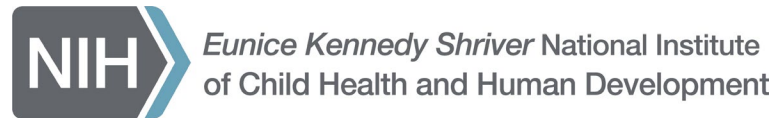


# **NICHD Director's Report** ***NACHHD meeting***

Diana W. Bianchi, M.D.

*January 24, 2023*



# Talk Outline

- FY 2023 Budget and Congress
- NIH and NICHD Research
- Training and Career Development
- NIH Clinical Center Pediatric Research Strategic Plan
- ARPA-H
- STRIVE (STrategies to enRich Inclusion and achieve Equity) Initiative
- NIH Staff

# FY23 NIH and NICHD Appropriations

- NIH appropriation: \$47.5B, an increase of \$2.5B over FY22
- NICHD appropriation: \$1.75B, an increase of \$66M
- NICHD-specific appropriations include the following set asides:
  - \$30M for IMPROVE
  - \$10M for MIS-C (an increase of \$2.5M)
  - \$3M for research on the impact of COVID-19 on Pregnant and Lactating Women
  - \$15M for research on the Health Impacts on Children of Technology and Social Media Use



# FY23 NIH-Wide Appropriations that Affect NICHD

- \$90M for the **INCLUDE Initiative**
- \$10M for research on **developmental delays**, including speech and language delays in infants and toddlers, characterizing speech and language development and outcomes from infants through early adolescence
- \$40M for research on the **health impacts of climate change**
- \$76.4M to **Office of Research on Women's Health (ORWH)**, including \$5M for BIRCWH and \$10M to establish an office on autoimmune disease research within ORWH
- \$12.5M for **firearms research**
- \$180M for **ECHO**



# Congressional Briefings

- Investigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE)
  - Senator Moran
- Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) recommendation implementation update
  - Senate HELP staff
- Maternal Health
  - Representative Underwood



# Stillbirth Working Group of Council

- Stillbirths in the U.S.
  - 65 stillbirths occur per day= nearly 24,000/year (more than SUID)
  - Increased risk of maternal death
  - Emotional toll on parents and families
- FY22 Appropriations Report language established a task force on stillbirth in the U.S. (delegated to NICHD as a subcommittee of Council)
- Members to include the CDC, NIH, outside specialty organizations, and maternal and fetal medicine specialists
- NICHD held 4 task force meetings encompassing 4 focus areas specified by Congress, and a listening session with input from the public
- Findings and recommendations presented later in today's meeting
- Report due to Congress in March 2023





# **NIH and NICHD Research Updates**





# Background and Objectives

- Neonatal opioid withdrawal syndrome (NOWS) follows *in utero* opioid exposure
  - Opioid epidemic → high incidence of NOWS
  - Newborns are irritable, do not eat or sleep well, spend many days in hospital
  - Infants undergo repeated subjective evaluations (e.g., Finnegan scale)
  - If symptomatic enough, care providers treat infant with opioids
- Substantial hospital variation in management of NOWS
  - No evidence-based standard of care
- Objective: Test effectiveness and safety of new approach vs. usual care
  - Simpler assessment—Eat, Sleep, Console
  - Prioritize non-pharmacologic care, e.g., holding, swaddling, rocking
  - Caretaker involvement



# Study Design

- Collaboration across 2 NIH pediatric clinical trial networks
  - Office of the Director (ECHO) and NICHD (NRN) collaboration
- Stepped wedge cluster randomized trial
  - Randomly allocated 26 hospitals to transition from usual care to Eat, Sleep, Console care at designated time points
- Whole of practice change
  - Trained ~5000 nurses
- Led by 3 early-stage Investigators



