

NICHD Updates

IMPAACT 2022 Meeting

Rohan Hazra, M.D.
June 28, 2022



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



Talk Outline

- NICHD Staff Updates
- NICHD 60th Anniversary
- NICHD Clinical Trial Networks
- COVID-19 Research
- Selected non-COVID 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
- 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



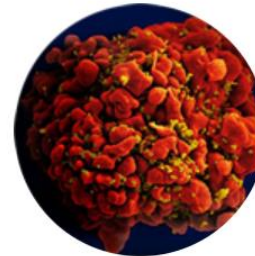
Division of Extramural Research



Child Development and Behavior Branch (CDBB)



Contraception Research Branch (CRB)



Maternal and Pediatric Infectious Disease Branch (MPIDB)



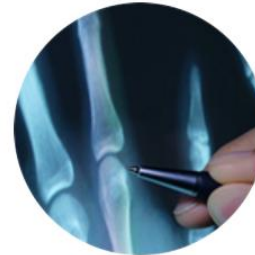
Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)



Developmental Biology and Structural Variation Branch (DBSVB)



Fertility and Infertility Branch (FIB)



Pediatric Growth and Nutrition Branch (PGNB)



Pediatric Trauma and Critical Illness Branch (PTCIB)



Gynecologic Health and Disease Branch (GHDB)



Intellectual and Developmental Disabilities Branch (IDDB)



Population Dynamics Branch (PDB)



Pregnancy and Perinatology Branch (PPB)



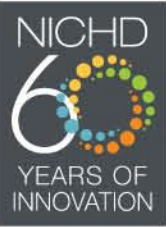
NICHD Division of Extramural Research



- 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! (<https://www.nichd.nih.gov/about/jobs>)**
 - Three extramural branch chief openings
 - Maternal and Pediatric Infectious Disease (MPIDB), Gynecologic Health and Disease (GHDB), Fertility and Infertility (FIB)
 - Four extramural staff openings:
 - MPIDB, FIB, Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB), and Child Development and Behavior Branch (CDBB)

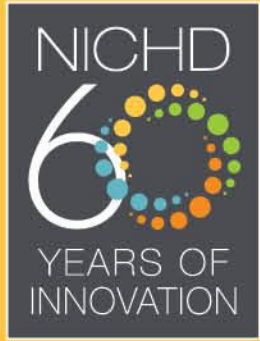


Join Us in Celebrating NICHD's 60th Anniversary

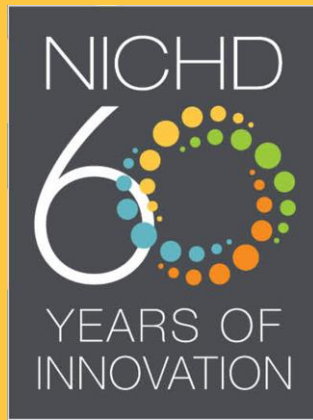


- Visit the NICHD 60th anniversary webpage: <https://www.nichd.nih.gov/60years>
 - Highlights key advances and milestones in NICHD's history
 - Focus on the people who help NICHD achieve its mission
 - Learn about NICHD's future research directions
 - Get updates on anniversary activities and events
- Hold the date!
 - October 17, 2022: 60th Anniversary Symposium:
Healthy Pregnancies, Healthy Children, and Healthy and Optimal Lives
 - More details to come





NICHD Clinical Trial Networks



Multicenter Clinical Trials: Leveraging Network Infrastructure to Advance Research and Outcomes for Women, Children, and Pregnant and Lactating Individuals

NACHHD June Council 2022

Bob Tamburro, MD, MS on Behalf of the Division of Extramural Research



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



Initiative Background

Amniocentesis: HEW Backs Test for Prenatal Diagnosis of Disease

The study, which was conducted by researchers at nine major medical centers,* was coordinated and supported by the National Institute of Child Health and Human Development (NICHD). The study was designed to answer two basic questions about the use of amniocentesis during the middle 3 months of pregnancy.

*The participating institutions were: Children's Memorial Hospital, Chicago; Eunice Kennedy Shriver Center, Boston; Johns Hopkins University School of Medicine, Baltimore; Mount Sinai School of Medicine, New York; University of California at Los Angeles-Harbor General Hospital, Torrance; University of California School of Medicine, San Diego; University of Michigan School of Medicine, Ann Arbor; University of Pennsylvania School of Medicine, Philadelphia; Yale University School of Medicine, New Haven.

