NICHD Director's Report
NACHHD Council

Diana W. Bianchi, M.D.

September 12, 2022

Eunice Kennedy Shriver National Institute of Child Health and Human Development
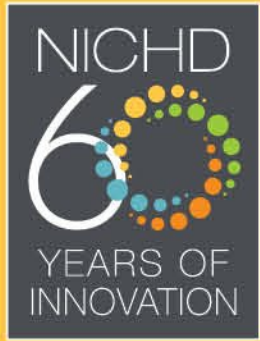
Talk Outline

- NICHD 60th Anniversary
- NIH Leadership Updates
- NIH Appropriation Updates
- NICHD Racial and Ethnic Equity Plan
- Pediatric RECOVER
- Maternal Health Research
- Data and Specimen Hub (DASH)
- Clinical Center Pediatric Research Strategic Plan
- NICHD Staff Updates

Join Us in Celebrating NICHD's 60th Anniversary

- October 17, 2022: 60th Anniversary Symposium: Healthy Pregnancies, Healthy Children, and Healthy and Optimal Lives
  - Agenda available on the registration website: https://web.cvent.com/event/d23ccb32-83c3-49e3-8cb1-a7c726f19e0b/summary

- Visit the NICHD 60th anniversary webpage: https://www.nichd.nih.gov/60years
  - Highlights key advances and milestones in NICHD's history
  - Focus on the people who help NICHD achieve its mission
  - Learn about NICHD's future research directions
  - Get updates on anniversary activities and events
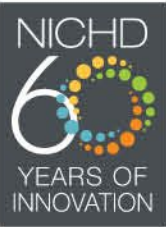
NIH Leadership Update

NIH Director

- Dr. Francis Collins stepped down as NIH Director in December of 2021

- Dr. Larry Tabak is "Performing the Duties of the NIH Director"

- The White House is conducting the search for the next NIH Director

  - Political appointment requiring Senate confirmation
  - No candidates expected to be named until late this year at the earliest
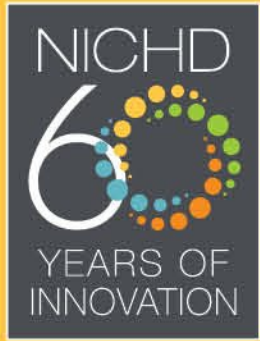
Monica Bertagnolli, M.D.
Director, National Cancer Institute

- Political appointment; Senate confirmation not required

- Surgeon oncologist

- Professor of Surgery at Harvard Medical School, surgeon at Brigham and Women's Hospital and member of the Gastrointestinal Cancer and Sarcoma Disease Center at Dana-Farber Cancer Institute

- Will spearhead President Biden's Cancer Moonshot^{SM} Initiative
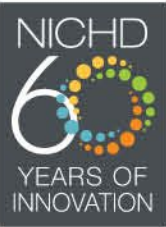
- Pediatric research interests

NIH Appropriation Updates

FY23 President's Budget

- Proposes $62.5B for NIH

- Proposes $1.68B for NICHD

- NICHD's Congressional Justification:
  https://www.nichd.nih.gov/sites/default/files/inline-files/CJ_NICHD_FY2023.pdf
  - Includes a Fact Sheet and selected program highlights

- FY23 budget unlikely by Sept. 30; Continuing Resolution likely

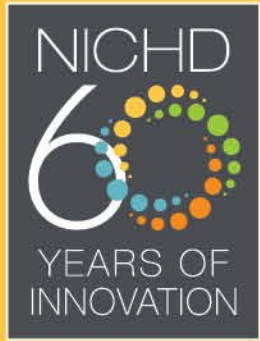- Challenges arise from late appropriations
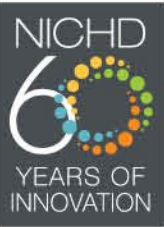
Stillbirth Task Force

- Stillbirth affects one in 160 pregnancies; Rate of early stillbirth unchanged in 30 years

