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

DASH Data and Specimen Hub

September 2022

DASH Quarterly eUpdate

In this issue:

Preparing for the NIH Policy for Data Management and Sharing

DASH and the NIH Policy for Data Management and Sharing

DASH is a key resource for many NICHD extramural researchers to comply with the new NIH Data Management and Sharing (DMS) Policy (DMS Policy), which goes into effect 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 will soon implement Digital Object Identifiers (DOIs) as a unique persistent identifier for tracking and citing all datasets shared through DASH.

Most NICHD researchers collecting clinical data from human participants should be able to share scientific data through DASH. Submission Resources in DASH include items that will help researchers with elements of their Data Management and Sharing Plans as part of their grant applications or intramural clinical protocols. Researchers planning to use DASH should describe how they will prepare for data submission to DASH in their Data Management and Sharing Plan. This includes using the DASH Codebook (as described in the Promoting Data Interoperability: DASH Codebook section in this eUpdate), describing standards applied to the data that will be documented in the codebook, de-identifying data prior to submission, using standard data formats, providing associated documentation about the data, providing timelines for sharing data (at the time of an associated publication or at the end of the award period, whichever comes first), and completing DASH-related data submission agreements in a timely manner.

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

The DMS Policy will apply to funding applications and proposals submitted to NIH on or after January 25, 2023. The NICHD Office of Data Science and Sharing (ODSS) is a trusted informational resource for NICHD staff and researchers on all NIH data and specimen sharing policies. The NICHD ODSS website now contains a Data Management and Sharing Policy Resources section for the NICHD researcher community. The website will be regularly updated as we get close to the DMS Policy effective date of January 25, 2023.

NIH Resources and Guidance for the DMS Policy

NIH has launched a new Scientific Data Sharing site. At this site, you can stay up to date on NIH data sharing policy-related statements, news, and events, and look for training opportunities. To learn more about the NIH DMS Policy, select the **Policy Information Materials** in this list:

- NOT-OD-21-013 Final NIH Policy for Data Management and Sharing
- NOT-OD-21-014 Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
- NOT-OD-21-015 Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
- NOT-OD-21-016 Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research
- NOT-OD-22-189 Implementation Details for the NIH Data Management and Sharing Policy
- NOT-OD-22-198 Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023
- NOT-OD-22-195 New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

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:

- **Understanding the New NIH DMS Policy (September 22, 2022) – Webinar**
  The NIH Office of Science Policy (OSP) and the Office of Extramural Research (OER) invite you to join them for an engaging and interactive webinar focused on the new DMS Policy which goes into effect on January 25, 2023. The second webinar of this two-part series is

titled: "Diving Deeper into the NIH Data Management and Sharing Policy." This webinar expands upon the information presented in the first webinar held August 11, 2022, and dives deeper into topics including privacy protections for data from human participants and justifiable limitations on sharing data. Don't miss this valuable opportunity to hear from policy experts and get your questions answered, September 22, 2022, 1:30 PM EST. Register at Part 2 – Diving Deeper Into DMS Policy Registration. The DMS Webinar Resource Slide Deck and DMS Webinar Recording from Part 1 of the DMS Policy Webinar series are also available from the NIH Scientific Data Sharing website.

- **Data Curation Network (November 15, 2022) – Event Series**

  The Office of Data Science Strategy (ODSS), in partnership with the National Library of Medicine (NLM), organized an event series led by the Data Curation Network (DCN). To prepare for the implementation of the NIH DMS Policy, researchers will need to gain new skills in managing and sharing their data. This event series provided new approaches, methods, and best practices from representatives of the Data Curation Network on management, curation, and sharing to promote transparency, reproducibility, and reuse of research data. Videos of the first session, “Introduction to Data Curation & Services for Researchers” and the second session, “Towards Authenticity: Critical Appraisal of Data Management Plans” are available on the Data Curation Series Webpage.

  The third session, “Applying the CURATE(D) Model for Data Curation”, will take place on November 15, 2022, from 1:00 to 4:00 PM EST. This workshop, geared toward researchers and information professionals, will provide an overview of curating research data through the Data Curation Network’s CURATE(D) model.

