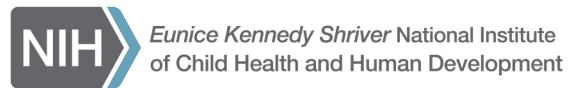


NICHD Data Resources

Charles Hood Foundation

August 6, 2019





- NICHD Data and Specimen Hub (DASH)
 - NICHD DASH Overview
 - Exploring the DASH site
 - Requesting Data
- Biospecimen Repository Access and Data Sharing (BRADS)
 - BRADS Overview
 - Data Request and Approval Process
- Additional NICHD Research Resources

Study Topics in DASH (*biospecimens available)

Autism Spectrum Disorders
Birth Defects
Cerebral Palsy
Children's Bone Health & Calcium
Diabetes
Driving Risk
Early Learning
High-Risk Pregnancy
HIV/AIDS*
Infant Care & Health
Infant Mortality
Infertility & Fertility
Labor & Delivery
Neuroscience
Necrotizing Enterocolitis
Obesity & Overweight
Obstetrics
Pediatric Injury

Pelvic Floor Disorder
Pharmacology
Preconception & Prenatal Care
Preeclampsia & Eclampsia
Pregnancy*
Pregnancy Loss
Preterm Labor & Birth*
Primary Ovarian Insufficiency
Rehabilitation Medicine
Sleep
Spinal Cord Injury
Stillbirth
Stroke
Sudden Infant Death Syndrome
Traumatic Brain Injury
Turner Syndrome
Women's Health

**139** Studies**35** Study Topics**161** Data Requests**16** Data Use Publications**8** Studies Offering Biospecimens

DASH Data and Specimen Hub
<https://dash.nichd.nih.gov>

- Centralized resource for researchers to store de-identified data and to access data and associated biospecimens from NICHD supported studies
- Can help investigators meet NIH's data sharing requirements for their own studies
- Data sharing launched in August 2015; biospecimen request launched in March 2019
- Governed by the NICHD DASH Committee
- Aims to accelerate scientific findings to ultimately improve human health

Questions? Contact supportdash@mail.nih.govFor NICHD studies not archived in DASH, visit: <https://dash.nichd.nih.gov/Resource/LinksToOtherArchives>

Study Topics with Biospecimens in DASH

HIV/AIDS
PregnancyPreterm Labor & Birth
More to come!

Biospecimens Currently Available

Amniotic Fluid
Blood
Breastmilk
DNA/RNA/Proteins
SalivaSerum Plasma
Tissue Samples
Urine
Vaginal Fluid**New DASH Function:
Managing Requests
for NICHD
Biospecimens**

- **Genomic and Proteomic Network for Preterm Birth Research (GPN)**
Expression profiling, GWAS case control, and longitudinal cohort studies
- **NICHD International Site Development Initiative (NISDI)**
4 studies of pregnant women with HIV, their infants with and exposed to HIV, and children with and exposed to HIV in Latin American Countries
- **Mothers and Infants Cohort Study (MICS)**
Study of perinatal transmission of HIV and developmental outcomes of children with HIV

**8 Studies Offering Biospecimens**Questions? Contact supportdash@mail.nih.govFor NICHD studies not archived in DASH, visit: <https://dash.nichd.nih.gov/Resource/LinksToOtherArchives>

Exploring DASH



DASH Data and Specimen Hub

[Sign Up/ In](#)

[Explore Studies](#) [Explore Data](#) [Explore Biospecimens](#) [Submit Study](#) [Resources](#)



Welcome to the Data and Specimen Hub

DASH is a centralized resource for researchers to store de-identified data and to access data and associated biospecimens from NICHD supported studies for use in secondary research.

Search Studies

Search for studies...



New to DASH?

New users are encouraged to visit our Tutorial



Explore Studies

Find and request studies of interest



Share Your Data

Learn about how to share your data



Have Questions?