- FY22 Appropriations Report language requires HHS Secretary to establish a task force on stillbirth in the U.S. (delegated to NICHD)
  - **Subcommittee of NACHHD Council**

- Members to include CDC, NIH, outside specialty organizations, and maternal and fetal medicine specialists

- Focus on:
  - Known risk factors for stillbirth
  - Current barriers to collecting data on stillbirths in the U.S.
  - Communities at higher risk of stillbirth
  - Psychological impact and treatment for mothers following stillbirth

- Timeline: Meetings in 2022; recommendations presented to NACHHD Council January 2023; report due to Congress in March 2023

NICHD Racial and Ethnic Equity Plan

NICHD Racial and Ethnic Equity Plan (REEP)

- Major component of NIH's UNITE program
    - "I" Committee: Improving the NIH Culture and Structure for Equity, Inclusion, and Excellence

- NICHD submitted our REEP in May 2022 and immediately began implementation

- The REEP activities helped identify additional targets for projects and programs and the plan was integrated into our existing STRIVE program
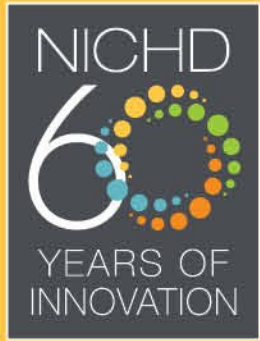
Initial NICHD REEP Activities

- Activities included:
  - Conducting a pulse survey of NICHD's climate and disseminating the survey results
  - Examining workforce data related to demographics, equity, and inclusion across positions and pay grades
  - Examining recruitment, retention, and award data for institute employees based on demographics
  - Establishing training curricula and opportunities for development of our own personnel
  - Providing opportunities for staff to provide leadership in roles within and outside the institute in an open and transparent fashion.

Pediatric RECOVER

What is RECOVER?

RECOVER stands for **Re**searching **COV**ID to **E**nhance **R**ecovery

It's a research project that aims to learn about the long-term health effects of COVID

The goal is to better **prevent, test, and treat** Long COVID in the future

RECOVER is an **observational study**, which means researchers collect information from participants - this study will not give anyone a treatment or medicine for Long COVID

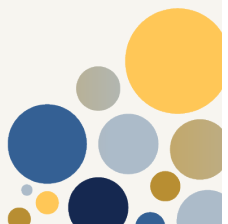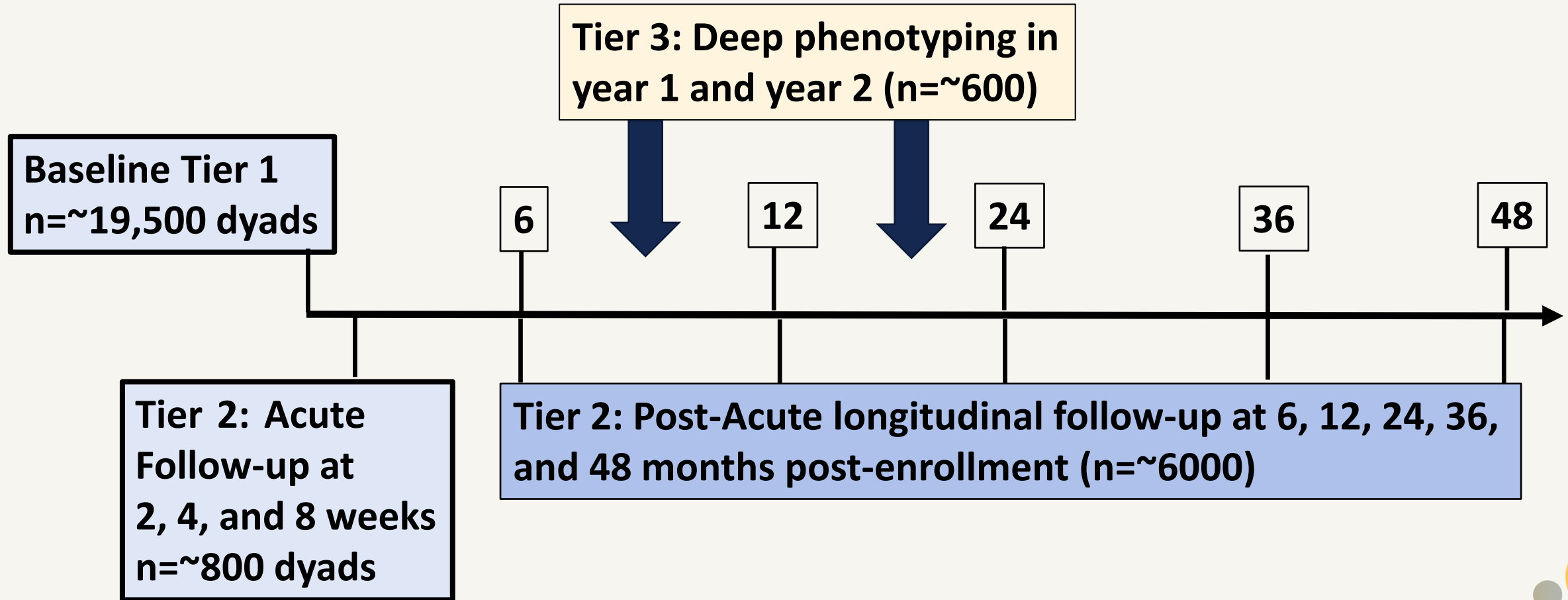RECOVER is funded by the National Institutes of Health (NIH)