- **NIH Data Management and Sharing Requirements Series (on demand) – Webinar**

  The National Library of Medicine (NLM) is hosting a webinar series on the NIH DMS Policy. The series is available as an on demand, online webinar. The class introduces the basics of data management and the new NIH requirements for data management and sharing that will be in place beginning in 2023. This course qualifies for the Data Services Specialization (DSS). This class has 5 modules that can be completed in any order. You can take 1 module or all of them. Each is designed to take 1 hour to complete. View webinars here…

  The modules include:

  1. Introduction to the NIH Data Management Sharing Plan
  2. Practitioner Perspectives: Internal Outreach and Policy
  3. Practitioner Perspectives Education
  4. Practitioner Perspectives: Infrastructure
  5. Policy Recap and Q&A

  The Network of the National Library of Medicine has made recordings of the five webinars available from their “NIH Data Management and Sharing Requirements Series”. This series introduces the basics of data management and the new requirements for data management and sharing that will be in place beginning in 2023. The goal of this series is for attendees to be able to: 1.) Describe basic best practices in data management, 2.) Advise researchers on steps to adhere to the NIH DMS Policy requirement, and 3.) Create a plan for outreach at their own institution.

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 share its data science activities each month. Recordings of past seminars are available on the Seminar Web page.

Other Upcoming Events

- **NLM CDE Training: Standardize Your Research Data with the NIH Common Data Elements Repository (October 4, 2022)**
  NLM is pleased to offer a new training course on common data elements (CDEs). Through active participation and hands-on exercises, this live, interactive, online training course is intended to introduce researchers to CDEs and how to use the NIH Common Data Elements Repository. For more details, see the NIH CDE Repository Resources page.

  Register for the webinar "Standardize Your Research Data with the NIH Common Data Elements Repository" that will take place on October 4, 2022, at 2:00 PM EST.
- **GREI Collaborative Webinar Series on Data Sharing in Generalist Repositories (Various dates)**
  Join us for a series of presentations and panel discussions by generalist repositories to learn about available repository resources and best practices for sharing NIH-funded research. Presented by the members of the NIH Generalist Repository Ecosystem Initiative (GREI): Dryad, Dataverse, Figshare, Mendeley Data, Open Science Framework, and Vivli. View webinars…

DASH Updates

Promoting Data Interoperability: DASH Codebook

Investigators who plan to share data through DASH are now required to submit a DASH Codebook as part of their study submission. The DASH Codebook is a templated data dictionary that captures information about datasets, variables, and coded values for all data submitted for a given study. The DASH Codebook supports quality assurance and data management workflows as well as facilitates search and discovery of study data by enabling visualization of annotated variables and associated statistics in DASH.

The DASH Codebook Template and a User Guide for filling out the DASH Codebook are available for download from the Submission Resources page in DASH. The DASH Team also hosted a DASH Codebook Training/Webinar in June targeted towards investigators who plan on sharing data through DASH. The slide deck that was presented during the Webinar and the Webinar video recording are available from the Submission Resources page in DASH. The DASH Team is available to provide user support as needed and assist investigators with the development of their DASH Codebook.

Investigators are encouraged to develop their study's DASH Codebook early in the data collection process and to make use of the recommended data standards and ontologies provided in the template. Early planning will facilitate the DASH data submission process and contribute to variable-level harmonization across DASH studies.

Annotation and Visualization of Study Variables

The annotation and visualization of study variables in DASH helps users explore dataset content by reviewing variable-level metadata (such as variable descriptions, units, and coded values) and associated statistics, directly from the DASH Dataset Explorer. On the Datasets Search Results page, select any dataset title to access the Dataset Overview page which has the variable-level information.

This feature is currently available for datasets from fifteen studies in DASH. To view a listing of all datasets for a particular study, select the **Study Name** from the following list:

- National Children's Study (NCS)
- Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)
- Consortium on Safe Labor (CSL)
- Antenatal Late Preterm Steroids: A Randomized Placebo Controlled Trial (MFMU ALPS)
- Clinical Trial of Low-Dose Aspirin (60 mg) as a Preventive of Preeclampsia (MFMU LRA)
- Clinical Trial of Low-Dose Aspirin to Prevent Preeclampsia in High Risk Women (MFMU HRA)
- Mid-Trimester Endovaginal Sonography in Women at High Risk for Spontaneous Preterm Delivery (MFMU CRVUS)
- Obstetrical Determinants of Neonatal Survival (MFMU ODNS)
- Screening for Risk Factors for Spontaneous Preterm Delivery (MFMU PREDS)
- Extremely Low Birth Weight (ELBW) Infants Exposed to Furosemide or Bumetanide in the Neonatal Intensive Care Unit (BPCA DPD01)
- Pharmacokinetics of Diazepam in Children with Status Epilepticus (BPCA DZP01)
- Safety of Fluconazole Prophylaxis in Infants (BPCA Fluc Safety)
- Multiple Dose Pharmacokinetic Study of Meropenem in Young Infants (<91 days) with Suspected or Complicated Intra-abdominal Infections (BPCA Meropenem)
- Safety and Pharmacokinetics of Multiple-Dose Intravenous and Oral Clindamycin in Pediatric Subjects with BMI ≥85th Percentile (BPCA CLN01)
- Pharmacokinetics of Antistaphylococcal Antibiotics in Infants - Rifampin (BPCA STA01-Rifampin)

UPCOMING Feature: Digital Object Identifiers

DASH will soon be implementing digital object identifiers (DOIs) to help facilitate search, discovery, and citation of datasets shared through DASH. A DOI is a persistent identifier used to unambiguously identify (and access) published content. DOIs will facilitate linkages between data shared through DASH and published articles, documents, datasets, and other digital objects – increasing transparency in research. DOIs will enable researchers to properly cite data obtained from DASH used for research – increasing the visibility of the original study in DASH. DOIs will also enable DASH data submitters to easily track reuse of their datasets using publicly available tools such as PlumX, Altmetric, Lagotto, Mendeley, and Crossref Event Data (CED).

NEW Feature: NIH Researcher Auth Service

DASH has replaced the NIH Single Sign On (SSO) option with the NIH Researcher Auth Service (RAS) registration and login. Non-NIH users can now login with their eRA Commons and/or Login.gov credentials using RAS. All NIH users will continue to log in with their PIV card to access DASH functionalities that require DASH login.

RAS is a service provided by NIH's Center for Information Technology (CIT) Auth Services to facilitate access to NIH's open and controlled data assets and repositories in a consistent and user-friendly manner. The RAS initiative is advancing data infrastructure and ecosystem goals defined in the NIH Strategic Plan for Data Science. For more information, please visit the NIH RAS Website.

New Studies Available in DASH

There are 204 studies available in DASH covering 53 research topics, including Infant Care and Health, Infant Mortality, Pharmacology, Pediatric Injury, Child Health, and Traumatic Brain Injury. To learn more about a recently submitted study in DASH, select the title of a **Study Name** in the following list:

- Environmental Influences on Child Health Outcomes (ECHO)-wide Cohort (ECHO Cohorts), a program supported by the NIH

  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 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. Data available in DASH are based on an August 31, 2021 data lock.

  Release Date: August 30, 2022

- Efficacy and Impact of Botulinum Toxin A versus Anticholinergic Therapy for the Treatment of Bothersome Urge Urinary Incontinence (ABC Trial) from Gynecologic Health and Disease Branch (GHDB)

  Study Description: Urinary incontinence is a condition that markedly impacts quality of life. Conservative first line treatments for urge incontinence combined with other overactive bladder (OAB) symptoms include behavioral therapy, pelvic floor training +/- biofeedback, or the use of anticholinergic medications. These treatment modalities may not result in total continence and are often not sustained for various reasons. Thus, the objective of the Anticholinergic versus Botox Comparison Study (ABC) was to determine whether a single intra-detrusor injection of botulinum toxin A (Botox A®) is more effective than a standardized regimen of oral anticholinergics in reducing urge urinary incontinence (UUI). Oral anticholinergic therapy and Botox A® by injection were associated with similar reductions in the frequency of daily episodes of UUI. The group receiving Botox A® was less likely to have dry mouth and more likely to have complete resolution of UUI but had higher rates of transient urinary retention and urinary tract infections.

  Release Date: July 16, 2022

- A Phase II Multicenter, Randomized, Double-Blind, Parallel Group, Dose-Ranging, Effect-Controlled Study to Determine the Pharmacokinetics and Pharmacodynamics of Sodium

Nitroprusside (SNP) in Pediatric Subjects (BPCA SNP1) from Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)

Study Description: This was a randomized, double-blind, parallel group, dose-ranging, effect-controlled, multicenter study examining the effects of sodium nitroprusside (SNP) in pediatric patients requiring relative induced hypotension during a surgical or medical procedure. The study goals were to define the onset and offset of blood pressure lowering effects of SNP, to construct a dose-response model that defines the relationship between SNP infusion rate and changes in blood pressure in pediatric patients, and to assess the safety of SNP in pediatric patients requiring controlled reduction of blood pressure. Additional goals were to establish the starting and maximum infusion rates for optimum blood pressure control and a safe dosing regimen. A total of 211 participants were enrolled, and 203 included in the intent-to-treat population. Results indicate that a reasonable starting dose for SNP in this group would be 0.3 µg/kg/min. The clinician can then increase infusion rate to achieve the desired reduction in blood pressure

