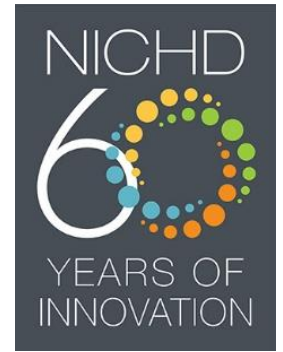# DASH Quarterly eUpdate

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 and intramural 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 creates Digital Object Identifiers (DOIs) as unique persistent identifiers for tracking and citing all datasets shared through DASH.

New Resource for Researchers Planning to Submit Data to DASH

The new 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 the following milestones when developing a DMS budget. Costs associated with biospecimen sharing should not be included in DMS budgets.

- 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.

NICHD Office of Data Science and Sharing (ODSS) Resources for the DMS Policy

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](#) contains a Data Management and Sharing Policy Resources section for the NICHD researcher community, including a new resource to support development of a Data Management and Sharing Plan: **[Tips for Writing a DMS Plan](#)**.

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, resources, news, and events, and look for training opportunities.

Intranet and public site contents include:

- **Flyers and 1-pagers**
  - [Are you ready for NIH's DMS Policy?](#) – A *printable 1-page PDF DMS Policy overview*
  - [The who, what, where, and when of the DMS Policy](#) – *1-pager outlining when the policy goes into effect, what the policy expects, who needs to comply, and where data can be shared*
  - [NIH Data Sharing Policy Comparison](#) – *Table outlining key differences between the 2003 Data Sharing Policy and the new Data Management and Sharing Policy*

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](#)

- NOT-OD-21-213 [Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data](#)

- NOT-OD-22-214 [Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data](#)

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 – Webinar Series**

  The NIH Office of Science Policy (OSP) and the Office of Extramural Research (OER) hosted a two-part webinar series focused on the new NIH DMS Policy which goes into effect on January 25, 2023. The first webinar in this series titled: "*Understanding the New NIH Data Management and Sharing Policy*" covered DMS Policy expectations, the applicability of the policy, how to prepare a Data Management and Sharing Plan, and considerations for sharing data responsibly. The second webinar titled: "*Diving Deeper into the NIH Data Management and Sharing Policy*" expanded upon the information presented in the first webinar and dove deeper into topics including privacy protections for data from human participants and justifiable limitations on sharing data.

  The Resource Slide Deck and Webinar Recording from both parts of the DMS Policy Webinar series are available on the [NIH Scientific Data Sharing website](#)

- **Data Curation Network – Event Series**

  The NIH Office of Data Science Strategy (ODSS), in partnership with 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](#), and the video of the third session, "Applying the CURATE(D) Model for Data Curation, will be available soon.

- **NIH Data Management and Sharing Requirements Series – Webinar Series**

  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.

  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 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. The Network of the National Library of Medicine has also made recordings of the five webinars available from the "NIH Data Management and Sharing Requirements Series" webpage. [View NIH DMS Policy webinars here…](#)

- **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 GREI webinars…

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.

DASH Updates

NEW Feature: Digital Object Identifiers For Existing Studies

The DASH Team has published DOIs for all 207 studies in DASH as part of the NIH DataCite Consortium. These DOIs are now searchable by the public via DataCite Commons. DASH has implemented the Schema.org standard so that studies in DASH are findable in Google Dataset Search – a search engine that searches for metadata of datasets in repositories across the Web. Google Dataset Search relies on dataset providers (such as DASH) to add structured metadata to their sites using the open Schema.org standard.

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).

In the coming months, DASH will implement a feature to capture digital object identifiers (DOIs) during the study submission process to further facilitate search, discovery, and citation of datasets shared through DASH.

NEW: DASH Modernization Contract

On September 26th, 2022, NICHD's ODSS awarded a new contract for DASH Operations and Maintenance and Modernization. The contract was awarded to Deloitte, who assumed primary ownership of the system on December 1st. The modernization effort on this contract will focus on transforming the system into a more modular, web services-based system and will include updates to DASH's user interface, information management standardization, interoperability and security feature development, and new tools and functionalities.

New Studies Available in DASH

There are 207 studies archived in DASH covering 54 research topics including Pregnancy, 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:

- Prospective Cohort Study of HIV and Zika in Infants and Pregnancy (HIV ZIP) from Maternal and Pediatric Infectious Disease Branch (MPIDB)

  Study Description: The aims of this two-phase study of pregnant women and their infants were to compare the incidence of ZIKV infection among pregnant women with and without HIV infection and to determine the risk of adverse maternal and child outcomes associated with ZIKV/HIV co-infection at clinical sites in Brazil, Puerto Rico, and the continental United States. Phase I was designed to enroll

pregnant women/infant pairs who were infected with HIV only, infected with ZIKV only, infected with HIV and ZIKV, and not infected with either HIV or ZIKV. A key goal was to assess the feasibility of enrolling 200 women/infant pairs within a year, with a target of 150 WLHIV, 50 HIV-uninfected women, and a minimum of 20 who were co-infected with HIV/ ZIKV. If the feasibility of Phase I proved successful, Phase II would enroll additional pregnant women/infant pairs to the same four groups, and follow the women and the infants for one year after birth. Primary outcome measures noted HIV suppression at the time of delivery in HIV-infected alone versus HIV/ZIKV co-infected pregnant women, cumulative incidence of ZIKV infection during pregnancy among women with and without HIV infection, incidence of adverse pregnancy outcomes in each cohort and incidence of vertical transmission of HIV and/or ZIKV in women infected with HIV or ZIKV alone versus HIV/ZIKV Co-infection. Observed major congenital malformations were as follows: anhydramnios, cerebral ventriculomegaly, clubfoot, down syndrome, hydrops, hypospadias, patient ductus arteriosus, polydactyly, Potter syndrome, short stature, and syndactyly.

