

June 2024

DASH Quarterly eUpdate

In this issue:

- **DASH Updates**
 - [Studies Available in DASH](#)
 - [Recently Released Studies](#)
 - [Studies Offering Biospecimens in DASH](#)
 - [Publications Resulting from Data Reuse](#)
 - [DASH Data/Biospecimen Use Acknowledgments](#)
- **Implementing the NIH Policy for Data Management & Sharing**
 - [DASH and the Data Management and Sharing Policy](#)
 - [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](#)
 - [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**

Please visit this [link](#) to manage your subscription to this quarterly DASH update

DASH Updates

Studies Available in DASH

There are 228 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

- [Pharmacokinetics of Anti-epileptic Drugs in Obese Children - Topiramate \(BPCA AED01 - Topiramate\)](#)
Study Description: This was a multi-center, prospective, open-label, pharmacokinetic (PK) and safety study of anti-epileptic drugs in obese children age 2 to less than 18 years of age who received drugs per standard of care (SOC), as prescribed by a treating clinician. Participants were enrolled under multiple drugs of interest, including topiramate. Simulation results (with the currently recommended dosing regimens) did not reveal any meaningful difference in the steady-state topiramate trough concentrations between the subgroups of children with and without obesity, across the major pediatric age groups. Therefore, the currently recommended dosing regimen of topiramate can be universally applied to children, irrespective of their obesity status. No AEs were reported in topiramate participants, and no safety concerns were identified in this SOC study.

Release Date: April 2, 2024

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](#)
- [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 122 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 [Publications from DASH Data Reuse](#) page.

Recent Publications:

- [Influence of Food Security Status and Diet Quality on Maternal Gestational Weight Gain](#)
Authors: Joshua R. Sparks, Candice A. Myers, Suzanne Phelan, Robert L. Newton Jr, Shengping Yang, Leanne M. Redman
Publication Date: March 29, 2024
DASH Study: [National Children's Study \(NCS\)](#)
- [Comparing Impact of Overactive Bladder Therapies on Nocturia](#)
Authors: Feven W. Getaneh, Paul Kolm, Hailegeorgis Awulachew, Cheryl B. Iglesia, Alexis A. Dieter
Publication Date: March 1, 2024
DASH Studies: [Efficacy and Impact of Botulinum Toxin A versus Anticholinergic Therapy for the Treatment of Bothersome Urge Urinary Incontinence \(ABC Trial\)](#), [Effects of Surgical Treatment Enhanced with Exercise for Mixed Urinary Incontinence](#), [Refractory Overactive Bladder: Sacral Neuromodulation v. Botulinum Toxin Assessment](#)

- [Longitudinal Fluctuations in Treatment Response After OnabotulinumToxinA and Sacral Neuromodulation for Refractory Urgency Incontinence](#)
Authors: Whitney K. Hendrickson, Chong Zhang, J. Eric Jelovsek, Ingrid E. Nygaard, and Angela P. Presson
Publication Date: October 23, 2023
DASH Study: [Refractory Overactive Bladder: Sacral Neuromodulation v. Botulinum Toxin Assessment \(ROSETTA\)](#)
- [The effect of 12-month postoperative weight change on outcomes following midurethral sling for stress urinary incontinence: a secondary analysis of the ESTEEM and TOMUS randomized trials](#)
Authors: Feven W. Getaneh, Nancy Ringel, Paul Kolm, Cheryl B. Iglesia, Alexis A. Dieter
Publication Date: September 26, 2023
DASH Studies: [Efficacy and Impact of Botulinum Toxin A versus Anticholinergic Therapy for the Treatment of Bothersome Urge Urinary Incontinence \(ABC Trial\)](#), [Effects of Surgical Treatment Enhanced with Exercise for Mixed Urinary Incontinence](#), [Refractory Overactive Bladder: Sacral Neuromodulation v. Botulinum Toxin Assessment](#)
- [Racialized/ethnic disparities in pathways linking social determinants of health, markers of allostatic load, and hypertensive disorders of pregnancy among nulliparous US women](#)
Authors: Monica Keith, Melanie Martin
Publication Date: September 16, 2023
DASH Study: [Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be \(nuMoM2b\)](#)
- [Applying Artificial Intelligence and Machine Learning to Improve Healthcare Outcomes in Marginalized Patient Populations](#)
Authors: Anemone Ahmad Kasasbeh
Publication Date: May 9, 2023
DASH Study: [Consortium on Safe Labor \(CSL\)](#)

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

The [NIH Data Management and Sharing \(DMS\) Policy](#) (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

The DASH [Submission Resources](#) 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 [Institutional Certification](#) 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 [NICHD ODSS website](#) contains a Data Management and Sharing (DMS) Policy Resources section for the NICHD researchers developing and implementing their DMS Plans, including [Tips for Writing a DMS Plan](#), [Example DMS Plans](#), the [NICHD Data Repository Finder](#) to help researchers find data repositories where they can share data, and links to data repository, and informed consent informational resources.

