NICHD Director's Report

NACHHD Council

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NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Talk Outline

- NICHD 60th Anniversary
- NIH Budget Updates
- COVID-19 Research Updates
- New NICHD Non-COVID-19 Research Updates
- NIH-Wide Initiatives With Major NICHD Engagement
- NIH and NICHD Staff Updates

Join Us in Celebrating NICHD's 60th Anniversary

- 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
- Hold the date!
  - October 17, 2022: 60th Anniversary Symposium: Healthy Pregnancies, Healthy Children, and Healthy and Optimal Lives
  - More details to come

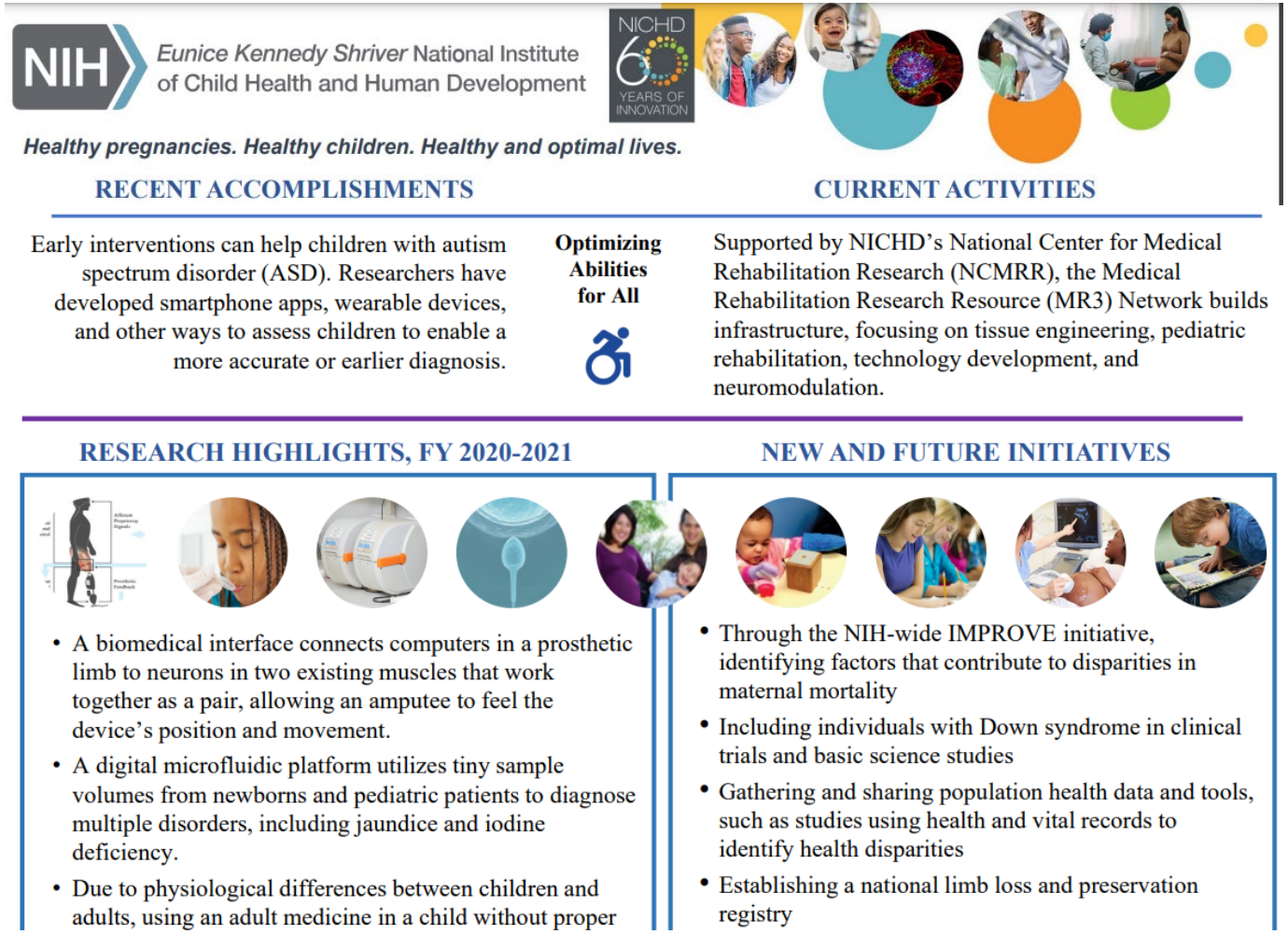
NIH Budget Updates

NIH FY22 Appropriations

- $45B for NIH
- $1.68B for NICHD, which includes
  - $7.5M for impact of COVID-19 on children
  - An increase of $30M for IMPROVE
- $12.6M to the NIH Common Fund for the Gabriella Miller Kids First Research Act
- $1B to establish ARPA-H

FY23 President's Budget (PB)

- 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



NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

NICHD 60 YEARS OF INNOVATION

Healthy pregnancies. Healthy children. Healthy and optimal lives.

RECENT ACCOMPLISHMENTS

Early interventions can help children with autism spectrum disorder (ASD). Researchers have developed smartphone apps, wearable devices, and other ways to assess children to enable a more accurate or earlier diagnosis.

Optimizing Abilities for All

CURRENT ACTIVITIES

Supported by NICHD's National Center for Medical Rehabilitation Research (NCMRR), the Medical Rehabilitation Research Resource (MR3) Network builds infrastructure, focusing on tissue engineering, pediatric rehabilitation, technology development, and neuromodulation.

RESEARCH HIGHLIGHTS, FY 2020-2021

- A biomedical interface connects computers in a prosthetic limb to neurons in two existing muscles that work together as a pair, allowing an amputee to feel the device's position and movement.
- A digital microfluidic platform utilizes tiny sample volumes from newborns and pediatric patients to diagnose multiple disorders, including jaundice and iodine deficiency.
- Due to physiological differences between children and adults, using an adult medicine in a child without proper

NEW AND FUTURE INITIATIVES

- Through the NIH-wide IMPROVE initiative, identifying factors that contribute to disparities in maternal mortality
- Including individuals with Down syndrome in clinical trials and basic science studies
- Gathering and sharing population health data and tools, such as studies using health and vital records to identify health disparities
- Establishing a national limb loss and preservation registry

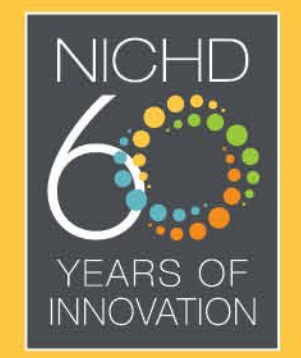
White House and Congressional Activities

- Maternal Health Action Plan Cabinet Meeting at the White House
  - Vice President's opening remarks: https://www.youtube.com/watch?v=sJuCQ9Mt12k
- Briefed Senate Appropriations Committee staff on IMPROVE initiative
- Briefed Congress on PRGLAC implementation

Photo credit: White House

FY23 House Appropriations Subcommittee Hearing

- Testified at the House Appropriations Subcommittee on Labor, Health and Human Services, and Education on May 11
- Major topics: ARPA-H, mental health, opioids
- NICHD-related questions: IMPROVE, stillbirth, youth mental health
- Other pediatric questions: ECHO, drug addiction, firearms



COVID-19 Research Updates

Predicting Viral-Associated Inflammatory disease severity in children with Laboratory diagnostics and artificial Intelligence (PreVAIL kIds)

**Note: MIS-C is a form of post acute sequelae of COVID-19 also known as Long COVID*

Goals: Develop translational tools to **understand the spectrum of pediatric SARS-CoV-2** illness, **rapidly diagnose and characterize MIS-C** associated with SARS-CoV-2, and **predict the longitudinal risk of disease severity** after exposure to and/or infection by SARS-CoV-2

Includes:

- Genetics, Omics, and other Biomarkers
- Viral Dynamics and Immune Profiling Studies
- Digital Health Platforms Leveraged for Children
- Artificial Intelligence

- **Funded through RADx®-Radical initiative**

PreVAIL kIds

- 8 awards
- Enrolling >4,500 prospective and 27,000 retrospective participants, including 700 with MIS-C across the US, Canada, United Kingdom, and South America
- Leveraging the NIH Small Business Education and Entrepreneurial Development (SEED) program to promote rapid translation and EUA application
- Examples of Success
  - Goal: To use RNA, protein, antibody, or clinical parameters to predict progression to severe COVID and MIS-C (PI: Burns)
    - Progress: Pre-EUA application for diagnostic algorithm to distinguish MIS-C, Kawasaki, and other febrile illnesses with >95% accuracy
  - Goal: Train machine learning algorithms to identify progressive disease cases at initial presentation (PI: Annapragada)
    - Progress: Preparing a Pre-EUA package based on an inflammatory cytokine/chemokine panel

Children born during the pandemic may experience slight neurodevelopmental delays

- SARS-CoV-2 passes from mother to fetus infrequently
- Studies of other viral infections during pregnancy suggest that the fetus may be affected by just the maternal immune response
  - This includes neurodevelopmental effects
- Researchers analyzed data from 255 children born to mothers with and without SARS-CoV-2 infection between March and December 2020
- Infants in both groups assessed at 6 months showed a slight decrease in gross motor, fine motor, and social skills compared to infants born pre-pandemic
- Study links maternal stress during pregnancy to potential neurodevelopmental effects in offspring
- Shuffrey, LC, et al. *JAMA Pediatrics. 2022*.
- https://www.nichd.nih.gov/newsroom/news/012822-COVID-pregnancy-neurodevelopment

Mandatory masking in schools reduced COVID-19 cases during Delta surge

- Study included more than 1.1 million students and 157,000 staff attending in-person school across nine states: North Carolina, Wisconsin, Missouri, California, Washington, Georgia, Tennessee, Kansas and Texas
- Schools with mandatory masking during the Delta surge had approximately 72% fewer cases of in-school transmission of SARS-CoV-2 when compared to schools with optional or partial masking policies
- Only about 10% of cases were school-acquired
- Boutzoukas AE et al. *Pediatrics 2022*
- https://www.nichd.nih.gov/newsroom/news/031022-school-masking-policies

New NICHD Non-COVID-19 Research Updates

Rehabilitation Research Updates

- Launched Limb Loss and Preservation Registry
  - Quality Registry in collaboration with Department of Defense
  - https://www.llpregistry.org/
- DEBUT - Undergraduate Prize Competition with NIBIB
  - New NCMRR-sponsored Rehabilitative and Assistive Technology Award currently under review
- Rehabilitation Research Speaker Series Featuring
  - Dr. Martina Mancini from Oregon Health and Science University
  - Dr. Lynn Worobey from University of Pittsburgh
  - Wearable Devices in Rehabilitation

LIMB LOSS *and* PRESERVATION REGISTRY

Activity is health.

Design by Biomedical Undergraduate Teams (DEBUT) Challenge

DEBUT

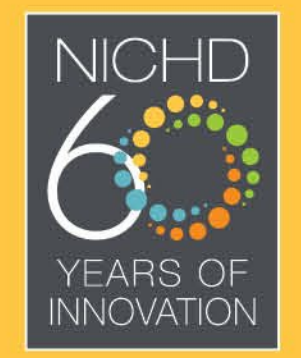
2022 Rules Announced!

NICHD Support for Firearms Research

- NICHD supports research on preventing violence from firearms, community-based interventions to prevent violence, social and academic factors leading to risky behaviors in youth, settings conducive to gun safety education, and population studies that analyze trends in gun ownership and access.
- In 2020, NICHD awarded nearly $2.5M to support research to improve understanding and prevention of firearm violence and mortality
- Two OBSSR-led FOAs (PAR 22-115) and (PAR 22-120) on Research on Community Level Interventions for Firearm and Related Violence Injury and Mortality Prevention
  - Support a network of research projects to develop and test prospective interventions at the community/community organization level that aim to prevent firearm and related violence, injury, and mortality
  - Cooperative agreements with a data coordinating center
  - Awards anticipated September 2022

Project Spotlight: Building Research Capacity for Firearm Safety Among Children

- R24 Research resource-generating award to University of Michigan Ann Arbor
- Gathers a multidisciplinary team of researchers and stakeholder partners (e.g., gun owners, firearms instructors) to define a pediatric-specific firearm injury prevention research agenda
- Conducts pilot studies that address key research questions
- Pilot project example: **Store Safely – Safe Firearm Storage for Families**
  - Develop and implement a new, online firearm safety education program tailored for families in rural communities
  - University/Community partnership developed culturally tailored messages
    - Focus groups asked about trusted messengers and message content
    - Respects the reasons for gun ownership while discussing ways to reduce harm
  - YouTube clip describing the program: https://www.youtube.com/watch?v=TsVGbCclpfM



NIH-Wide Initiatives With Major NICHD Engagement

NIH-wide Pediatric Research Consortium (N-PeRC)

- NIH-wide initiative beginning in June 2018 to capitalize on pediatric research expertise and resources across NIH's 27 institutes and centers
- NIH support for pediatric research currently totals **more than $4 billion;** nearly every IC supports this area to some extent
- Current focus
  - Pediatric Research Workforce
  - Pediatric Medical Devices

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

N-PeRC Pediatric Medical Devices Subgroup

- Stagnant number of devices being developed and/or evaluated for pediatric indications in the U.S.
- Challenges include:
  - Real and perceived ethical considerations to carry out trials in pediatric patients
  - Heterogeneous developmental range of children, from birth to 21 years
  - Experienced clinical trial infrastructure for child health research
  - Unclear regulatory pathways and financial environment
  - Lack of technical innovation for approaches to meet pediatric-specific needs
- Transdisciplinary, multi-stakeholder collaborative platforms could propel development of reasonable solutions
- **Proposed public-private partnership** vis the FNIH to support PMD development and commercialization

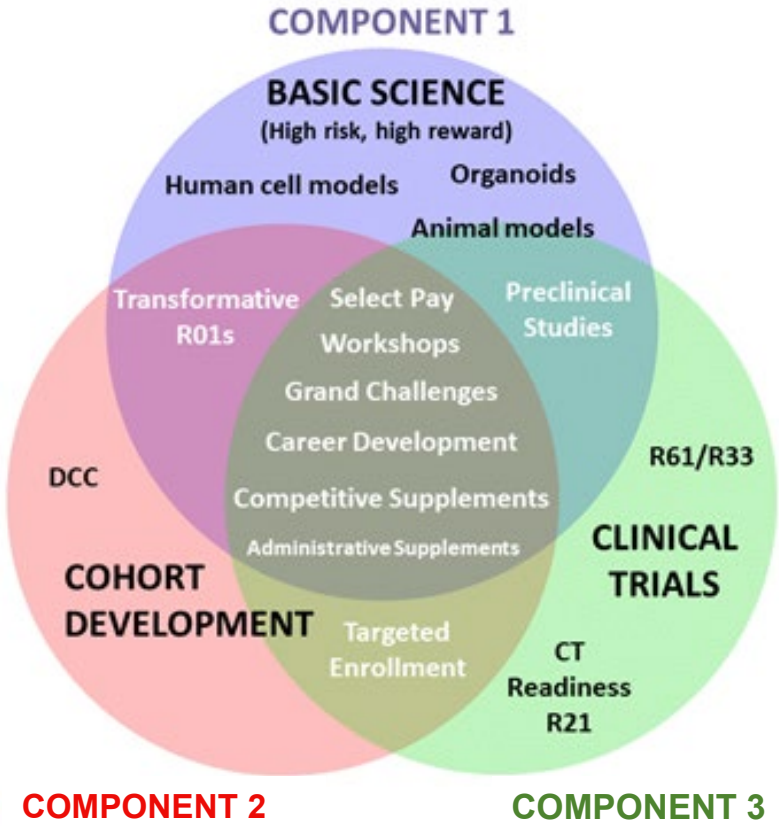
IMPROVE Initiative

- 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
  - Initiative to build research infrastructure with **community organizations**
  - Program to accelerate **technology** used for maternal health care in **maternity care deserts**
  - 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
  - Dissemination and Implementation research (NOT-OD-22-125)
- Maternal Health Centers of Excellence in FY23 (NOT-HD-22-022)

INCLUDE Project on Down Syndrome

3 components:

1. Conduct targeted, high-risk, high-reward basic science studies on chromosome 21.
2. Assemble a large study population of individuals with Down syndrome across the lifespan.
3. Include individuals with Down syndrome in existing and future clinical trials.

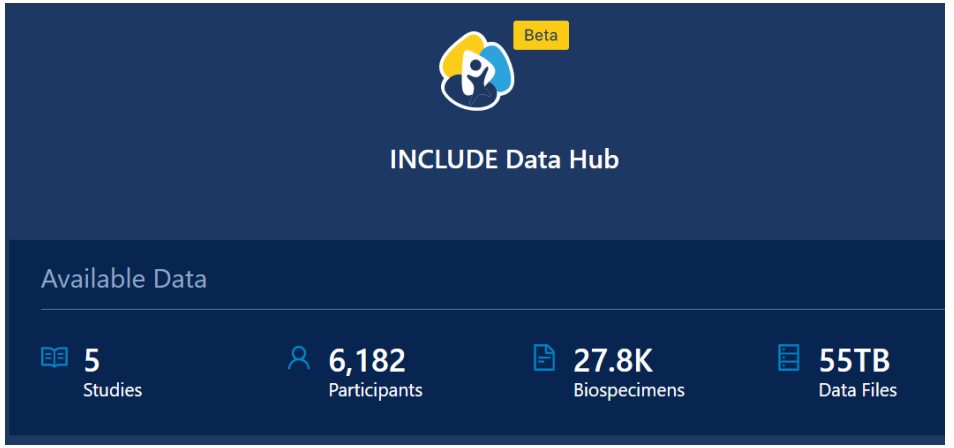


Some of the projects funded with $75 M FY22 Appropriation

- Support for early career scientists pursuing DS research
- Basic, applied, and clinical trials research
- Virtual workshop to enhance diversity within study cohorts and among investigators and trainees
- Virtual seminar series on special topics in conducting clinical trials with participants with DS

INCLUDE Data Hub

- Cloud-based resource developed through the INCLUDE Data Coordinating Center
- Provides free access to large-scale data resources and the capability to explore custom built cohort datasets based on participant, biospecimen, clinical, and ‘omics data
- Encourages collaboration
- Facilitates potential to uncover new insights into the biology of Down syndrome and co-occurring conditions



https://portal.includedcc.org/login?redirect_path=/dashboard

Nutrition Research

- 2020-2030 Strategic Plan for NIH Nutrition Research
  - Unifying Vision: Precision Nutrition
  - Focus areas: Advancing Precision Nutrition; Role of Nutrition and Microbiome in the Developmental Origins of Health and Disease
  - NICHD co-chairs the Nutrition Across the Lifespan implementation working group
- Nutrition for Precision Health, Powered by the *All of Us* Research Program
  - Supported by NIH Common Fund; grants managed by NICHD
  - NICHD staff serve as the Program Officials for the Clinical Centers and the Research Coordinating Center
- Meeting on malnutrition planned with ONR for Fall 2022

NIH Initiative on Climate Change and Health (CCH)

- Executive Orders have a renewed focus on Climate Change across agencies
- President's Budget & Congressional Markup
  - $100 Million to NIEHS for CCH Research (not appropriated)
- Seven Institute and Center Directors as NIH Leaders to develop CCH strategy
  - Drs. Bianchi (NICHD), Gibbons (NHLBI), Glass (FIC), Gordon (NIMH), Perez-Stable (NIMHD), Woychik (NIEHS), and Zenk (NINR)
- Re-energized NIH Working Group, co-chaired by NIEHS and FIC
- **Strategic Framework** articulates four major priority areas of science
- **Research across the continuum** includes:
  - Basic mechanistic research
  - Data integration
  - Behavioral\social sciences research
  - https://www.nih.gov/climateandhealth

Climate Change Affects Us Unequally

Under-served populations with health disparities
(Some communities of color; Low-income populations; Low-educational attainment groups; Immigrant groups; Indigenous populations)

Vulnerability by life stage
(Fetal/pre-natal, infants, young children, pregnant women, elderly)

Exposed workers
(e.g., farmers, construction workers)

Vulnerability associated with chronic medical conditions
(e.g., diabetes, asthma, cardiorespiratory diseases, psychiatric diseases)

Persons with disabilities

Populations in LMICs
(Higher rates of existing diseases, malnutrition, and extreme poverty)

USGCRP Climate Health Assessment, 2016

Climate Change and Health: New Funding Opportunities

- **Notice of Special Interest: Climate Change and Health** (NOT-ES-22-006)
  - Supports CCH research in the U.S. and globally, encouraging use of common data elements
- **Notices of Special Interest: Innovative Technologies for Research on Climate Change and Human Health (SBIR/STTR)** (NOT-ES-22-009 & NOT-ES22-010)
  - Supports technologies for capturing the effects of climate change/extreme weather on human health and to reduce the health threats posed by climate change
- **Research Coordinating Center for the Climate Change and Health Community of Practice** (U24 – Clinical Trial Not Allowed; RFA-ES-22-003)
  - Brings together multidisciplinary researchers and trainees to conduct solutions-driven research on health impacts of climate change
- **Community Engagement Alliance for Climate Change and Health** (ACE-CCH)
  - Supports teams to conduct community-engaged research focused on CC impacts on health and co-identification of mitigation of CC risks, vulnerabilities, and adaptation

