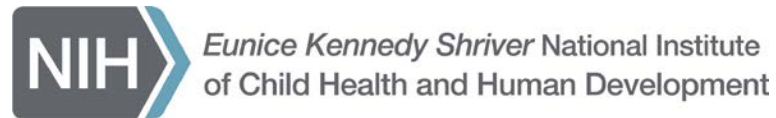


# NICHD Director's Report

Diana W. Bianchi, M.D.

September 9, 2020



## Talk Outline

- NIH Budget
- COVID-19 Research Updates
- NICHD Efforts to Increase Diversity and Combat Systemic Racism
- NICHD Strategic Plan Implementation
- Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)
- NICHD Staff Updates



# NIH Budget

# FY 2020 and FY 2021 Appropriations

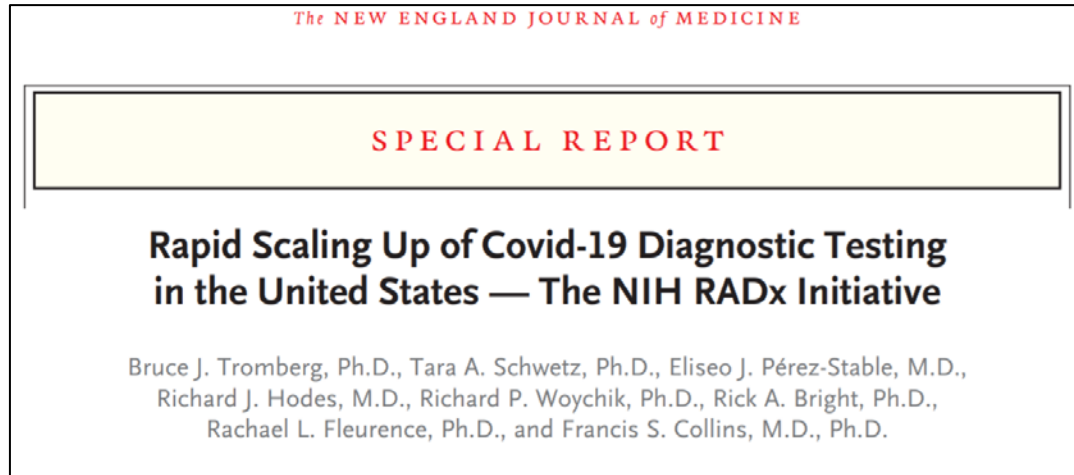
- Federal government currently funded through September 30, 2020
- COVID-19 Stimulus Funds
  - H.R. 748 Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
    - \$945.4 million to NIH to “prevent, prepare for, or respond to coronavirus, domestically or internationally” Included specific funding for NIAID, NHLBI, NIBIB, NCATS, NLM, and the OD
    - Additional supplement?
- FY 2021 Budget
  - FY21 appropriations passed in the House; no action yet in the Senate; continuing resolution very likely





**COVID-19**

# The NIH RADx<sup>SM</sup> Initiative



- **RADx Tech**

- Speed development, validation, and commercialization of innovative point-of-care and home-based tests, and improve clinical laboratory tests
- July – awarded 7 biotech companies nearly \$250M to accelerate scale up efforts
- September – awarded 9 biotech companies nearly \$130M for scale up and manufacturing

- **RADx Underserved Populations (RADx-UP)**
  - Understand factors associated with disparities in COVID-19 morbidity and mortality and lay the foundation to reduce disparities
  - Phase I awards will be made soon
  - Phase II announcement released in future
- **RADx Radical (RADx-rad)**
  - New, non-traditional approaches that address current gaps in COVID-19 testing
  - FOAs in 7 areas (e.g., wastewater detection, chemosensory detection, PreVAIL klds)
  - Applications due September 2020; Awards made by December
- **RADx Advanced Technology Platforms (RADx-ATP)**
  - Increase testing capacity and throughput by identifying existing and late stage testing platforms for COVID-19





# COVID-19: Research Goals for Pediatric Population

- Understand the range of clinical manifestations of SARS-CoV-2/COVID-19
- Understand the etiology and clinical manifestations of MIS-C
- Determine the risk profile for patients that develop
  - MIS-C
  - Severe COVID-19
- Understand the variations in immune response underlying the wide range of clinical manifestations in children infected with SARS-CoV-2, and identify predictive and prognostic immune biomarkers
- Understand long-term consequences of SARS-CoV-2, COVID-19, and MIS-C



