



January 2024

DASH Quarterly eUpdate

In this issue:

- DASH Updates
 - Highlight of the Month: Second Release of Public-use ECHO Data
 - Studies Available in DASH
 - o Recently Released Studies
 - Studies Offering Biospecimens in DASH
 - Publications Resulting from Data Reuse
 - o DASH Data/Biospecimen Use Acknowledgments
- Implementing the NIH Policy for Data Management & Sharing
 - o DASH and the Data Management and Sharing Policy
 - o Plan to Submit Your Data to DASH
 - NICHD Office of Data Science and Sharing (ODSS) Web Resources
 - NIH Resources and Guidance for the DMS Policy
 - o Webinars and Trainings on Implementing the NIH Data Management and Sharing Policy
 - NIH Data Sharing and Reuse Seminar Series
- NICHD Funding Opportunities and Notices
- NICHD Relevant Funding Opportunities and Notices

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DASH Updates

Highlight of the Month: Second Release of Public-use ECHO Data

As of January 2024, researchers have access to the second release of de-identified public-use data from the ECHO Cohort in DASH.

This new release provides data on 63,215 ECHO Cohort participants. The release adds extra data from participants included in the initial release as well as data on participants enrolled in the ECHO Cohort Study between Sept. 1, 2021, and Aug. 31, 2022.

Within the new data are bioassay results regarding chemicals such as flame retardants, metals and metalloids, tobacco metabolites, fungicides and herbicides, and other analytes.

Also available: Additional harmonized data for household chemical exposure for the child and during pregnancy; child strengths and difficulties questionnaire; perceived stress scale; caregiver general cognition; child blood pressure; early childhood education; gender identity; and public assistance.

Note: Your access to the first release does not automatically transfer to the new release. Please submit a new request in DASH for ECHO v2 new release.

Please find more information on the ECHO Cohort v2 in Recently Released Studies section below.

Studies Available in DASH

There are 225 studies archived in DASH covering 60 research topics including Pregnancy, Infant Care and Health, Infant Mortality, Pharmacology, Pediatric Injury, Child Health, and Traumatic Brain Injury.

Recently Released Studies

• Environmental influences on Child Health Outcomes (ECHO)-wide Cohort - 2nd Release (ECHO Cohort v2)

Study Description: The National Institutes of Health launched the Environmental influences on Child Health Outcomes (ECHO) initiative in September 2016. The Program focuses on five pediatric outcome areas: obesity, neurodevelopment, upper and lower airways, pre-, peri-, and postnatal outcomes, and positive health. The ECHO-wide Cohort Study, presented here, incorporates longitudinal data on a growing 30,000 pregnancies and 50,000 children from 69 pediatric cohorts to investigate how exposure to environmental factors — including physical, chemical, biological, social, behavioral, natural, and built environments — impact child health and development. By bringing data together into one large ECHO-wide Cohort, scientists can address questions that no single cohort, or a few working together, can answer. Most of the cohorts existed prior to ECHO, bringing a wealth of extant data for compilation and harmonization, in addition to standardized collection of new essential and recommended data elements.

Release Date: January 8, 2024

 Get Connected: Linking YMSM to Adequate Care through a Multilevel, Tailored WebApp Intervention (ATN 139)

Study Description: Get Connected (GC) was a WebApp that motivated YMSM to get tested for HIV and other sexually transmitted infections (STIs), and to use Pre-Exposure Prophylaxis (PrEP). Participants were randomly placed in one of two conditions. The first condition, included the full version of GC, which included content tailored to users' demographic characteristics (e.g., age, race/ethnicity, relationship status), HIV/STI prevention behaviors (e.g., HIV/STI testing history) and sociocultural context (e.g., homelessness, incarceration). The second condition, called the control, only included the GC testing locator (TLO). Participants were recruited from three cities characterized by high HIV incidence, and followed over 12 months. Assessments were collected at 30 days and at 3, 6, 9 and 12 month follow-up. We tested the efficacy of GC for increasing HIV-negative or HIV-unknown YMSM's successful uptake of HIV prevention services (e.g., routine HIV/STI testing) and PrEP awareness and willingness, as compared to the attention-control condition over a 12-month period. We found both versions of GC were efficacious in increasing routine HIV and STI testing over a 12-month period. Regional differences were observed. HIV/STI testing was higher among the GC version in multi-site, whereas the TLO encouraged greater HIV/STI testing in multi-site. No differences between conditions were noted for multi-site. PrEP uptake was similar across both versions of the GC WebApp.

