NICHD Data Resources

Charles Hood Foundation

August 6, 2019

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

Overview

- 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

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DASH Data and Specimen Hub

https://dash.nichd.nih.gov

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

- 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

139 Studies

35 Study Topics

161 Data Requests

16 Data Use Publications

8 Studies Offering Biospecimens

Questions? Contact supportdash@mail.nih.gov

For NICHD studies not archived in DASH, visit: https://dash.nichd.nih.gov/Resource/LinksToOtherArchives

Last updated 07/31/2019

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Study Topics with Biospecimens in DASH

HIV/AIDS	Preterm Labor & Birth
Pregnancy	More to come!

Biospecimens Currently Available

Amniotic Fluid	Serum Plasma
Blood	Tissue Samples
Breastmilk	Urine
DNA/RNA/Proteins	Vaginal Fluid
Saliva	

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

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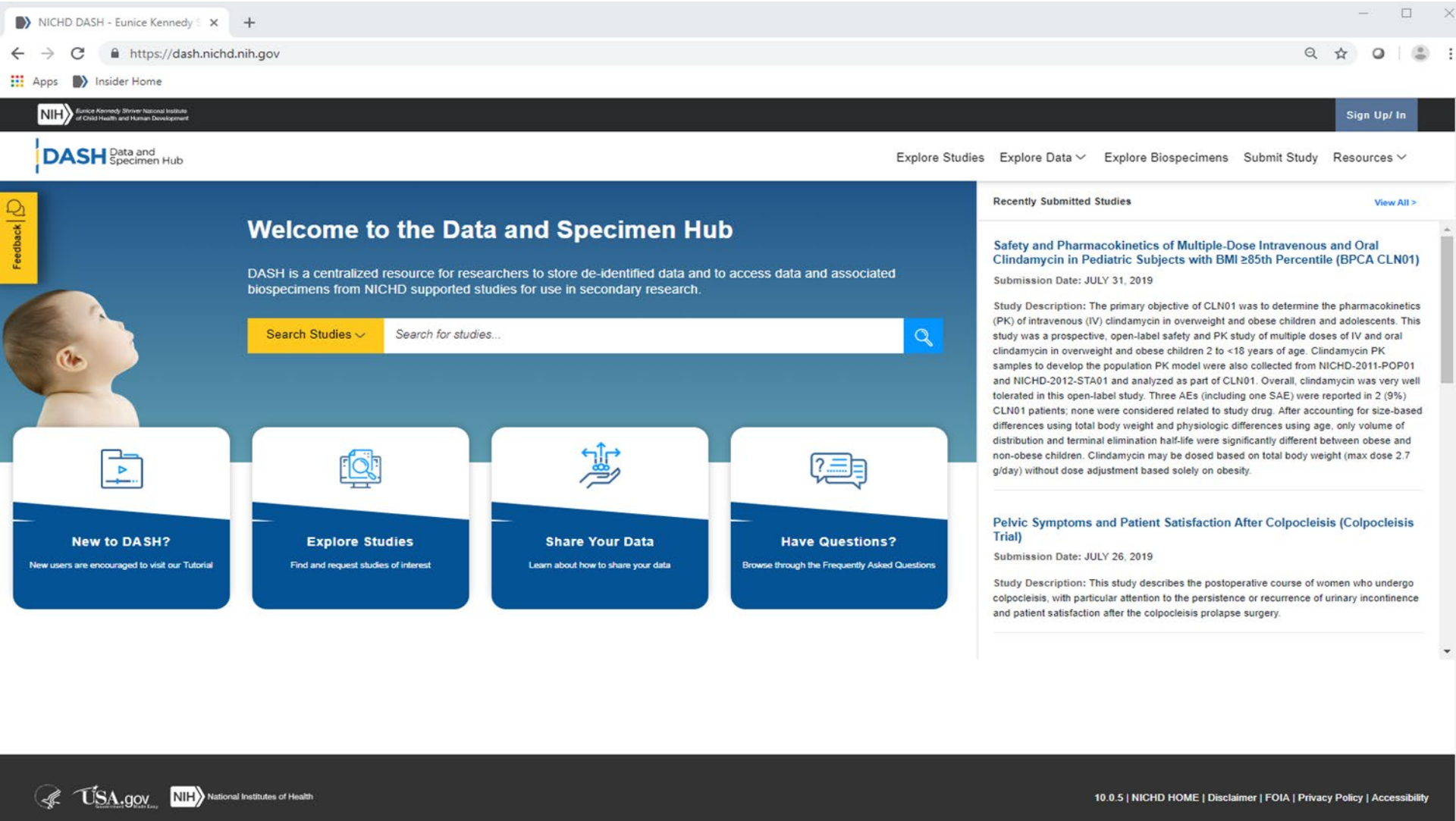
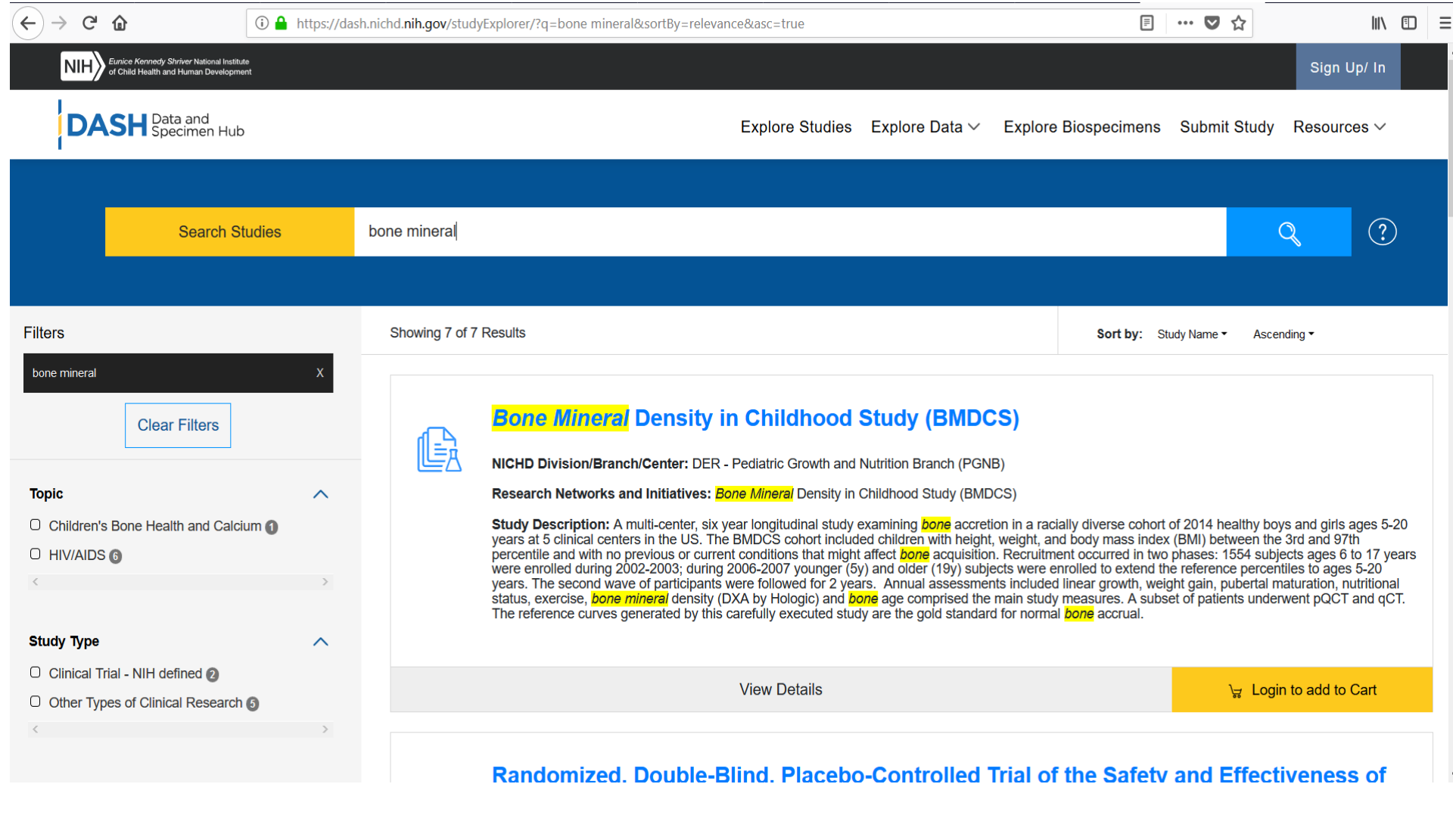
Exploring DASH