Browse through the Frequently Asked Questions

Recently Submitted Studies

[View All >](#)

Safety and Pharmacokinetics of Multiple-Dose Intravenous and Oral Clindamycin in Pediatric Subjects with BMI \geq 85th Percentile (BPCA CLN01)

Submission Date: JULY 31, 2019

Study Description: The primary objective of CLN01 was to determine the pharmacokinetics (PK) of intravenous (IV) clindamycin in overweight and obese children and adolescents. This study was a prospective, open-label safety and PK study of multiple doses of IV and oral clindamycin in overweight and obese children 2 to <18 years of age. Clindamycin PK samples to develop the population PK model were also collected from NICHD-2011-POP01 and NICHD-2012-STA01 and analyzed as part of CLN01. Overall, clindamycin was very well tolerated in this open-label study. Three AEs (including one SAE) were reported in 2 (9%) CLN01 patients; none were considered related to study drug. After accounting for size-based differences using total body weight and physiologic differences using age, only volume of distribution and terminal elimination half-life were significantly different between obese and non-obese children. Clindamycin may be dosed based on total body weight (max dose 2.7 g/day) without dose adjustment based solely on obesity.

Pelvic Symptoms and Patient Satisfaction After Colpocleisis (Colpocleisis Trial)

Submission Date: JULY 26, 2019

Study Description: This study describes the postoperative course of women who undergo colpocleisis, with particular attention to the persistence or recurrence of urinary incontinence and patient satisfaction after the colpocleisis prolapse surgery.



USA.gov



National Institutes of Health

Exploring DASH - BMCDs



← → ↺ 🏠 <https://dash.nichd.nih.gov/studyExplorer/?q=bone mineral&sortBy=relevance&asc=true> 📄 ⋮ ♥ ☆ 🏠 📄 ☰

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

Sign Up/ In

DASH Data and
Specimen Hub

Explore Studies Explore Data ▾ Explore Biospecimens Submit Study Resources ▾

Search Studies

bone mineral



Filters

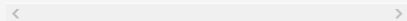
bone mineral



Clear Filters

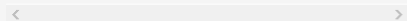
Topic

- ☐ Children's Bone Health and Calcium 1
- ☐ HIV/AIDS 6



Study Type

- ☐ Clinical Trial - NIH defined 2
- ☐ Other Types of Clinical Research 4



Showing 7 of 7 Results

Sort by: Study Name ▾ Ascending ▾



Bone Mineral Density in Childhood Study (BMDCS)

NICHD Division/Branch/Center: DER - Pediatric Growth and Nutrition Branch (PGNB)

Research Networks and Initiatives: Bone Mineral Density in Childhood Study (BMDCS)

Study Description: A multi-center, six year longitudinal study examining bone accretion in a racially diverse cohort of 2014 healthy boys and girls ages 5-20 years at 5 clinical centers in the US. The BMDCS cohort included children with height, weight, and body mass index (BMI) between the 3rd and 97th percentile and with no previous or current conditions that might affect bone acquisition. Recruitment occurred in two phases: 1554 subjects ages 6 to 17 years were enrolled during 2002-2003; during 2006-2007 younger (5y) and older (19y) subjects were enrolled to extend the reference percentiles to ages 5-20 years. The second wave of participants were followed for 2 years. Annual assessments included linear growth, weight gain, pubertal maturation, nutritional status, exercise, bone mineral density (DXA by Hologic) and bone age comprised the main study measures. A subset of patients underwent pQCT and qCT. The reference curves generated by this carefully executed study are the gold standard for normal bone accrual.

View Details

🛒 Login to add to Cart

Randomized. Double-Blind. Placebo-Controlled Trial of the Safety and Effectiveness of



Bone Mineral Density in Childhood Study (BMDCS) - 34.3 MB

 [Login to add study to Cart](#)

Study Information

NICHD Division/Branch/Center: DER - Pediatric Growth and Nutrition Branch (PGNB)

Clinical Research Network Name: Bone Mineral Density in Childhood Study (BMDCS)