Study Questions

- How **many** children are getting Long COVID?

- Why do **some** children get Long COVID and **others do not**?

- What **symptoms** do children feel when they get Long COVID?

- How **long** do children feel sick when they get Long COVID?

- What **causes** Long COVID to happen?

- How does having Long COVID **affect later** physical health, mental health and development in children?

- How do clinical manifestations of congenital exposure to SARS-CoV-2 infection during pregnancy affect child physical health and child development?

Pediatric Cohort Study: Three Tiers

Tier 3: Deep phenotyping in year 1 and year 2 (n=~600)

Baseline Tier 1 n=~19,500 dyads

6   12   24   36   48

Tier 2: Acute Follow-up at 2, 4, and 8 weeks n=~800 dyads

Tier 2: Post-Acute longitudinal follow-up at 6, 12, 24, 36, and 48 months post-enrollment (n=~6000)

recoverCOVID.org

Site Activation and Enrollment

- Beta phase March 21 – April 5

- Opened enrollment – April 20, 2022

- As of August 18, 2022
    - 50% of sites activated (57 of 114)
    - Enrolled 578 participants (of ~19,500)

Did your child just test positive for COVID? We need your help.

You and your child can join a study to help us learn about the long-term health effects of COVID, called Long COVID.

Researchers will compare children who have COVID now to children who never had COVID. This helps us learn things that may be related to Long COVID, such as certain symptoms or health conditions.

Why join this study?
- Join thousands of people across the country helping us learn how to better prevent and treat Long COVID
- Get paid for your time
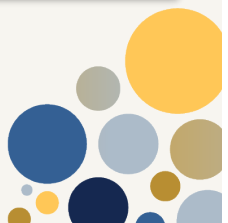
What would I do if I join?
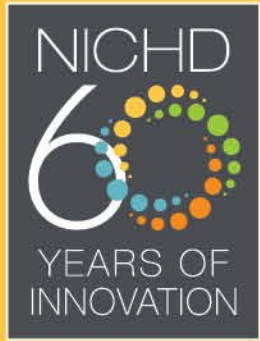
We may ask you to:
- Answer survey questions
- Have checkups
- Give very small amounts of blood, spit (saliva), pee (urine), poop (stool), and fluid from your nose
- Take part for up to 4 years

You will not get treatment for COVID in this study.

