



July 13, 2026

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

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

The undersigned organizations are members of the Alliance for Childhood Cancer, which consists of organizations representing Americans who care deeply about childhood cancer. We submit these comments in strong opposition to the Office of Management and Budget's (OMB) proposed rule change to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, or the "Uniform Guidance." The proposed rule threatens any future research breakthroughs for children with cancer, research already underway, and the critical pipeline of early investigators families rely on. Our comments are directed at both OMB generally, as well as the Department of Health and Human Services (including the Food and Drug Administration and the National Institutes of Health (NIH)), National Science Foundation, and the Department of Defense. We believe that OMB should rescind this rule in its entirety and revert to previous guidance. However, our concerns on specific portions of the proposed rules follow.

Diminished Role of Peer Review (§200.205(c)–(d), 200.205(b))

Cancer remains the most common cause of death by disease among children in the United States. Decades of sustained federal funding for cancer have significantly improved survival rates for some childhood cancers. The proposed rule affects all 42 federal grantmaking agencies, including the NIH, Advanced Research Projects Agency for Health (ARPA-H), Defense Health Agency (DHA), and National Science Foundation (NSF). Together, these agencies form the bedrock of all medical research breakthroughs in the United States.

OMB proposes that peer review evaluations and recommendations for discretionary grantmaking must not be binding and only treated as advisory. This is a stark departure from how agencies such as the National Institutes of Health (NIH) have successfully operated, whereby independent peer review by a panel of experts in the field is the primary measure of merit and fundability. Over the past fifty years, research has transformed childhood leukemia from an incurable disease to one with a five-year survival rate of 86%. This progress to improve outcomes for children with cancer would not be possible without longstanding, trusted peer-reviewed research.

Children are not just tiny adults, and many childhood cancers are biologically different than adult cancers, even if they share the same name. Thus, childhood cancer and rare disease research requires pediatric experts to guide decision-making on limited public resources dedicated to their

diseases. We have seen what happens when pediatric oncology experts are not part of the complex advisory and review process: children are left behind. Recognizing this, Congress recently took important bipartisan action in passing the Childhood Cancer STAR Reauthorization Act (PL 117-350), which requires pediatric experts to be part of critical NIH advisory boards. OMB is now proposing to ignore this lesson and even go further. Under the OMB proposal, political appointees are empowered to effectively ignore the advice of independent scientists. An unbiased review by experts is essential for ensuring that limited federal dollars are being put towards the best science with the greatest potential for improving outcomes, and even more so for children with cancer and their families.

Despite the significant unmet need for new FDA-approved pediatric cancer therapies, pharmaceutical companies have been reluctant to develop new pediatric oncology drugs since they likely will not recoup the high costs associated with their research, development, marketing, and distribution following approval. As a result, children with cancer fundamentally rely on publicly funded highly scored peer-reviewed research for standard of care changing landmark discoveries.

The Children's Oncology Group (COG), a member of the National Cancer Institute (NCI) National Clinical Trials Network (NCTN), is the world's largest organization devoted exclusively to childhood and adolescent cancer research. 60% of COG's \$78 million annual budget comes from the NIH¹. Childhood cancer treatments are often decades old and cause severe or life-threatening conditions due to the toxicity of the treatment that initially saved their life. It is critical and necessary to study more commonly diagnosed childhood cancers even when the cure rate is already high. Thanks to stable and predictable public grant funding, COG is the only organization equipped to perform large scale childhood cancer studies of this magnitude.

Most recently, this successful model allowed COG to conduct the largest scale study of blinatumomab in children with B-cell acute lymphoblastic leukemia (B-ALL) to date. While B-ALL has a cure rate of 88%, it also causes significant side effects affecting survivors for the rest of their lives. COG's blinatumomab study improved patients' disease-free survival rate from 88% to 96% without the toxicities of older treatments², changing front line therapy for newly diagnosed kids for generations. A complex study such as this – which simply wouldn't be undertaken by private industry – can only be properly understood and scored by expert pediatric oncologists, not a non-scientist political appointee.