Study Description: A multi-center, six year longitudinal study examining bone accretion in a racially diverse cohort of 2014 healthy boys and girls ages 5-20 years at 5 clinical centers in the US. The BMDCS cohort included children with height, weight, and body mass index (BMI) between the 3rd and 97th percentile and with no previous or current conditions that might affect bone acquisition. Recruitment occurred in two phases: 1554 subjects ages 6 to 17 years were enrolled during 2002-2003; during 2006-2007 younger (5y) and older (19y) subjects were enrolled to extend the reference percentiles to ages 5-20 years. The second wave of participants were followed for 2 years. Annual assessments included linear growth, weight gain, pubertal maturation, nutritional status, exercise, bone mineral density (DXA by Hologic) and bone age comprised the main study measures. A subset of patients underwent pQCT and qCT. The reference curves generated by this carefully executed study are the gold standard for normal bone accrual.

 [Show Details](#)

Explore Study Content

 [Explore 54 Datasets](#)

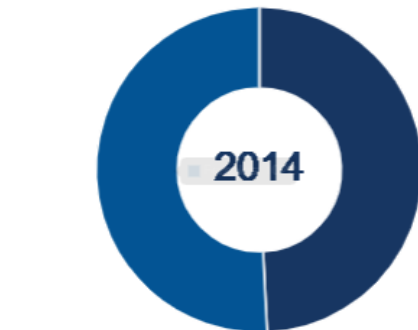
 [Explore 64 Documents](#)

Exploring DASH - BMCDs



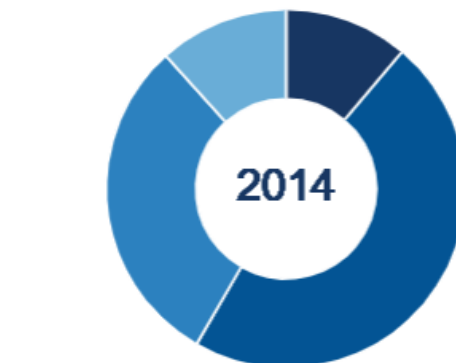
A multi-center, six year longitudinal study examining bone accretion in a racially diverse cohort of 2014 healthy boys and girls ages 5-20 years at 5 clinical centers in the US.

Sex



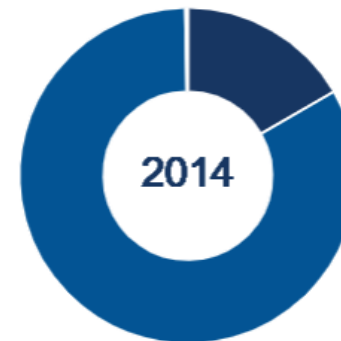
992 Males
1022 Females

Life Stage



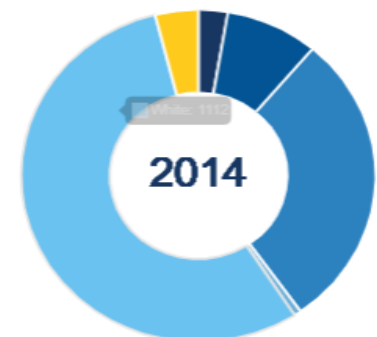
225 Early Childhood (2 - 5 yrs)
949 Middle Childhood (6 - 11 yrs)
605 Early Adolescence (12 - 18 yrs)
235 Late Adolescence (19 - 21 yrs)

Ethnicity



336 Hispanic
1673 Non-Hispanic
5 Unknown


Race



54 American Indian or Alaska Native
171 Asian
585 Black or African American
13 Native Hawaiian or other Pacific Islander
1112 White
79 Unknown



Bone Mineral Density in Childhood Study (BMDCS) - 34.3 MB


 [Login to add study to Cart](#)

Study Information

NICHD Division/Branch/Center: DER - Pediatric Growth and Nutrition Branch (PGNB)

Clinical Research Network Name: Bone Mineral Density in Childhood Study (BMDCS)

Study Description: A multi-center, six year longitudinal study examining bone accretion in a racially diverse cohort of 2014 healthy boys and girls ages 5-20 years at 5 clinical centers in the US. The BMDCS cohort included children with height, weight, and body mass index (BMI) between the 3rd and 97th percentile and with no previous or current conditions that might affect bone acquisition. Recruitment occurred in two phases: 1554 subjects ages 6 to 17 years were enrolled during 2002-2003; during 2006-2007 younger (5y) and older (19y) subjects were enrolled to extend the reference percentiles to ages 5-20 years. The second wave of participants were followed for 2 years. Annual assessments included linear growth, weight gain, pubertal maturation, nutritional status, exercise, bone mineral density (DXA by Hologic) and bone age comprised the main study measures. A subset of patients underwent pQCT and qCT. The reference curves generated by this carefully executed study are the gold standard for normal bone accrual.