Exploring DASH - BMCDS



Exploring DASH - BMCDS

DASH Data and Specimen Hub

Explore Studies Explore Dat

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

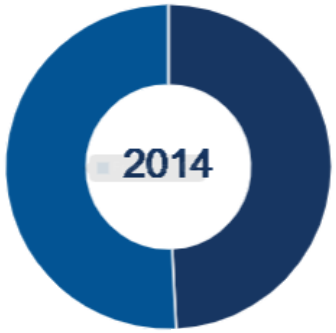
Explore 54 Datasets

Explore 64 Documents

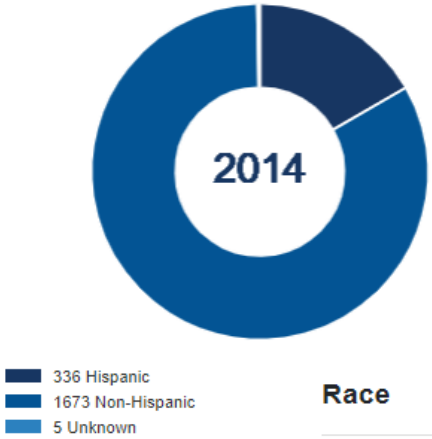
Exploring DASH - BMCDS

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.

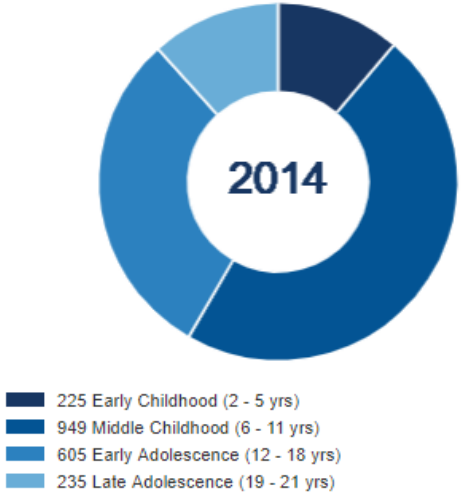
Sex



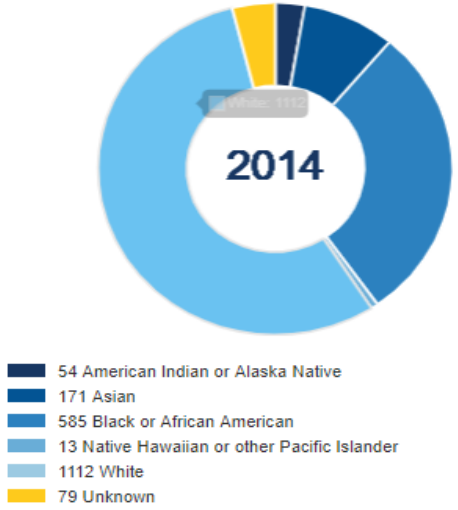
