March 10, 2025

The Honorable Shelly Moore Capito
Chair
Committee on Appropriations
Subcommittee on Labor, HHS & Education
United States Senate
136 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
Ranking Member
Committee on Appropriations
Subcommittee on Labor, HHS & Education
United States Senate
136 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Robert Aderholt
Chairman
Committee on Appropriations
Subcommittee on Labor, HHS & Education
United States Congress
2358-B Rayburn House Office Building
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
Committee on Appropriations
Subcommittee on Labor, HHS & Education
United States Congress
1036 Longworth House Office Building
Washington, DC 20515

Dear Chair Capito and Ranking Member Baldwin and Chairman Aderholt and Ranking Member DeLauro:

As the organizations that are driving our nation's child health research agenda and working daily to improve the health of our nation's children, we write to express our strongest concerns with the recent administration policy change to dramatically alter how the National Institutes of Health (NIH) establishes facilities and administration (F&A) or indirect rates to support medical research. **As you work to address Fiscal Year 2025 federal funding, we urge you, as leaders of the appropriations subcommittees responsible for funding the NIH, to ensure the longstanding bipartisan prohibition on such a unilateral change remains in effect in any final or short-term appropriations bill.** Continuing this precedent via the annual appropriations law will be necessary to prevent a massive destabilization of our national medical research enterprise, and particularly pediatric medical research that has been at the core of improving the longevity, health, and well-being of children in our nation and throughout the world.

Since the change was put forward, pediatric researchers and patients have been living with an uncertainty that is resulting in myriad grave consequences: early-career researchers who are leaving the profession, hiring freezes that are inhibiting research from moving forward and, ultimately, delays in our collective ability to conduct the scientific exploration that will result in new therapies and treatments for our children. We are more than willing to have a discussion about F&A costs, including what they encompass and how they are calculated, as well as a

conversation about how NIH policies can ensure that federal investments remain the bedrock of American leadership in medical breakthroughs. But we cannot have this discussion amidst this destabilization.

Facilities & Administration (F&A) Costs in Children's Health Research

Fair and equitable federal F&A rates enable our research institutions to provide the state-of-the-art laboratory space, the advanced research technology, equipment, and secure data systems, and the trained and skilled professionals needed to support these endeavors. Whether an NIH grant is specific to the treatment of a rare childhood disease or the testing of a new intervention for a common pediatric condition, every grant is supported by a number of other costs that are partly funded through F&A or "indirect" payments.

While these shared resources are not specific to any single project, they are essential for conducting ethical, safe, and effective research that drives the development of new and improved treatments for children and adults. F&A payments also help to cover the cost of staff needed to properly manage all aspects of receiving federal funding including ensuring the dollars are distributed as intended, that all costs are documented, and that all reports are filed properly. Expenses covered by F&A rates are not optional or extraneous, they are essential components of conducting medical research which drives innovation. Following are just some examples of the research functions that are funded through indirect rather than direct payments:

- Many advanced research instruments and infrastructure – such as imaging equipment, novel genomics technologies and biospecimen repositories – are used to support multiple individual research projects. The costs of acquiring, operating and maintaining these research cores to extend their lifespans is included within the F&A category.

- High-performance servers and cloud-based data management systems that ensure the security of research participant data and provide the advanced computing necessary to analyze ever-growing and increasingly complex research data sets are also used to support an array of individual grants and thus included within F&A costs.

- Maintenance of laboratories with advanced equipment and technology requires specialized staff who ensure the lab is properly supplied to conduct the research and appropriately cleaned and maintained to facilitate the development of new therapies in a safe environment for workers and patients.

- The cost of clinical trials infrastructure – including costs to protect patients enrolled in trials, such as pharmacy staff to ensure the safety of any experimental therapy and personnel to ensure trials are conducted ethically – are incurred as F&A costs. These expenses are often greater when trials involve children given additional necessary safety, human protection and oversight needs that are not reflected in direct trial costs.

We hope these examples help clarify that F&A costs help cover many the fundamental research expenses that are not reflected in individual grants but are necessary to perform the research. We welcome the chance to provide additional context and to discuss these points more directly.

Particular Considerations in Child Health

Sweeping changes to F&A payment rates will impact research institutions of all sizes, located in states throughout the country and focused on an array of research pursuits. However, children's hospitals and pediatric research departments and programs are particularly vulnerable given other realities that include:

- **Limited research funding opportunities:** Pediatric research is a smaller field relative to research overall, resulting in fewer sources of funding from public, private and philanthropic sources. In the context of the NIH, this has meant child health dimensions from being excluded, ineligible or under-represented in programs over the years such as the *All of Us* Research Program, the Clinical and Translational Science Awards (CTSA) program and most cancer center activities, among others.

- **Limited commercial interest**: Myriad challenges have historically impeded efforts to develop therapies for children, including the higher costs associated with pediatric clinical research and the smaller market size for many therapies that make it to market. This limited interest places the onus for children's health research upon the backs of children's hospitals and pediatric academic departments, particularly the basic and early-stage scientific agenda that fuels later-stage activities.

- **Limited clinical margins for pediatrics care**: Children's hospitals and departments are far more heavily reliant on Medicaid than most adult institutions. Medicaid's current – and potentially future – funding challenges result in lower margins and limited resources that can be allocated to pursuits like medical research.

We share these examples to further elucidate the fragile state of our pediatric research enterprise and the profound impact the proposed reduction of F&A rates would have on it.

Conclusion

Reducing F&A costs to a single artificially low, one-size-fits-all level that does not reflect the true costs of operating a world-class research operation would be detrimental to children's health research in states and communities throughout the country. The impact will be even more pronounced among institutions with limited resources to compensate for this stark reduction, such as those in rural regions of the country working to grow their research programs as well as institutions tied to safety net providers with limited resources. Ultimately, the consequences will be a diminished child health research ecosystem that will fall behind global competitors and fail to enable us to achieve goals in improving the health and well-being of our children.

We urge that you prevent this from happening by ensuring that the longstanding prohibition on a unilateral change to federal F&A rates remains in a continuing resolution or final FY 25 spending bill. As Congress continues to study this topic further, as well as to consider other reforms at the NIH, we invite you to reach out to our organizations for information on how proposed changes will impact pediatric medical research and the children who rely on the development of new treatments and therapies. Providing every child with a strong foundation to enable them to grow into adults and achieve prosperity for future generations is only possible through a robust commitment to pediatric medical research. Thank you for considering this request, and we welcome the opportunity to discuss this more fully at your convenience.

CC: The Honorable Susan Collins
The Honorable Patty Murray
The Honorable Tom Cole