

# 0925-0744-NEW\_DASH\_ATTACHMENT A.2-2\_DATA SUBMISSION (APPROVED OMB NUMBER: 0925-0744)

Explore Data ▾ Explore Biospecimens Submit Study Resources ▾ Feedback Curator Officer

## Submission

Preview Submission Pages

Submission Start Date: 12/28/2020

OMB Control Number: 0925-0744  
Expiration Date: 01/31/2022

- Study Registration
- Contact Information
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- Data Preparation
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### Study Registration

All fields marked with an asterisk ( \* ) are required.  
NOTE: Be sure to de-identify all your study data prior to submission.

### STUDY INFORMATION

Study Name \*

Abbreviation \*

Single Site  Multi Site

NICHD Division/Branch/Center \*  
Please select the NICHD Division/Branch/Center associated with your study from the drop-down list. If you are unsure of what to enter, please contact the primary NICHD program person responsible for this study for guidance.

NICHD Research Networks and Initiatives \*  
Please select the NICHD Research Network or Initiative for your study. If the appropriate network or initiative does not appear in the list below, please select "Other Initiatives" at the bottom of the list.

### Related Studies in DASH \*

Is the study you are submitting related, either by study participants or study protocol, to another study that is currently archived in DASH?

Yes  No

### Related Studies Outside of DASH \*

Is the study you are submitting related, either by study participants or study protocol, to another study that is not archived in DASH?

Yes  No

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Public reporting burden for this collection of information is estimated to average two hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0744). Do not return the completed form to this address.



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## Policy Compliance

All fields marked with an asterisk ( \* ) are required.

### 1. Is this Study compliant with HHS human subjects regulations (45 CFR Part 46)? \*

HHS human subjects research (45 CFR Part 46) offers basic protections to human subjects involved in both biomedical and behavioral research conducted or supported by HHS. [45 CFR Part 46 Protection of Human Subjects](#)

Yes  No

### 2. Is this Study compliant with FDA human subjects regulations (21 CFR Parts 50 and 56)? \*

FDA human subjects regulations (21 CFR Parts 50 and 56) deals with the policies surrounding human subjects and Institutional Review Boards (IRBs). Part 50 applies to all clinical investigations regulated by the FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA. Part 56 contains the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations regulated by the FDA. [21 CFR Parts 50 and 56 FDA Human Subjects Regulations](#)

Yes  No

3. Is this Study compliant with the Health Insurance Portability and Accountability Act of 1996? \*  
Health Insurance Portability and Accountability Act Privacy Rule (45 CFR Part 164) establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. [Information about HIPAA 1996 \(PDF-157 KB\)](#)

Yes  No

4. Is this Study compliant with the Privacy Act of 1974, as amended (5 U.S.C. § 552a)? \*

Privacy Act (42 U.S.C. § 241; 281-290b). Section 308(d) (42 U.S.C. 242 m (d) a United States federal law, establishes a Code of Fair Information Practice that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by federal agencies. [Information about Privacy Act 1974](#)

Yes  No

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### Study Information

All fields marked with an asterisk ( \* ) are required.

#### STUDY DETAILS

##### Study Description \*

Please provide a brief description (1024 characters including spaces) of the study to include study aims/goals, hypothesis tested, methodology used and the resulting outcomes. It is not necessary to provide information that may be duplicated in other study documents that are being submitted (example - eligibility criteria or outcome measures that are available in the study protocol).

Provide a description of the study being submitted to archive (1024 characters)

##### Study Timeline \*

Are there study enrollment and data collection dates associated with your study?

Yes  No

##### Keywords \*

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**Topics \***

Select and add a topic

**Study**

**Study Type \***

[Click here to view the decision tree for NIH Clinical Trial definition](#)

Clinical Trial - NIH defined  Other Types of Clinical Research

This page a  
The Study  
collections,

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visits, sample

Note: As yo  
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**FUNDING INFORMATION**

**Funding Source \***

NIH Extramural  NIH Intramural  Other

**Funding Type \***

Contract  Grant  Other

**Funding Identifying Number \***

Add "N/A" if Unknown

Select  Enter the identifying number (128 characters)

**URL LINKS**

Please provide the following URLs related to your study. The URLs should be a direct link and not include search terms in the URL.

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Study Website

ClinicalTrials.gov

dbGaP

**PUBLICATIONS URLS**

You may provide up to ten URLs for primary publications from this study. The URLs should be a direct link and not include search terms in the URL. If more than ten publications, please create a list of all publications related to this study and include the list with your study submission.

Add publications one at a time

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## Study Population

All fields marked with an asterisk ( \* ) are required.