To learn more or join, visit RECOVERcovid.org

RECOVER

An initiative Funded by the National Institute of Health

Maternal Health Research: Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative

IMPROVE Initiative

- NIH-wide effort supporting research focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery

- Emphasizes health disparities and disproportionately affected populations

- New appropriation of $30M in NICHD's base budget, beginning in FY22

  - Dissemination and Implementation research NOSI (NOT-OD-22-125)

  - Community **implementation studies** of evidence-based maternal health interventions

  - Enables a longitudinal **health record** for pregnant person and child and **linkages** for woman across pregnancy

  - *Maternal health challenge opportunities*

  - *Maternal Health Centers of Excellence in FY23*

Challenges/Prize Competitions

- A way for federal agencies to crowdsource and engage public innovators directly to find interesting ideas or solutions to important problems

- Can offer monetary and non-monetary (e.g., meeting with key official; opportunity to speak at a conference) benefits to competition participants

- NIH conducted 62 challenges from FY2011-2020; NICHD successfully completed its first challenge this fiscal year

- Challenge benefits:
  - No obligation of award – payment for winning solution(s) only
  - Many possible solutions; can encourage creative and unanticipated solutions
  - Broader pool of entrants / increase number and diversity of solvers
  - Raise awareness of a particular public health need
  - Encourage application of NIH research data to address public health or medical issues
  - Stimulate private sector investment

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 will be distributed across multiple phases

- Also includes non-monetary incentives such as mentoring and assistance to write research proposals and build infrastructure for research activities

- Challenge announcement: www.challenge.gov/?challenge=community-maternal-health

- Submission portal: www.herox.com/CommunityMaternalHealth
  - **Registration closes September 29, 2022**

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

- Challenge announcement:

  www.challenge.gov/?challenge=radx-tech-maternal-health

- Submission portal will open September 15, 2022
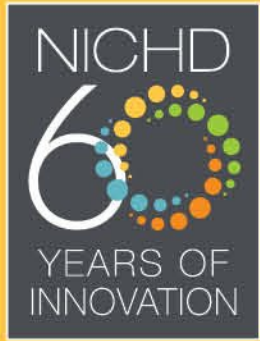
- **Submission deadline: November 1, 2022**

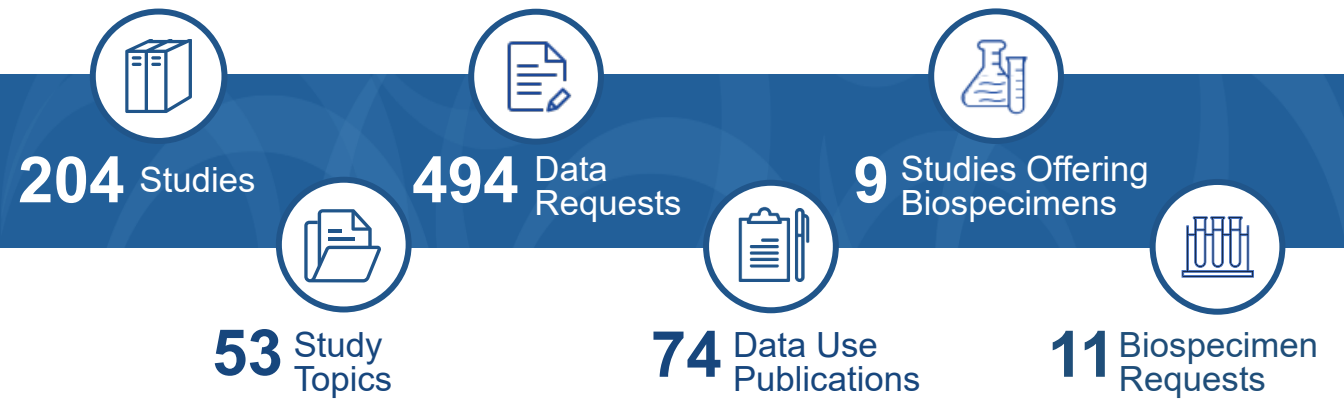# FY23: Maternal Health Research Centers of Excellence