The exciting progress we've made such as the blinatumomab study is only due to non-political federal dollars that do not change between administrations. OMB proposes to eliminate this standard and instead benchmark grants against "Gold Standard Science", without defining the term. Make no mistake, when funding decisions are made by non-scientist political appointees,

¹ Boyle, P. (2025, April 24). What's at stake when clinical trials research gets cut. AAMC News. <https://www.aamc.org/news/whats-stake-when-clinical-trials-research-gets-cut#>

² Gupta S et al. Blinatumomab in Standard-Risk B-Cell Acute Lymphoblastic Leukemia in Children. *N Engl J Med*. 2025 Feb 27;392(9):875-891. doi: 10.1056/NEJMoa2411680. Epub 2024 Dec 7. PMID: 39651791; PMCID: PMC11864901.

rather than scientific experts, rare disease patients like children with cancer are among the most significantly harmed.

Termination of Active Grants Without Cause (§§ 200.340–200.343)

OMB proposes to codify authority to terminate any active grants mid-award “including if a Federal award does not effectuate program goals, Federal agency priorities, or the national interest as they exist at the time of the termination.” Grants may be terminated with only a brief written rationale and without any findings of noncompliance or wrongdoing. This proposal is especially alarming for childhood cancer and rare disease research, where patient populations are smaller.

Children with cancer uniquely rely on stable and predictable federal research programs appropriated by Congress to provide the basic research infrastructure that makes all childhood cancer research possible. This includes critical resources all investigators use to conduct pediatric studies. For example, to make childhood cancer research even feasible, biospecimens such as tissue or fluid samples collected from newly diagnosed patients must be sent to one centralized location for researchers’ use. This unique strategy ensures cost-effective childhood cancer research can overcome geographic challenges common in rare disease populations. The Children’s Oncology Group Biorepository maintains the largest pediatric cancer biospecimen bank in the nation, containing biospecimens from more than 144,000 children with childhood cancer and related diseases. The biorepository is wholly reliant on a peer reviewed NIH grant to maintain operations.

The COG Biorepository also plays a key role in childhood cancer clinical trials. For many children with cancer, especially children suffering from a relapse or refractory disease, a clinical trial is their best and only treatment option. Children with pediatric brain tumors rely on biospecimens to be processed and certain biomarkers must be confirmed as a requirement for clinical trial enrollment. Even if the clinical trial is self-funded, many trials cannot move forward without biorepository processing and biomarker confirmation. If the biorepository’s funding were to lapse, be abruptly canceled, or suspended by a political appointee without sufficient scientific experience or understanding, biospecimens currently in the bank would be threatened and many could be lost forever absent new funding to maintain their refrigeration and storage conditions. Childhood cancer researchers reliant on these biospecimens would be forced to suspend their work, and children on active trials would be forced to stop treatment. An inability to complete studies for arbitrary reasons wastes critical investments into developing new treatments for children with cancer and puts kids’ lives needlessly at risk.

Further, newly diagnosed children would be unable to enroll in a trial that could save their life, which we’ve unfortunately seen most recently with the NIH’s decision to close the Pediatric Brain Tumor Consortium (PBTC) and pause enrollment last year. Since August, pediatric brain tumor patients have been unable to enroll in already underway PBTC trials due to the delay, and some children’s condition will have worsened to the point that they will be longer eligible once reopened.

Finally, not only will this threaten nearly half of all studies currently active,² it will create a severe chilling effect on future biomedical research and discourage the next generation of pediatric oncologists and researchers from ever entering the field. As we've already seen, introducing new hurdles to a potential career in pediatric oncology, coupled with sudden and arbitrary cuts to funding, will further impede access to care for children with cancer in the U.S.^{3 4 5 6}.

International Collaboration (§§ 200.202(e), 200.322, and 200.220)

OMB proposes to limit the ability of grantees to collaborate with international scientific partners. In addition to fully banning collaborations with certain covered foreign countries and entities, it requires a senior political appointee to approve primary grants to international organizations, and other international collaborations be justified by compelling needs.