7 NOVEMBER 1975

- NICHD has long supported multicenter clinical studies
- NICHD formed its first clinical research networks in 1985
 - Neonatal Intensive Care Units
 - Maternal-Fetal Medicine Units
- Perform large scale clinical trials
- Network support resulted in clinical practice changes

Initiative Background



Building Better Clinical Trials through Stewardship and Transparency

By Mike Lauer and Carrie Wolinetz

Posted September 16, 2016



- NIH proposed to enhance clinical trial stewardship
- Individual Institutes/Centers asked to develop their own clinical trial FOAs
- **Four principles** for continued commitment of NICHD Network infrastructure for rigorous multisite clinical trials
 - Notice (NOT-HD-19-034): *Infrastructure for NICHD Multisite Clinical Trials*
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-HD-19-034.html>
 - Webinar: *Strategic Plan 2020 Implementation: NICHD's vision for multi-site clinical trials infrastructure*
 - <https://www.youtube.com/watch?v=kzgFRuH9rnE>



Notice Number: NOT-HD-19-034

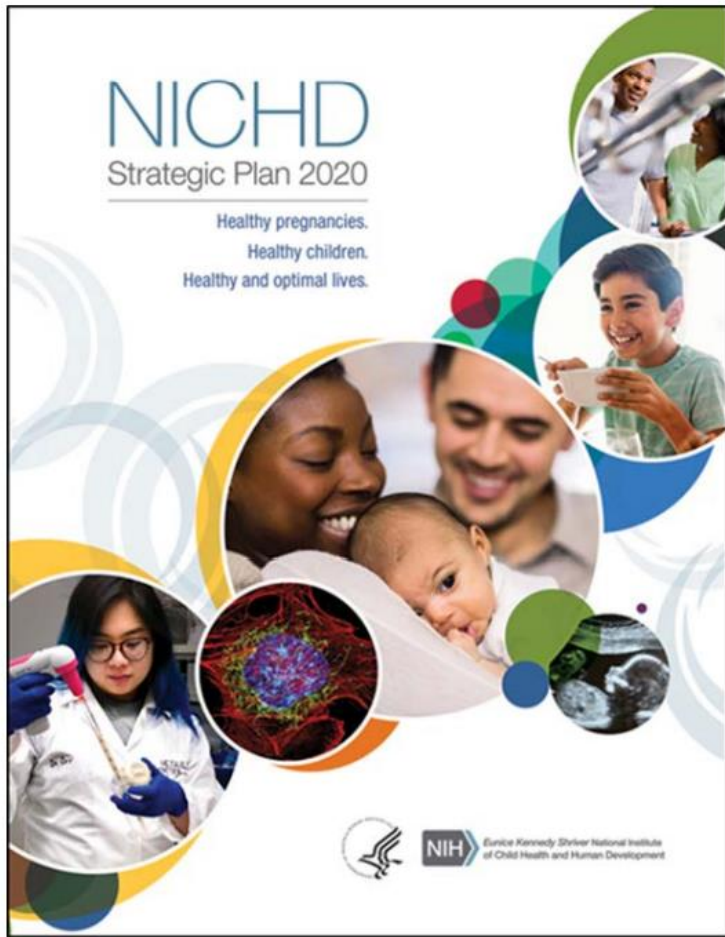
Key Dates

Release Date: October 10, 2019

Related Announcements

- ***Enhance the rigor and reproducibility of clinical trial protocols***
- ***Promote greater availability of multisite clinical trial infrastructure to support trials from a wider range of investigators***
- ***Facilitate data sharing and access to biospecimens to efficiently expand research capacity for all investigators***
- ***Facilitate greater involvement of diverse populations in multisite clinical trials***

NICHD Strategic Plan 2020



- *Goal #1:* Promoting an Inclusive Scientific Workforce
- *Goal #2:* Facilitating Data Sharing and Access to Biospecimens
- *Goal #6:* Improving Clinical Trial Oversight and Management

NICHD Maternal-Fetal Medicine Units (MFMU) Network: Clinical Centers (UG1 Clinical Trial Optional)

[UG1 Clinical Research Cooperative Agreements - Single Project](#)

Reissue of [RFA-HD-16-019](#)

- **May 19, 2022** - Notice of Pre-Application Webinars for the Maternal-Fetal Medicine Units Network and Neonatal Research Network Funding Opportunity Announcements. See Notice [NOT-HD-22-023](#)

RFA-HD-23-016

[RFA-HD-23-017](#), [U24 Resource-Related Research Project \(Cooperative Agreements\)](#)