- **Goal:** Move the needle in reducing maternal morbidity and decreasing 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

- **Notices:** RFA-HD-23-035; RFA-HD-23-036; RFA-HD-23-037

Data and Specimen Hub

DASH Data and Specimen Hub

NICHD 60 YEARS OF INNOVATION

- Centralized resource for researchers to share de-identified data from studies funded by NICHD

- Serves as a portal for requesting biospecimens from selected studies in DASH

- Aims to accelerate scientific findings to ultimately improve human health

204 Studies
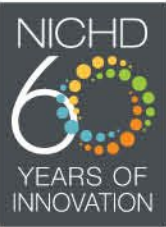
494 Data Requests

9 Studies Offering Biospecimens

53 Study Topics

74 Data Use Publications

11 Biospecimen Requests

DASH Content

Top Study Topics

Breastfeeding & Breast Milk*
Cerebral Palsy
Child Health*
Early Learning
Early Labor and Birth
Fertility Problems
High-Risk Pregnancy
HIV/AIDS*
Infant Care & Health*
Infant Mortality
Infertility & Fertility

Labor & Delivery
Newborn Screening
Obesity & Overweight
Pelvic Floor Disorders
Pharmacology
Pregnancy*
Preterm Labor & Birth*
Stillbirth
Women's Health*

*biospecimens available

Currently Available Biospecimens

Amniotic fluid
Blood
Breast Milk
Buffy Coat
Cord Blood (Buffy Coat, RBC, Plasma, Serum)
DNA/RNA/Proteins
Environmental Samples
Erythrocytes (RBC)

Hair
Lymphocytes
Meconium
Nail
Saliva
Serum/Plasma
Tissue samples
Urine
Vaginal Fluid

Last updated 08/31/2022

https://dash.nichd.nih.gov

New Research Findings Using Consortium on Safe Labor (CSL) Data Deposited in DASH

- 113 approved requests for CSL data (out of 494 total)

- 39 publications from CSL secondary data use (out of 74 DASH associated with DASH requests)

- Objective: Build machine-learning risk-prediction models of labor progression and outcomes

- Machine-learning models promote individualization of clinical decisions using baseline and labor characteristics of each patient

- NICHD intramural researchers also using CSL data and machine learning methods to identify risk factors for prolonged second stage labor

RESEARCH ARTICLE

Impact of labor characteristics on maternal and neonatal outcomes of labor: A machine-learning model
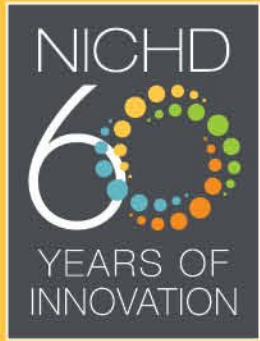
Sherif A. Shazly[1], Bijan J. Borah[1,2,3], Che G. Ngufor[3,4], Vanessa E. Torbenson[1], Regan N. Theiler[1], Abimbola O. Famuyide[1]*

1 Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, Minnesota, 2 Division of Health Care Delivery Research, Mayo Clinic, Rochester, Minnesota, 3 The Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, 4 Department of Artificial Intelligence and Informatics, Mayo Clinic, Rochester, Minnesota

Consortium on Safe Labor:
Collected detailed information from electronic medical records in 228,562 deliveries from 19 hospitals across the U.S. from 2002 to 2008
Released in DASH 4/4/2016