# MIS-C Hospitalized Cohort

- Leveraging networks from NICHD, NHLBI, NIAID to create a centralized cohort
  - **Clinical data will be harmonized** across MIS-C cohort studies
  - Shareable data, including WGS, will create a large searchable data set with common data elements and widely available measures for **interoperable sharing across data platforms**
  - Aim to follow children with MIS-C for five years through longitudinal protocol
  - Capitalize on strengths of each network: immune profiling; cardiac effects; PK/PD





# MIS-C Hospitalized Cohort NICHD Pediatric Trials Network

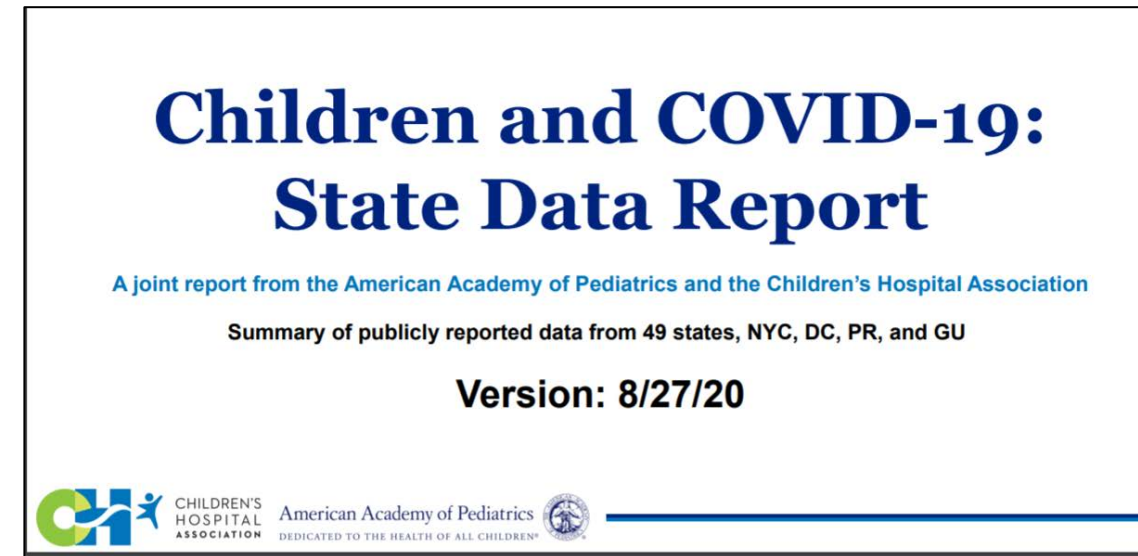


- Infrastructure for investigators to conduct trials that improve pediatric labeling through opportunistic PK/PD research
- Study protocol expanded to include 12 drugs of interest to treat COVID-19 and **to collect data on children testing positive for SARS-CoV-2 (including those with MIS-C)**
  - Characterize pharmacokinetics of these drugs across the pediatric age range
  - Nearly 65 children enrolled thus far; 7 with MIS-C
- Mechanism to collect data quickly at many sites, **targeting hotspots**
  - 23 active sites with plans to bring up to 30 more online by December



# American Academy of Pediatrics State-level COVID-19 Data

- AAP and Children's Hospital Association report state level data every 2 weeks, including:
  - Cumulative COVID-19 cases in children in the U.S.
  - Percent change in COVID-19 cases in children over the previous two weeks
  - Percent of testing that includes children and percent of children testing positive
  - Hospitalizations
  - Mortality
- Use to identify hot spots



<https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>



# At Risk Cohort - PreVAIL kids (RADx-rad)

PREDICTING VIRAL-ASSOCIATED INFLAMMATORY DISEASE SEVERITY IN CHILDREN WITH  
LABORATORY DIAGNOSTICS AND ARTIFICIAL INTELLIGENCE (PREVAIL KIDS)

- **Purpose and Objective:** Develop novel, nontraditional approaches, testing strategies and technologies 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 to tailor management and optimize health outcomes
- Studies must include:
  - Genetics, Omics & Other Biomarkers
  - Viral Dynamics & Immune Profiling Studies
  - Digital Health Platforms Leveraged for Children
  - Artificial Intelligence (AI) & Machine Learning
- Milestone-driven award transition to advance only approaches, strategies and technologies with promise to lead to an accurate and reliable MIS-C prognostic algorithm to enhance the treatment of children
- Applications due September 30, 2020
- <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-023.html>



