COALITION FOR PEDIATRIC MEDICAL RESEARCH

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UNC Health Children's
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July 13, 2026

The Honorable Russell T. Vought
Director
Office of Management and Budget
Eisenhower Executive Office Building
725 17th Street NW
Room 252
Washington, DC 20503

Re: Regulation for Federal Financial Assistance

Dear Director Vought:

On behalf of the Coalition for Pediatric Medical Research, we are writing to urge that the Office of Management and Budget withdraw the proposed Regulation for Federal Financial Assistance. We make this request after full and careful review of the proposed regulation and our assessment of the profound negative impacts it would have on the federally supported scientific research ecosystem that has helped make the United States the global leader in biomedical and larger scientific innovation.

Founded nearly two decades ago, the Coalition consists of children's hospitals and related institutions that are deeply committed to advancing research to improve the health and well-being of our nation's children and population. Children are the frontline of disease

manifestation that often evolve into the many chronic conditions of adulthood – such as diabetes, heart disease and mental illnesses. The Coalition's mission is to improve the health and well-being of our nation's children through a robust commitment to pediatric medical research. Central to this goal is a well-supported commitment by the federal government – primarily via the National Institutes of Health (NIH) – to fund the strongest science possible.

The longstanding research contract between the federal government and research entities to spur scientific innovation has been anchored in several fundamental principles including:

- A meritocracy approach to making awards where funding decisions are driven by the quality and potential impact of what is being proposed and free of undue political influence.

- Ensuring that taxpayer dollars are well-spent by utilizing a multi-level expert review process to make funding recommendations overseen by senior officials with experience in the subject area.

- Trusting that the terms of an award – including the amount and timeframe – will be honored unless a recipient engages in activities deemed non-compliant with the grant terms. This enables research institutions to make long-term investments in the personnel and infrastructure needed to discharge a cutting-edge research program.

- Enabling grantees to use federal funds to cover costs that are essential to the conduct of research, including sharing of results within the broader scientific community to allow for greater understanding and scrutiny to enable additional progress.

- Supporting grantees in discharging the strongest science possible, including activities involving domestic or international partners. This is particularly important in the field of child health where most diseases are considered rare and often require multi-center research networks, including international partnerships.

Unfortunately, the proposal, if implemented, would negate or severely undermine these principles, fundamentally altering the longstanding policies and processes used to support a robust commitment to scientific research and the myriad benefits this has yielded to the American people. The proposal would make sweeping changes to the conditions under which research institutions apply for, receive, administer, and rely on federal awards to support our scientific innovation ecosystem. It would threaten productive research partnerships with international collaborators, would artificially limit how funds can be used and places greater burdens on already-strained child health research institutions.
While our orientation is around child health medical research, the consequences are far-reaching and, if finalized as proposed, will threaten the nation's leadership role in scientific research and the myriad tangible benefits that leadership results in for our nation. For these reasons, we urge that it be withdrawn.

Proposed Sec. 200.205 – Federal agency merit review of proposals and pre-issuance reviews

As written, this provision would fundamentally shift the longstanding process of assessing and selecting applicants based on the quality and anticipated impact of their scientific proposals as determined by an impartial panel of experts to a process that is driven by political appointees and designed to support the agenda of the President in power. The negative consequences associated with this change are profound.

For decades, the National Institutes of Health (NIH) and other agencies that fund scientific research have built, refined, and maintained a system using independent and well-established experts to vet the merits of grant applications and to make recommendations for funding. Recommendations are subsequently reviewed by scientific advisory councils – consisting of special government employees working under the advisement of Institute or Center leadership – and finally by the directors of the respective Institute or Center. While refinements or modifications must always be considered, the current process works and balances quality of proposals with the strategic priorities of the respective agency. As written, this provision would fundamentally shift the longstanding process of assessing and selecting applicants based on the quality of their scientific proposals, as determined through expert peer review, toward a process in which discretionary awards will be influenced by political priorities. The Coalition is concerned that embedding such considerations into government-wide regulation would severely weaken the merit-based foundation of federal research funding and undermine our shared goal of pursuing gold standard science to improve the nation's health and well-being.

In child health research and medicine, the stakes are not abstract. Many medications, vaccines, diagnostics, dosing standards, and treatment interventions that are now the standard of care were made possible by NIH-funded grants selected based on scientific merit, not the identity or perceived viewpoint of the applicant. These include the development of surfactant replacement therapy to support the lung development of infants born very prematurely, saving tens of thousands of babies over the past several decades; the evidence-based medication dosing thresholds for pediatric sepsis management; the administration of prenatal steroids to prevent brain injury in premature babies; gene therapies for sickle cell disease; immunotherapies for pediatric cancers; and the immunological research that underpins our understanding of chronic childhood autoimmune conditions. They also extend into countless other disease states and research areas and include groundbreaking cell and gene therapies and other novel interventions.

The longstanding merit-based approach to supporting research has enabled more children to survive serious illness, reduced suffering for families, lowered healthcare costs, and given millions of children the opportunity to reach their full potential. Rigorous merit review is the mechanism that helps identify the research most likely to achieve those outcomes.

We also wish to express concerns about the specific clause:

> *(3) All else being equal, preference for discretionary awards should be given to institutions with lower indirect cost rates.*

In the preamble of the proposal, the Administrations references its proposal to cap indirect rates but states that in response to statutory and report language "OMB is not proposing updates to the indirect cost rate negotiation system through this document." Clause 3 appears to conflict with this statement by driving decision-making toward lower indirect rates. A lower indirect cost rate does not necessarily indicate a more efficient or higher-value research proposal. For children's hospitals, indirect costs reflect specialized infrastructure, compliance systems, pediatric research protections, data-security obligations, clinical research support, and facilities necessary to conduct research involving children safely and responsibly. For example, a children's hospital conducting an early-phase gene therapy trial for a life-threatening pediatric disorder must maintain specialized clean-room capacity, pediatric research pharmacy support, data security, intensive regulatory oversight, and child-specific safety monitoring. These costs are necessary to support the work being done. If awards are steered toward institutions with lower indirect rates, this would penalize institutions best equipped to discharge an advanced pediatric research agenda.

Proposed Sec. 200.220 – Prohibition of using Federal funds for covered foreign collaborations

We are extremely concerned about the impact the proposal will have on international research collaborations, particularly those addressing diseases that impact children, including rare and ultra-rare conditions. The Coalition supports measures to protect federally funded research from research-security risks, undue foreign influence, data misuse, intellectual property theft, and other legitimate threats. But these objectives should be addressed through targeted action rather than categorical restrictions that will impede scientifically necessary collaborations that best address a given disease condition through international collaborations.

Because of the rare nature of most pediatric conditions, no single nation will likely have an adequate number of patients to generate reliable evidence, a challenge that is compounded further when applied to ultra-rare conditions or subpopulations of a disease. The ability to analyze and pool data across multiple nations allows researchers to build adequately powered cohorts, validate biomarkers, characterize natural history, and distinguish true treatment effects from site-specific or population-specific noise. Projects involving international collaborations leverage multi-country registries or biosamples and other data from a far larger population than what would be possible from a project limited to a single country. Programs involving clinical research could use harmonized research protocols, coordinated clinical trials infrastructure and other approaches to reduce overall costs and provide greater gains in knowledge and understanding, benefits that accrue to the American people.

The field of pediatric infectious disease research demonstrates why international collaboration is essential. Pediatric diseases that cross borders, including influenza, RSV, tuberculosis, and emerging novel pathogens, cannot be studied through domestic data sources alone. Multisite international clinical trials are the gold standard for evaluating pediatric vaccine efficacy across genetically and epidemiologically diverse populations. The proposed prohibition, which extend well beyond China, would sever longstanding scientific partnerships built over decades, disrupting ongoing trials and eliminating research

collaborations that protect American children from diseases that do not respect national borders.

The ability to collaborate internationally can also help stretch scarce research resources by achieving an adequately powered study without having to do the entirety of the work in the United States, where the costs of conducting research are high. International research collaborations are also needed so that we are prepared to address and respond to conditions that may not be endemic but that are moving into North America, such as Dengue, Zika and Chikungunya, and to address non-endemic diseases contracted via travel.

To underscore the critical importance of international collaborations in child health, consider the following specific examples:

- Rheumatic heart disease affects an estimated more than 40 million people worldwide and causes more than 300,000 deaths annually. Multi-year research driven by Cincinnati Children's focused on rheumatic heart disease and based in Uganda has helped lead to marked improvements in early detection and intervention of the condition.

- Over many decades, the Children's Oncology Group (COG) has transformed care for myriad pediatric cancers. COG is a global network that includes sites throughout the nation and world with more than 100 active clinical trials at any one time. COG exemplifies what is possible through greater collaboration nationally and internationally

- Through international collaboration with a group in the Netherlands, a team at Boston Children's Hospital has studied novel molecules in human breast milk to understand how they change with different stages of lactation and determine if they could be used for better baby formula additives. Without this collaboration, it would not be possible to profile these molecules or make these discoveries.

- Because pediatric chronic kidney disease is rare, the Chronic Kidney Disease in Children cohort enrolled children across the United States and Canada over many years to generate enough longitudinal data to characterize disease progression, identify meaningful outcomes, and inform future randomized clinical trial design. Prohibiting international collaborations like this would make it more difficult to assemble adequately powered pediatric cohorts, slow the development of child-specific therapies, and leave clinicians relying on adult evidence that may not translate safely to children.

- To address the need for more efficacious cancer treatments, the NCI/NIH funded Cancer Grand Challenges "NexTGen" program was created to address the complex Cancer Grand Challenge of solid tumors in children. This program consists of collaborative teams from Children's Hospital of Philadelphia, Children's National Hospital, Boston Children's Hospital as well as researchers from the United Kingdom

and Europe. The Teams are currently running multiple clinical trials evaluating next generation CAR-T cell therapies for children with relapsed solid tumors who have exhausted all treatment options. Halting this and other similar international collaborations effectively stop the rapid development of new treatments specific for pediatric cancer.

Proposed Sec. 200.340 – Termination and Suspension

We strongly oppose the provisions that would allow agencies to suspend or terminate awards for "discretionary" reasons because a project is or may be viewed as not addressing the goals or priorities of the awarding agency. Allowing for termination or suspension of projects because they do not fit an Administration's political priorities will cause tremendous amounts of uncertainty for individual researchers and research institutions and undermine the ability to execute research along timelines required to make meaningful impacts.

For example, consider a five-year award made during the third year of one Administration. Eighteen months later, after a change in Administration, the award could be suspended or terminated just as research activity is accelerating, even though the recipient remains compliant and the science being conducted continues to be meritorious. Scenarios like this are destabilizing for individual researchers, particularly the early-career researchers that the NIH's current Unified Strategy prioritizes recruiting and retaining,[1] and for research institutions as they undermine the ability for institutions to make long-term investments in research infrastructure – both advanced research equipment and the personnel – required to conduct high-quality research. In cases involving clinical research, such as a trial for a novel therapy, the impact of a termination or suspension on the patient and family is profound. For example, if a study is paused or terminated and can no longer recruit participants, patients are left behind, and all who would stand to benefit from the potential intervention are left to go without.

The proposed policy also threatens to waste vast amounts of resources in the form of work started and paid for but terminated mid-course without any final outcomes or publication of results. This reality stands in stark contrast with the Administration's stated priorities on responsible stewardship of research resources as the proposed rule fails to recognize these sizable costs and squandered resources.

