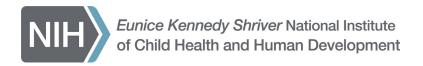
### **Updates from the NICHD Acting Director**

National Advisory Council for Child Health and Human Development

Alison N. Cernich, PhD June 09, 2025



#### **Talk Outline**

- NICHD Program Updates
- HHS/NIH Leadership Updates
- NICHD Budget Update
- NIH Program and Policy Updates



#### NICHD Strategic Plan 2025: Research Goals



3. Setting the Foundation for Healthy Pregnancies and Lifelong Wellness

Advancing
 Gynecologic,
 Andrologic, and
 Reproductive
 Health

Understanding the Molecular, Cellular, and Structural Basis of Development



 Improving Child and Adolescent Health and the Transition to Adulthood

 Fostering Safe and Effective Therapeutics and Devices for Pregnant Women, Lactating Women, Children, and People with Disabilities



Available at: <a href="https://go.nih.gov/OVf7m5t">https://go.nih.gov/OVf7m5t</a>

#### 2024 Research Highlights Recap

Visit NICHD's <u>2024 Selected Research Advances showcase</u>:



- Supporting Women's Health
- Improving Postpartum Health Outcomes
- Advancing Fetal and Neonatal Health
- Improving Care for Pediatric Injury
- Advancing Child and Adolescent Health
- Treating and Understanding Pediatric
   Infections
- Addressing Health Disparities for People with Disabilities

- Expanding Research on Intellectual and Developmental Disabilities
- Advancing Medical Rehabilitation Research
- Discovering How Cells are Programmed







#### NICHD Data and Specimen Hub (DASH)

- Centralized resource that allows researchers to share and access de-identified data from studies funded by NICHD
  - More than 230 studies on over 60 topics
- Migrating data to another long-running NIH data repository platform that will provide additional functionality and security
- Data unavailable beginning May 5, 2025
- Anticipate data being available again in Fall 2025





#### **Autism Data Science Initiative**

OTA-25-006: DPCPSI \$50M Autism Data Science Initiative will explore causation of autism spectrum disorder (ASD) link)

#### Strategic Aims:

- Create integrated data resources leveraging existing data (with appropriate privacy protections)
- Identify and address gaps via targeted data generation
- Support analysis of integrated data resources that link genetic and non-genetic factors
- Provide venue for replication of these analyses by independent teams to validate findings
- Complement distinct effort to develop a Real World Data Platform

Application Due Date: June 27, 2025

Total Cost/Award: Up to ~ \$5M per 24- to 36-month project period



#### NASEM study: Strategies to Enhance Pediatric Health Research Funded by NIH

- NASEM committee examining current NIH pediatric research portfolio and structure
- Several NIH ICs participated in webinars
- Call for Perspectives Closes June 30 and July 1, respectively
  - Pediatric Patients and Families <a href="https://survey.alchemer.com/s3/8328252/Patient-and-">https://survey.alchemer.com/s3/8328252/Patient-and-</a>
     Family-Perspectives-on-NIH-funded-Pediatric-Research
  - Pediatric Health Researchers <a href="https://survey.alchemer.com/s3/8274911/NIH-Call-for-Perspectives">https://survey.alchemer.com/s3/8274911/NIH-Call-for-Perspectives</a>
- Report release anticipated in January 2026





#### **HHS Leadership and Priorities**

- February 13, 2025: President Trump established the Make America Healthy Again Commission and requested an assessment to address childhood chronic disease
- May 22, 2025: MAHA Commission Report published with 4 key focus areas
  - Poor diet
  - Exposure to environmental chemicals
  - Lack of physical activity and chronic stress
  - Overmedicalization
- Ten recommended research areas range from long-term nutrition trials to lifestyle interventions to precision toxicology
- Operation Stork Speed initiative to ensure the safety, reliability, and nutritional adequacy of infant formula
  - Request for Information on Infant Formula Nutrient Requirements



HHS Secretary Robert F. Kennedy, Jr.



#### **NIH Leadership**

- Dr. Jay Bhattacharya, NIH Director
- Dr. Matt Memoli, NIH Principal Deputy Director
- NIH IC leadership New Acting Directors
  - NINR: Courtney Aklin
  - NIMH: Andrea Beckel-Mitchener
  - NICHD: Alison Cernich
  - NHGRI: Carolyn Hutter
  - NIAID: Jeff Taubenberger
  - NIMHD: Monica Webb Hooper
  - DPCPSI: Nicole Kleinstreuer
  - OER: Jon Lorsch (also NIGMS Director)







#### **NIH Leadership Priorities**

- Focus on Improving Population Health: NIH must address the health needs of the American people, including the chronic disease crises.
- Reproducibility and Rigor: NIH must conduct and support rigorous, reproducible, and unbiased research.
- Innovation and Collaboration: NIH must be at the forefront of biomedical innovation.
- Research Safety and Transparency: NIH must NIH research must meet the highest ethical standards, and NIH must maintain the highest standards of transparency.
- Academic Freedom: Advances in science require the freedom to think differently from the scientific consensus.