Medical researchers focused on rare diseases, like childhood cancer, face significant challenges due to the small patient populations they study. As a result, regulators and researchers must take unique approaches to challenges in collecting childhood cancer data necessary to complete U.S.-based clinical trials and develop new pediatric treatments. These challenges often require unique research collaborations among investigators worldwide. The COG unites over 12,000 experts at its 220 leading hospitals, universities, and cancer centers across the U.S. and trusted international partners.

International childhood cancer research programs are essential to long-term scientific partnerships with COG. They enroll patients in hard-to-complete trials for rare cancers and contribute significant scientific research expertise. Without our international partners, childhood cancer data collection, which is required to establish safety and efficacy to make breakthrough discoveries, would take decades longer to achieve. International childhood cancer research partnerships are essential to developing new, effective, and less toxic treatments for children with cancer in the U.S., as we saw with the landmark blinatumomab study, which relied on collaboration with institutions in Canada, Australia, and New Zealand.

OMB's proposed rule would restrict American researchers' ability to partner with researchers in other countries and cause clinical trials to take years longer to complete, threatening progress against childhood cancer and harming children in the process.

Multi-Year Awards (§ 200.202(f))

³ UCLA Health, "Stagnant Funding of NIH Is Shackling Young Research Scientists," March 11, 2008, UCLA Health, <https://www.uclahealth.org/news/release/stagnant-funding-of-nih-is-shackling-young-research-scientists>.

⁴ Anna Volerman and Valerie Press, "Five Years Ago, Early Career Researchers Needed Help to Survive the Pandemic. Now They Need It Again," STAT, March 24, 2025, <https://www.statnews.com/2025/03/24/early-career-researchers-medicine-nih-grants-pipeline/>.

⁵ Nada Fadul et al., "The Chaos of NIH Cuts Has Left Early-Career Scientists Scrambling," Wired, March 24, 2025, <https://www.wired.com/story/the-chaos-of-nih-cuts-has-left-early-career-scientists-scrambling/>.

⁶ Karow, Julia, "Survey: Researchers Devastated by NIH Funding Cuts, Question Future of US Biomedical Science," GenomeWeb July 16, 2025, <https://www.genomeweb.com/policy-legislation/survey-researchers-devastated-nih-funding-cuts-question-future-us-biomedical>

OMB's proposal would disfavor an incremental funding approach, instead encouraging agencies to design awards as multi-year awards. We are particularly concerned this policy will fundamentally change NIH's proven model. NIH's traditional incremental funding model enables the U.S. to support more researchers from more institutions across the country simultaneously, accelerating the next big discovery, for children with cancer and patients with other conditions. Moving away from this established model would lead to one of the largest cuts to cancer research ever considered, a devastating blow which children with cancer can't afford.

Conclusion

OMB should rescind this rule in its entirety and revert to previous guidance. Should you have any questions or want to discuss these comments further, please contact Rosalie Abbott, Co-Chair of the Alliance for Childhood Cancer, at Rosalie.abbott@stbaldricks.org, or Dr. Michael Link, Co-Chair of the Alliance for Childhood Cancer, at mlink@stanford.edu.

Sincerely,

The Alliance for Childhood Cancer

American Association for Cancer Research

American Cancer Society Cancer Action Network

American Childhood Cancer Organization

American Society of Pediatric Hematology/Oncology

The Andrew McDonough B+ Foundation

Association of Pediatric Hematology/Oncology Nurses (APHON)

Blood Cancer United

Children's Brain Tumor Foundation

Children's Cancer Cause

Dana-Farber Cancer Institute

International Society of Pediatric Oncology, North America

Mattie Miracle Cancer Foundation

MIB Agents Osteosarcoma

National Brain Tumor Society

National Comprehensive Cancer Network

Pediatric Brain Tumor Foundation

Rally Foundation for Childhood Cancer Research

St. Baldrick's Foundation

St. Jude Children's Research Hospital