NICHD Neonatal Research Network (NRN): Data Coordinating Center (U24 Clinical Trial Optional)

[U24 Resource-Related Research Projects – Cooperative Agreements](#)

Reissue of [RFA-HD-18-010](#)

- **May 19, 2022** - Notice of Pre-Application Webinars for the Maternal-Fetal Medicine Units Network and Neonatal Research Network Funding Opportunity Announcements. See Notice [NOT-HD-22-023](#)

RFA-HD-23-001

[RFA-HD-23-002](#), [UG1 Clinical Research Cooperative Agreements - Single Project](#)

NICHD Neonatal Research Network (NRN): Clinical Centers (UG1 Clinical Trial Optional)

[UG1 Clinical Research Cooperative Agreements - Single Project](#)

Reissue of [RFA-HD-16-020](#)

- **May 19, 2022** - Notice of Pre-Application Webinars for the Maternal-Fetal Medicine Units Network and Neonatal Research Network Funding Opportunity Announcements. See Notice [NOT-HD-22-023](#)

RFA-HD-23-002

[RFA-HD-23-001](#), [U24 Resource-Related Research Project \(Cooperative Agreements\)](#)

NICHD Maternal-Fetal Medicine Units (MFMU) Network: Data Coordinating Center (U24 Clinical Trial Optional)

[U24 Resource-Related Research Projects – Cooperative Agreements](#)

Reissue of [RFA-HD-13-013](#)

- **May 19, 2022** - Notice of Pre-Application Webinars for the Maternal-Fetal Medicine Units Network and Neonatal Research Network Funding Opportunity Announcements. See Notice [NOT-HD-22-023](#)

RFA-HD-23-017

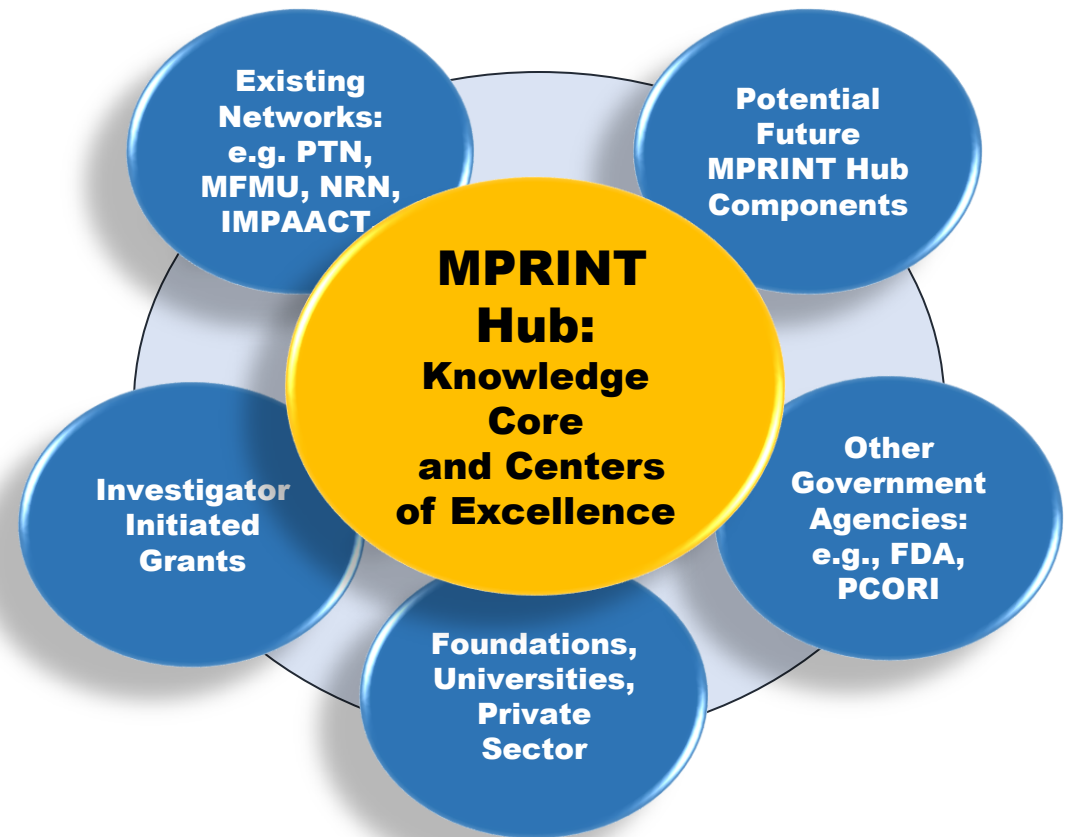
[RFA-HD-23-016](#), [UG1 Clinical Research Cooperative Agreements - Single Project](#)



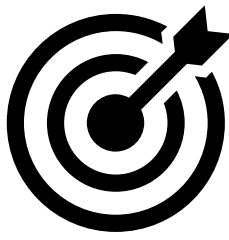
Maternal and Pediatric pRecision *in* Therapeutics Hub

MPRINT Hub is a service center and science catalyst:

- Provide knowledge and expertise to the scientific community
- Catalyze and accelerate maternal and pediatric therapeutics towards precision medicine
- Synergize with other resources and networks
- Build upon prior efforts and lay groundwork for future efforts



High-level MPRINT Hub objectives

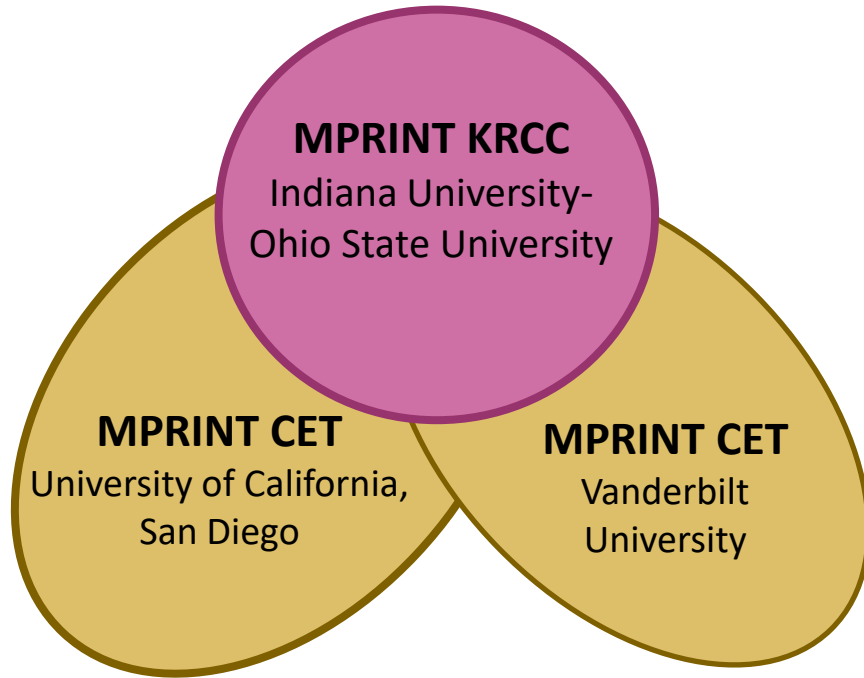


- **Create a broadly accessible, integrated platform** in maternal and pediatric therapeutics research to facilitate research, regulatory science, drug development, and synergy across the broader scientific community.
- **Serve as a centralized knowledge and tool repository** and resource and oversee an Opportunity Pool of funds.
- **Address key knowledge deficits** in maternal and pediatric pharmacology and therapeutics through the conduct of cutting edge clinical, translational, basic, and/or data sciences research.
- **Enable and catalyze new research and drug development opportunities** in areas of high unmet medical need in maternal and pediatric therapeutics and enhance the inclusion of individuals with disabilities.



Hub Model

Structure of Each Center



MPRINT KRCC

Indiana University & The Ohio State University

- Dr. Sara Quinney
- Dr. Li Lang

MPRINT CET

University of California San Diego

- Dr. Adriana Tremoulet
- Dr. Christina Chambers
- Dr. Victor Nizet
- Dr. Shirley M. Tsunoda
- Dr. Lars Bode

MPRINT CET

Vanderbilt University

- Dr. Prince Joseph Kannankeril
- Dr. Sara Van Driest





PEDIATRIC TRIALS NETWORK

Making drugs safer & more effective
for use in the youngest patients



WHY PTN MATTERS



OUR RESEARCH



GET INVOLVED



FDA Label Changes

Under the Best Pharmaceuticals for Children Act (BPCA), the PTN works to provide the Food and Drug Administration (FDA) with information to inform label changes with the necessary information to prescribe the most appropriate doses of the medications to

Pharmacokinetics and Safety of Commonly Used Drugs in Lactating Women and Breastfed Infants (CUDDLE)

Pharmacokinetics, Pharmacodynamics, and Safety Profile of Understudied Drugs Administered to Children per Standard of Care (POP02)