# NICHD Global Network for Women's and Children's Research

- Global Network study to track the prevalence and impact of SARS-CoV-2 infection among approximately 16,000 pregnant women in seven low- and middle-income countries
- Using antibody testing at delivery, the study seeks to compare the maternal, fetal, and neonatal outcomes of SARS-CoV-2-infected women to those of non-infected women
- Will follow women through pregnancy and 12 months after childbirth
- Sites in Kenya, Zambia, Guatemala, India (Belagavi and Nagpur), Democratic Republic of the Congo, Pakistan, and Bangladesh





# **NIH and NICHD Efforts to Increase Diversity and Combat Systemic Racism**

# NICHD's Increased Efforts in Workforce Equity and Diversity

- NICHD must do more to address health disparities and systemic racism. We are also committed to diversifying the scientific workforce, both within our institute and in the broader extramural community.
- Working with NICHD's Office on Health Equity to focus on several activities
  - Plans to diversify our internal workforce
  - Efforts to increase the diversity of the extramural workforce and encourage applications from investigators and trainees who are underrepresented in the biomedical science community
  - Efforts to examine our health disparities portfolio and determine the best way forward to address systematic racism and institutional discrimination as it relates to our research populations

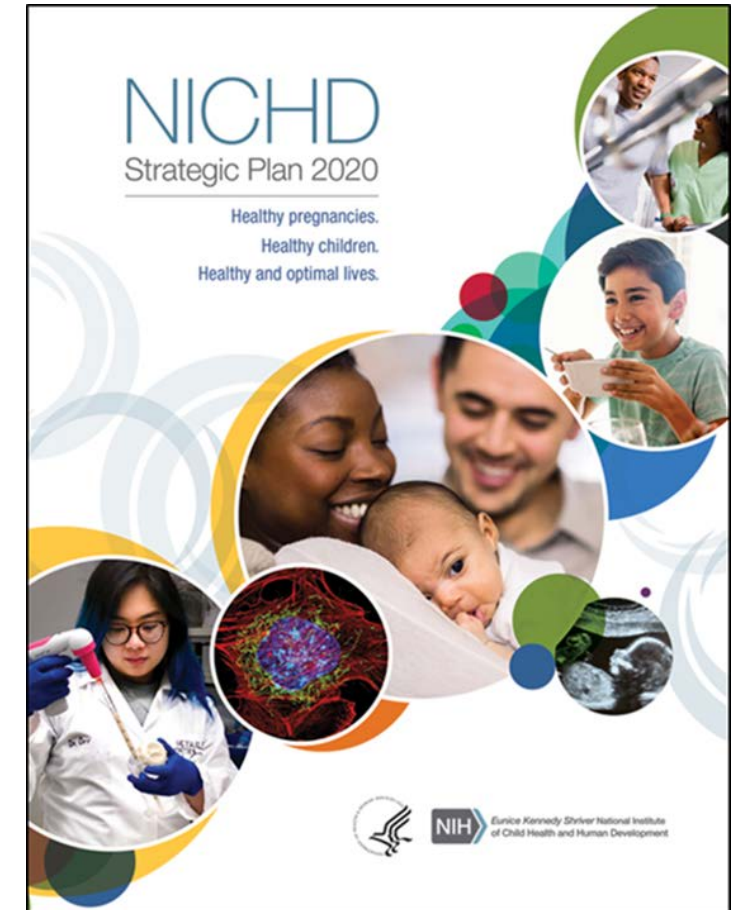




# **NICHD Strategic Plan Implementation**

# NICHD Strategic Plan 2020 - One Year Anniversary! Implementation Progress

- Engaging NICHD staff to develop activities to make progress towards each objective
- Cannot focus on everything simultaneously; will prioritize based on scientific opportunity and resource availability
- Implementation process will remain flexible to accommodate advances in technology, *national health priorities*, etc.
- Transparency – we are reporting progress regularly to you, our Advisory Council





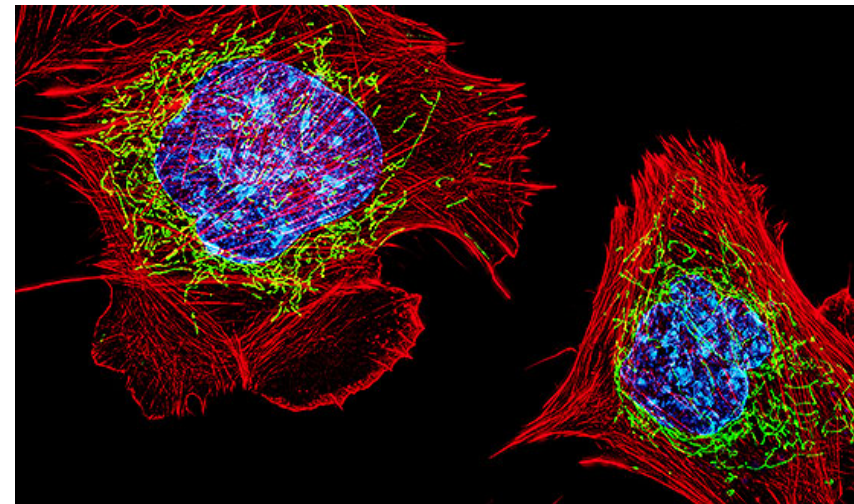
# Theme 1: Understanding the Molecular, Cellular, and Structural Basis of Development

