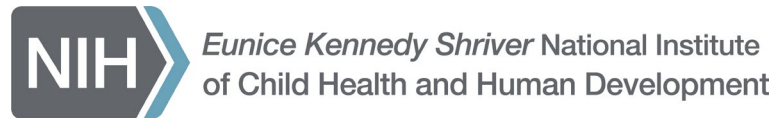


# **Strategies to Enhance Pediatric Health Research Funded by NIH**

## ***Sponsor Briefing***

Sarah Glavin, PhD; Rohan Hazra, MD; Tracy King, MD, MPH

*December 5, 2024*



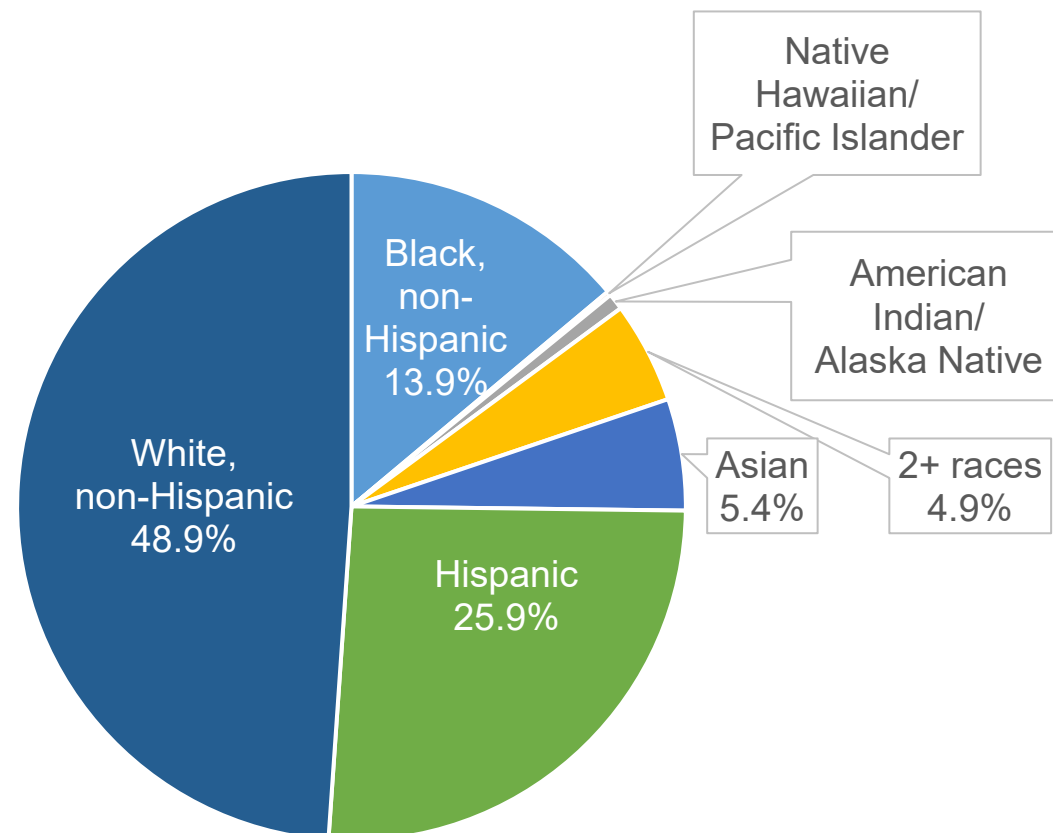


# **Pediatric Research at NIH**

# America's Children

- There are 74.4 million children in the United States, making up **22% of the population**.
- In 2019, 14.4% of children were living in poverty. The poverty rate is higher for non-Hispanic Black and Hispanic children than for non-Hispanic White children.
- 1 in 5 children has obesity, up from 1 in 18 in the late 1970s. A larger proportion have overweight.