NIH Clinical Center Pediatric Research Strategic Plan
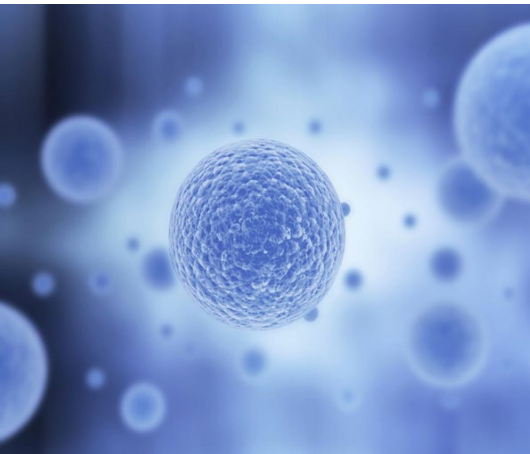
NIH Clinical Center

- Every patient participates in a research protocol

- Currently about 1,600 active research 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

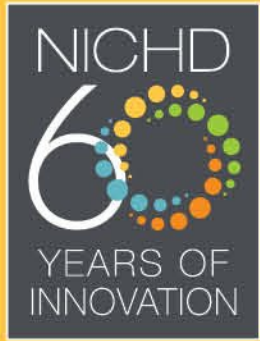- Funding model provides opportunity for research equity

Clinical Center Pediatric Research Strategic Plan Working Group Charge
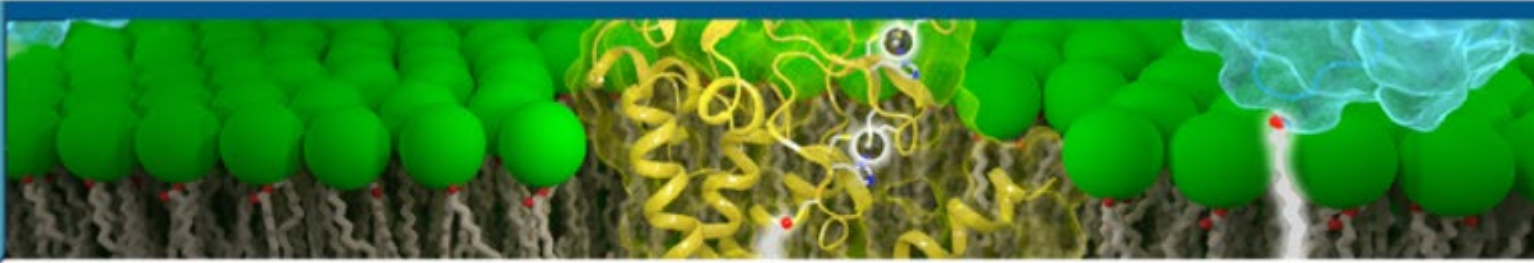
To identify the most impactful scientific areas of pediatric research in which the NIH can play a major role to substantially improve child health. Using this horizon scanning, to perform long-term, strategic planning for intramural trans-NIH clinical pediatric research to occur over the next decade and beyond.

NICHD Staff Updates

✓ <u>Scientific Director Search Update</u>

   ✓ Four excellent finalists

✓ <u>Clinical Director Search Update</u>

   ✓ Search committee formed and charged

   ✓ Applications received

   ✓ Search committee is deciding whom to interview

   ▪ Reference checks will be performed for finalists

   ▪ Best Qualified candidates recommended for Director's consideration
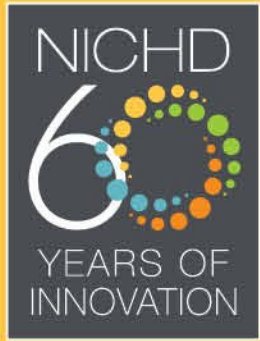
We're Hiring!

- Office of Health Equity

- Extramural Branch Chiefs

    - Maternal and Pediatric Infectious Disease Branch

    - Gynecologic Health and Disease Branch

    - Fertility and Infertility Branch

- Scientific Review Officer, Program Officers (CDBB, FIB, OPPTB), Program Analysts

- Full list and more details: https://www.nichd.nih.gov/about/jobs

Thank You!
Questions??