Ethnicity



Life Stage



Race



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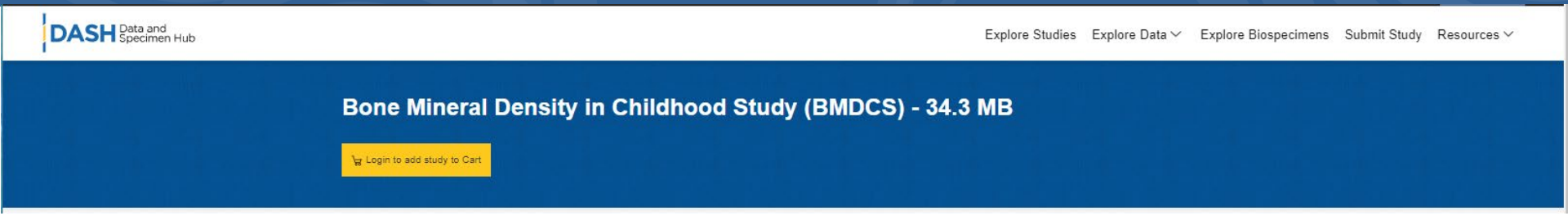


Descriptive Documents

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

Exploring DASH - BMCDS

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)

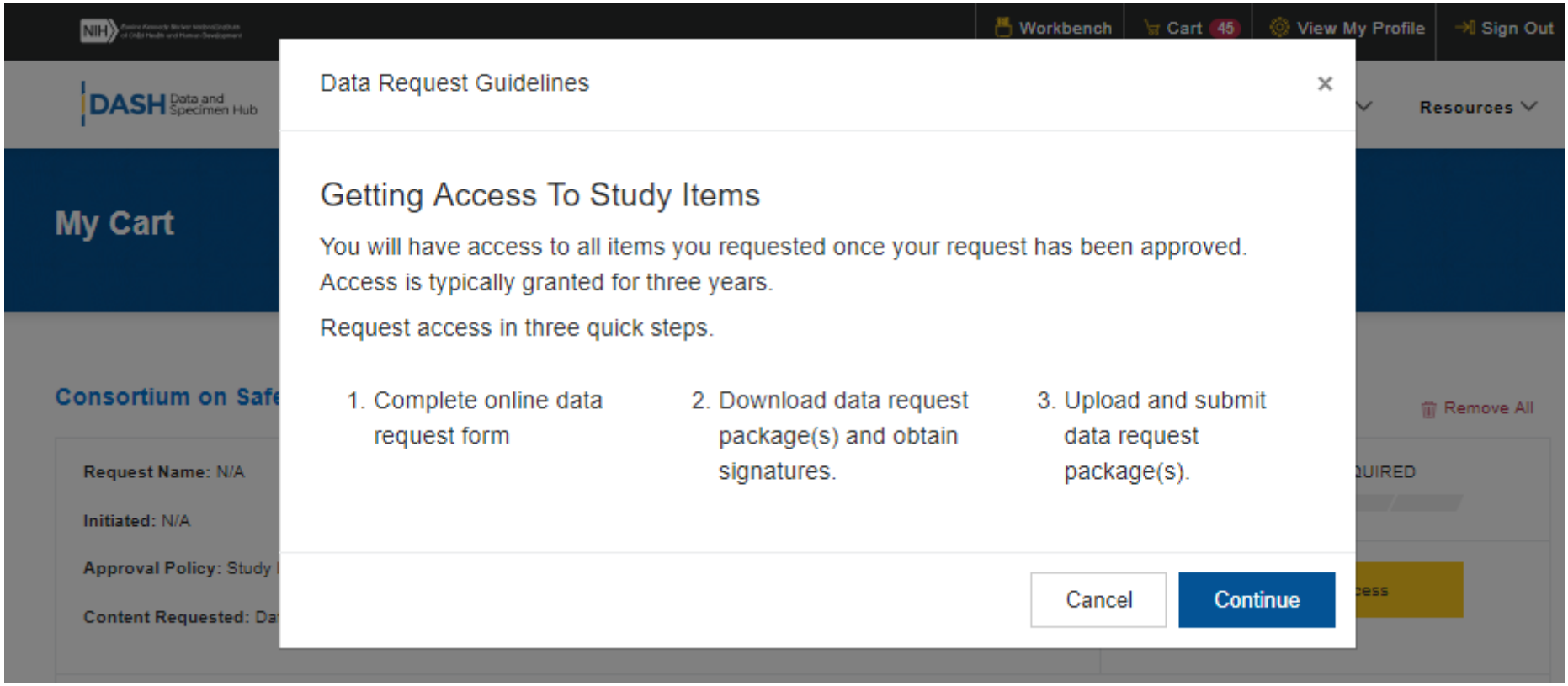
Dataset Description: Data on performance of specific DXA scans, measurements obtained or not obtained, and any problems encountered