#### **NICHD Budget**

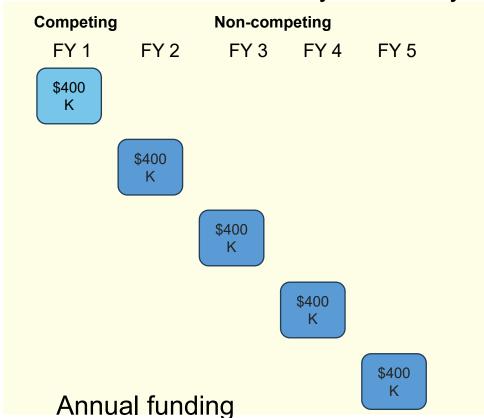
- FY25
  - NICHD plans to obligate all FY25 funds
- FY26 President's "Skinny" Budget (May 2, 2025)
  - Includes \$18B cut to NIH; consolidation to 8 ICs
  - NICHD proposed to merge with the National Institute on Deafness and Other Communication Disorders (NIDCD)
  - Eliminated ICs: FIC, NIMHD, NINR, NCCIH
- FY26 HHS Budget in Brief (May 30, 2025)
  - Proposed 40% budget cut for combined NICHD-NIDCD institute titled: National Institute for Child and Women's Health, Sensory Disorders, and Communication
- FY26 HHS Budget in Brief (June 5, 2025)
  - Includes additional guidance on multi-year funding for FY25 and FY26 and personnel

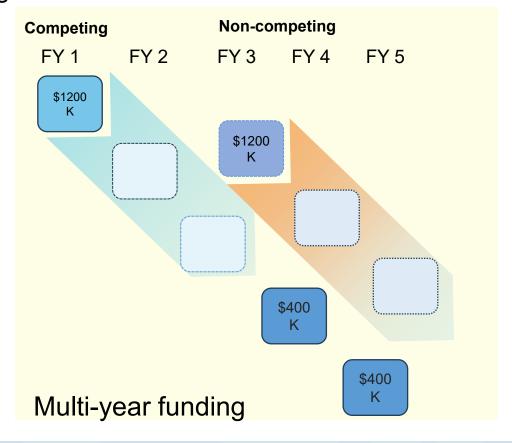


#### Potential Multi-Year Funding (MYF) of Grant Awards

- MYF provides funds for multiple years of a grant award in one year
- Cons: Expensive in the year of obligation, limiting total awards that FY

Pros: Offers more flexibility in the outyears







#### **Recent Challenges**

- Reduction in workforce
- NICHD lost staff in key functional areas
  - Some functions may be centralized at NIH or HHS
- Other challenges
  - Pause in acquisitions, travel, communications, meetings (now re-starting)
  - Pause in Councils and reviews (re-started)
  - Reduction in number of Notices of Funding Announcement (NOFOs)
  - o Halt on paying foreign subawards/increased need for foreign justifications in grant applications
  - Award holds and terminations





## **NIH Program and Policy Updates**

#### NIH Prioritization of Human-Based Research Technologies

- Initiative to develop and expand use of nonanimal models
- Intent to establish the Office of Research Innovation, Validation, and Application (ORIVA) within the NIH Office of the Director
  - Coordinate NIH-wide efforts to develop, validate, and scale use of nonanimal approaches
  - Alternatives to use either alone or in combination with animal models include:
    - Organoids, tissue chips, other in vitro systems
    - Computational models
    - Real world data



#### **New NIH Foreign Subaward Structure**

- Guide Notice NOT-OD-25-104
- Temporary pause for foreign subawards while NIH finalizes new award structure (anticipated September 2025)
- Applies to all new, renewal, and non-competing continuation awards
- Effective May 1, 2025, NIH will:
  - Not issue awards to domestic or foreign entities that include a subaward to a foreign entity.
  - No longer accept requests to add a new foreign component or subaward to an ongoing project.
  - Renegotiate awards to remove subawards to foreign entities; allow rebudgeting for the prime recipient when the work can be performed domestically
  - Work with recipients to negotiate bilateral termination if a project is no longer viable without the foreign subaward, with consideration to ensure participant safety and/or animal welfare



# **Extending Opportunities to Support Early Career Researchers**

- NIH has granted automatic extension of Early Stage Investigator (ESI) eligibility of one, two, or three receipt cycles
  - Eligibility details: <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-114.html">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-114.html</a>
- Extended eligibility for some mentored career development (K) awards
  - For awards ended prematurely after January 1, 2025, recipients may apply for a new mentored career development award
  - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-115.html





# Thank You! Questions?