 [Show Details](#)

Explore Study Content


 [Explore 54 Datasets](#)

 [Explore 64 Documents](#)

Exploring DASH - BMDCDS



Bone Mineral Density in Childhood Study (BMDCS) - 34.3 MB

 [Login to add study to Cart](#)

Descriptive Documents

Document	Document Name
Study Protocol	BMDCS Protocol.zip
Data Collection Instruments	BMDCS Data Collection Instruments.zip
Codebook/Variable Dictionary	BMDCS Codebook_Variable Dictionary.zip
De-Identification Methodology	BMDCS Data De-identification Methodology.pdf
List of Publications	BMDCS Publications.docx



BMDCS UCSF DXA Results 'Uncorrected Data' Dataset

Study Name: [Bone Mineral Density in Childhood Study \(BMDCS\)](#)

Dataset Description: Timing of DXA scans and uncorrected results of each, including bone mineral content, bone mineral density, and measurement of areas within the whole body, AP spine, hip, and forearm scans

Type of Data: Analytical

Dataset Format: sas7bdat

[View Study Details](#)



BMDCS UCSF DXA Results 'Full Correction' Dataset

Study Name: [Bone Mineral Density in Childhood Study \(BMDCS\)](#)

Dataset Description: Timing of DXA scans and proportionally corrected bone mineral density and bone mineral content measurements

Type of Data: Analytical

Dataset Format: csv

[View Study Details](#)



BMDCS Form 06_Performance of DXA Dataset

Study Name: [Bone Mineral Density in Childhood Study \(BMDCS\)](#)

Dataset Description: Data on performance of specific DXA scans, measurements obtained or not obtained, and any problems encountered


Type of Data: Analytical

Dataset Format: csv

[View Study Details](#)

DASH Data Request



 National Institutes of Health
Division of Data Science and Informatics

DASH Data and Specimen Hub

My Cart

Consortium on Safe

Request Name: N/A

Initiated: N/A

Approval Policy: Study I

Content Requested: Da

Workbench

Cart **45**

View My Profile

Sign Out

Resources

Remove All

REQUIRED

cess

Data Request Guidelines

Getting Access To Study Items

You will have access to all items you requested once your request has been approved. Access is typically granted for three years.

Request access in three quick steps.