Helping to End Addiction Long-term (HEAL) Initiative

- Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)
  - Provides evidence for the ways babies with NOWS are assessed, treated, and followed long-term
  - Eat, Sleep, Console clinical trial – enrollment completed!
  - Shorten Pharmacologic Treatment of Children with NOWS – still enrolling
  - Longitudinal follow up studies are ongoing
- Prescription After Cesarean Trial (PACT)
  - Opioid Prescription Protocols at Discharge after cesarean delivery
  - Enrollment completed!
- Potential New Opportunity
  - Opioid Exposure and Effects on Placenta Function, Brain Development, and Neurodevelopmental Outcomes (concept to be reviewed)

NIH Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative and Blueprint for Neuroscience Research

- NICHD staff involved with *many* BRAIN and Blueprint working groups relevant to NICHD research priorities
- NIH Infant and Toddler Toolbox - first round of validation studies successfully completed; new measures added this year for visual reception and sway/balance
- BRAIN Research Advances
  - Dr. Ngai's blog on BRAIN payoffs: https://brainblog.nih.gov/brain-blog/brain-director-whats-payoff
  - BRAIN Initiative Cell Census Network reports the generation of a multimodal cell census and atlas of the mammalian primary motor cortex (*Nature*, 2021)
  - Electrical brain stimulation showed 1) stimulation in one location may activate entire circuits in the brain and 2) electrical stimulation during learning improved performance on visual memory tasks
  - Novel approach to neurostimulation: Noninvasive ultrasound array that can stimulate and record neural activity in nonhuman primates that could be adapted for humans (Jones et al., 2022)

NIH and NICHD Staff Updates

NICHD Division of Extramural Research

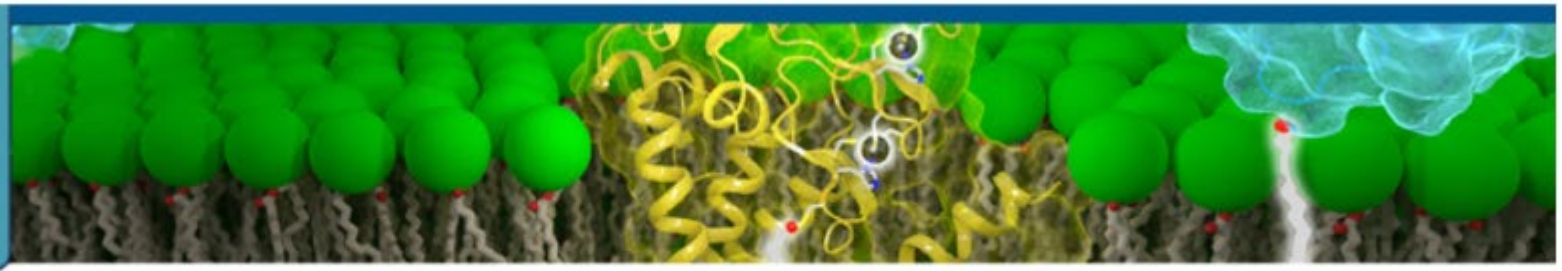
- Rohan Hazra, M.D. - Director, Division of Extramural Research
  - Oversees NICHD's 12 extramural scientific research branches
  - Previously Chief of NICHD's Maternal and Pediatric Infectious Disease Branch and Acting DER Director

- Rebekah Rasooly, Ph.D. - Director of Extramural Activities
  - Will oversee NICHD's scientific review and grants management branches, as well as the extramural policy and training offices
  - Previously Chief of the Office of Wellness, Technology, and Training at NINR

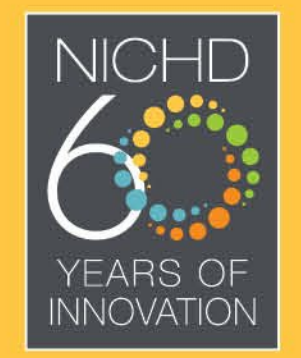
NICHD Division of Extramural Research

- Dr. Nahida Chakhtoura, M.D. – Chief, Pregnancy and Perinatology Branch
  - Previously a medical officer and physician with NICHD's Maternal and Pediatric Infectious Disease Branch

- **We are hiring!**
  - Three extramural branch chief openings
    - MPIDB, GHDB, FIB



- Scientific Director Search Update
  - Four excellent finalists
- Clinical Director Search is Open
  - Search committee formed and charged
  - Job announcement (open June1 to August 1)
    - https://hr.nih.gov/jobs/search/executive/job-58441
  - Search committee interviews and reference checks;
  - Best Qualified candidates recommended for Director's consideration



Thank You!
Questions??