Release Date: November 29, 2022

- [Neuromodulation for Accidental Bowel Leakage (NOTABLe)](#) from Gynecologic Health and Disease Branch (GHDB)

  Study Description: This study was a multi-center, randomized clinical trial of women 18 years or older with refractory accidental bowel leakage (ABL) symptoms who had failed to achieve satisfactory symptom control from 2 first-line treatments for ABL: supervised pelvic muscle training (PMT) and constipating medication. The purpose of this study was to compare percutaneous tibial nerve stimulation (PTNS) to a validated sham to determine if PTNS was effective for the treatment of moderate-to-severe fecal incontinence (FI) in women. The study found that although symptom reduction after 12 weeks of PTNS met a threshold of clinical importance, it did not differ from sham stimulation. The findings of this study did not support the use of PTNS as conducted for the treatment of FI in women.

  Release Date: November 22, 2022

- [Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care - Trimethoprim-Sulfamethoxazole (BPCA POP01-TMP/SMX)](#) from Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)

  Study Description: Aim: Characterize the pharmacokinetics (PK) of enteral TMP and SMX administered to children per standard of care (SOC) as prescribed by their treating caregiver. Methods: The PK analyses include plasma TMP-SMX data following enteral administration from NICHD-2011-POP01, a multicenter, prospective opportunistic PK study of understudied drugs in children less than 21 years of age who received drugs per SOC, as prescribed by a treating caregiver. The NICHD-2011-POP01 study enrolls participants under multiple drugs of interest (DOI) including TMP-SMX, and is actively enrolling participants for other DOIs. Results: A one-compartment model with first-order absorption and elimination described the PK data for both TMP and SMX. No AEs or SAEs related to study procedures were reported. No serious, unexpected, suspected, adverse reactions to TMP-SMX were reported.

  Release Date: September 11, 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 80 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:

- Breastfeeding Duration Is Inversely Associated with Postpartum Allostatic Load: A Possible Mechanism for Improved Maternal Health

  Authors: Bi-sek Hsiao, Holly Laws, Lorraine Cordeiro, Patricia O'Campo, Lindiwe Sibeko
  DASH Study: [Community and Child Health Network (CCHN)](#) (from PPB)

- Demographic and socioeconomic factors predict maternal postpartum rehospitalization: a retrospective nuMoM2b dataset

  Authors: Colin Wakefield, Martin G. Frasch
  DASH Study: [Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)](#) (from PPB)

- Machine learning provides an accurate prognostication model for refractory overactive bladder treatment response and is noninferior to human experts. Neurourology and Urodynamics, 41(3), 813-819.
  Authors: Glenn T Werneburg, Eric A Werneburg, Howard B Goldman, Andrew P Mullhaupt, Sandip P Vasavada
  DASH Study: [Refractory Overactive Bladder: Sacral Neuromodulation v. Botulinum Toxin Assessment](#) (from GHDB)

- Neural networks outperform expert humans in predicting patient impressions of symptomatic improvement following overactive bladder treatment. International Urogynecology Journal, 1-8.
  Authors: Glenn T Werneburg, Eric A Werneburg, Howard B Goldman, Andrew P Mullhaupt, Sandip P Vasavada
  DASH Study: [Refractory Overactive Bladder: Sacral Neuromodulation v. Botulinum Toxin Assessment](#) (from GHDB)

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

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-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)](#)
- PAR-20-126 [NICHD Resource Program Grants in Bioinformatics (P41 Clinical Trial Not Allowed](#)
- PAR-21-229 [Screening and Functional Validation of Human Birth Defects Genomic Variants (R01 Clinical Trial Not Allowed)](#)
- RFA-HD-24-006 [Using Archived Data and Specimen Collections to Advance Maternal and Pediatric HIV/AIDS Research (R21 - 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)](#)

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-AI-23-009 [Notice of Special Interest (NOSI): Administrative Supplements to Prepare Data Assets for Infectious and Immune-mediated Diseases for Inclusion into the NIAID Data Ecosystem](#)
  - [Register now for the Pre-Application Webinar on December 16th from 12:00 p.m. – 1:00 p.m. EST](#)! NIAID staff will present details on context of this NIAID Data Ecosystem NOSI, including time for potential applicants to ask clarifying questions.

    The purpose of this NOSI is to highlight interest in supporting supplemental funding applications for award recipients currently funded by participating NIH Institutes and Centers to prepare data assets relevant for infectious- and immune-mediated disease research for inclusion in the NIAID Data Ecosystem. Research may include studies that strive to generate a better understanding of

mechanisms for the prevention, diagnosis, and treatment of infectious- and immune mediated diseases.

- RFA-RM-23-003 Pilot Projects Enhancing Utility and Usage of Common Fund Data Sets (R03 Clinical Trial Not Allowed)

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 opt out of receiving the DASH Quarterly eUpdate, select Unsubscribe

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Eunice Kennedy Shriver National Institute of Child Health and Human Development