While not limited to child health, the negative consequences of this policy if implemented would be particularly damaging to child health research since multi-year/longitudinal studies are critical to establish therapeutic efficacy given the long timelines typically involved in evaluating child health from infancy to adulthood. The threat is especially acute for long-term projects, including longitudinal studies focused on children's health, including priorities the Administration has identified. For example, the 2025 MAHA Strategy Report to identify and address the drivers of childhood chronic diseases calls for:

[1] See Advancing NIH's Mission Through a Unified Strategy | National Institutes of Health (NIH)

- Leveraging of existing NIH longitudinal studies to identify the root causes and modifiable root causes of chronic disease across life stages;

- Using Department of Veterans Affairs data to support longitudinal analyses across multiple topics including ADHD, diabetes and use of pharmaceuticals; and

- Developing a Real World Data Platform (RWDP) to support studies of chronic diseases, including autism.

All of these projects and others like them would stand to be at risk under the proposal.

We also oppose related provisions to suspend research activities for up to 90 days (*proposed Sec. 200.340*); issue termination notices with only a "brief summary" of the reasons (*proposed Sec. 200-341*); and the non-allowance of appeals except for terminations based on noncompliance (*proposed Sec. 200.342*).

A 90-day or three-month suspension poses significant challenges for researchers. As noted in the proposal, a suspension order would "Direct the recipient or subrecipient to temporarily stop all or part of the activities under the Federal award." While the impact will vary by grant awards, a three-month suspension on research activities carries sizable consequences, including untold amounts of work lost that must be repeated and a squandering of taxpayer dollars. Suspensions will also likely result in a loss of jobs, particularly at smaller institutions that are less able to carry employees if their funding is suspended for months.

The operational impact on pediatric research cannot be overstated, including the real risks to children participating in clinical trials of novel therapeutics and medical devices when follow-up visits used to monitor the effectiveness and side effects of experimental treatments are terminated. A longitudinal study of childhood neurodevelopmental outcomes cannot be paused and restarted without catastrophic loss of data integrity. A clinical trial of a new pediatric vaccine cannot be halted midway without both invalidating the scientific record and exposing enrolled children to risk. A cohort study following premature infants through early childhood takes years to produce meaningful results. These are not quarterly deliverables. They are sustained scientific enterprises whose value lies precisely in their continuity.

A real-world example is the Chronic Kidney Disease in Children study following children with chronic kidney disease that is funded by several NIH Institutes and Centers. The study follows children with chronic kidney disease, many of whom were born prematurely and who are experiencing development delays, and it measures development and early life exposure. If a 90-day suspension occurs during a scheduled assessment window, investigators cannot simply "make up" the missed visit months later. Growth, kidney function, neurodevelopmental testing, biospecimen collection, medication exposure, and family-reported outcomes are time-sensitive. Missed windows can invalidate comparisons across participants, reduce statistical power of the study, and require years of additional follow-up to recover lost information, recovery that may not even be possible.

Similar to the cancellation of awards for political reasons, suspensions for political reasons

are also an affront to stated commitments and intentions to be good stewards of federal research funding and to support Gold Standard Science. Additionally, allowing federal agencies to cancel research projects on discretionary grounds and requiring that they provide only brief summaries and not allow any appeals unless awards are cancelled for noncompliance results in an entirely one-sided process that leaves recipients absent any processes to challenge such decisions. Over the past year-and-a-half, the research community has been rocked by suspensions and cancellations that were based on grant abstract word searches or other specious claims only to be reversed. This proposed policy would ingrain this approach into grantmaking regulations and cause significant disruption, chaos and higher costs.

Proposed Sec. 200.432 – Conferences

We oppose the proposal to make attendance at scientific meetings largely unallowable unless explicitly included in the award. Scientific meetings are not ancillary perks; they are a core part of the research and education process. They allow investigators to present findings, receive expert critique, identify errors or limitations, form collaborations, learn emerging methods, and accelerate the translation of research into clinical practice. For pediatric researchers, conferences are especially important because many fields are small, patient populations are limited, and collaboration across institutions is often necessary to advance the science.