Release Date: December 12, 2023

Vitamin D Oral Replacement in Asthma (VDORA1)

Study Description: The overall objective of the study was to determine the pharmacokinetics of Vitamin D supplementation in children who have asthma and are overweight or obese. This study had two parts. In part 1, study participants were randomized to receive one of four doses of vitamin D supplementation in international units (IU) over at 16-week period: 1) Single 50,000 IU loading dose + 6000 IU daily dose; 2) Single 50,000 IU loading dose + 10,000 IU daily dose: 3) 6000 IU daily dose; or 4) 600 IU daily dose. Based on pharmacokinetic analysis, one of the doses (1-3) was selected to use in part 2. In part 2, study participants were randomized to the dose selected in part 1 or the 600 IU daily dose of vitamin D supplementation which were administered over a 16-week dosing period. Across both parts, safety of each dose regimen of vitamin D supplementation was evaluated, and the effectiveness of each dose to achieve a serum level of 25(OH)D greater than or equal to 40 ng/ml was assessed.

Release Date: November 16, 2023

• <u>Triggered Escalating Real-time Adherence Intervention to Promote Rapid HIV Viral Suppression among</u> Youth Living with HIV Failing Antiretroviral Therapy: The TERA Study (ATN 152)

Study Description: ATN 152 TERA was a multi-site two-arm RCT comparing HIV-1 RNA viral suppression and electronic dose monitored (EDM) ART adherence in youth living with HIV with detectable viral load assigned to receive either the TERA intervention or standard of care for HIV. Participants assigned to the 12-week intervention condition received 3 remote coaching sessions through video enabled conferencing and interacted via text and phone in real-time for any delayed or missed doses signaled by the participant's EDM. The intervention was evaluated on viral suppression at week 12 and participants were followed through to week 48. Viral suppression and adherence, as well as psychosocial functioning, across the 48 weeks were also examined. The intervention did not improve viral suppression, but did improve ART adherence as measured by the EDM through week 36.

Release Date: November 13, 2023

A Multi-center Randomized Trial of Laparotomy vs. Drainage as the Initial Surgical Therapy for ELBW Infants with Necrotizing Enterocolitis (NEC) or Isolated Intestinal Perforation (IP): Outcomes at 18-22 months Adjusted Age (NEST)

Study Description: This was a multicenter, randomized clinical trial to determine which initial surgical treatment resulted in the lowest rate of death or neurodevelopmental impairment (NDI) in premature infants with necrotizing enterocolitis (NEC) or isolated intestinal perforation (IP). The randomized cohort included 308 infants aged $\leq 8\,0/7$ weeks of age and $\leq 1,000\,$ g birthweight that were born at centers with the ability to perform both laparotomy and drainage for which a decision was made by the attending pediatric surgeon to perform surgery for suspected NEC or IP. Death or NDI occurred in 69% of infants in the laparotomy group versus 70% with drainage. There was no overall difference in death or NDI rates at 18 to 22 months corrected age between initial laparotomy versus drainage. However, the preoperative diagnosis of NEC or IP modified the impact of initial treatment.

Release Date: November 13, 2023

• An Observational Study of Cesarean Section and Vaginal Birth after Cesarean Section (CSEC)

Study Description: This study, also known as the Cesarean Registry, was a prospective four-year observational study of all women with a singleton gestation and a prior cesarean delivery at 19 academic medical centers. Maternal and perinatal outcomes were compared between women who underwent a trial of labor and women who had an elective repeated cesarean delivery without labor. The primary objective was to determine the efficacy and safety of trial of labor in this population. The primary analysis concluded that a trial of labor by women with a history of cesarean delivery is associated with an increased risk of adverse perinatal outcomes and a higher rate of maternal adverse events, as compared with elective repeated cesarean delivery. The magnitude of these risks is small; however, this information is important for women and health care providers who are making choices about the type of delivery. The data released in DASH contains 70,411 women and 73,257 infants. Eight centers participated throughout the four years while eleven participated for two years. Demographic data, details of the obstetrical history, and information about intrapartum and postpartum events were recorded. Neonatal data were collected up to 120 days after delivery or at the time of hospital discharge, including the clinical course for infants admitted to the NICU. Separate data-collection forms were completed for maternal or infant complications.