COVID-19 Research Updates

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



**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

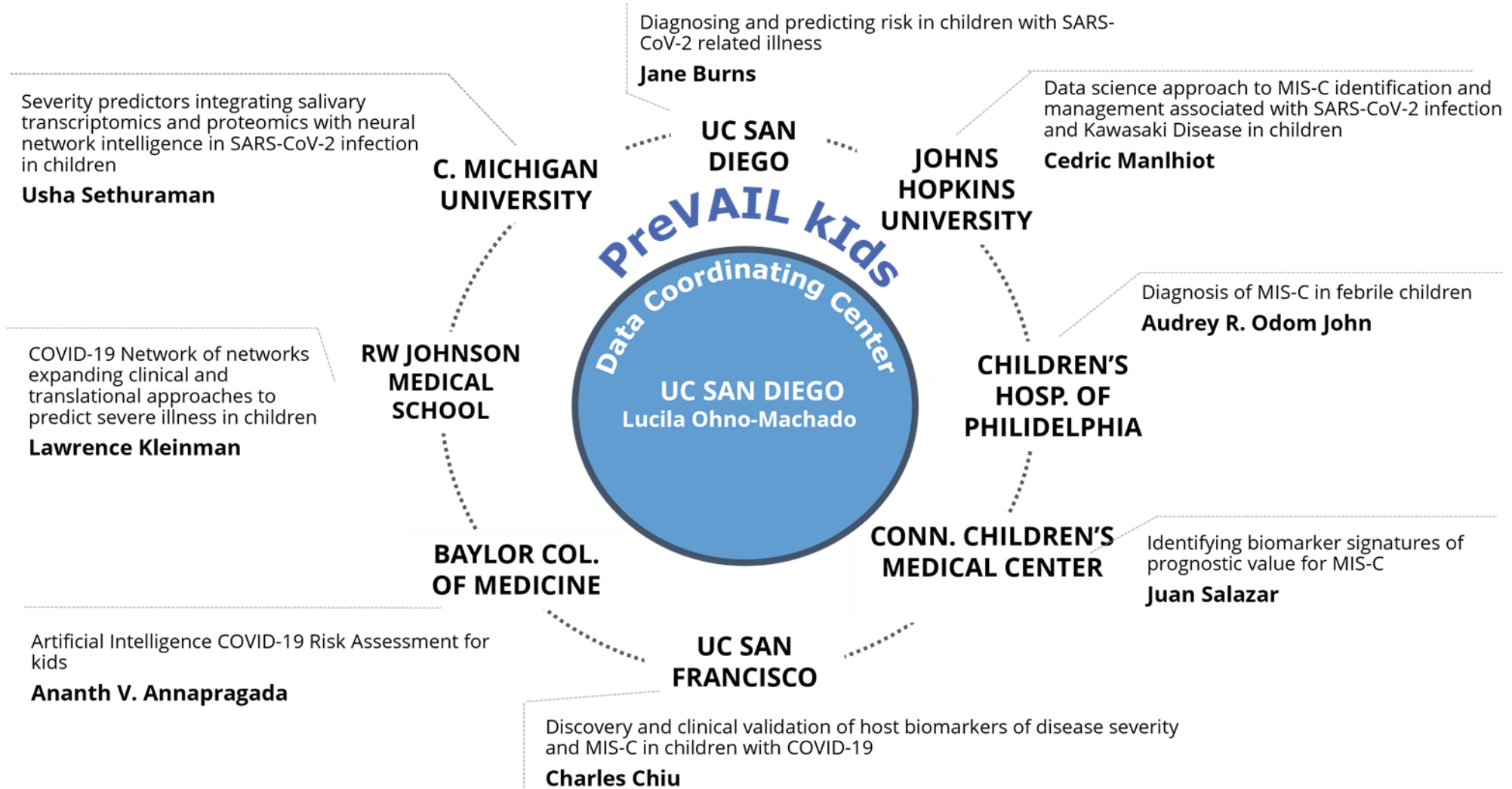
Includes:

- 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





RADx-UP Return to School

Diagnostic Testing Approaches

Goal

Develop and test COVID-19 diagnostic testing approaches to safely return children and staff to the in-person school setting in underserved and vulnerable communities.

Approach

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies

Return to School Phase I and II

OTA-21-004 and OTA-21-007

Program Information: ~\$60M awarded; 16 projects

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies, including in-school testing, in community pediatric primary care clinics, childcare centers, preschool, and school settings serving primarily underserved or disadvantaged children and their families.