## Population Demographics

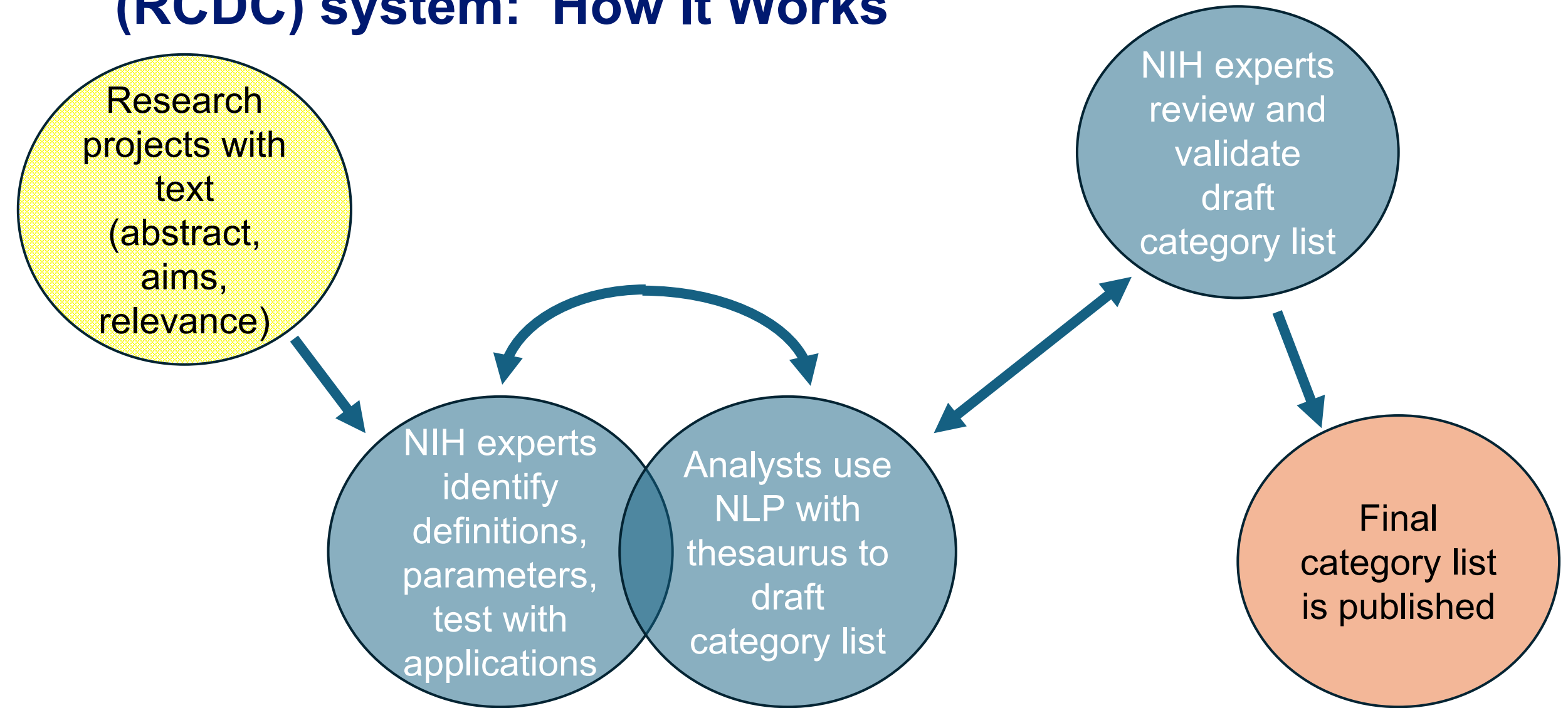


# What Might It Mean to Say a Research Study is Pediatric? (Research in children, or research about children)

- A. A clinical study that is not an adult-only study – **children are not excluded** as research subjects
- B. A clinical study where a significant percentage of **children are included** among its research subjects
- C. A research study where the **research aims and public health relevance focus** on conditions or developmental processes that typically originate and manifest in childhood



# NIH Research, Condition, and Disease Categorization (RCDC) system: How It Works

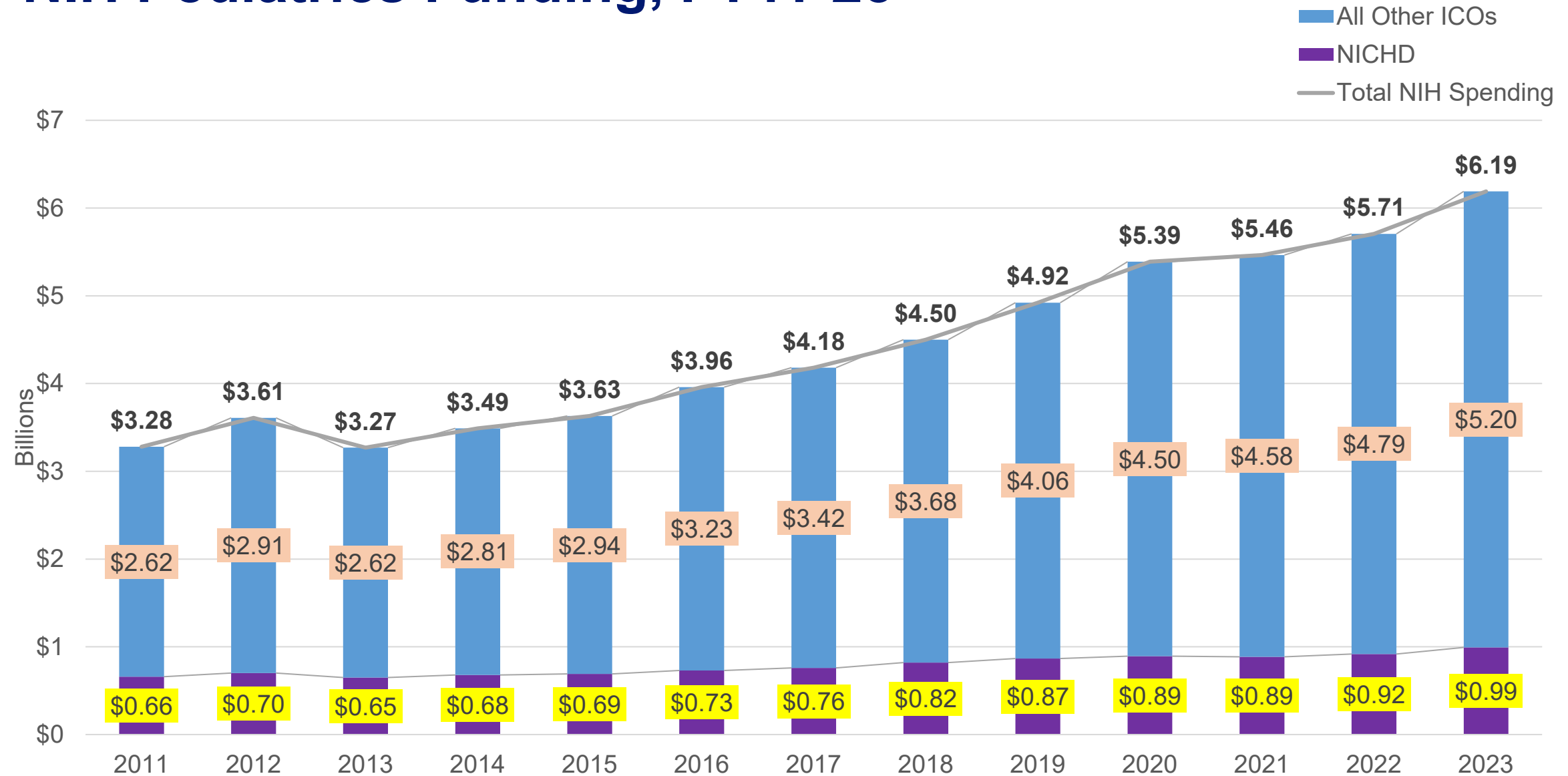


# Things to Remember About RCDC Data

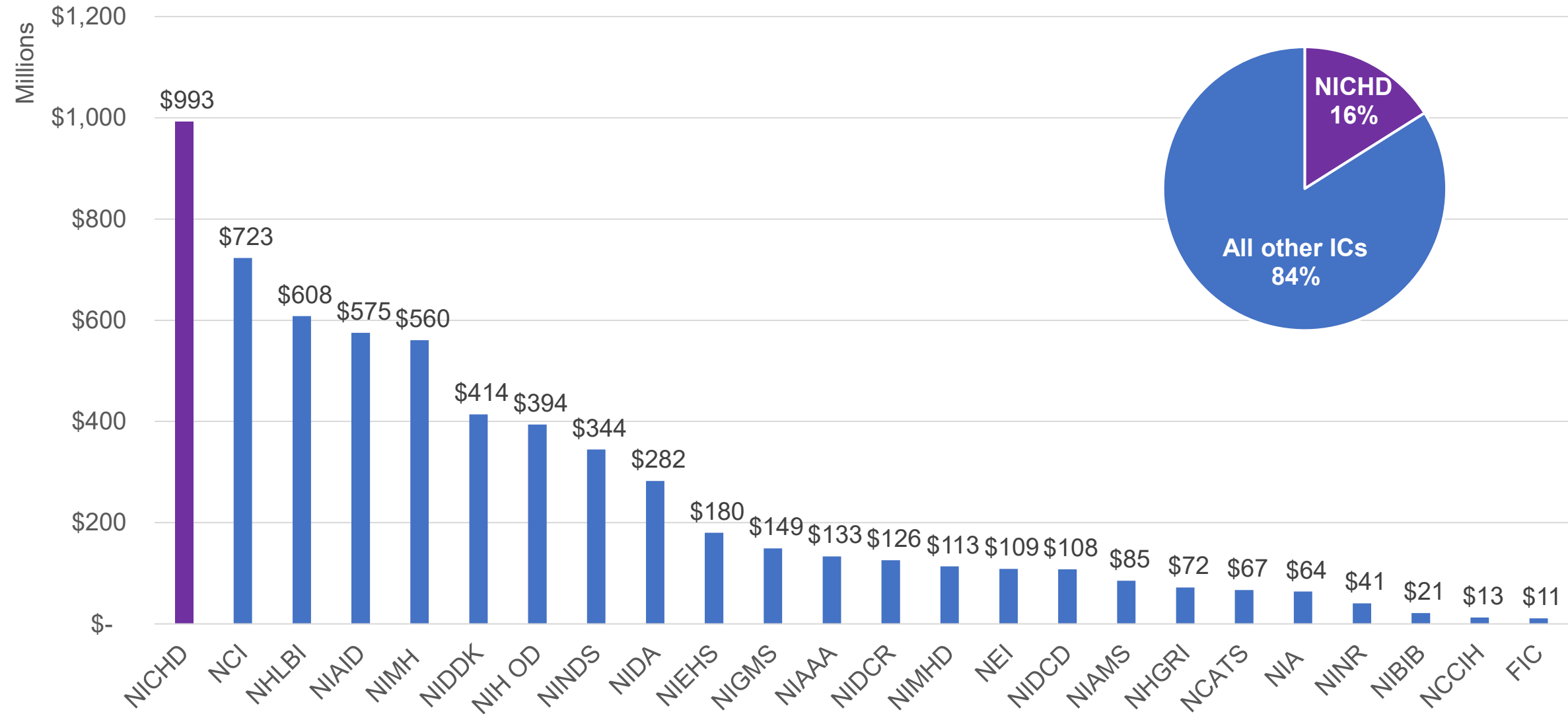
- 1) RCDC Categories reflect NIH legislative mandates for reporting. They are not a systematic taxonomy.
- 2) Categories are neither exclusive nor exhaustive.
- 3) All categories are NIH-wide, and all ICs are welcome to participate.
- 4) RCDC categories are not used for budgeting or prioritization
- 5) RCDC categories include all NIH research funded with appropriated \$
  - Basic, translational, clinical, population
  - Human and non-human
  - Not just extramural grants -- intramural, contracts, interagency agreements too



# NIH Pediatrics Funding, FY11-23

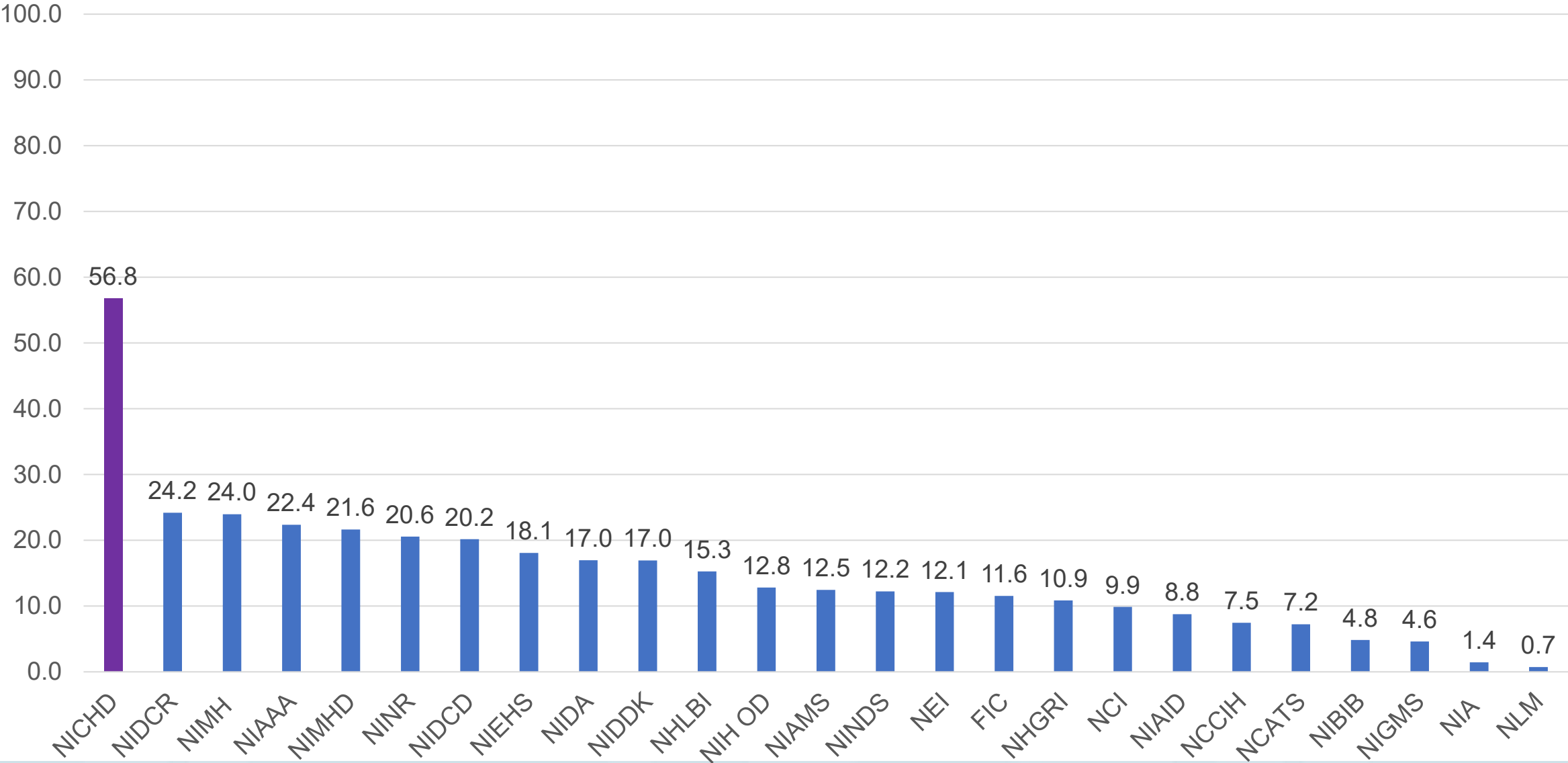


# FY23 NIH Pediatrics Funding by Institute, Center, or Office (ICO)





# FY23 NIH Pediatrics Funding by % of ICO Appropriation



# Possible Views of the Grants and Projects in the NIH Pediatric Research Portfolio

*In or  
About  
Children*

- Not excluding children
- Including children
- Focus on childhood



- Investigator-initiated
- Targeted opportunities



- NIH wide programs



- Grantee institutions
- Performance sites
- Size, type, etc.



- Specific Research Topics



- Cooperative and collaborative efforts



- Scientists
- Principal Investigators
- Trainees



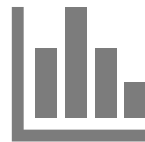
- Basic, clinical, and translational research



- Health disparity populations



- Intramural
- Extramural



- Funding mechanism (RPG, center, contract, etc.)



- Trends over time



# **Strategies to Enhance Pediatric Health Research Funded by NIH**

## **Statement of Task**

# Strategies to Enhance Pediatric Health Research at NIH

- Study required by FY 2024 Congressional appropriations report language
- Statement of Task for the Committee adheres largely to the language specified by Congress
- NIH was not consulted on report language





# Statement of Task

- Examine the current NIH pediatric research portfolio and structure including:
  - The methods and rationale involved in categorizing projects as “Pediatrics” research using the Research, Condition, and Disease Categorization (RCDC) Process;
  - How pediatric components have been included or excluded from larger NIH initiatives;
  - Structural or process impediments to pediatric research applicants;
  - How pediatric research priorities are established within and across ICs;
  - How pediatric research activity is coordinated across NIH ICs; and,
  - Ways in which the NIH Clinical Center (CC) could be used to advance innovative pediatric research



# Including Pediatric Components in Large NIH Initiatives

- NICHD leadership and staff, along with pediatric research experts across NIH, have consistently advocated for including pediatric components in major NIH initiatives, with varying effectiveness.
  - Support for including or adding a pediatric component is often delayed and may be comparatively underfunded
  - Some examples of NIH-wide initiatives that include pediatric components to varying degrees: *All of Us* Research Program, Helping to End Addiction Long-term (HEAL) Initiative, COVID-19 research, MoTrPAC (Molecular Transducers of Physical Activity Consortium)





# Consider Ways to Enhance Pediatric Components in Large NIH Initiatives

- Include pediatric research questions in the design of NIH-wide initiatives to make them integral to the success of the project
  - Pediatrics must be intentionally included from the outset (instead of merely “not excluded”)
  - Specific requirements or incentives may be needed to achieve this goal
- Early consideration of barriers (e.g., recruitment, expertise) and identification of best practices could benefit future programs
- Early consultation with the NIH Pediatric Research Consortium (NPeRC) could facilitate effective study design and enhance engagement and coordination across NIH



# Establishing Priorities and Coordinating Pediatric Research Across ICs

- Each IC has a Strategic Plan informed by consultation with external experts and the public
- A majority of NIH ICs have at least one pediatrician or pediatric researcher on their advisory council
- ICs routinely engage in coordination tasks
  - Examples: Use referral guidelines to assign applications to IC based on research focus; active participation in NIH-wide committees on certain research topics; sign on to funding opportunities from other ICOs; co-funding awards or issuing joint funding opportunities
- NIH Pediatric Research Consortium (NPeRC) facilitates discussion of common areas of interest and/or needs in pediatric research





# NIH Pediatric Research Consortium (NPeRC)

- Established in 2018 to increase collaboration and coordination of pediatric research across NIH
- Focus areas thus far include:
  - Pediatric pain research
    - Collaboration with HEAL initiative
  - Pediatric medical devices
    - Public-private partnership
  - Transition from adolescent to adult healthcare
    - Workshop and Notice of Special Interest (NOSI)
  - COVID-19
    - Funding for pediatric research
  - Pediatric clinical trials
  - Pediatric research workforce



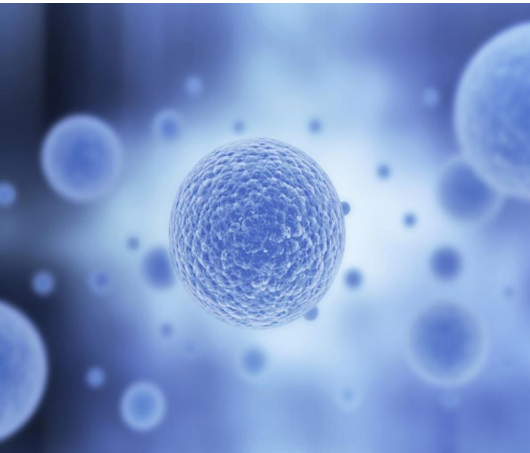
# NIH Pediatric Research Consortium (NPeRC) Value

- Consistent, voluntary engagement across Institutes and Centers
  - Notable for a group without dedicated resources
- Key conversations and connections to support program/initiative development



# Innovating Pediatric Research at the NIH Clinical Center

- Working group charged with identifying the most impactful scientific areas of pediatric research in which the NIH can play a major role to substantially improve child health. Using this horizon scanning, perform long-term, strategic planning for intramural NIH-wide clinical pediatric research to occur over the next decade and beyond.
- Co-chaired by Drs. Diana Bianchi (NICHD) and Brigitte Widemann (NCI) with representation from ICs most engaged in pediatric research at the Clinical Center
- NIH Clinical Center Pediatric Research Strategic Plan (completed October 2023):
  - <https://www.cc.nih.gov/sites/default/files/assets/home/pdf/CC-Peds-Research-Strategic-Plan.pdf>





## **Sponsor Considerations and Goals**

# Key Considerations from the Study Sponsor

- Recommendations should focus on improving NIH's overall support of child health research.
- The Committee should focus on pediatric research NIH-wide, given the breadth of support across ICs.
- If structural or process changes are recommended, the Committee should include consideration of burden (including financial) on researchers, research institutions, and NIH staff.
  - Structural and process changes take substantial time and money to implement. Consider tradeoffs and research impacts, particularly in times of tight budgets and inflation in research costs





# Sponsor Goals for the Study

- Consider ways to enhance pediatric components in large NIH initiatives
  - Shift paradigms to make including pediatric research questions the “norm”
- Recommendations MUST be practicable and feasible
  - For maximum effect, the Committee should consider whether recommended ideas can be implemented within the context of NIH and federal laws and policies (e.g., privacy)
- Broaden participating institutions that receive NIH funding
- More can be done with more resources





**Thank You!**

**Questions?**