# Results, Conclusions, Next Steps

- Eat, Sleep, Console care approach
  - Substantially decreased time until infants medically ready for discharge from hospital
  - Significantly decreased pharmacologic treatment
  - Did not affect safety outcomes through 3 months of age
  - Provides strong support for standard care for NOWS
- Presented at a national meeting Dec 5, 2022
- Manuscript under review
- Next
  - 2-year follow-up for family well-being, child neurodevelopment



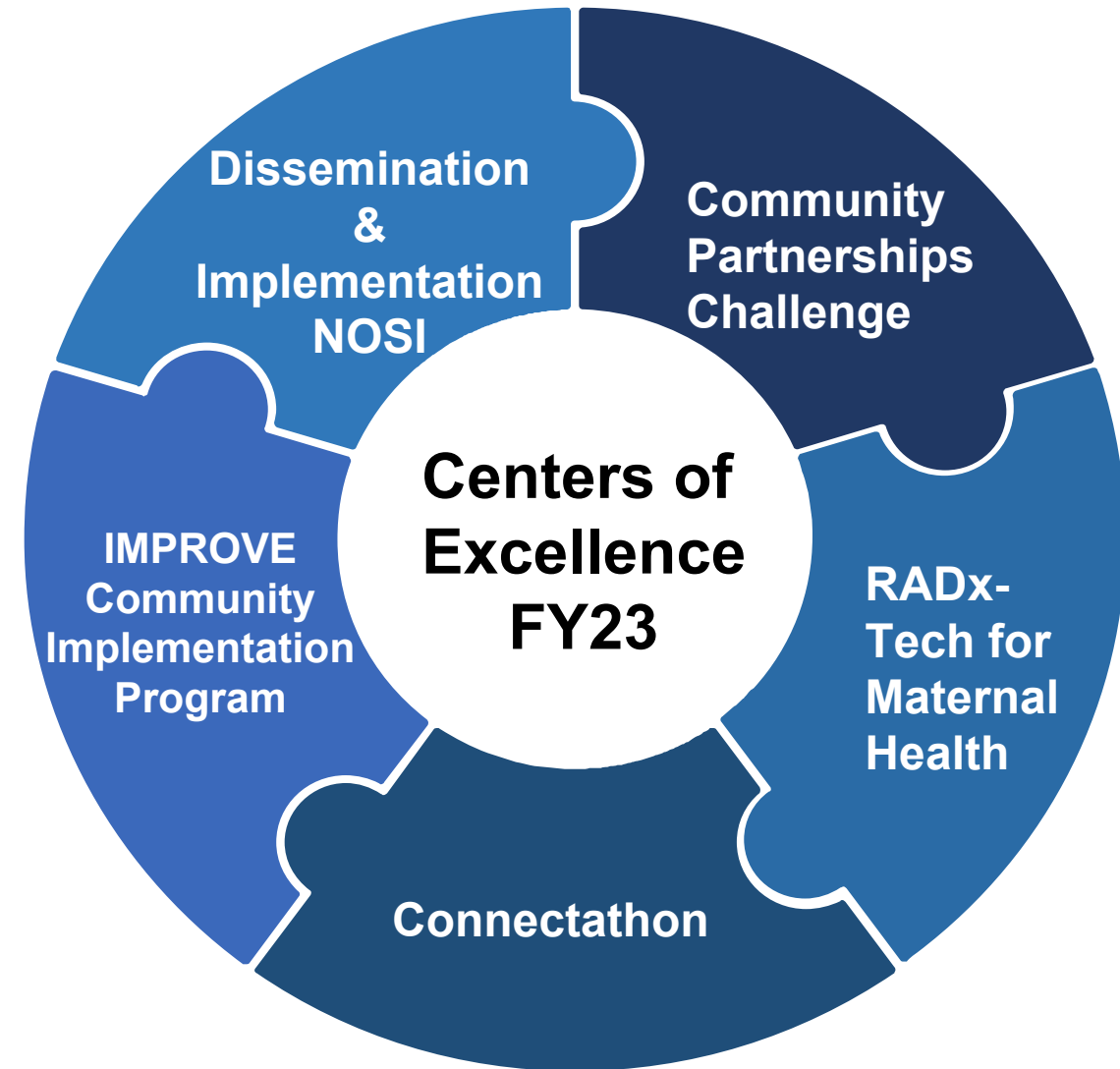
# IMPROVE Initiative

- Focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery
- New appropriation of \$30M in NICHD's base budget
- Emphasizes health disparities and disproportionately affected populations
  - Black women have higher rates of morbidity and mortality
  - **Particular needs in Tribal communities**; 93% of maternal deaths are preventable
  - Tribal consultation for Maternal Health Research Centers of Excellence (COEs)



# IMPROVE FY22 and FY23 Initiatives

- Dissemination and Implementation research
  - NOSI - [NOT-OD-22-125](#) (FY22 awards; FY23 reissue)
- Connectathon
  - Longitudinal health record for pregnant person and child; linkages across pregnancy
- RADx-Tech for Maternal Health Challenge
- IMPROVE Community Implementation Program
  - Community implementation studies of evidence-based maternal health interventions
- Community Partnerships Challenge
- Maternal Health Research Centers of Excellence (FY23)



# Progress of Maternal Health Challenges

- RADx® Tech for Maternal Health Challenge
  - Prioritizes home-based or point-of-care diagnostic devices, wearables, and other remote sensing technologies to extend postpartum care in regions lacking access to maternity care
  - Up to \$8M in prizes awarded through several phases
  - Initial selectees (15) moving towards the Deep Dive phase
- Connecting the Community for Maternal Health Challenge
  - Encourages community-based and advocacy organizations in the U.S. to develop the infrastructure and capabilities necessary to conduct maternal health research
  - Total prize purse of ~\$3M distributed across multiple phases; non-monetary incentives such as mentoring and proposal writing assistance
  - Challenge announcement: [www.challenge.gov/?challenge=community-maternal-health](http://www.challenge.gov/?challenge=community-maternal-health)