## New and Ongoing Activities

- Working with KOMP2 program, sponsoring In-Depth Phenotyping for Models with Embryonic or Perinatal Lethality or Subviability
- Supporting bioinformatics resource centers for developmental biology
- Spearheading pediatric component of NIH-wide dGTEX project
- With other IC co-funding, new Centers for Collaborative Research in Fragile X and FMR1-Associated Conditions

## 2019-2020 Advances

- Identified 8 rare and damaging genetic variants associated with spina bifida
- Discovered genetic mutation that enhances cognitive flexibility in mice



# Theme 2: Promoting Gynecologic, Andrologic, and Reproductive Health

## New and Ongoing Activities

- Centers to Advance Research in Endometriosis
- RFA: Genomic Predictors of Pregnancy Loss
- SBIR RFA on Non-invasive Diagnostics to Improve Gynecologic Health

## 2019-2020 Advances

- FDA approved drug for heavy menstrual bleeding due to fibroids
- Drug-containing nanoparticles reduce size of fibroid tumors in mice
- Vitamin and mineral supplements not effective in improving male fertility
- Genetic analysis suggests distinct subtypes of PCOS
- Endometriosis linked to DNA changes



# Theme 3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness

## New and Ongoing Activities

- With BMGF, clinical trial of one-dose antibiotic for the prevention of maternal and infant sepsis (APLUS Study)
- Tracking COVID-19 in Pregnant and Lactating Women
- RFA: Role of Nutrition in Care and Development of Preterm Infants

## 2019-2020 Advances

- Hospital quality improvement effort reduces racial disparities in severe maternal morbidity
- Low-dose aspirin may reduce preterm birth risk among first-time mothers
- Key molecules for placental function become impaired in women with preeclampsia
- Adverse pregnancy outcomes more common among women who are deaf or hard of hearing



# Theme 4: Improving Child and Adolescent Health and the Transition to Adulthood

## New and Ongoing Activities

- Identifying children at risk for MIS-C
- SPROUTS study: neurobehavioral factors, feeding practices, and early life food exposures on diet and growth in 3-5 year olds
- Collaborative Pediatric Critical Care Research Network: critical care research in Pediatric Intensive Care Units (PICUs)
- Adolescent Transition Workshop (Sept 30-Oct 1)

## 2019-2020 Advances

- High Tech Platform to Maximize Diagnostic Tests while Minimizing Volumes of Test Samples Collected from the Youngest Patients
- Benefits of fetal surgery to repair spina bifida persist through school age
- Reducing False-Positive Results in Newborn Screening Using Machine Learning



# Theme 5: Advancing Safe and Effective Therapeutic Devices for Pregnant and Lactating Women, Children, and People with Disabilities

## New and Ongoing Activities


- Maternal and Pediatric Precision in Therapeutics (MPRINT)
- Rehabilitation Research Infrastructure centers
- Evaluating drugs prescribed to children with COVID-19
- Improving access to clinical trials for people with disabilities

## 2019-2020 Advances

- 7 pediatric label changes under BPCA in FY 2019-2020; most of these are for antibiotics
- Enzyme levels affect methadone treatment for infants with NOWS
- Use of PPE does not affect quality of compressions in pediatric CPR



# Next Steps

- Continue refining implementation plans for all three focus areas of the Strategic Plan (Scientific Research Themes, Scientific Stewardship, Management & Accountability)
- Engage in new activities (and continue ongoing activities) to achieve the Goals and Objectives outlined in each focus area
- Develop metrics and track progress toward meeting Objectives
- Report progress externally via website (coming soon!) 

## Explore the Plan



### Scientific Research Themes and Objectives

The NICHD Strategic Plan presents NICHD's research goals and objectives under five broad research themes that will enable NICHD to focus its efforts on the most significant public health challenges and advance science in these areas of priority.



### Aspirational Goals

NICHD encourages the field to transcend what is currently considered possible to advance research that could lead to healthy and optimal lives for all.

## Check Our Progress



See how NICHD is making progress toward our goals.