Type of Data: Analytical

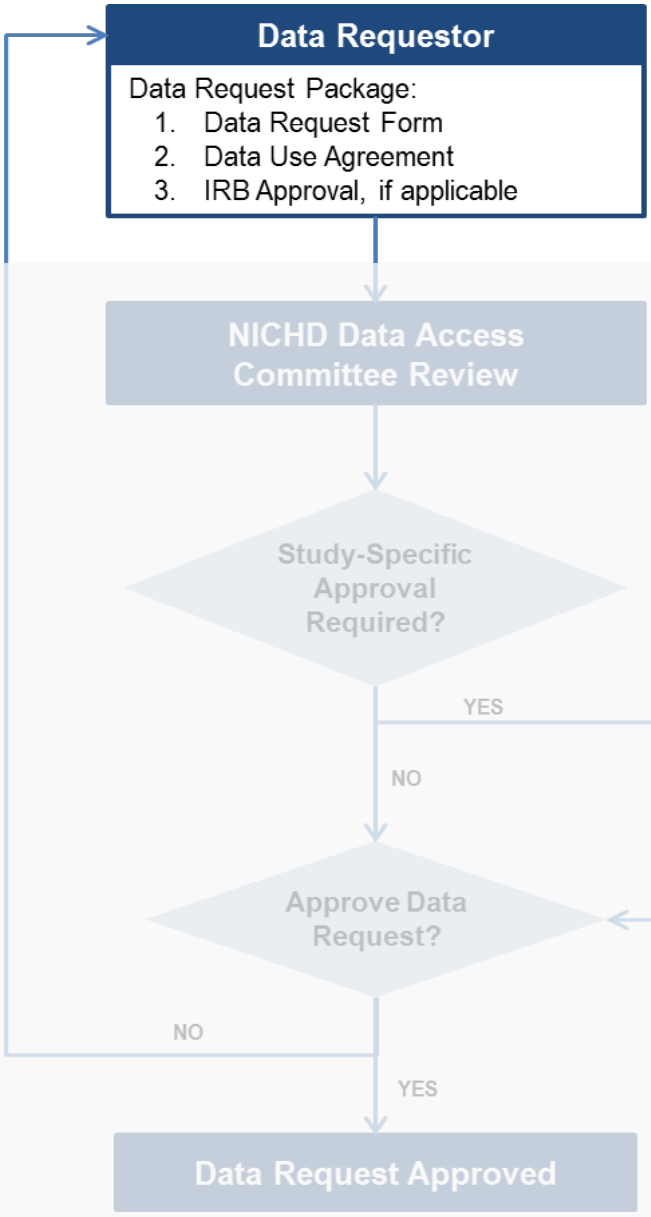
Dataset Format: csv

View Study Details

DASH Data Request



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	[redacted]
3. Requester Information	
Name	[redacted]
Job Title / Position	[redacted]
Institution	[redacted]
Mailing Address	[redacted]
Email Address	[redacted]
Phone Number	[redacted]
4. Institutional and Funding Information	
Institution Type	Not for Profit
Funding Type	Contract: NA