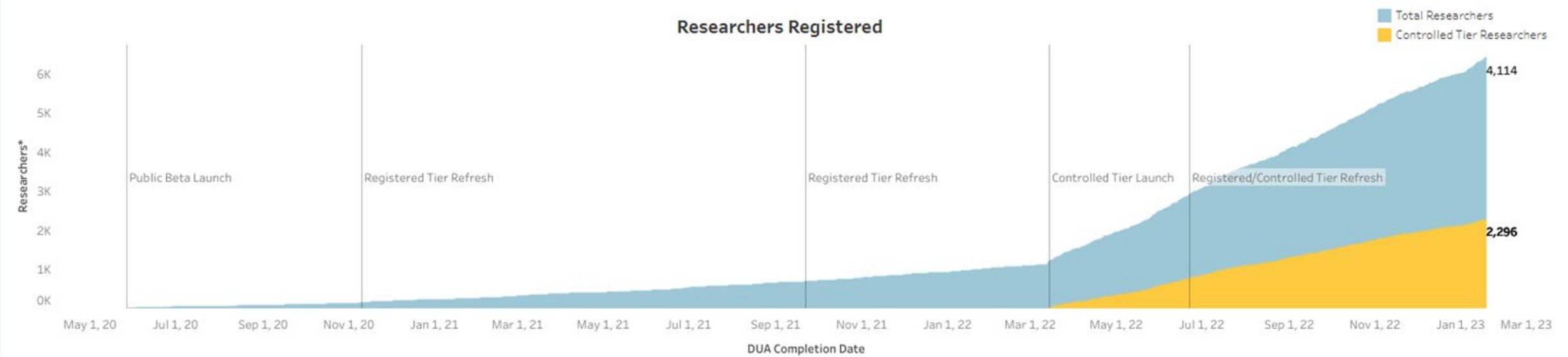
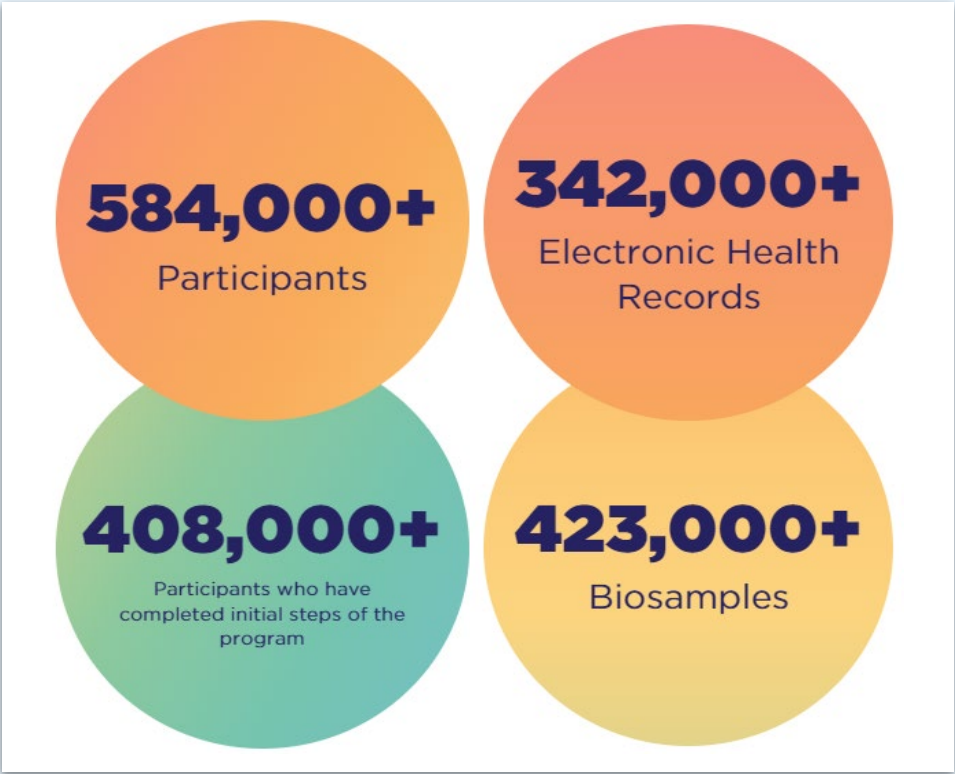


# FY23: Maternal Health Research Centers of Excellence

- **Goal:** Move the needle to reduce maternal morbidity and decrease preventable mortality by partnering with the communities affected and incorporating their needs and perspectives in the maternal health research performed by the Centers of Excellence
- **Structure:** Several research centers with a common data resource/coordinating hub as well as an implementation science resource hub
- **Key benefits:**
  - Community partnership from inception of research projects
  - Expand the cadre of researchers in maternal health
  - Data Hub resources such as Common Data elements/models including Social Determinants of Health and Structural Factors collected across the Research Centers
  - Implementation Science Research Hub will provide expertise to all research centers and will to better understand how evidence-based research can be translated in more equitable care models
- Robust application response; awards anticipated in July 2023



# By the Numbers: Participants & Researchers As of January 18, 2023



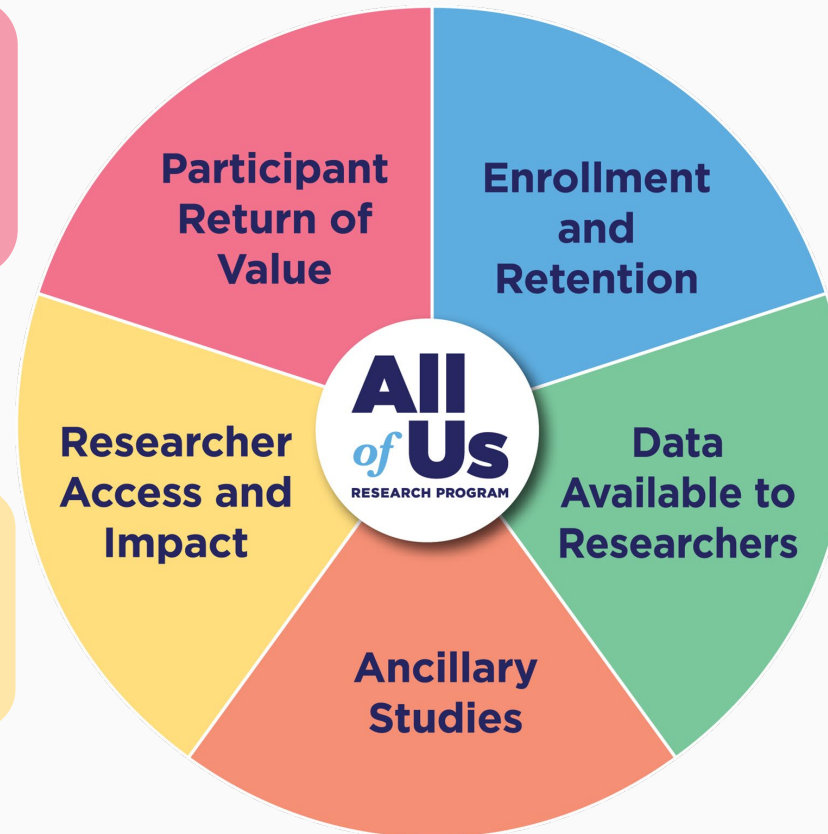


# Establishing Our Five Year Goals

***By end of 2026, we will:***

Incorporate participant **return of value** into data collections and assess its impact, including return of information to participants on **genomics** and **EHR**.

Establish a **diverse global community of 10,000 researchers** productively using *All of Us* data.



**Enroll 1 million participants** who reflect the **diversity** of the U.S., cover the **lifespan**, and have **shared all baseline elements**. Of these participants, **500,000 are actively engaged** in the program.

**Expand data available for 1 million participants** to include survey, health data streams, a whole genome sequence, **environmental** data, and physical measures.

Launch **ancillary studies** as a core and scalable capability, expanding the cohort and delivering phenotypic, lifestyle, environmental, and biologic data.

# *All of Us* Names First Director of Pediatrics

- Dr. Van Driest will develop a model for pediatric recruitment into *All of Us*
- The program is eager to enroll children
- Former Associate Professor of Pediatrics and Medicine at Vanderbilt
- Co-Director at VUMC Center for Precision Medicine
- Led the Vanderbilt Center of Excellence in Maternal and Pediatric Precision Therapeutics (NICHD grantee)



