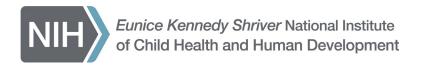
NICHD Director's Report

Diana W. Bianchi, M.D. September 9, 2021



Talk Outline

- NIH Budget
- COVID-19 Research Updates
- Maternal Morbidity and Mortality
- STrategies to EnRich Inclusion and AchieVe Equity (STRIVE) Initiative
- NICHD Staff Updates



FY 2022 Appropriations

- President's Budget released May 28, 2021
 - NIH \$51 billion
 - NICHD \$1.94 billion, which includes:
 - \$30 M for the IMPROVE initiative (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone)
 - \$15 M for research on SARS-CoV-2 infection in children
 - Proposed moving INCLUDE and ECHO (and their budgets) to NICHD
- House Appropriations bill released in July
 - NIH -\$49 billion
 - NICHD \$1.69 billion
 - Includes \$30 M for IMPROVE
 - \$15 M for SARS-CoV-2 research in children
 - \$3 billion Advanced Research Projects Agency for Health
 - NIH listening sessions

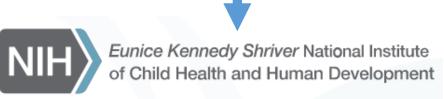




FY 2022 Appropriations – Next Steps

- <u>Senate Appropriations</u> bill and report language timing TBD
- Reconcile House and Senate bills; pass into law
- NIH funding increases include set aside funds for many initiatives, including cybersecurity enhancements;
 Gabriella Miller Kids First Research Program
 - The increases (if passed) will support these initiatives in addition to investigator-initiated projects
- NICHD funds are allocated to intramural research and across extramural research branches to support investigator-initiated applications and targeted funding announcements





Healthy pregnancies. Healthy children. Healthy and optimal lives.





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

Keeping up with NICHD and COVID



Home > Research > Supported Networks & Initiatives > COVID-19 Research and NICHD

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COVID-19 Research and NICHD

Since the beginning of the COVID-19 pandemic, NICHD has worked to understand the effects of the virus among populations central to the NICHD mission, including pregnant and postpartum women, children and adolescents, and people with disabilities.

For the latest COVID-19 public health information and treatment/prevention guidance, visit https://www.cdc.gov/coronavirus/2019-ncov/index.html.

The institute has generated research proposals and projects; collaborated with other NIH institutes, centers, and offices (ICOs) and federal agencies; and initiated studies to help build a research base on the SARS-CoV-2 virus.

Supported Networks and Initiatives

COVID-19 Research and NICHD

COVID-19 in NICHD Populations

Basic Science and COVID-19

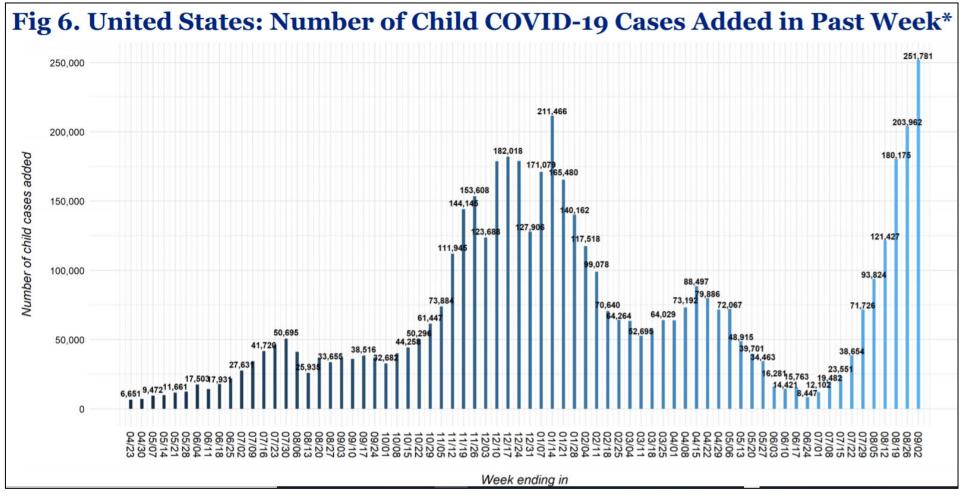
<u>COVID-19 Projects, Data, and Data</u> Harmonization