Release Date: November 13, 2023

• Promoting Recovery Optimization with WALKing Exercise after Stroke (PROWALKS)

Study Description: The specific objective of this study was to test whether and for whom combining fast walking training with a step activity monitoring program (FAST+SAM) is superior in improving real-world walking activity compared to fast walking training alone (FAST) or a step activity monitoring and feedback program alone (SAM) in those with chronic stroke. Using a randomized controlled experimental design, 250 chronic (> 6 months) stroke survivors were randomized to 12 weeks of fast walking training (FAST), a step activity monitoring program (SAM) or a fast walking training + step activity monitoring program (FAST+SAM). The primary (steps per day) and secondary (self-selected walking speed, walking endurance, oxygen consumption) outcomes were assessed by blinded evaluators prior to initiating treatment and after the last treatment. Steps per day significantly increased in both the SAM and FAST+SAM groups but not in the FAST group. All groups showed similar improvement in walking speed and endurance, and none of the groups showed changes in oxygen consumption following the intervention.

Release Date: November 8, 2023

• Feasibility Trial of the iAMHealthy Intervention for Healthy Weight in Rural Children Recruited From Primary Care Clinics (iAmHealthy)

Study Description: The iAmHealthy Trial was a 6-month feasibility trial comparing the iAmHealthy behavioral intervention versus newsletter intervention. The trial was conducted in four clinics affiliated with the IDeA States Pediatric Clinical Trial Network and assessed: participant recruitment, participant retention, intervention dose, and blinding. The iAmHealthy behavioral intervention included group and individual sessions for caregivers and children delivered via video conference on study-supplied tablets. These sessions focused on nutrition, physical activity, and behavior change. The iAmHealthy behavioral intervention also included a monthly newsletter that focused on general child health. The newsletter intervention used only the same monthly newsletter. The objectives of the study were to determine which of 2 recruitment methods works best to get rural participants to join a research study about children who weigh more than is considered healthy and to determine what works to keep participants in the study. The study involved a total of 104 children between 6 to 11 years of age who live in a rural area and one of their caregivers. Key outcomes include the determination that the traditional recruitment method produced a higher percent success rate (21.7%) but a 23 times lower number of candidates (23 vs. 535 for the consecutive recruitment strategy) and a 20 percent lower number of enrolled participants (5 vs. 99). Each intervention had a high retention rate, 86.5% for the iAmHealthy intervention and 96.2% for the News Letter only intervention.

Release Date: November 8, 2023

• Safety of Furosemide in Premature Infants at Risk of Bronchopulmonary Dysplasia (BPCA FUR01)

Study Description: The primary objective of this multi-center, randomized, dose-escalating, placebocontrolled study was to describe the safety of furosemide in premature infants at risk of bronchopulmonary dysplasia (BPD). The secondary objectives were to evaluate the preliminary effectiveness and pharmacokinetics of furosemide. The rates of adverse events (AEs), serious adverse events (SAEs) and related SAEs were similar by cohort among furosemide treated participants. Among most safety events of special interest (death, failed hearing test, nephrocalcinosis/nephrolithiasis), there were no significant differences seen between furosemide versus placebo treated participants. The lack of difference between furosemide and placebo group for failed hearing test and nephrocalcinosis/nephrolithiasis is consistent with recent manuscripts comparing infants exposed to furosemide versus unexposed and with systematic reviews of the safety of furosemide. However, there were more electrolyte abnormality AEs in the furosemide versus placebo infants. There was no difference in the preliminary effectiveness outcomes of moderate to severe BPD or death or in the change of BPD over time. In the population pharmacokinetics analysis of furosemide in premature neonates and infants, body weight and postnatal age were found to be influential covariates on furosemide clearance. In premature infants at risk for BPD, furosemide increased the risk of electrolyte AEs but did not increase overall risk of AEs, hearing loss, or nephrocalcinosis/nephrolithiasis.

Release Date: October 20, 2023

 Management of Myelomeningocele Study - A Randomized Trial of Prenatal Versus Postnatal Repair of Myelomeningocele (MOMS, MOMS2)

Study Description: The Management of Myelomeningocele Study (MOMS), a randomized trial of prenatal versus postnatal repair for myelomeningocele, randomly assigned eligible women to undergo either prenatal surgery before 26 weeks of gestation or standard postnatal repair. One primary outcome was a composite of fetal or neonatal death or the need for placement of a cerebrospinal fluid shunt by the age of 12 months. Another primary outcome at 30 months was a composite of mental development and motor function. This study found that prenatal surgery resulted in reduced hindbrain herniation and need for shunt diversion at 12 months of age and better motor function at 30 months. (Funded by the National Institutes of Health; ClinicalTrials.gov number, NCT00060606.) In the MOMS2 study, we compared adaptive behavior and other outcomes at school age (5.9–10.3 years) between prenatal versus postnatal surgery groups for 161 children who were enrolled in MOMS. Assessments included neuropsychological and physical evaluations. Children were evaluated by trained blinded examiners at either a MOMS center or their home. We concluded that there was no significant difference between surgery groups in overall adaptive behavior. Long-term benefits of prenatal surgery included improved

mobility and independent functioning and fewer surgeries for shunt placement and revision, with no strong evidence of improved cognitive functioning.

Release Date: October 2, 2023

Studies Offering Biospecimens in DASH

Over 190,000 biospecimens and 29 sample types from eight studies are available for request through DASH. These collections span research topics including HIV/AIDS, Infant and Child Health, Women's Health, Pregnancy, Preterm Labor and Birth, and Breastfeeding. Additional biospecimen collections will also be added in the future. To explore available samples in DASH, select the **Study Name** in the following list of studies offering biospecimens:

- Genomic and Proteomic Network for Preterm Birth Research Expression Profiling Study (GPN-PBR EP) biospecimens
- Genomic and Proteomic Network for Preterm Birth Research GWAS Case Control Study (GPN-PBR CC) biospecimens
- Genomic and Proteomic Network for Preterm Birth Research Longitudinal Cohort Study (GPN-PBR LS) biospecimens
- Prospective Study of Perinatal Transmission of HIV Infection and Developmental Outcome of Children Infected with HIV: Mothers and Infants Cohort Study (MICS) biospecimens
- <u>A Prospective, Observational Study of HIV-Infected Pregnant Women and HIV-Exposed, Uninfected</u> Children at Clinical Sites in Latin American Countries (NISDI LILAC) biospecimens
- <u>A Prospective, Observational Study of HIV-Infected Pregnant Women and Their Infants at Clinical Sites</u> in Latin American and Caribbean Countries (NISDI Perinatal) biospecimens
- A Prospective, Observational Study of HIV-Exposed and HIV-Infected Children at Clinical Sites in Latin American and Caribbean Countries (NISDI Pediatric) biospecimens
- NISDI Pediatric Latin American Countries Epidemiological Study: A Prospective, Observational Study of HIV-infected Children at Clinical Sites in Latin American Countries (NISDI PLACES) biospecimens

Additional Specimens Available: The Reproductive Medicine Network (RMN) has serum, semen and/or DNA biospecimens available for request. If you are interested in obtaining biospecimens from these studies, please refer to the RMN Biospecimen Sharing Policy under the list of Descriptive Documents on the study pages:

- Pregnancy in Polycystic Ovary Syndrome II: A 25 Week Double-Blind Randomized Trial of Clomiphene
 Citrate and Letrozole for the Treatment of Infertility in Women with Polycystic Ovary Syndrome (PPCOS
 II) serum
- Assessment of Multiple Intrauterine Gestations from Ovarian Stimulation (AMIGOS) serum, semen, and DNA
- Males, Antioxidants, and Infertility Trial (MOXI) serum, semen, and DNA

Publications Resulting from Data Reuse

Since the launch of DASH in August 2015, there have been 106 peer-reviewed publications resulting from DASH data reuse, with an average time of 1.6 years to publish. We encourage you to look through these publications on the <u>Publications from DASH Data Reuse</u> page.

Recent Publications:

• Association of Adolescents' Body Mass Index Classification With Preventive Clinical Care Receipt

Authors: Sujatha Seetharaman, Pamela A Matson, Maria E Trent, Annemarie McCartney Swamy, Arik V Marcell

Publication Date: December 1, 2023

DASH Study: Next Generation Health Study (NEXT)

• Low-dose aspirin and racial disparities in spontaneous preterm delivery in low-risk individuals

Authors: Veronica A Kane, Maria Andrikopoulou, Clara Bertozzi-Villa, Joseph Mims, Kelsey Pinson,

Cynthia Gyamfi-Bannerman

Publication Date: October 1, 2023

DASH Study: Clinical Trial of Low-Dose Aspirin (60 mg) as a Preventive of Preeclampsia (MFMU LRA)

Psychosocial Stressors as a Determinant of Maternal Cardiovascular Health During Pregnancy

Authors: Theresa M. Boyer, Vennela Avula, Anum S. Minhas, Arthur J. Vaught, Garima Sharma,