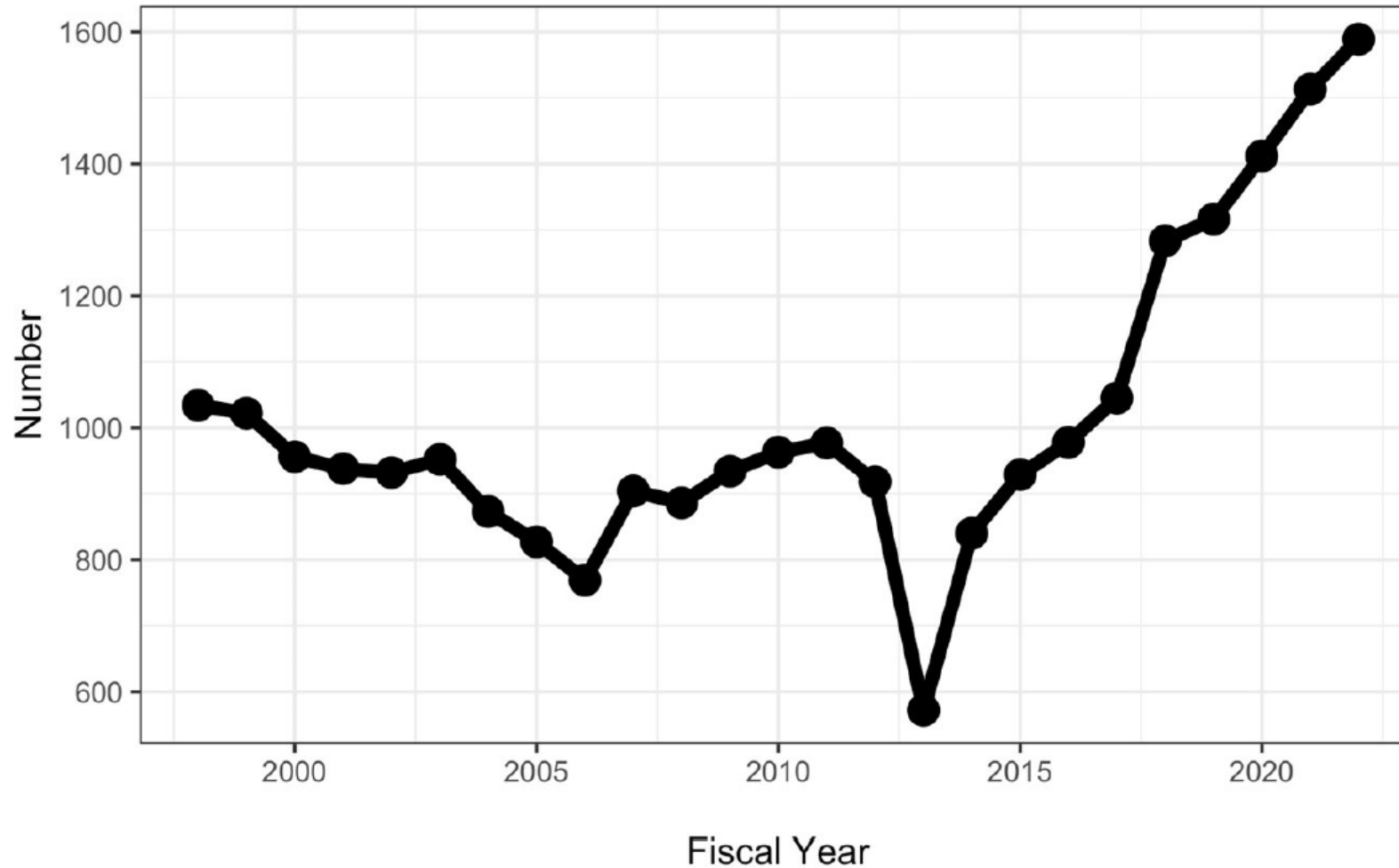
Sara Van Driest, M.D. Ph.D.





# **Training and Career Development**

# Early Stage Investigators (ESI) Funded on First R01-Equivalents



- NIH's goal is to fund 1100 ESI per year
- In 2022, NIH funded a record **1589 ESI applicants**



# Coming Soon!

- NIH-wide Pediatric Research Consortium (N-PeRC) website will soon feature a list of training and career development opportunities for pediatric researchers
- List includes opportunities from 17 ICs and Offices across NIH



<https://www.nichd.nih.gov/research/supported/nperc>





# **NIH Clinical Center Pediatric Research Strategic Plan**

# Opportunities to Increase Child Health Research @ NIH CC

- Largest research hospital in the world
- Every patient participates in a research protocol at no cost
- Currently about 1,600 active research studies
  - Relatively small number of pediatric studies
- About half are studies of the natural history of disease, especially rare diseases
- Most other studies are clinical trials, often first-in-human studies of new drugs and therapies
- Funding model provides opportunity for research equity



# Clinical Center Pediatric Research Strategic Plan Working Group Charge

To identify 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, to perform long-term, strategic planning for intramural trans-NIH clinical pediatric research to occur over the next decade and beyond.