Research News, Events, and Features

COVID-19 Resources and Websites

Funding Opportunities and Notices

AAP/CHA State-Level Case Counts in Children



- Data from 49 states, DC, NYC, PR, GU
- Cases at the highest point of the pandemic
- 10% increase in cases over the past two weeks
- Children represented 26.8% of the weekly reported cases
- Caveat: Number of cases in children is an underestimate; geographic variability is significant and metrics such as definition of age vary at the state level*



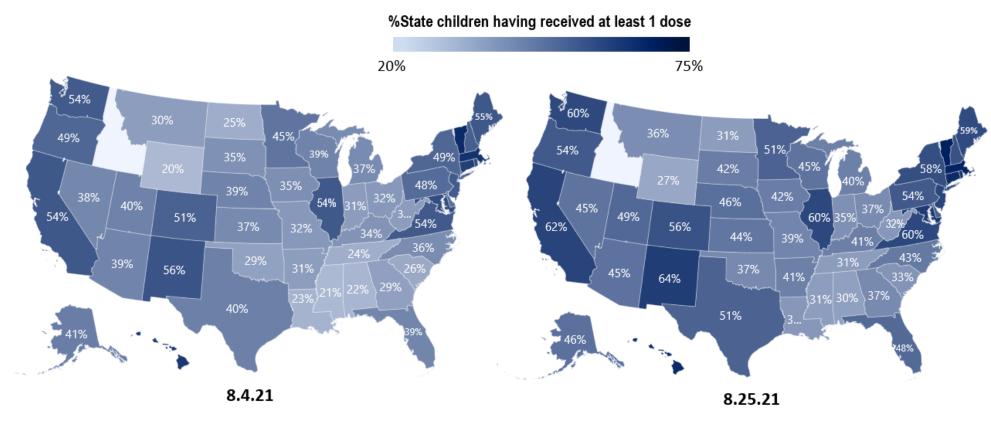
Children and COVID-19 – Hot Topics

Delta variant severity

Masking

- Effects on transmission and child development
- Vaccination
- Return to School

At Least 1 Dose Among Children 12-17 Years---3 Week Improvement



Source: AAP analysis of data series titled 'COVID -19 Vaccinations in the United States, Jurisdiction'. CDC COVID -19 Data Tracker (URL: https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc). Idaho information not available. Check state's web sites for additional or more recent information



NIH Rapid Acceleration of DiagnosticsSM-Underserved Populations Return to School Diagnostic Testing Initiative

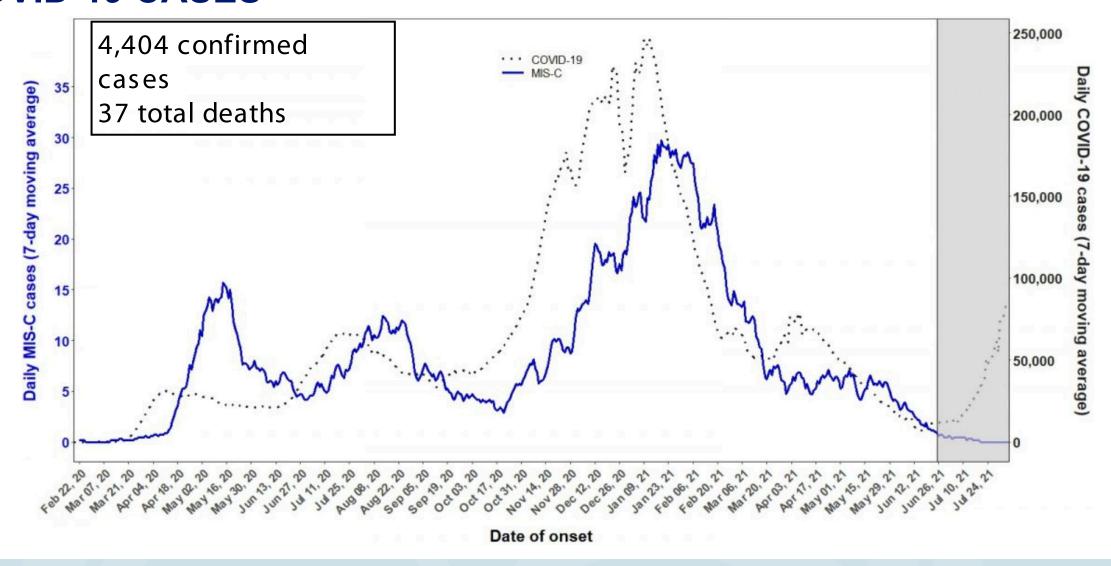
- <u>Goals</u>: Provide evidence to aid efforts to keep students in inperson learning environments, with special focus on underserved and vulnerable populations
 - Demonstrate effectiveness, sustainability, and scalability of COVID-19 testing approaches and mitigation strategies (e.g., masking, physical distancing, vaccination as applicable) in school settings
 - Provide information to understand the social, behavioral, and ethical implications of implementation of COVID-19 testing within identified communities
- \$58 M program plans to enroll 600,000 students and at least 75,000 supporting staff/adults at sites across 13 states



Sonia Lee, Ph.D.

