NICHD Data and Specimen Hub (DASH)

Controlled Access to DASH Data

Webinar – August 19, 2022

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Topics

- NICHD DASH Overview
- Controlled Data Access – Process & DASH Policy Requirements
- Resources for Data Requesters
- Q&A

NICHD DASH Overview

DASH Data and Specimen Hub

- Centralized resource for researchers to share de-identified data from studies funded by NICHD
- Serves as a portal for requesting biospecimens from selected studies in DASH
- Launched in August 2015 and governed by the DASH Core Group
- Aims to accelerate scientific findings to ultimately improve human health

203 Studies

487 Data Requests

9 Studies Offering Biospecimens

50 Study Topics

74 Data Use Publications

11 Biospecimen Requests

DASH Content

Top Study Topics

- Breastfeeding & Breast Milk *
- Cerebral Palsy
- Child Health *
- Early Learning
- Early Labor and Birth
- Fertility Problems
- High-Risk Pregnancy
- HIV/AIDS *
- Infant Care & Health *
- Infant Mortality
- Infertility & Fertility
- Labor & Delivery
- Newborn Screening
- Obesity & Overweight
- Pelvic Floor Disorders
- Pharmacology
- Pregnancy *
- Preterm Labor & Birth *
- Stillbirth
- Women's Health*

*biospecimens available

Currently Available Biospecimens

- Amniotic fluid
- Blood
- Breast Milk
- Buffy Coat
- Cord Blood (Buffy Coat, RBC, Plasma, Serum)
- DNA/RNA/Proteins
- Environmental Samples
- Erythrocytes (RBC)
- Hair
- Lymphocytes
- Meconium
- Nail
- Saliva
- Serum/Plasma
- Tissue samples
- Urine
- Vaginal Fluid

Last updated 08/18/2022

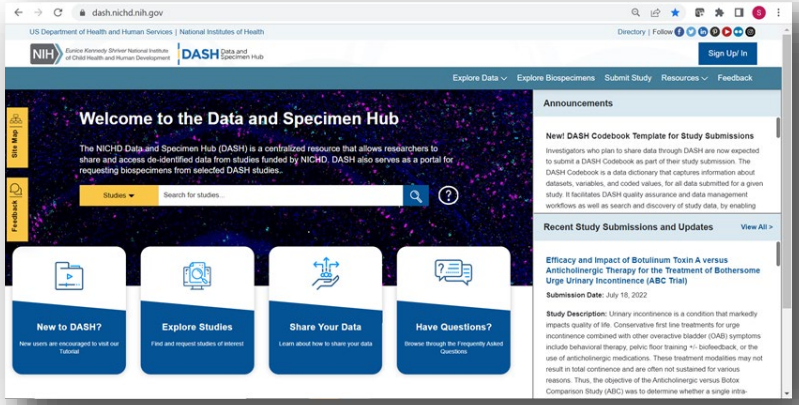
https://dash.nichd.nih.gov

DASH Study Submission and Request – Overview

NICHD Funded Investigators

External Research Investigators

NICHD DATA AND SPECIMEN HUB



Submit De-identified Data

- Institutional Certification
- Study Documents

Submit De-identified Biospecimen Catalog *

- Institutional Certification
- Biospecimen Documents

Request & Access Data

- Research Plan
- Data Use Agreement
- DASH Data Access Committee Approval

Request Biospecimens

- Research Plan
- Material Transfer Agreement
- DASH Biospecimen Access Committee Approval

NICHD (FISHER) BIOREPOSITORY

Receive Biospecimens

* Information about biospecimens (such as type, amount available, participant age, etc.) from a study, that are available for sharing, and stored in the NICHD (Fisher) Biorepository

Data Submission – DASH Policy Requirements

1. Data are **de-identified of the 18 HIPAA identifiers** and coded, and keys to the code are retained by the submitting institutions