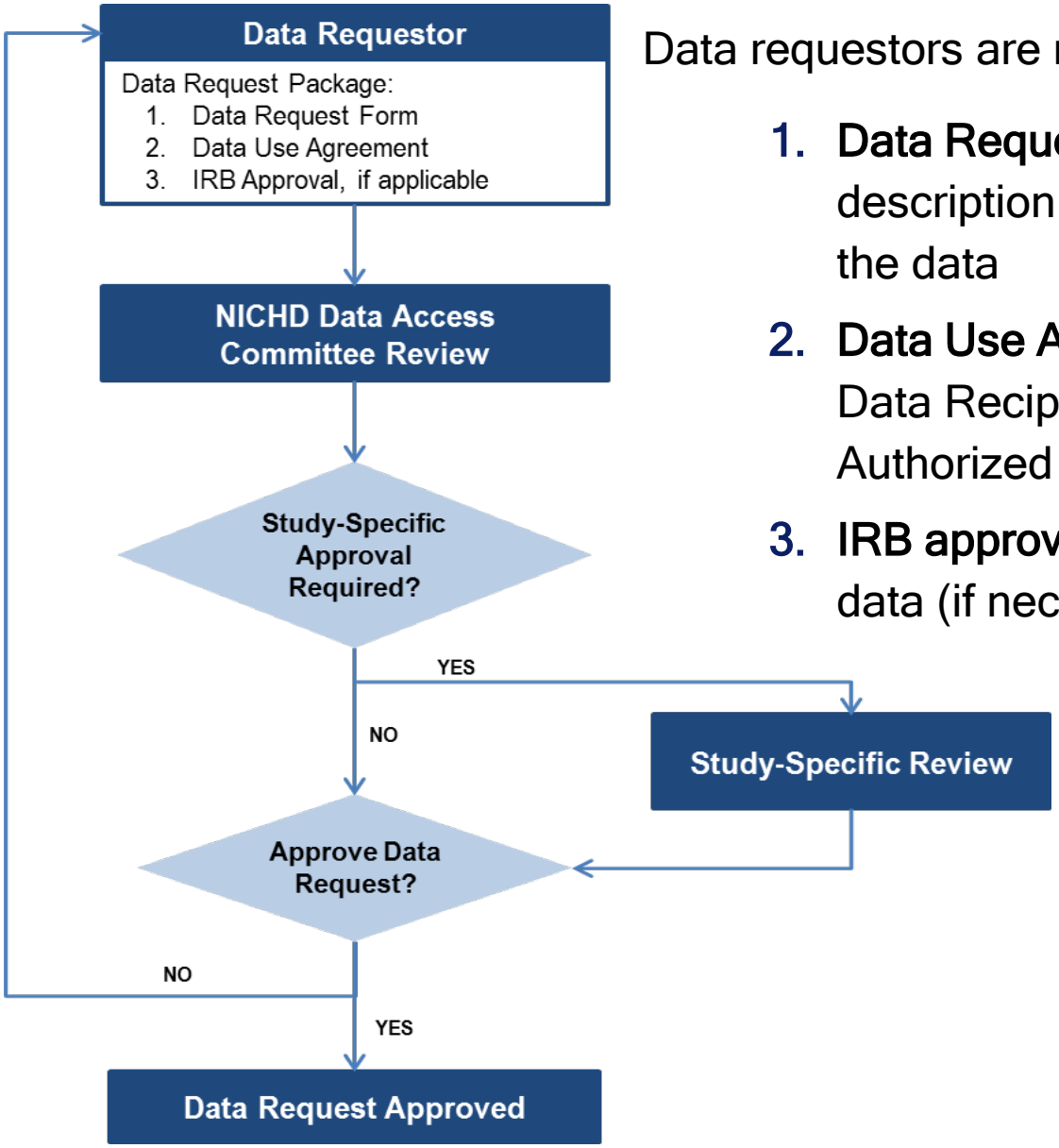
DASH Request Form (partial)