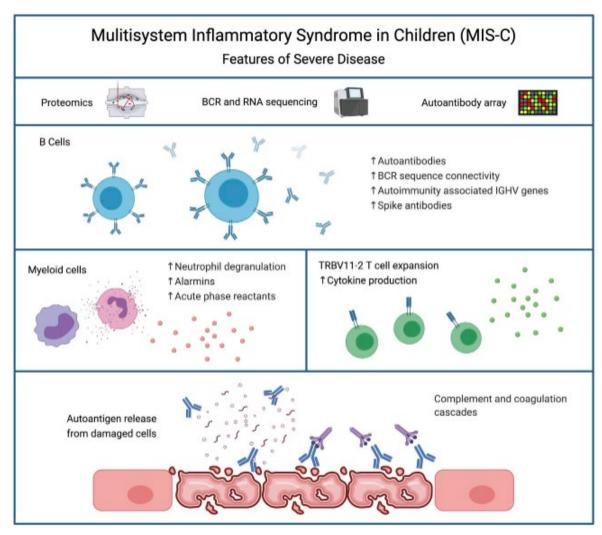


DAILY Multisystem Inflammatory Syndrome in Children (MIS-C) AND COVID-19 CASES



Toward Predictive Biomarkers for MIS-C

- Autoimmune signature of MIS-C
 - Autoantibodies targeted to both ubiquitously expressed and tissuespecific antigens
 - Suggests autoantigen release and excessive antigenic drive resulting from systemic tissue damage
- Identified a cluster of patients with enhanced neutrophil responses and high anti-spike IgG and autoantibody titers
- Potential pathogenic pathways

