisms to protect sensitive technologies, controlled information, and national security interests. Rather than imposing broad restrictions that may inadvertently discourage low-risk scientific collaboration, federal policy should distinguish between collaborations that present legitimate security concerns and those that advance shared public health objectives with trusted international partners. Overly broad restrictions on international collaboration could isolate U.S. investigators, slow scientific discovery, delay patient access to innovative therapies, and reduce the competitiveness of American research institutions. They may also weaken international surveillance networks that are essential for responding to emerging infectious diseases and protecting the nation's blood supply. Policies intended to strengthen national security should avoid inadvertently limiting the scientific partnerships that contribute to the health, preparedness, and economic competitiveness of the United States.

Therefore, AABB urges OMB to ensure that any restriction on international collaboration is narrowly tailored to address demonstrable national security risks while preserving legitimate scientific partnerships with trusted international collaborators. Such an approach would protect U.S. interests while maintaining the international cooperation that has been instrumental to advances in blood safety, biotherapies, and biomedical innovation.

VI. The proposed changes to cost allowability will impede research dissemination and delay advances from reaching Americans.

Scientific discovery does not improve patient care until research findings are disseminated, critically evaluated, independently replicated where appropriate, and incorporated into clinical practice. Publication, scientific meetings, professional societies, and access to scientific literature are therefore not ancillary activities. They are essential components of the biomedical research enterprise and the primary mechanisms through which taxpayer-funded discoveries become improvements in patient care, public health, and national preparedness.

AABB is concerned that several proposed changes to cost allowability would impede dissemination of federally funded research and reduce the return on taxpayer investment. Restricting support for publications, scientific meetings, professional societies, and access to the scientific literature would slow the translation of scientific discoveries into clinical practice, delay patient access to new therapies, and weaken the collaborative scientific ecosystem that has made the United States the global leader in biomedical innovation. These proposed restrictions are therefore inconsistent with the

administration's stated goals of promoting transparency, accountability, and measurable public benefit from federal investments.

- **Publication costs (2 CFR § 200.461):** Publication is the primary mechanism by which federally funded discoveries are communicated, independently evaluated, and incorporated into clinical practice. Making publication costs generally unallowable unless specifically authorized in advance would delay dissemination of research findings, and slow improvements in patient care, blood safety and availability, and biotherapies.

- **Conference costs (2 CFR § 200.432(b)):** Scientific meetings accelerate the translation of research into practice by allowing investigators to share preliminary findings, establish collaborations, harmonize methodologies, and disseminate best practices. Restricting support for conference participation would slow scientific progress, reduce collaboration across institutions, and delay the adoption of innovations that improve patient care.

- **Professional membership costs (2 CFR § 200.454(a)):** Professional societies play a central role in developing clinical guidelines, consensus standards, educational programs and scientific collaborations that translate research into practice. Preventing researchers from participating in these organizations would isolate investigators from the broader scientific community and weaken the mechanisms through which federally funded discoveries improve patient care.

- **Subscriptions to periodicals (2 CFR § 200.454(b)):** Access to current scientific literature is fundamental to conducting rigorous, efficient research. It enables investigators to build on existing knowledge, avoid unnecessary duplication, identify emerging discoveries and ensure that federally funded research reflects current scientific standards. Restricting access would diminish research quality while reducing the efficiency of federal research investments.

Federal research funding should support the complete research lifecycle from discovery through dissemination and implementation. Scientific publications, conferences, professional engagement, and access to scientific literature are the mechanisms through which research findings are validated, reproduced, incorporated into evidence-based guidelines, and ultimately translated into improvements in patient care. Limiting support for these activities weakens the effectiveness of the federal research enterprise and diminishes the public value of taxpayer-funded science.

Accordingly, AABB urges OMB to retain the longstanding allowability of reasonable costs associated with publication, scientific meetings, professional society participation, and access to scientific literature. These activities are essential investments that maximize transparency, accelerate innovation, and ensure that federally funded research delivers measurable benefits to patients and the American public.

VII. Conclusion

For more than half a century, the United States has led the world in biomedical innovation through a research enterprise built on scientific excellence, merit-based peer review, stable federal investment, and collaboration among government, academia, healthcare organizations, nonprofit institutions, and private industry. This partnership has produced safer blood products, transformative cell and gene therapies, advances in trauma resuscitation, improved preparedness for public health emergencies, and countless other medical innovations that improve and save lives every day.

While AABB supports OMB's commitment to responsible stewardship of taxpayer resources, transparency, and accountability in federal financial assistance, we are concerned that the proposed rule would undermine these very objectives. Weakening independent scientific peer review, expanding broad and undefined award termination authority, restricting productive scientific collaboration, and limiting the dissemination of federally funded research would introduce unnecessary uncertainty into the biomedical research enterprise. Rather than improving efficiency, these changes risk slowing scientific progress, increasing long-term costs, delaying patient access to lifesaving therapies, weakening national preparedness, and diminishing the return on decades of federal investment in biomedical research.

AABB believes that accountability and scientific excellence are complementary, not competing, objectives. Policies that promote transparency and responsible stewardship should also preserve the stability, predictability, and scientific integrity that enable researchers to translate discoveries into improvements in patient care, public health, economic growth, and national security.

AABB respectfully urges OMB to withdraw the proposed rule in its entirety and engage with the biomedical research community in developing reforms that strengthen accountability while preserving the research enterprise that has made the United States a global leader in biomedical innovation.

If you have any questions or need additional information, please contact Leah Stone, Vice President, Public Policy and Advocacy at lmstone@aabb.org.

Sincerely,

Debra BenAvram, FASAE, CAE
Chief Executive Officer
AABB