1. Complete online data request form

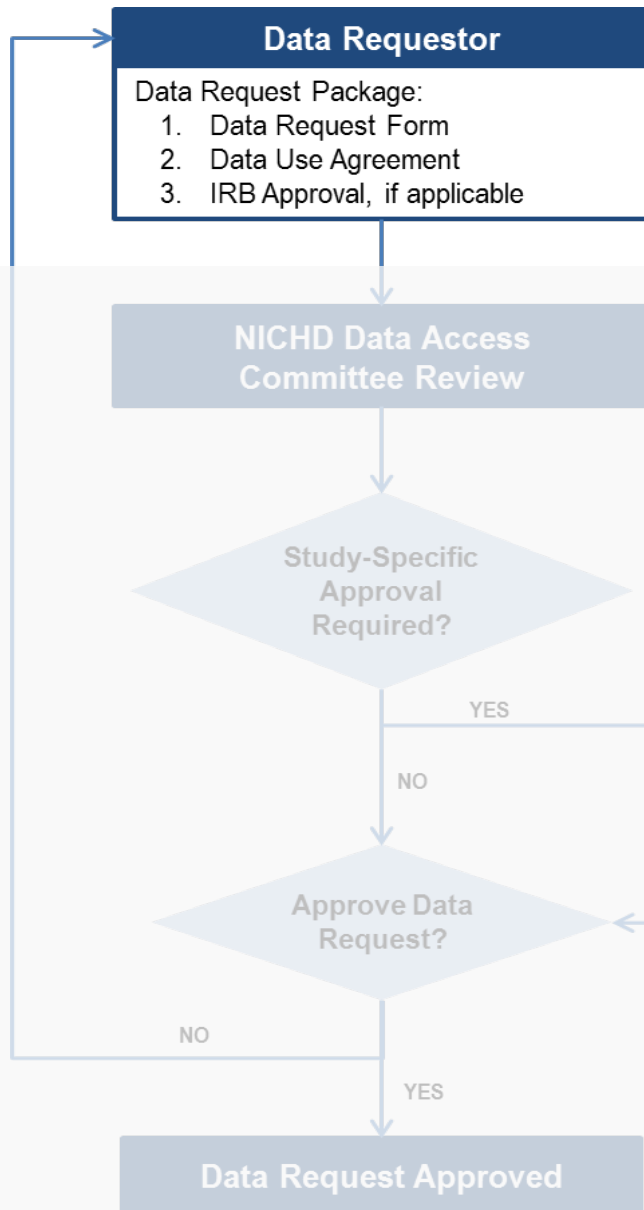
2. Download data request package(s) and obtain signatures.

3. Upload and submit data request package(s).

Cancel

Continue

DASH Data Request Process



Data requestors are required to submit:

1. **Data Request Form: Research Plan** a brief description of the proposed research use of the data
2. **Data Use Agreement**, co-signed by the Data Recipient (Lead Investigator) and the Authorized Organizational Representative
3. **IRB approval (Optional)**, for the requested data (if necessary per the study submitter)

DASH Request Form (partial)



NICHD DATA REQUEST FORM	
1. Request Information	
Request Type	Data Download
Requested Study Title	Bone Mineral Density in Childhood Study
2. Request Identifier	
Request Name	
3. Requester Information	
Name	
Job Title / Position	
Institution	
Mailing Address	
Email Address	
Phone Number	
4. Institutional and Funding Information	
Institution Type	Not for Profit
Funding Type	Contract: NA

DASH Request Form (partial)