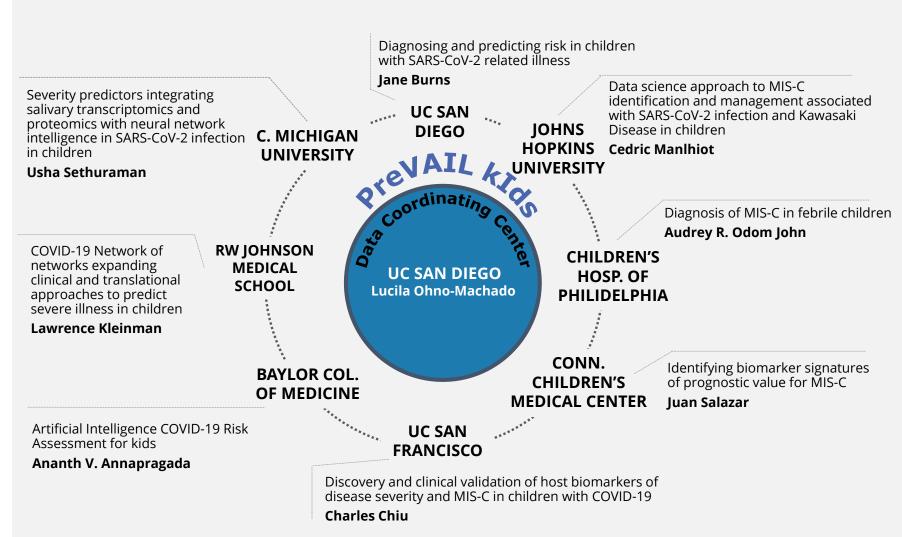


Porritt et al. J Clin Invest. https://doi.org/10.1172/JCI151520



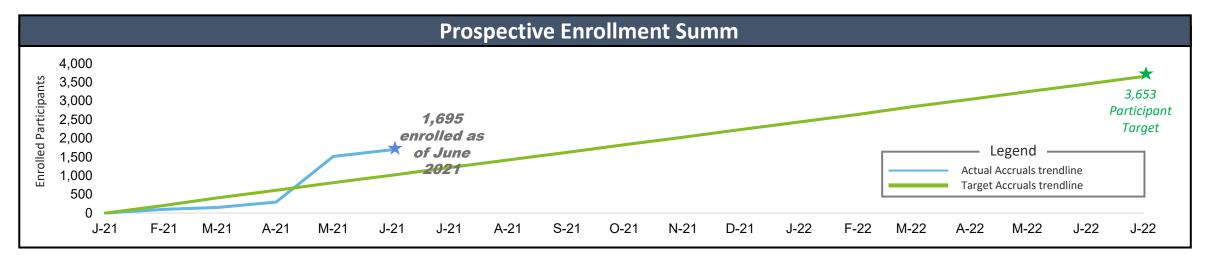
<u>Pre</u>dicting <u>Viral-Associated Inflammatory disease severity in children with <u>Laboratory diagnostics</u> and artificial <u>Intelligence</u></u>

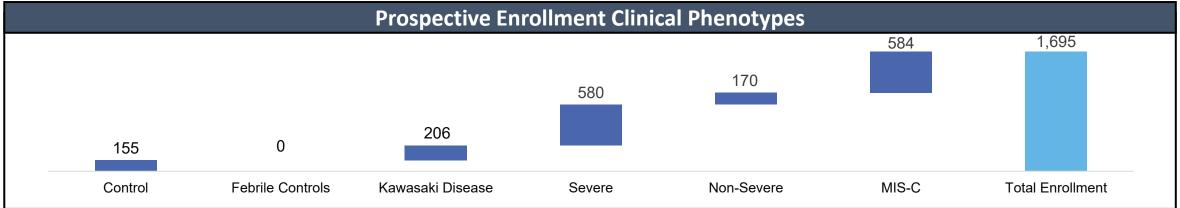




- 8 Teams w/ multi-disciplinary expertise to address Program aims
- Access to diverse patient populations in > 75 sites across 30 US States
- International collaborations in UK, Canada, Asia, & S. America
- Enrolling >16,000 children with substantial racial and ethnic diversity
- Leveraging established biorepositories
- The studies include both prospective and retrospective enrollments

Progress on PreVAIL klds Enrollment as of [6/24]



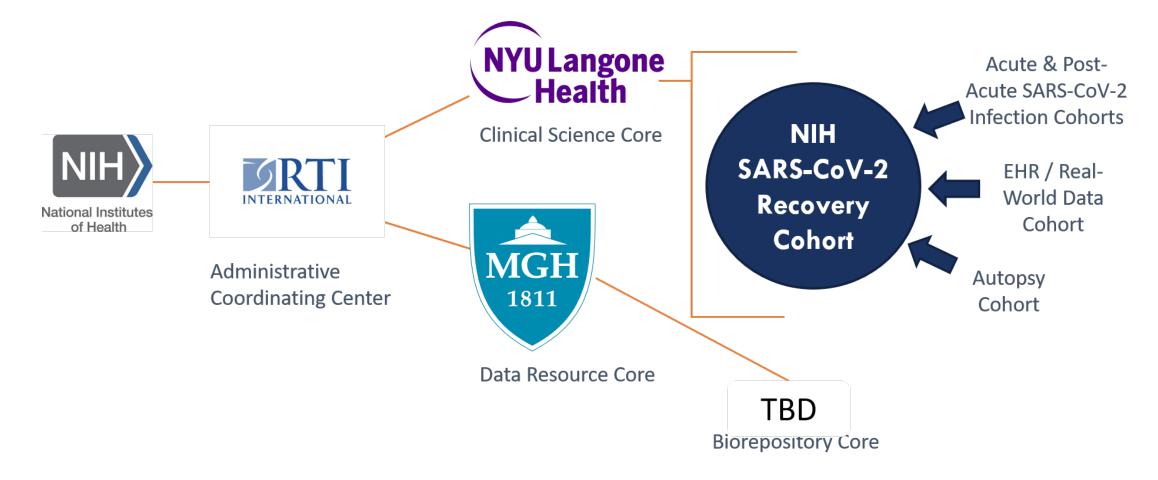


Retrospective Enrollment 5 awards enrolled 21,651 patients retrospectively across all clinical phenotypes



Researching COVID to Enhance Recovery (RECOVER): Cores & Cohorts







COVID-19 Pandemic's Impact on Fertility Writ Large

- Newly supported research areas:
 - COVID-19 effects on population fertility
 - Roles of pandemic-related stress on fertility plans
 - COVID-19 birth outcomes and differential impact across population subgroups
 - Families with low income, families of color, families in rural and urban areas
- Future research may include studies of COVID-19 vaccines and fertility
 - No evidence to date of an association
 - More evidence needed to address vaccine hesitancy in people of reproductive age