2. Submissions are accompanied by an **Institutional Certification** from an Authorized Organizational Representative at **the submitting institution** attesting that an IRB or equivalent Privacy Board has determined that sharing data through NICHD DASH is consistent with relevant policies, regulations, and participant consents, and that the data have been de-identified as per NICHD DASH Policy

3. Submissions should comprise high-quality **individual level data** that is cleaned, de-identified, and usable for secondary analysis

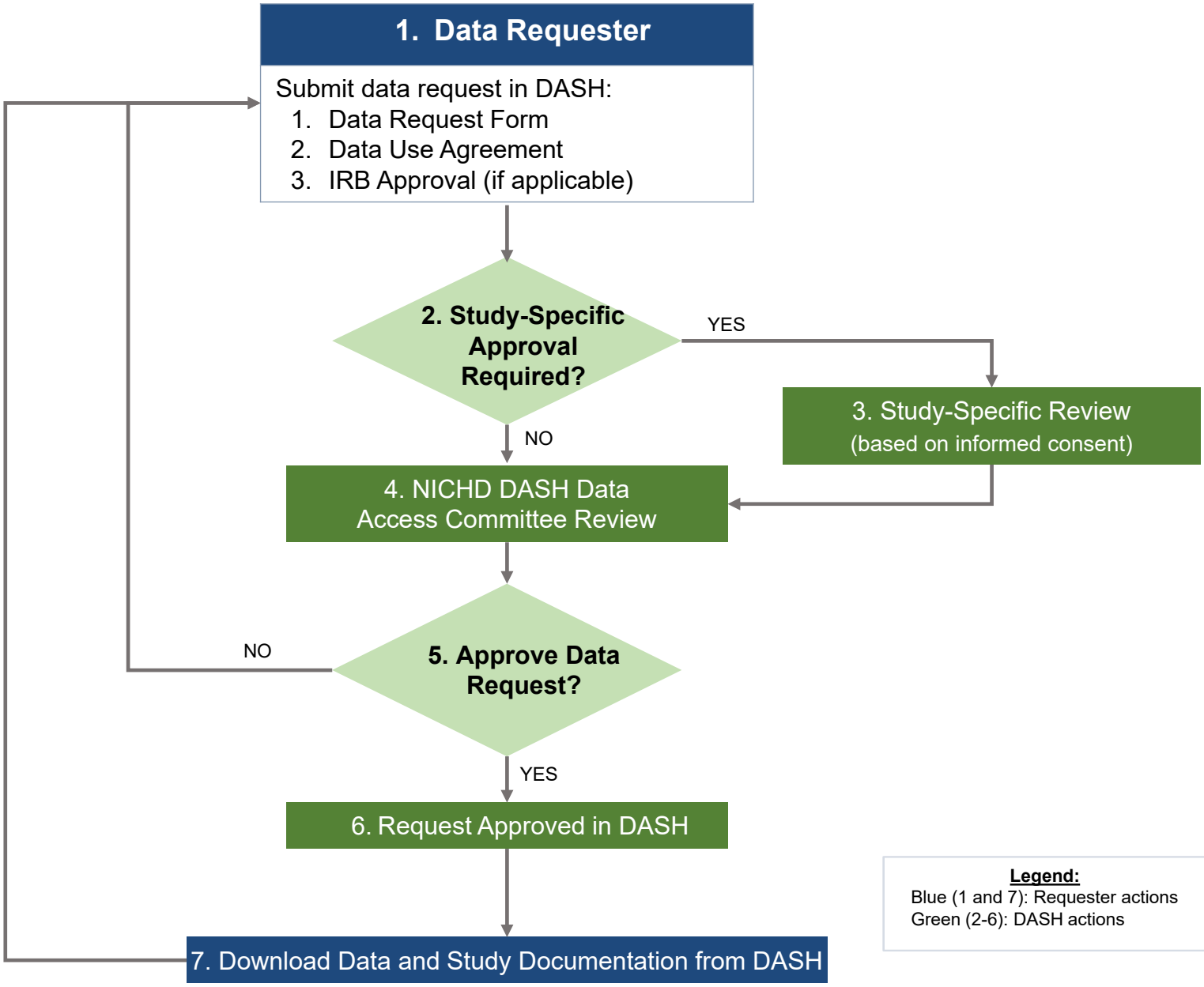
4. **Study documentation** should be provided to ensure meaningful use of the data
   - Required: Study Protocol, Codebook/Data Dictionary, Data Collection Instruments, De-identification Methodology
   - Optional: Data Collection Methodology, Data Analysis Plan, Project Summary, Publications, etc.

DASH Policy: https://dash.nichd.nih.gov/resource/policies

Controlled Data Access in DASH

Process & DASH Policy Requirements

DASH Data Access – High Level Process



Controlled Data Access – DASH Policy Requirements

- Users requesting access to DASH data must comply with the following requirements:

1. **Research Plan** – a brief description of the proposed research use for the data, which is provided by the data requesters in the online DASH Data Request Form
2. **DASH Data Access Committee Approval** – a data request must be approved by the Committee prior to obtaining access to data from DASH
3. **Data Use Agreement (DUA)** – signed by the institutional Authorized Organizational Representative (AOR) and the Data Recipient (Lead Investigator)
    - Institutions are responsible for the terms and conditions of the DUA
    - DUA is valid for three years; recipients can renew their DUA for continued use
    - Each Data Recipient is permitted to have multiple data users from their own institution working on the same research plan (known as Affiliates)
    - Collaborators from different institution/s working with the Data Recipient on the same research plan must execute a separate DUA

DASH Data Access Committee – Overview

- The objective of the Data Access Committee (DAC) review is to ensure that access to data from studies available through DASH aligns with the DASH Policy
- The DAC consists of NICHD staff with relevant expertise in scientific disciplines, human subject data management, and research participant protection and privacy
- The DAC will review requests for data to determine whether the proposed use is scientifically and ethically appropriate based on these criteria:
  - Does not conflict with research data use limitations identified by the study submitters per the informed consent
  - Meets any IRB requirements as defined by the study submitters per the informed consent
  - The requested study contains datasets that are appropriate to address the requester's proposed research plan
  - Consistent with the terms of the informed consent and compliant with applicable regulations for human subjects research protection and privacy protection

Controlled Data Access – DUA Terms & Conditions

- DUA is executed between the Recipient Institution and NICHD, with the following terms and conditions:
  - Use the research data only for the approved research plan
  - Must not share research data with individuals other than those listed in the DUA
  - Protect research data and biospecimen confidentiality
  - Must not attempt to identify individual study participants
  - Follow appropriate security protections for data
  - Follow all applicable laws, regulations, and local institutional policies and procedures for handling data
  - Agree to report violations of the DUA to DASH and, for non-material breaches, remediate them for continued use of the data
  - Material breaches may lead to termination and requirement to destroy data
  - Provide Annual Use Report each year for the three-year term of the DUA to ensure there are no changes to research plan and that Recipient is with the institution that signed the DUA
  - Must destroy all data when the term of a DUA is completed

Resources for Data Requesters

DASH Resources

General DASH Resources

- NICHD DASH Policy: Outlines DASH policies and governance for data submission and request: https://dash.nichd.nih.gov/resource/policies
- DASH User Agreement: Outlines the terms and conditions users must agree to for using DASH: https://dash.nichd.nih.gov/resource/DASHUserAgreement
- Frequently Asked Questions: Provides answers to common user questions: https://dash.nichd.nih.gov/resource/FAQs
- DASH Tutorial: Step-by-step instructions on how to create a DASH account, search for and/or request data and biospecimens, and submit studies: https://dash.nichd.nih.gov/resource/tutorial

Request Resources

- Data Request Checklist
- DASH Data Use Agreement – Sample Template