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



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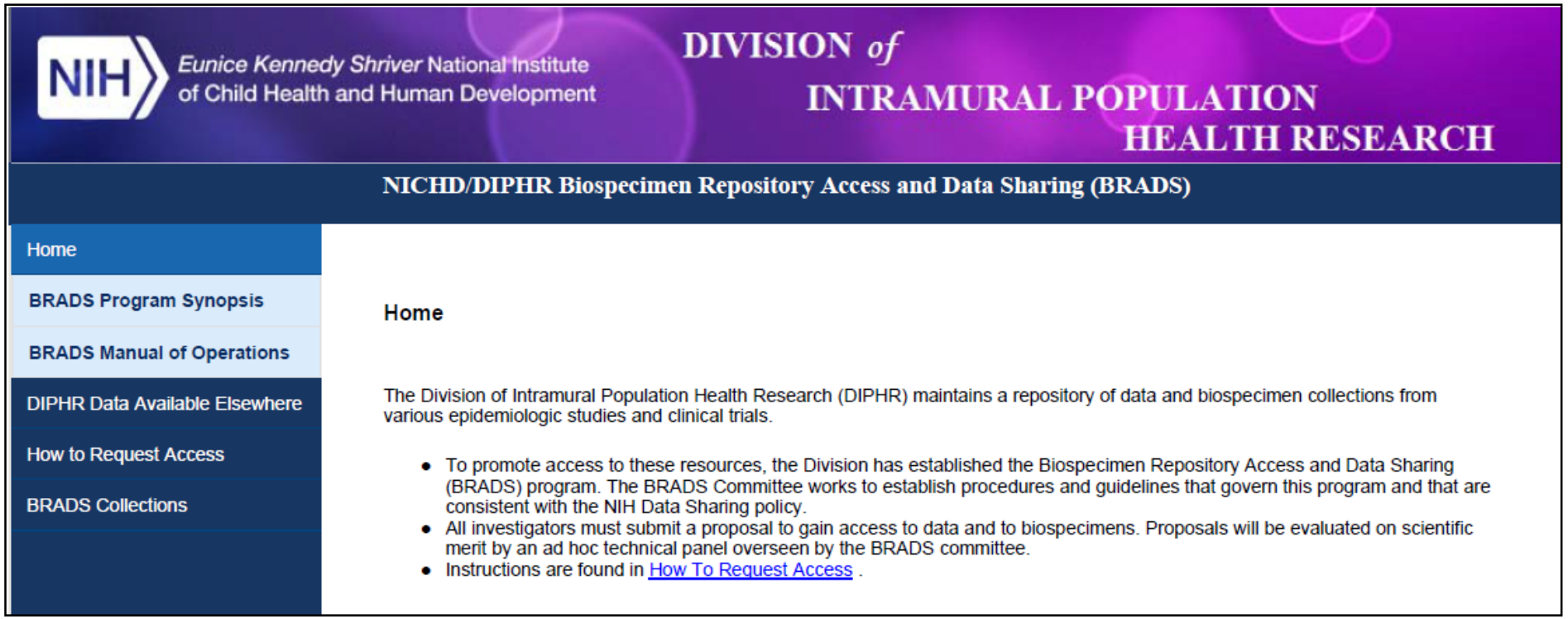
BRADS

https://brads.nichd.nih.gov/



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

BRADS – Collections

- 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

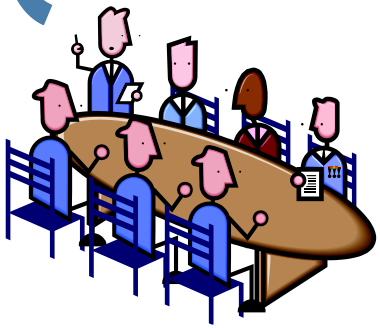
BRADS has publicly available data from 11 studies (5 with biospecimens)

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



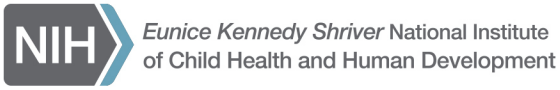
NICHD Datasets & Research Resources

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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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

DASH Resources for Investigators

- 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