- In June 2024, NICHD ODSS released a new DMS Policy Resource [Common Issues in NIH NIH Data Management & Sharing \(DMS\) Plans](#). The DMS Policy also encourages the use of data standards to improve the usability of shared data, see our [Data Standards page](#) for more.
- In April 2024, NICHD ODSS made a number of updates to the DMS Policy Resource section of the website, including adding tips for "secondary analysis plans" to [Tips for Writing a DMS Plan](#), and additional NICHD-relevant [data standards](#).

NIH Resources and Guidance for the DMS Policy

NIH continues to update their [Scientific Data Sharing](#) 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: [NOT-OD-23-161: NIH Application Instruction Updates – Data Management and Sharing \(DMS\) Costs](#)

OER announced that NIH plans to implement new DMS Policy questions for RPPRs submitted on or after October 1, 2024. See: [NOT-OD-24-123: Reporting Data Management and Sharing \(DMS\) Plan Activities in the Research Performance Progress Report \(RPPR\)](#)

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

- **NIH Repositories for Sharing Scientific Data:** <https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data>
- **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:**
 - <https://www.nlm.gov/finder>
 - 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:** [Video](#), [PowerPoint](#), [Transcript](#)
 - **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 [FDP Data Management and Sharing pilot](#) 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 [NIH Learning webpage](#).

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 [Seminar Web page](#).

This month's seminar was hosted by Dr. Michael Schatz who presented "BioDIGS: BioDiversity and Informatics for Genomics Scholars" on June 14, 2024, at 12:00 PM EST.

Next month's seminar will be hosted by Dr. Satra Ghosh who will present "The Transformative Potential and Challenges of Open Data and Technologies in Neuroscience" on July 12, 2024, at 12:00 PM EST. [Webinar Registration](#).

NICHD Funding Opportunities and Notices

All active Funding Opportunity Announcements issued by NICHD can be found on the [NICHD Grants and Contracts](#) page. To learn more about a funding opportunity, select the **Name of the Funding Opportunity** in the following list:

- NOT-HD-24-017 [Notice of Expiration of PAR-22-261 "Archiving and Documenting Child Health and Human Development Data Sets \(R03 Clinical Trial Not Allowed\)](#)
- 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-DC-24-010 [Notice of Special Interest \(NOSI\): Tackling Acquisition of Language in Kids \(TALK\) R01 Research Projects](#)
- RFA-NS-24-019 [HEAL Initiative: Non-addictive Analgesic Therapeutics Development \[Small Molecules and Biologics\] to Treat Pain \(UG3/UH3 Clinical Trial Optional\)](#)
- RFA-NS-24-028 [BRAIN Initiative Connectivity across Scales Data Coordinating Center \(BRAIN CONNECTS DCC\) \(U24 Clinical Trial Not Allowed\)](#)
- RFA-NS-24-023 [HEAL INITIATIVE: 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 [Archiving and Documenting Child Health and Human Development Data Sets \(R03 Clinical Trial Not Allowed\)](#)
- PAR-23-075 [Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data \(R03 Clinical Trial Not Allowed\)](#)
- PAR-23-037 [Multisite Clinical Research: Leveraging Network Infrastructure to Advance Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities \(U01 Clinical Trial Optional\)](#)
- PAR-21-229 [Screening and Functional Validation of Human Birth Defects Genomic Variants \(R01 Clinical Trial Not Allowed\)](#)

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-PM-24-003 [Request for Information \(RFI\) on Future Data Linkages within the Center for Linkage and Acquisition of Data for the All of Us Research Program](#)
- NOT-GM-24-020 [Topic Areas of Interest for Joint NIH/NSF Science of Science Approach to Analyzing and Innovating the Biomedical Research Enterprise \(SoS:Bio\) Program](#)
- RFA-DA-25-021 [Effect of HIV and Substance Use Comorbidity on the Placenta and Maternal Outcomes \(R01 Clinical Trial Optional\)](#)
- RFA-NS-24-023 [HEAL INITIATIVE: 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 [Enhancement and Management of Established Biomedical Data Repositories and Knowledgebases \(U24 Clinical Trial Not Allowed\)](#)
- RFA-HG-23-002 [Broadening Opportunities for Computational Genomics and Data Science Education \(UE5 Clinical Trial Not Allowed\)](#)
- 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](#)
- 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 \(R01 Clinical Trial Not Allowed\)](#)
- NOT-OD-23-068 [Notice of Special Interest \(NOSI\): Revision Applications to add a Curation and Informatics Component to existing Animal and Biological Material Resource Centers \(P40\) \(Clinical Trials Not Allowed\)](#)
- NOT-LM-23-001 [Notice of Special Interest \(NOSI\): Computational and Statistical Methods to Enhance Discovery from Health Data](#)
- PAR-22-261 [Archiving and Documenting Child Health and Human Development Data Sets \(R03 Clinical Trial Not Allowed\)](#)
- 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 [NICHD ODSS Website](#) in the NICHD Data and Specimen Hub (DASH) section.

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

To subscribe or unsubscribe from this quarterly DASH update, please visit the [link](#) below



Eunice Kennedy Shriver National Institute
of Child Health and Human Development