Overview

- **Awarded 8 projects** in April 2021; **additional 8 projects** in June/July 2021
- **Strategies for school-based settings** to combine frequent testing with proven safety measures to reduce the spread of COVID-19



About

Research

Related Activities

News

Contact



About CARING for Children with COVID

The CARING for Children with COVID program is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and National Heart, Lung, and Blood Institute (NHLBI) in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID). This program leverages the clinical networks of NICHD, NHLBI, and NIAID to research SARS-CoV-2 infection in children and related conditions, including **multisystem inflammatory syndrome in children (MIS-C)**.

More information about the clinical networks **is available in the following sections** and more details about the research they are conducting is available on the **Research page**.

CARING4KidswithCOVID.nih.gov

Menstruation in the Media

The New York Times

No, We Don't Know if Vaccines Change Your Period

We do know that researchers do not study menstruation enough.

April 20, 2021

OPINION

The False Rumors About Vaccines That Are Scaring Women

We don't know everything about Covid-19, but getting immunized is still the best way to protect your health.

Jan. 26, 2021

ARIZONA NEWS

Valley doctor says COVID-19 vaccine will not impact periods or fertility

BY ALI VETNAR | MAY 17, 2021 AT 4:35 AM
UPDATED: MAY 17, 2021 AT 8:05 AM

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Doctor explains how COVID vaccine might be affecting menstrual cycles

by Rebecca Pryor | Sunday, May 16th 2021



A private school in Miami, citing false claims, bars vaccinated teachers from contact with students.



Awards Made

Awarded August 2021: \$1.67 million to five institutions

Boston University
PI: Lauren A. Wise, Sc.D.

Uses a prospective pre-conception study of over 15,000 geographically and racially/ethnically diverse women. Extensive control of confounders like stress and information bias.

Harvard Medical School
PI: Laura Allen Payne, Ph.D.

Focuses completely on adolescents who are being followed as part of the parent study on gynecologic pain. Mechanistic component - will collect saliva for hormone and immune markers.

Oregon Health and Science University
PI: Alison B. Edelman, M.D.

Uses two large preexisting US-based datasets from two FDA-approved fertility awareness applications, Clue and Natural Cycles (which contain data from over 2 million US women during the pandemic).

Michigan State University
PI: Stacey Ann Missmer, Sc.D.

Uses 3 different existing cohorts (together over 65000 female participants) with menstrual tracking for years, one of which oversamples for people with endometriosis and regularly collects blood samples.

Johns Hopkins University
PI: Mostafa Borahay, Ph.D.

Supplements existing cohort of participants with menstrual diary tracking with additional recruitment. Mechanistic component examining menstrual effluent.



RECOVER: Researching COVID to Enhance Recovery

www.recovercovid.org

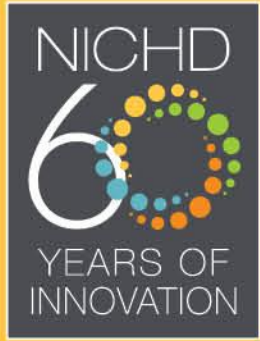


RECOVER

Researching COVID to Enhance Recovery



National Institutes of Health
Researching COVID to Enhance Recovery



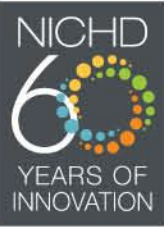
Selected non-COVID Updates

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



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
 - COVID-19
 - Pediatric Research Workforce
 - Pediatric Medical Devices



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





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](#))



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>



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)



- Centralized resource for researchers to share de-identified data from studies funded by NICHHD
- Serves as a portal for requesting biospecimens from selected studies in DASH
- Aims to accelerate scientific findings to ultimately improve human health



<https://dash.nichd.nih.gov>

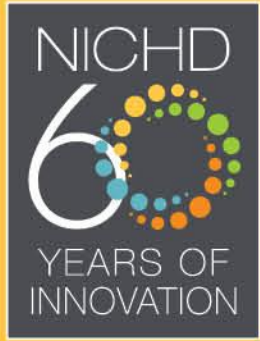


Selected NICHD Funding Opportunities



- **NICHD Program Project Grants for HIV Research (P01) (RFA-HD-23-026)**
- **Notice of Special Interest (NOSI) - Emerging and Existing Issues of Coronavirus Disease 2019 (COVID-19) Research Related to the Health and Well-Being of Women, Children and Individuals with Physical and/or Intellectual Disabilities (NOT-HD-22-002,-003)**





Thank You!
Questions??