### TOTAL STUDY POPULATION

Total Population \*

Total Population Description \*

### SUBJECTS BY SEX

**NOTE:** Please provide all applicable information

Males	Females
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Unknown	Undifferentiated
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>

### SUBJECTS BY LIFE STAGE

**NOTE:** Please provide all applicable information

Infant (0 - 1 yr)	Toddler (13 mo - <2 yrs)
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Early Childhood (2 - 5 yrs)	Middle Childhood (6 - 11 yrs)
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Early Adolescence (12 - 18 yrs)	Late Adolescence (19 - 21 yrs)
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Adults	Unknown
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>

### SUBJECTS BY ETHNICITY

**NOTE:** Please provide all applicable information

Hispanic	Non-Hispanic
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Unknown	
<input type="text" value="Enter Total Number"/>	

### SUBJECTS BY RACE

**NOTE:** Please provide all applicable information

American Indian or Alaska Native	Asian
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Black or African American	Native Hawaiian or other Pacific Islander
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
White	Multi Race
<input type="text" value="Enter Total Number"/>	<input type="text" value="Enter Total Number"/>
Unknown	
<input type="text" value="Enter Total Number"/>	

### SUBJECTS BY LOCATION

**NOTE:** Please provide all applicable information

<input type="text" value="Select a U.S. Location"/> <input type="button" value="+ Add"/>	<input type="text" value="Select an International Location"/> <input type="button" value="+ Add"/>
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## Biospecimen Information

All fields marked with an asterisk ( \* ) are required.

**Were biospecimens collected for this study? \***

Yes

No

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## Data Distribution

All fields marked with an asterisk ( \* ) are required.

### 1. Are you submitting to DASH all data collected based on your study protocol? \*

NOTE: Please ensure that partially submitted study data can be meaningfully used

Yes  No

### 2. All data requests will be reviewed by the DASH Data Access Committee. Does the consent language require additional approval from a study-specific approving entity? \*

Yes  No

### 3. Are there any limitations to the use of data as per the study consent form? \*

Yes  No

### 4. Does the informed consent require data requesters to submit IRB approval to obtain your study data? \*

NOTE: Study data stored in DASH are de-identified and all requesters have to sign a Data Use Agreement before receiving data from DASH.

Yes  No

### 5. Did you use any proprietary data collection instruments in your study? \*

NOTE: Proprietary instruments are those with associated costs and/or licenses for use.

Yes  No

### 6. Did you use any licensed coding standards (e.g., SNOMED, MedDRA) to code any of your study data? \*

Yes  No

## Acknowledgment Instructions

Please provide instructions for researchers to acknowledge use of your study data in future presentations or publications

Please provide a brief description of acknowledgement instructions (2048 characters)

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## Institutional Certification

All fields marked with an asterisk ( \* ) are required.

All study submissions to NICHD DASH must be accompanied by an Institutional Certification from responsible Institutional Official(s) of the submitting institution stating that an IRB or equivalent Privacy Board has determined that sharing of data via NICHD DASH is consistent with the informed consent and that the identities of research participants will not be disclosed to NICHD.

You must use the [DASH Institutional Certification template](#).

### Institutional Certification \*

If you are also submitting a biospecimen catalog to DASH for biospecimens available for sharing that are stored in the NICHD Contracted Biorepository, please complete the [DASH Biospecimen Catalog Institutional Certification](#) and upload below.

### Biospecimen Catalog Institutional Certification

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## Data Preparation

### PREPARING YOUR DATA

Currently, DASH will accept datasets and documents but not images. If you have a study with images, please contact the DASH Administrator at [supportdash@mail.nih.gov](mailto:supportdash@mail.nih.gov). Below are some guidelines for de-identifying and preparing your files prior to annotation:

1. Data to be submitted to DASH should be de-identified according to [NICHD DASH Policy](#). For guidance on data de-identification, please refer to the [Data and Biospecimen Catalog De-Identification Guidance](#).
2. Provide a detailed de-identification methodology document to assist other users with evaluating whether they can use the de-identified data for secondary use.
3. Datasets should be in a format that can be easily accessed by others. For example, if your datasets were prepared using a statistical software package such as SAS, please also provide your datasets as .CSV files since not all users may have access to SAS software.
4. For documents, .PDF is preferred over .DOC or .DOCX, but all are accepted, including .RTF and .TXT files.

If you have questions about preparing your data for archiving in DASH, please contact [supportdash@mail.nih.gov](mailto:supportdash@mail.nih.gov).

### DOWNLOAD DATA PREPARATION TOOL

The Data Preparation Tool (DPT), available for download below, will allow you to work offline to prepare your study for upload into DASH.

Be sure that all of your data is de-identified according to the NICHD DASH Policy (Guidance is available at [Data and Biospecimen Catalog De-Identification Guidance](#)) and that your study items (datasets and documents) are saved in a single, easy-to-find location on your computer.

Available download for Windows:

[Download \[76.6 MB\]](#)

Available download for Mac OS X:

[Download \[109.2 MB\]](#)

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## Review and Submit

Please review the study information that will appear on the Study Overview Page in DASH for your study. If you need to make changes, use the navigation bar on the left or the "Previous" button to return to a previous section.

[Preview Study Overview Page](#)

Once you have reviewed and verified the entries for this study, click "Submit Study". You will receive an email confirmation from the NICHD DASH Administrator that your submission has been received.

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