COVID-19 Vaccination and Menstruation

- NICHD awarded \$1.6 million in one-year supplemental grants to five institutions to explore links between COVID-19 vaccination and menstrual changes
- The new awards will help to provide evidence as to whether menstrual changes are linked to vaccination, how long the changes last and determine underlying mechanisms
- One grant focused exclusively on adolescents



Washington Post, September 7, 2021



Standardized definition of placental SARS-CoV-2 infection

- A panel of experts convened by the National Institutes of Health has recommended standardized criteria to define infection of the placenta with SARS-CoV-2: https://doi.org/10.1016/j.ajog.2021.07.029
 - Includes best methods to evaluate placental SARS-CoV-2 infection for research and clinical applications
- Recommendations include:
 - Techniques to detect SARS-CoV-2 replication, viral transcripts, or proteins in placental tissue
 - Methods to classify SARS-CoV-2 infection
 - Reporting guidelines for publication, including standards for reporting methodology
 - Guidance for handling, processing, and examining placental tissue



American Journal of Obstetrics and Gynecology

Available online 5 August 2021

In Press, Journal Pre-proof (7)



SPECIAL REPORT: A standardized definition of placental infection by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a consensus statement from the National Institutes of Health/Eunice Kennedy Shriver National Institute of Child Health and Human Development (NIH/NICHD) SARS-CoV-2 placental infection workshop

Drucilla J. Roberts ¹ A M. Andrea G. Edlow ², *, Roberto J. Romero ³, *, Carolyn B. Coyne ⁴, David T. Ting ⁵, Jason L. Hornick ⁶, Sherif R. Zaki ⁷, Upasana Das Adhikari ⁸, Lena Serghides ⁹, Stephanie L. Gaw ¹⁰, Torri D. Metz ¹¹, all members of the NIH/NICHD SARS-CoV-2 Placental Infection Workshop ¹²





Maternal Morbidity and Mortality

Congressional Interaction

- Meeting with the Black Maternal Health Caucus on July 20, 2021
 - NIH Director Francis Collins, NICHD Director Bianchi, NINR Director Shannon Zenk, and ORWH Director Janine Clayton
- Six Members of Congress participated in the meeting
 - Representatives Lauren Underwood (D-IL) and Alma Adams (D-NC) (caucus co-chairs); and Caucus Members Representatives Lisa Blunt Rochester (D-DE), Billy Long (R-MO), Ayanna Pressley (D-MA), and David Trone (D-MD)
- Conversation focused on addressing health disparities in maternal mortality and the IMRPOVE Initiative





New Maternal Health Activities

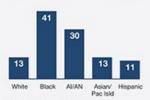
- New NIH-wide Maternal Morbidity and Mortality reporting category for FY 2020
- White House Interagency Policy Committee on Maternal Health
- IMPROVE initiative supplements for research focused on the intersection of maternal health, structural racism, and discrimination, and how these were affected by the pandemic
- Decoding Maternal Morbidity Data Challenge
 - Submissions due October 15
 - https://www.challenge.gov/challenge/decoding-maternalmorbidity-data-challenge/
- Interdisciplinary community-engaged research to reduce/eliminate infections/sepsis as MMM causes

Accelerating Research to Prevent Maternal Morbidity & Mortality (MMM): At-A-Glance

The United States has the highest maternal mortality ratio of developed countries.



Blacks & American Indians/ Alaska Natives are at highest risk for maternal mortality* in the United States.



*Deaths ner 100 000 live hirths

National Institutes of Health (NIH) research has identified risk factors, explored disparities. & developed & tested treatments to improve maternal health & care, but more action is needed to make pregnancy & childbirth safer in the United States.

NIH 2020 MMM Research by the Numbers



\$224 Million



551



Institutes & Centers Involved

(+ NIH Office of the Director)

NIH 2020 MMM Research Highlights

re-pregnancy & Pregnancy Loss

- · NIH launches the Implementing a Maternal Health & PBregnancy Outcomes Vision for Everyone (MPROVE) initiative to study all aspects of maternal health, including racial/ethnic disparities in MMM.
- Low-dose aspirin may improve pregnancy & live birth chances for some women, while cannabis & opioid use may reduce pregnancy chances.
- · Pre-pregnancy cardiovascular health factors in first-time mothers may increase pregnancy complication risks.

- Gestational Research Assessment for COVID-19 (GRAVID) study early findings: Severe COVID-19 disease increases complication risks.
- Maternal & Pediatric pBecision IN Therapeutics (MPRINT) Hub expands pharmacology studies in pregnant & lactating women.
- Risk of prenatal & postpartum death is significantly higher for women living in maternity care deserts (counties lacking obstetric care hospitals or midwives).

In the U.S., 700 die and 50,000 are at risk for severe disease from

problems

in/after

pregnancy.

abor & Delivery

- · Women in U.S. rural areas are more likely to need blood transfusions during labor & delivery.
- Single-dose azithromycin during labor may reduce risk of maternal infections & death in low- & middle-
- Using MRI & specialized software, researchers can track the electrical signals of contractions across the entire surface of the uterus during labor to detect possible problems.

Postpartum

- · First-ever drug treatment specifically approved for postportum degression, which research shows may persist for up to 3 years after birth.
- Risk for postpartum stroke is highest in the first 10 days after giving birth.
- In first-time mothers, pregnancy complications double the risk for high blood pressure & other problems later in life.



https://www.nichd.nih.gov/health/topics/maternalmortality/accelerating-research



STrategies to EnRich Inclusion and AchieVe Equity (STRIVE) Initiative

STRIVE: Health Disparities Workshop and IdeaScale

Advanced Search

NICHD STRIVE for Cha...





About Campaign Trending Search Ideas **NICHD STRIVE for Change** Improving equity, diversity, and inclusion and **Active Campaigns** addressing disparities through research STRIVE **Current Campaigns** Browse Ideas The STrategies to EnRich Inclusion and AchieVe Equity www.nichd.gov/strive (STRIVE) initiative, led by the Eunice Kennedy Shriver National Institute of Child Health and Human NICHD STRIVE for Change ^ Development (NICHD) Office of Health Equity, will chart a bold new course to promote equity, diversity, and Improving equity, diversity, and inclusion (EDI) in the institute's workforce and among inclusion and addressing... See those who participate in and conduct its research STRIVE consists of three committees that focus on 5 Ideas Posted (i)

Visit the STRIVE website for more information. https://www.nichd.nih.gov/strive; send comments or ideas to NICHD STRIVE@nih.gov.

Workshop Series: Visit https://www.nichd.nih.gov/about/org/strive/engagement for details.

- July 14, 2021, STRIVE for Change: Establishing a New Frontier in Health Disparities Research Across the Lifecourse (videocast available)
- **August 4, 2021**, How Social Identity Can Impact and Promote Health: A Look Across Populations, Lifespans, and Generations (videocast available)
- August 25, 2021, Societal Influences on Health and Health Disparities During Childhood
- **September 15, 2021**, Community-Engaged Research Strategies to Mitigate Health Disparities in NICHD Populations
- October 6, 2021, STRIVE for Change: Weaving Translation and Implementation Science into the Fabric of Health Disparities Research





Chris McBain, PhD Acting Scientific Director

- Previously Deputy Scientific Director for NICHD Intramural Research
- Joined NICHD in 1993 as an investigator within the Laboratory of Cellular and Molecular Neurophysiology; now Chief of that lab
- BSc from the University of Aberdeen, Scotland
- PhD from the University of Cambridge, England
- Postdoctoral fellowship at the University of North Carolina at Chapel Hill and Duke University
- Dr. McBain will give the annual update from the Intramural Research Program





Welcome to New NICHD Staff!



Rebecca Rosen, PhD

Director

Office of Data Science

and Sharing



Helena Ahn, PhD

Program Officer

GHDB/DER

New Team Lead for Grants Management: Teri Pailen



Welcome to New NICHD Fellows!



Emma Carpenter, PhD

Presidential Management

Fellow

OD



Dave Gutekunst, PhD

AAAS Fellow

NCMRR



Karen Mulak, PhD

AAAS Fellow

OD/OSPRA



Leadership Positions: Searches Underway

NICHD Scientific Director

- Readvertised the position
- Deadline was August 1; robust group of applications
- Search Committee reviewed applications and interviews are being scheduled
- We are hiring for multiple other positions
 - Tenure track investigators in basic and translational science
 - Opportunities in Division of Extramural Research
 - More info at https://www.nichd.nih.gov/about/jobs





Thank You!

Questions?