Additionally, conference and related scientific meetings are often forums for researchers to connect with industry partners and investors. These connections are critical to translate research findings into early-stage diagnostics and therapeutics and, ultimately, toward commercially viable products. We urge the Administration to recognize the role these specialized meetings play in spurring economic development and that absent support through grant funds, researchers will have to forego attendance, chilling these economic development pursuits.

Yet again, the impact of this policy will be felt most heavily on early-career researchers, the very ones the NIH wants to develop more fully. Consider an early-career researcher who travels to a conference to present their findings. While at the meeting, they learn of complementary work and form professional relationships that lead to a collaboration on study with a larger sample size and they make contacts with industry partners and investors. If these activities are not supported, opportunities like this would be lost and progress slowed down.

Proposed Sec. 200.454 – Memberships, subscriptions and professional activity costs

Similarly, we oppose the proposed limitations on legitimate professional membership and subscription costs as well as the tact taken to equate such prohibitions with memberships in country or social clubs or lobbying costs. Just as with many other professions, scientific researchers benefit from professional memberships that provide opportunities for professional learning and development. In pediatrics, professional societies and specialty journals often serve as the primary venues through which investigators learn evolving standards for pediatric trial design, child protection in research, rare disease methods, vaccine safety, neonatal care, and disease-specific clinical guidance.

As with conference attendance, eliminating support for these activities would disproportionately affect early-career investigators and investigators from smaller programs that lack discretionary funds, making it harder for them to maintain scientific competence. This outcome runs counter to the stated desire of the NIH to expand the universe of entities receiving NIH funding by undercutting a critical development function. Finally, treating these costs as comparable to social club memberships mischaracterizes their role in maintaining scientific competence and professional standards. Making these costs unallowable will only impede opportunities for further learning and professional development.

Proposed Sec. 200.461 – Publication and printing costs

Prohibiting federal funds from being used to cover legitimate costs associated with publishing a researcher's findings will further stymie the ability for researchers to share their findings. While there are legitimate questions and concerns – such as those raised by the National Institutes of Health during a summer 2025 Request for Information (RFI) focused on levels of funding for publication costs known as article processing charges or APCs – a blanket prohibition on paying for any publication costs will impede the ability of researchers to share research findings.

This proposal is particularly troublesome given that the federal mandate for open-access publication of NIH-funded research, codified in policy for over a decade, is premised on the recognition that public dissemination of publicly funded research is a core obligation. It also seems to contradict stated priorities of radical transparency and the desire to drive reproducibility and replicability research since publishing results and their underlying data is a prerequisite to enable such follow-on work.

These proposed policies will impact researchers across the board, regardless of their fields, institutions or level of experience. But we fear the most significant negative impact will again be felt by early career researchers as well as those at institutions with more modest resources as they will be the least able to identify resources from other sources to cover these essential costs. This would in turn negatively impact stated interest in diversifying recipients of federal research dollars including in regions and institutions that have not historically had robust funding.

Conclusion

As laid out, the proposed rule would negate and undermine the core attributes of our federal research enterprise that have enabled the United States to lead the world in research and development, including in biomedical discovery and pediatric innovation. This leadership has yielded incalculable benefits to the American citizenry over the past three quarters of a century. As written, the proposal would hamstring merit-based review of research proposals, destabilize multi-year research activities, upend individual and institutional planning, restrict scientifically necessary collaboration and impede the dissemination of federally funded findings. These harms would be especially acute for pediatric research, where patient populations are smaller, studies often require longer time horizons, and discoveries depend on sustained collaboration across institutions and borders.

The current system can and should continue to be improved through responsible stewardship, transparency, research-security safeguards, and appropriate oversight. But the proposed rule would not merely refine the system; it would alter foundational principles in ways that threaten research benefiting children and families across the country. For these many significant concerns, the Coalition urges OMB to withdraw this proposal.

Sincerely,

The Coalition for Pediatric Medical Research Steering Committee:

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