**ARPA-H**



# ARPA-H

- Director Renee Wegrzyn, PhD
- \$1B initial budget
- Independent component of HHS within NIH, reporting directly to HHS Secretary
- No internal research labs; **disease agnostic**
  - **Potential opportunities to address needs in NICHD populations**
- Program Manager driven ideas and decision-making
  - Rational risk-takers
  - Recognized expertise, Drive, Insatiable Curiosity, No fear of failure, Interdisciplinary track record, Technical honesty
- Lean and nimble management structure
- High Risk/High Consequence Research



# Program Lifecycle



## DESIGN PROGRAMS

- ARPA-Hard and well-defined problems in health
- Heilmeier Framework
- High risk/High consequence
- Stakeholder Insights



## BUILD A PERFORMER TEAM

- Solicit Solutions from the community
- Find the best non-traditionals, industry, and academics to solve
- Build new coalitions



## EXECUTE & MEASURE

- Active program management against metrics; PM = CEO
- Stakeholder engagement throughout to ensure transition
- Pivot resources when needed



## LEARN & GROW

- Capture and share insights
- Technical honesty
- Advance the state of the art; 10x+ improvement, no incremental change

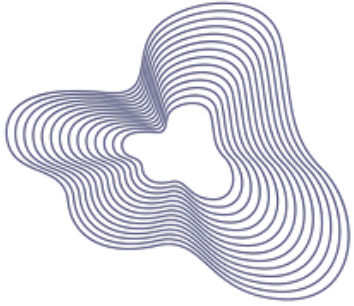


## COMMERCIALIZE & TRANSITION

- Assist company formation or licencing
- Provide mentorship, connections to customers, investors
- De-risk investments



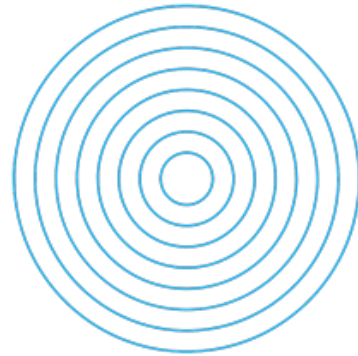
# Initial Mission Focus Areas



## Health Science Futures

### Expanding what's technically possible

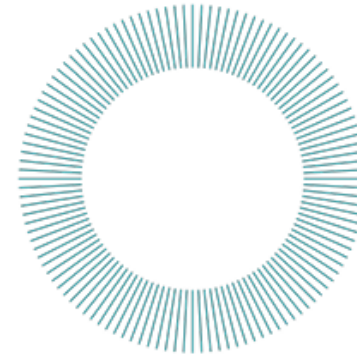
Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.



## Scalable Solutions

### Reaching everyone quickly

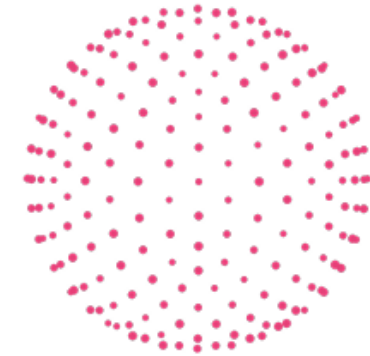
Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.



## Proactive Health

### Keeping people from being patients

Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans' health, whether those are viral, bacterial, chemical, physical, or psychological.



## Resilient Systems

### Building integrated healthcare systems

Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.





# **STRIVE Initiative Update (STrategies to enRich Inclusion and achieve Equity)**

# STRIVE Action Plan Overview

**STRIVE's Mission:** STRIVE Committees will **develop three comprehensive *Action Plans*** that outline strategies to:

- 1) Hire, train, retain and promote diverse talent within the NICHD
- 2) Train and support the careers of diverse scientific talent in the extramural community
- 3) Propose health disparities research priorities and identify approaches to mitigate key drivers of health disparities.