Research Plan

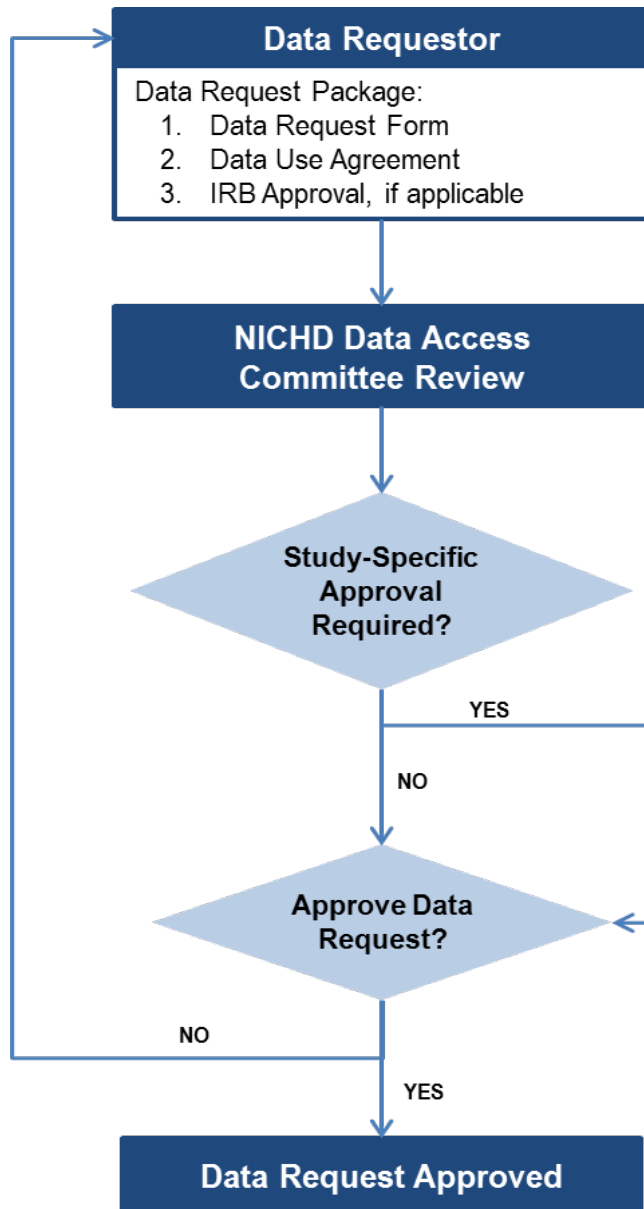
Design and Analysis Plan

DASH Data Use Agreement



- Valid for three years and can be renewed
- Recipient agrees to:
 - Use the data only for the **approved Research Plan**
 - Not share the data
 - Protect **data privacy**; not attempt to identify participants
 - Report data breaches or accidental re-identification of respondents immediately
 - Follow all applicable laws, regulations, and local institutional policies and procedures for handling data
 - Acknowledge the **contribution of the data submitter** and NICHD DASH in publications
 - Provide **annual progress reports to DASH** on research using the data

DASH Data Request Process



Data requestors are required to submit:

1. **Data Request Form: Research Plan** a brief description of the proposed research use of the data
2. **Data Use Agreement**, co-signed by the Data Recipient (Lead Investigator) and the Authorized Organizational Representative
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<https://brads.nichd.nih.gov/>



Eunice Kennedy Shriver National Institute
of Child Health and Human Development

DIVISION of
INTRAMURAL POPULATION
HEALTH RESEARCH

NICHD/DIPHR Biospecimen Repository Access and Data Sharing (BRADS)

Home

BRADS Program Synopsis

BRADS Manual of Operations

DIPHR Data Available Elsewhere

How to Request Access

BRADS Collections

Home

The Division of Intramural Population Health Research (DIPHR) maintains a repository of data and biospecimen collections from various epidemiologic studies and clinical trials.

- To promote access to these resources, the Division has established the Biospecimen Repository Access and Data Sharing (BRADS) program. The BRADS Committee works to establish procedures and guidelines that govern this program and that are consistent with the NIH Data Sharing policy.
- All investigators must submit a proposal to gain access to data and to biospecimens. Proposals will be evaluated on scientific merit by an ad hoc technical panel overseen by the BRADS committee.
- Instructions are found in [How To Request Access](#).

The Division of Intramural Population Health Research maintains a repository of datasets from completed Division studies, with associated biospecimens and ancillary data.



- Diabetes and Early Pregnancy
- Vaginal Infections and Prematurity
- Neural Tube Defects
- Danish Perinatal Study
- Norway – Alabama Fetal Growth Study
- Calcium for Preeclampsia Prevention
- NIH-DC Initiative to Reduce Infant Mortality in Minority Populations
- Epidural Analgesia During Labor and Delivery
- Longitudinal Study of Vaginal Flora
- Swimming Lessons and The Risk of Drowning
- Management of Early Pregnancy Failure Trial

BRADS has publicly available data from 11 studies (5 with biospecimens)