Alison Gemmill

Publication Date: August 15, 2023

DASH Study: Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)

• The impact of postinjection urinary tract infection on efficacy of intravesical onabotulinumtoxinA-A secondary analysis

Authors: Marina Guirguis Hanna, Megan Bradley, Halina Zyczynski, Li Wang, Lauren Giugale

Publication Date: August 1, 2023

DASH Study: Refractory Overactive Bladder: Sacral Neuromodulation v. Botulinum Toxin Assessment (ROSETTA)

• Evaluation of heterogeneity in effect of therapeutic hypothermia by sex among infants with neonatal encephalopathy

Authors: Elizabeth K Sewell, Seetha Shankaran, Girija Natarajan, Abbot Laptook, Abhik Das, Scott A McDonald, Shannon Hamrick, Michelle Baack, Matthew Rysavy, Rosemary D Higgins, Lina Chalak, Ravi Mangal Patel

Publication Date: April 4, 2023

DASH Study: Randomized Controlled Trial of Induced Hypothermia for Hypoxic-Ischemic Encephalopathy in Term Infants (Hypothermia)

• Temperature dysregulation during therapeutic hypothermia predicts long-term outcome in neonates with HIE

Authors: Ulrike Mietzsch, John J Flibotte, Janessa B Law, Mihai Puia-Dumitrescu, Sandra E Juul,

Thomas R Wood

Publication Date: March 8, 2023

DASH Study: Optimizing Cooling Strategies at <6 Hours of Age for Neonatal Hypoxic-Ischemic Encephalopathy (Optimizing Cooling)

• Racial/ethnic disparities in sleep-disordered breathing during pregnancy in the nuMoM2b study.

Authors: Maristella Lucchini, Yael Rayport, Linda Valeri, Sanja Jelic, Marie-Pierre St-Onge, Louise M.

O'Brien, Carmela Alcantara **Publication Date:** March 2, 2023

DASH Study: Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)

 Not within spitting distance: Salivary immunoassays of estradiol have subpar validity for predicting cycle phase

Authors: Ruben C. Arslan, Khandis Blake, Laura J. Botzet, Paul-Christian Bürkner, Lisa DeBruine, Tom Fiers, Nicholas Grebe, Amanda Hahn, Ben C. Jones, Urszula M. Marcinkowska, Sunni L.

Mumford, Lars Penke, James R. Roney, Enrique F. Schisterman, Julia Stern

Publication Date: February 28, 2023

DASH Study: The BioCycle Study (BioCycle)

DASH Data/Biospecimen Use Acknowledgments and DOI Usage

As a reminder, NICHD requires all investigators who access research data and biospecimens from NICHD DASH to acknowledge the contributing investigator(s) who conducted the original study, the funding organization(s) that supported the original study, and NICHD DASH in all resulting oral or written presentations, disclosures, or publications of the analyses. All DASH studies are uniquely identified with a Digital Object Identifier (DOI) and investigators should use the DASH DOI to cite the study in any manuscripts or other published content resulting from the use of data from that study.

Specific guidance for acknowledgement text and DOI citation is provided in the following DASH resources:

- The Data Request Form obtained from DASH when processing a request online; the Data Request Form also includes any study-specific acknowledgements as specified by the data submitter.
- The respective study overview page in DASH.

Implementing the NIH Policy for Data Management & Sharing

DASH and the Data Management and Sharing Policy

DASH is a key resource for many NICHD extramural and intramural researchers to comply with the new NIH Data Management and Sharing (DMS) Policy (DMS Policy), which went into effect on January 25, 2023. The final DMS Policy strongly encourages the use of established repositories such as DASH for sharing scientific data. DASH adheres to the desired characteristics for data sharing repositories described in Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research, including support for free and easy access, access controls for human participant data, curation and quality assurance, and security and integrity. DASH creates Digital Object Identifiers (DOIs) as unique persistent identifiers for tracking and citing all datasets shared through DASH.

Plan to Submit Your Data to DASH

All researchers funded by or seeking funding from NICHD for clinical and population health research can share data in DASH. Researchers seeking funding from another NIH Institute or Center in a research area relevant to the NICHD mission may also be able to share data through DASH. You may Contact SupportDASH@mail.nih.gov with a request to obtain a Letter of Approval for sharing your study data in DASH.

The new DASH <u>Submission Resources</u> page contains information to guide researchers developing Data Management and Sharing Plans as part of their grant applications or intramural clinical protocols. Researchers planning to use DASH should include DASH submission-specific milestones and timelines in their DMS Plan and should consider those milestones when developing a DMS budget. Costs associated with biospecimen sharing should not be included in DMS budgets. DMS Plan milestones include:

- Researchers who plan to share data through DASH are required to submit an <u>Institutional Certification</u> to verify that study data are appropriate for sharing in DASH, within the first year of grant award.
- By the second year of grant award, investigators should submit a draft DASH Codebook, which is a templated data dictionary that captures information about datasets, variables, and coded values for all data submitted for a given study.
- As soon as the data collection protocol is complete, researchers should submit the final DASH Codebook to DASH.
- Investigators will share data associated with a publication through DASH no later than the first date
 of electronic publication and will share all study data by the end of the award performance period. Plan
 to submit data to DASH 4-6 months prior to expected publication release date for a given dataset.

All researchers funded by or seeking funding from NICHD for clinical research can share clinical data in DASH and do not need a Letter of Approval to include data sharing in DASH in their Data Management and Sharing Plan.

NICHD Office of Data Science and Sharing (ODSS) Web Resources

The NICHD Office of Data Science and Sharing (ODSS) is a trusted informational resource for NICHD staff and researchers on all NIH data sharing policies. The <u>NICHD ODSS website</u> contains a Data Management and Sharing (DMS) Policy Resources section for the NICHD researchers developing and implementing their DMS Plans, including <u>Tips for Writing a DMS Plan</u>, <u>Example DMS Plans</u>, the <u>NICHD Data Repository Finder</u> to help researchers find data repositories where they can share data, and informed consent informational resources.

Check out the new <u>Data Standards page that describes common data standards that may be relevant to NICHD research and how adopting them can improve data usability and interoperability throughout the data lifecycle!</u>

NIH Resources and Guidance for the DMS Policy

NIH continues to update their <u>Scientific Data Sharing</u> site resource. At this site, you and your investigators can stay up to date on public-facing NIH data sharing policy-related statements, FAQs, resources (including the DMS Plan format page), news, and events, and look for training opportunities.

OER announced that instructions and processes for extramural researchers to budget DMS costs will change on October 5, 2023. See: <u>NIH Application Instruction Updates – Data Management and Sharing (DMS) Costs</u> (NOT-OD-23-161)

Additionally, researchers can use the following NIH-wide resources to identify data repositories for sharing their data:

- NIH Repositories for Sharing Scientific Data: <a href="https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data/policy/sharing-scientific-data/repositories-for-sharing-scientific-data/policy/sharing-scientific-
- **Genomic Data Repositories**: https://sharing.nih.gov/genomic-data-sharing-policy/submitting-genomic-data/where-to-submit-genomic-data
- National Library of Medicine repository resources:
 - o https://www.nnlm.gov/finder
 - o https://www.nlm.nih.gov/NIHbmic/domain specific repositories.html

Webinars and Trainings on Implementing the NIH Data Management and Sharing Policy

NIH is hosting several webinars to provide information and training on implementing the DMS Policy.

- Data Sharing Presentations from 2023 NIH Grants Conference Available
 - The 2022-2023 conference season is over, but the opportunity to learn from it isn't. Explore the
 recordings, slide sets, and transcripts. If you have questions, check out the FAQs and other
 resources on the NIH Grants & Funding site.
 - Genomic Data Sharing, Other Sharing Policies, and Open Q&A: <u>Video</u>, <u>PowerPoint</u>, <u>Transcript</u>
 - The NIH Final Policy for Data Management and Sharing is in Effect: Planning for Success!: Video, PowerPoint, Transcript
- NICHD Implementation of the DMS Policy at a FASEB DataWorks! Salon
 NICHD ODSS Deputy Director Valerie Cotton presented findings from NICHD implementation of the
 DMS Policy at a FASEB DataWorks! Salon on January 17, 2024. The Salon is a virtual conversation
 series about best practices and emerging issues in data management. January's topic is creating a
 quality data management plan, which focused on guidance to understand the DMS Policy and how to
 create quality plans as well as learnings/common mistakes to avoid as investigators make plans now
 that we have information from the policy's first year.
- Federal Demonstration Partnership (FDP) NIH Data Management & Sharing (DMS) Pilot

 NICHD's Office of Data Science & Sharing (ODSS), in collaboration with the FDP, is seeking feedback
 on DMS Plan templates as part of this newly launched pilot effort. The Alpha and Bravo templates are
 available on the FDP website or through the DMPTool. ODSS encourages researchers to review and
 use the templates to develop their DMS Plans, and provide-feedback on the templates' effectiveness
 and usability. The Alpha template guides the user through a structured, modular approach to limit the
 need for free text entry, while the Bravo template provides detailed prompts for each type of data and
 options for more free text entry. FDP and NIH will use feedback collected through the pilot to refine the
 templates and make the final versions available.
- NICHD ODSS presented at the third FDP DMS Town Hall. During this Town Hall, NICHD and other NIH
 program officials participating in the <u>FDP Data Management and Sharing pilot</u> shared their preliminary
 observations on the first rounds of DMS plans submitted to NIH. Information was also shared on Phase
 2 of the pilot which will focus on cost principles and budgeting issues related to data sharing. Slides and
 recording can be found on the <u>NIH Learning webpage</u>.

NIH Data Sharing and Reuse Seminar Series

The NIH Office of Data Science Strategy hosted a seminar series to highlight exemplars of data sharing and reuse. The monthly series highlighted researchers who took existing data and found clever ways to reuse the data or generate new findings. A different NIH institute or center (IC) also shares its data science activities each month. Recordings of past seminars are available on the <u>Seminar Web page</u>.

• On December 8, 2023, Dr. Joaquin M. Espinosa held a presentation on <u>"Being FAIR in the pan-omics era:</u> lessons from the INCLUDE Project".

In June 2018, NIH launched the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome) Project to address critical health and quality-of-life needs for individuals with Down syndrome. INCLUDE studies conditions that affect individuals with Down syndrome and the general population, such as Alzheimer's disease/dementia, autism, cataracts, celiac disease, congenital heart disease, and diabetes. The NICHD Intellectual and Developmental Disabilities Branch (IDDB) leads multiple INCLUDE activities and is leveraging existing Down syndrome research and outreach efforts to augment the power of the INCLUDE project.

IDDB worked across NIH on the NIH INCLUDE/Down Syndrome Research Plan, which was released in March 2023.

• This month's seminar was held on January 12, 2024 by Dr. Michelle Hribar who presented "Common Data Models for Ophthalmology Research Collaboration". Please visit the <u>Webinar Page</u> for more information.

NICHD Funding Opportunities and Notices

All active Funding Opportunity Announcements issued by NICHD can be found on the <u>NICHD Grants and Contracts</u> page. To learn more about a funding opportunity, select the **Name of the Funding Opportunity** in the following list:

- NOT-MH-24-115 Notice of Special Interest (NOSI): Translation of BRAIN Initiative Technologies to the Marketplace
- PAR-24-081 Omics Phenotypes Related to Down Syndrome for the INCLUDE Project (X01 Clinical Trial Not Allowed)
- NOT-OD-24-032 Notice of Special Interest (NOSI): Research on the Health of Women of Understudied, Underrepresented and Underreported (U3) Populations (Admin Supp Clinical Trial Optional)
- RFA-MH-25-115 <u>BRAIN Initiative: Marmoset Colonies for Neuroscience Research (U24 Clinical Trials Not Allowed)</u>
- RFA-MH-25-116 <u>BRAIN Initiative: Marmoset Coordination Center (U24 Clinical Trials Not Allowed)</u>
- RFA-DA-24-042 <u>BRAIN Initiative: Brain-Behavior Quantification and Synchronization Transformative</u> and Integrative Models of Behavior at the Organismal Level (R34 Clinical Trial Optional)
- NOT-DC-24-010 Notice of Special Interest (NOSI): Tackling Acquisition of Language in Kids (TALK)
 R01 Research Projects
- RFA-HD-25-008 <u>Development of Novel Nonsteroidal Contraceptive Methods (R61/R33 Clinical Trial Not Allowed)</u>
- RFA-NS-24-019 <u>HEAL Initiative: Non-addictive Analgesic Therapeutics Development [Small Molecules and Biologics] to Treat Pain (UG3/UH3 Clinical Trial Optional)</u>
- RFA-NS-24-028 <u>BRAIN Initiative Connectivity across Scales Data Coordinating Center (BRAIN CONNECTS DCC)</u> (U24 Clinical Trial Not Allowed)
- RFA-NS-24-023 <u>HEAL INITIATIVE</u>: Development and validation of remote or patient wearable device derived objective biosignatures or functional assessments to monitor pain for use as endpoints in clinical trials (UG3/UH3 - Clinical Trial Optional)

- PAR-22-261 <u>Archiving and Documenting Child Health and Human Development Data Sets (R03</u> Clinical Trial Not Allowed)
- PAR-23-075 <u>Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data</u> (R03 Clinical Trial Not Allowed)
- PAR-23-037 <u>Multisite Clinical Research: Leveraging Network Infrastructure to Advance Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities (U01 Clinical Trial Optional)</u>
- PAR-21-229 <u>Screening and Functional Validation of Human Birth Defects Genomic Variants (R01 Clinical Trial Not Allowed)</u>

NICHD - Relevant Funding Opportunities and Notices

Additional active Funding Opportunity Announcements relevant to NICHD are included below. To learn more about a funding opportunity, select the **Name of the Funding Opportunity** in the following list:

- NOT-GM-24-020 <u>Topic Areas of Interest for Joint NIH/NSF Science of Science Approach to Analyzing and Innovating the Biomedical Research Enterprise (SoS:BIO) Program</u>
- NOT-OD-24-031 Notice of Special Interest (NOSI): Administrative Supplement for Research and Capacity Building Efforts Related to Bioethical Issues (Admin Supp Clinical Trial Optional)
- RFA-MH-24-180 <u>Bidirectional Influences Between Adolescent Social Media Use and Mental Health</u> (R01 Clinical Trial Optional)
- RFA-MH-24-181 <u>Bidirectional Influences Between Adolescent Social Media Use and Mental Health</u> (R21 Clinical Trial Optional)
- RFA-DA-25-021 Effect of HIV and Substance Use Comorbidity on the Placenta and Maternal Outcomes (R01 Clinical Trial Optional)
- NOT-OD-24-005 Request for Information (RFI): Best Practices for Sharing NIH Supported Research Software
- RFA-NS-24-023 <u>HEAL INITIATIVE</u>: Development and validation of remote or patient wearable device derived objective biosignatures or functional assessments to monitor pain for use as endpoints in clinical trials (UG3/UH3 - Clinical Trial Optional)
- PAR-23-237 <u>Enhancement and Management of Established Biomedical Data Repositories and Knowledgebases (U24 Clinical Trial Not Allowed)</u>
- RFA-HG-23-002 <u>Broadening Opportunities for Computational Genomics and Data Science Education</u> (UE5 Clinical Trial Not Allowed)
- NOT-OD-23-165 Notice of NIH Participation in the National Science Foundation Solicitation NSF 23-614: Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science
- NOT-OD-23-166 Notice of Special Interest in Research on Family Support and Rejection in the Health and Well-Being of SGM Populations
- NOT-OD-23-123 Notice of Special Interest (NOSI): Administrative Supplements to Enhance Institutional
 Data Science Capacity
- PAR-23-132 NIDCR Small Research Grants for Analyses of Existing Genomics Data (R03 Clinical Trial Not Allowed)
- PAR-23-133 NIDCR Research Grants for Analyses of Existing Genomics Data (R01 Clinical Trial Not Allowed)
- RFA-DA-24-027 <u>Education Activities for Responsible Analyses of Complex, Large-Scale Data (R25-Clinical Trial Not Allowed)</u>

- PAR-23-089 <u>Data Harmonization</u>, <u>Curation and Secondary Analysis of Existing Clinical Datasets</u> (R61/R33 Clinical Trial Not Allowed)
- NOT-OD-23-068 <u>Notice of Special Interest (NOSI)</u>: Revision Applications to add a Curation and <u>Informatics Component to existing Animal and Biological Material Resource Centers (P40) (Clinical Trials Not Allowed)</u>
- NOT-LM-23-001 Notice of Special Interest (NOSI): Computational and Statistical Methods to Enhance
 Discovery from Health Data
- PAR-22-261 <u>Archiving and Documenting Child Health and Human Development Data Sets (R03</u> Clinical Trial Not Allowed)
- NOT-CA-23-026 Notice to Correct and Clarify Eligibility Requirements in PAR-21-306, NCI Research Specialist (Clinical Scientist) Award (R50 Clinical Trial Not Allowed)
- NOT-GM-23-015 Notice of Special Interest (NOSI): Optimization of Data Storage and Utilization for the Sequence Read Archive (SRA)

Previous issues of the DASH Quarterly eUpdate are available on the <u>NICHD ODSS Website</u> in the NICHD Data and Specimen Hub (DASH) section.

Questions? Please contact the DASH Administrator at SupportDASH@mail.nih.gov.

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