Release Date: July 12, 2022

Studies Offering Biospecimens in DASH

Over 350,000 biospecimens and 51 sample types from nine 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:

- National Children's Study (NCS) biospecimens and environmental samples:
- 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
- A Prospective, Observational Study of HIV-Infected Pregnant Women and HIV-Exposed, Uninfected Children at Clinical Sites in Latin American Countries (NISDI LILAC) biospecimens
- A Prospective, Observational Study of HIV-Infected Pregnant Women and Their Infants at Clinical Sites 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 74 peer reviewed publications resulting from DASH data reuse, with an average time of 1.7 years to publish. We encourage you to look through these publications on the Publications from DASH Data Reuse page.

Recent Publications:

- Using linear and natural cubic splines, SITAR, and latent trajectory models to characterise nonlinear longitudinal growth trajectories in cohort studies. BMC Med Res Methodol. 2022 Mar 15;22(1):68. doi: 10.1186/s12874-022-01542-8. PMID: 35291947

  Authors: Ahmed Elhakeem, Rachael A. Hughes, Kate Tilling, Diana L. Cousminer, Stefan A. Jackowski, Tim J. Cole, Alex S. F. Kwong, Zheyuan Li, Struan F. A. Grant, Adam D. G. Baxter-Jones, Babette S. Zemel & Deborah A. Lawlor

  DASH Study: Bone Mineral Density in Childhood Study (from Pediatric Growth and Nutrition Branch (PGNB))
- Genome-wide association study implicates novel loci and reveals candidate effector genes for longitudinal pediatric bone accrual. Genome Biol. 2021 Jan 4;22(1):1. doi: 10.1186/s13059-020-02207-9. PMID: 33397451

  Authors: Diana L. Cousminer, Yadav Wagley, James A. Pippin, Ahmed Elhakeem, Gregory P. Way, Matthew C. Pahl, Shana E. McCormack, Alessandra Chesi, Jonathan A. Mitchell, Joseph M. Kindler, Denis Baird, April Hartley, Laura Howe, Heidi J. Kalkwarf, Joan M. Lappe, Sumei Lu, Michelle E. Leonard, Matthew E. Johnson, Hakon Hakonarson, Vicente Gilsanz, John A. Shepherd, Sharon E. Oberfield, Casey S. Greene, Andrea Kelly, Deborah A. Lawlor, Benjamin F. Voight, Andrew D. Wells, Babette S. Zemel, Kurt D. Hankenson, and Struan F. A. Grant

  DASH Study: Bone Mineral Density in Childhood Study (from PGNB)
- Use of physiologically-based pharmacokinetic modeling to inform dosing of the opioid analgesics fentanyl and methadone in children with obesity. CPT Pharmacometrics Syst Pharmacol. 2022 May 2. doi: 10.1002/psp4.12793.

  Authors: Gerhart JG, Carreño FO, Ford JL, Edginton AN, Perrin EM, Watt KM, Muller WJ, Atz AM, Al-Uzri A, Delmore P, Gonzalez D; Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee.

  DASH Study: Pharmacokinetics of Multiple Dose Methadone in Children (from Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB))
- Bone mineral density and current bone health screening practices in Friedreich's Ataxia. Front Neurosci 16: 818750, Mar 2022 Notes: DOI: 10.3389/fnins.2022.818750. PMCID: PMC8964400

Authors: Julia Dunn, Jaclyn Tamaroff, Anna DeDio, Sara Nguyen, Kristin Wade, Nicolette Cilenti, David R Weber, David R Lynch, Shana E McCormack

DASH Study: Bone Mineral Density in Childhood Study (from PGNB)

DASH Data/Biospecimen Use Acknowledgments

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. Specific guidance for acknowledgement text is provided during the data and/or biospecimen request process.

NICHD Funding Opportunities and Notices

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

- NOT-HD-20-022 NOSI: Small Grants for Secondary Analyses of Existing Data Sets and Stored Biospecimens
- PAR-20-064 Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed)

Eunice Kennedy Shriver National Institute of Child Health and Human Development