## Spread the Word



Share the NICHD Strategic Plan with your colleagues and followers using these resources.





# **Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)**

# PRGLAC Implementation Plan

- Nearly 4 years of effort coming to fruition
- Implementation Plan has been submitted to HHS
- Major focus of NICHD Strategic Plan Theme 5
- Testing COVID-19 vaccines in pregnant women
- **Thank you, Lisa Kaeser!**







# **NICHD Staff Updates**

# Welcome New NCMRR Director!

## Theresa H. Cruz, Ph.D

- Served as Acting NCMRR Director for the past year
- She earned a B.S. in biomedical engineering with highest honors from Rutgers and received her M.S. and Ph.D. degrees in biomedical engineering from Northwestern University
- Previous research at the Rehabilitation Institute of Chicago focused on motor control and gait impairments of the lower limb following stroke
- Joined NIH and NCMRR in 2009, managing grants in the Devices and Technology Development and Rehabilitation Diagnostics and Interventions Programs as well as SBIR/STTR awards in medical rehabilitation
- Research detail at the Functional and Applied Biomechanics Laboratory in the Rehabilitation Medicine Department of the NIH Clinical Center in 2015
- Team lead in the NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, co-managing a portfolio in neurotechnology development



# Leadership Positions: Searches Underway

- **NICHD Scientific Director**

- Applications closed June 5, 2020
- Robust response
- Search Committee interviewed the highly qualified applicants and checked references
- List of best candidates has been presented to NICHD Director for second round of interviews

- **Director, Division of Population Health Research (DIPHR)**

- Selection process same as for Scientific Director
- The highly qualified applicants will have the first round of interviews in the next few weeks

- More info about hiring at NICHD at <https://www.nichd.nih.gov/about/jobs>



# Rohan Hazra, M.D.

## *Acting Associate Director for Extramural Research*

- Named Acting Associate Director in February 2020
- Earned his M.D. from the Johns Hopkins University School of Medicine, followed by a pediatric residency and pediatric infectious disease fellowship at Children's Hospital in Boston
- Board certified in both pediatrics and pediatric infectious diseases
- Joined NICHD in 2007 and has overseen the Pediatric HIV AIDS Cohort Study (PHACS), which overlaps with his research interests in studying the long-term impact of HIV and its treatment on children, adolescents, and young adults who are infected with HIV as infants
- Prior to joining NICHD, he conducted clinical studies in pediatric HIV in the NCI intramural program



# Eugene “Gene” Hayunga, Ph.D.

## *Acting Director, Division of Extramural Research*

- Named Acting Director in February 2020
- Earned his masters and doctorate degrees from SUNY Albany
- Conducted research in tropical medicine and parasitology at the USDA, the Uniformed Services University of the Health Sciences, and the Naval Medical Research Institute
- Worked on Medicare reform as a legislative fellow in the U.S. Senate
- Decorated combat veteran, serving active duty and reserve assignments in the U.S. Army
- Prior to joining NICHD, Dr. Hayunga was the chief of the Extramural Project Review Branch in the Office of Scientific Affairs at the NIAAA, and Research Policy Officer in the NIH Office of Research on Women's Health



# **Sonia S. Lee, Ph.D.**

## ***Acting Director, Maternal and Pediatric Infectious Disease Branch***

- Named Acting Director in February 2020
- Earned her bachelor's degree in psychology from the University of Pennsylvania, and her M.A. and Ph.D. in clinical psychology from American University
- Served as a psychologist on the Special Immunology Service at Children's National Medical Center, consulting on assessment and care of children, adolescents, and families living with HIV
- Joined NICHD in 2006, working with investigators on adolescent HIV prevention and treatment, especially to design and implement behavioral studies and behavioral components of biomedical studies in youth living with HIV or at risk for HIV



# Welcome to New NICHD Extramural Staff!



**Jim Griffin**  
*Branch Chief*  
CDBB



**Parisa Parsafar**  
*SRCD Fellow*  
CDBB



**Ashley Vargas**  
*Program Director*  
PGNB



**Jackie Wallace**  
*AAAS Fellow*  
PPB



# Welcome to New NICHD Extramural Staff!



Francine Mahase  
*Grants Program Analyst*  
OPPTB



Lesly Samedy Bates  
*Program Officer*  
OPPTB



Antonello Pileggi  
*Program Officer*  
OPPTB





# Welcome to New NICHD Extramural Staff!



Travis Kent  
*Program Officer*  
CRB



Clay Mash  
*Scientific Review Officer*  
SRB



Sonya Freeman  
*Lead Committee*  
*Management Specialist*  
OCM





**Questions?**