**Action Plans also** correspond to the NICHD strategic plan and larger NIH diversity activities through UNITE



# STRIVE Action Plan Goals by Committee

The STRIVE Action Plan outlines 8 Committee Goals with associated immediate, intermediate, and long-term actions

Committee	Goals	
<b>Diversity, Equity, Inclusion, and Accessibility (DEIA)</b>	1	<b>Increase collection and use of data</b> pertaining to DEIA and the demographic make-up of NICHD
	2	<b>Create an NICHD-specific training curriculum</b> pertaining to current issues in DEIA so that NICHD staff are equipped to contribute to an inclusive and accessible work environment
<b>Scientific Workforce Diversity (SWD)</b>	3	Evaluate baseline <b>training and workforce diversity</b> across NICHD (intramural and extramural trainees, extramural PD/PIs)
	4	Identify gaps and <b>revise policies and practices</b> to promote an inclusive and equitable workforce
	5	<b>Foster internal and external stakeholders</b> to gather additional insight
<b>Health Disparities Research (HDR)</b>	6	<b>Promote community-partnered research</b> to understand health disparities
	7	<b>Promote inclusion of populations experiencing health disparities</b> in all NICHD human subjects' research
	8	<b>Incorporate intersectionality of identities</b> into HDR





# **NIH and NICHD Staff Updates**



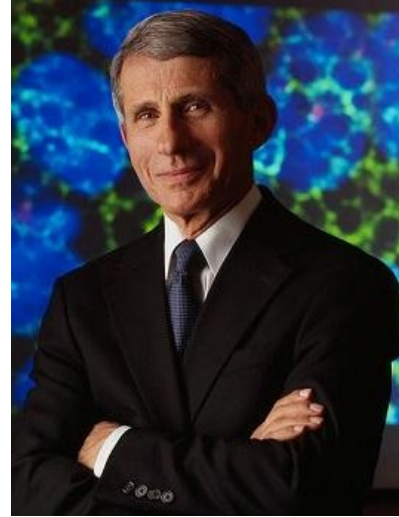
# New Branch Name!

- Internal reorganization we presented last year is final
- Developmental Biology and Structural Variation Branch is now **Developmental Biology and Congenital Anomalies Branch (DBCAB)**



# Retirements

- Anthony S. Fauci, MD
  - Director, National Institute of Allergy and Infectious Diseases
- Roger Glass, MD, PhD
  - Director, Fogarty International Center
- Andrea Norris, MBA
  - Director, Center for Information Technology; NIH Chief Information Officer



# Appointments

- Joni L. Rutter, PhD
  - Director, National Center for Advancing Translational Sciences
- Monica M. Bertagnolli, MD
  - Director, National Cancer Institute
- Nina F. Schor, MD, PhD
  - Deputy Director, Intramural Research



# New NICHD Scientific Director

- Acting NICHD Scientific Director since June 2021
- Previously Deputy Scientific Director for NICHD Intramural Research
- BSc from the University of Aberdeen, Scotland; PhD from the University of Cambridge, England
- Postdoctoral fellowship at UNC Chapel Hill and Duke University
- Joined NICHD in 1993 as an investigator within the Laboratory of Cellular and Molecular Neurophysiology; now its Chief



Chris McBain, Ph.D.



# NICHD is Hiring!

- Clinical Director Search
  - 3 finalists going through interviews and making structured presentations to IRP staff
- Other open positions
  - Branch Chiefs (Fertility and Infertility; Gynecologic Health and Disease)
  - Deputy Director, Division of Extramural Activities
  - Director, Office of Clinical Research, DER (new position)
  - Director, Office of Health Equity
  - Scientific Review Officer
  - Program Officers (CDBB, FIB, IDDB) and Program Analysts
  - <https://www.nichd.nih.gov/about/jobs>





**Thank You!**

**Questions?**