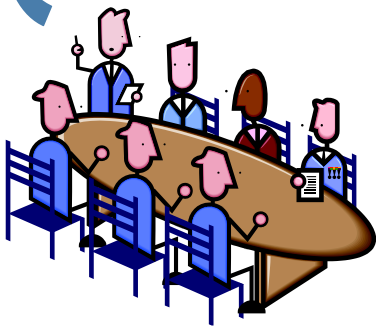
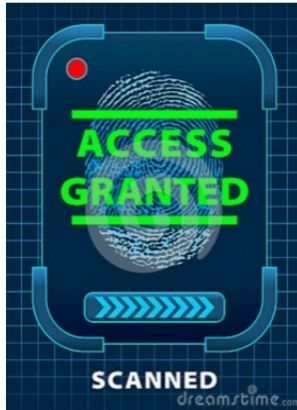
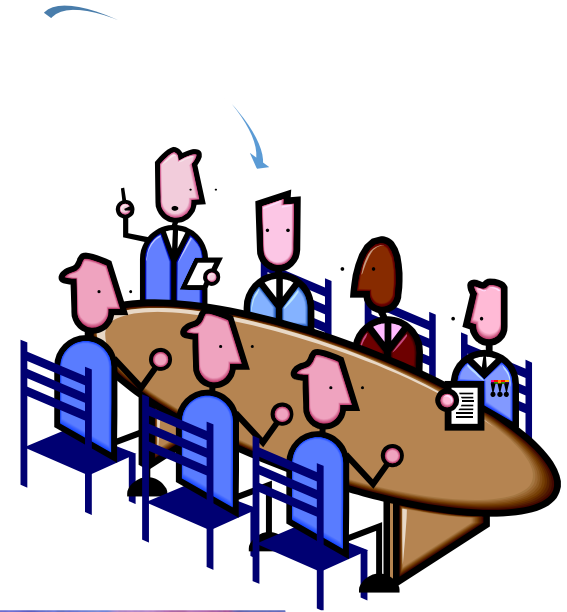
All data files contain clean, usable data

Accessing BRADS



- Justify the scientific, technical, and/or medical significance of the research and why scarce resources (samples) should be allocated to these research questions
- Clearly indicate how the proposed methodology will address the research goals
- Outline how the results from the laboratory analysis or findings from the original forms will be used
- Provide an analysis plan, including a description of the statistical methods, specifying the variables to be included in all analyses
- Provide power analysis results demonstrating that the sample size requested is appropriate (adequate to answer the statistical question but not larger than the minimum needed)

Accessing BRADS



Some examples:

- [ABCD Data Repository](#)
 - Houses all data generated by the Adolescent Brain Cognitive Development Study, the largest prospective study of brain development and child health in the United States
- [Data Sharing for Demographic Research](#) (DSDR)
 - Archives, preserves, and disseminates data relevant for population studies
- [Gabriella Miller Kids First Pediatric Research Program](#)
 - Integrated data resource to explore whether shared genetic pathways may contribute to both structural birth defects and cancer.



Questions?

Appendix

DASH Resources for Investigators



- [DASH Tutorial](#): Step-by-step instructions on how to create a DASH account, search for and/or request data, and submit studies
- [Frequently Asked Questions](#): Provides answers to common questions
- [NICHD DASH Policies](#): Outlines the DASH governance policies
- [DASH User Agreement](#): Outlines the terms and conditions users must agree to when registering for an account
- [Links to other archives with NICHD-funded studies](#)



- **Submission Resources**
 - [Guidance for Data De-Identification and Coding](#)
 - [DASH Data Preparation Tool](#)
 - [Institutional Certification](#)

- **Request Resources**
 - [DASH Data Use Agreement](#)
 - [Data Request Checklist](#)



NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources

- [NIH Statement on Sharing Research Data](#), Feb 2003
 - NIH expects and supports the timely release and sharing of final research data (i.e., no later than the acceptance for publication of the main findings from the final data set) from NIH-supported studies for use by other researchers
 - Applications with direct costs greater than \$500,000 in any single year expected to address data sharing in their application
 - Note: NIH's Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research issued in February 2015 proposes *all NIH-funded researchers* prepare data management plans
- [NIH Genomic Data Sharing \(GDS\) Policy](#), Aug 2014
 - GWAS Policy extended to wider range of genomic data
 - Data release: Depends on data processing level, generally 6 months or time of initial publication
- [NIH Intramural Research Program Human Data Sharing \(HDS\) Policy](#), Jul 2015
 - Effective on October 1, 2015; proposed studies beginning scientific review on or after that date must comply with this Policy
 - It governs the sharing of data among intramural investigators as well as the sharing of intramural Data from intramural investigators to investigators outside of the NIH.



18 identifiers defined as *protected health information* (PHI) under HIPAA*

*Health Insurance Portability and Accountability Act of 1996

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census: a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people. b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) addresses numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification