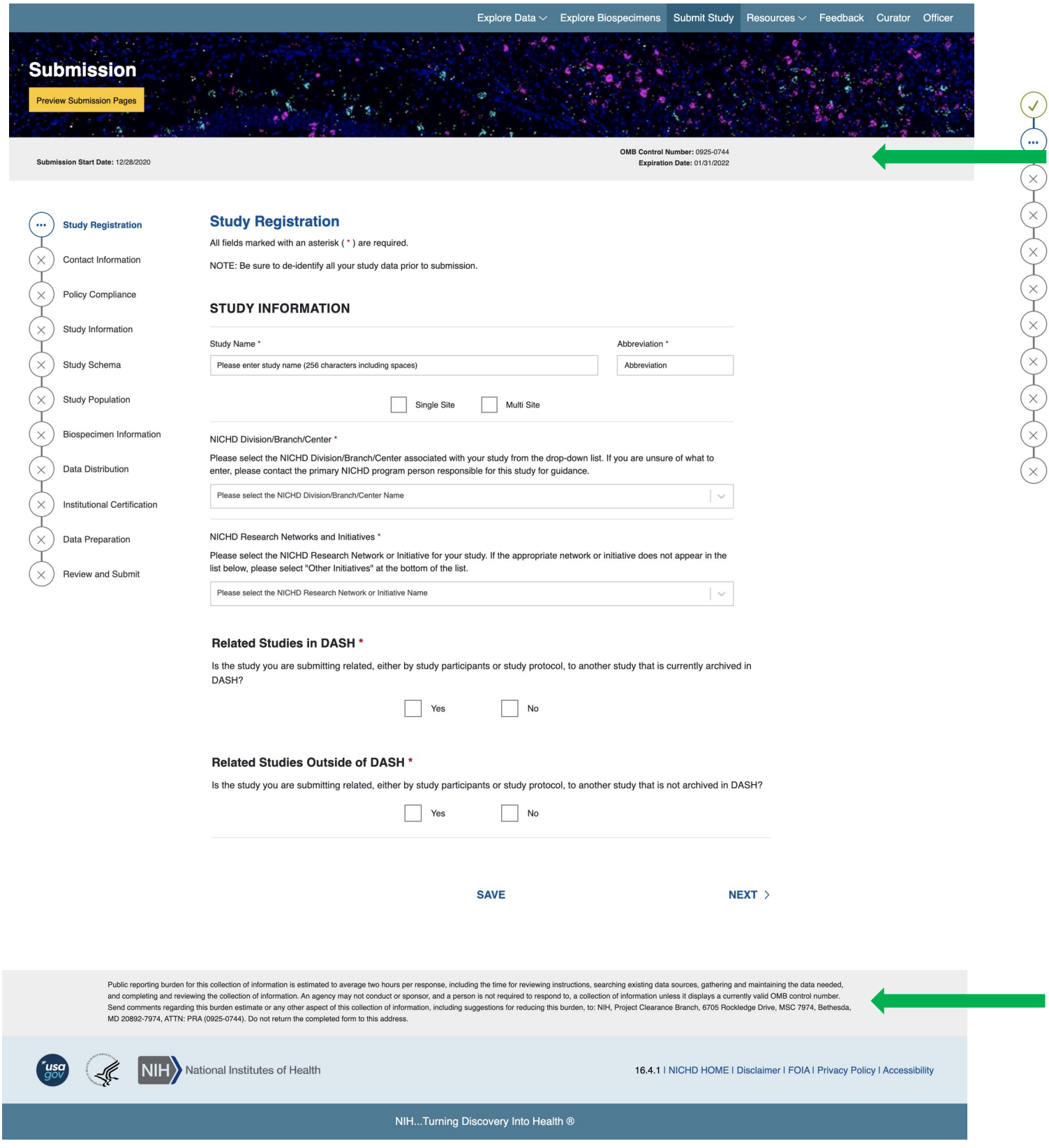
0925-0744-NEW_DASH_ATTACHMENT A.2-2_DATA SUBMISSION (APPROVED OMB NUMBER: 0925-0744)



- Study Registration
- Contact Information
- **Policy Compliance**
- Study Information
- Study Schema
- Study Population
- Biospecimen Information
- Data Distribution
- Institutional Certification

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

- Data Preparation
- Review and Submit

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).

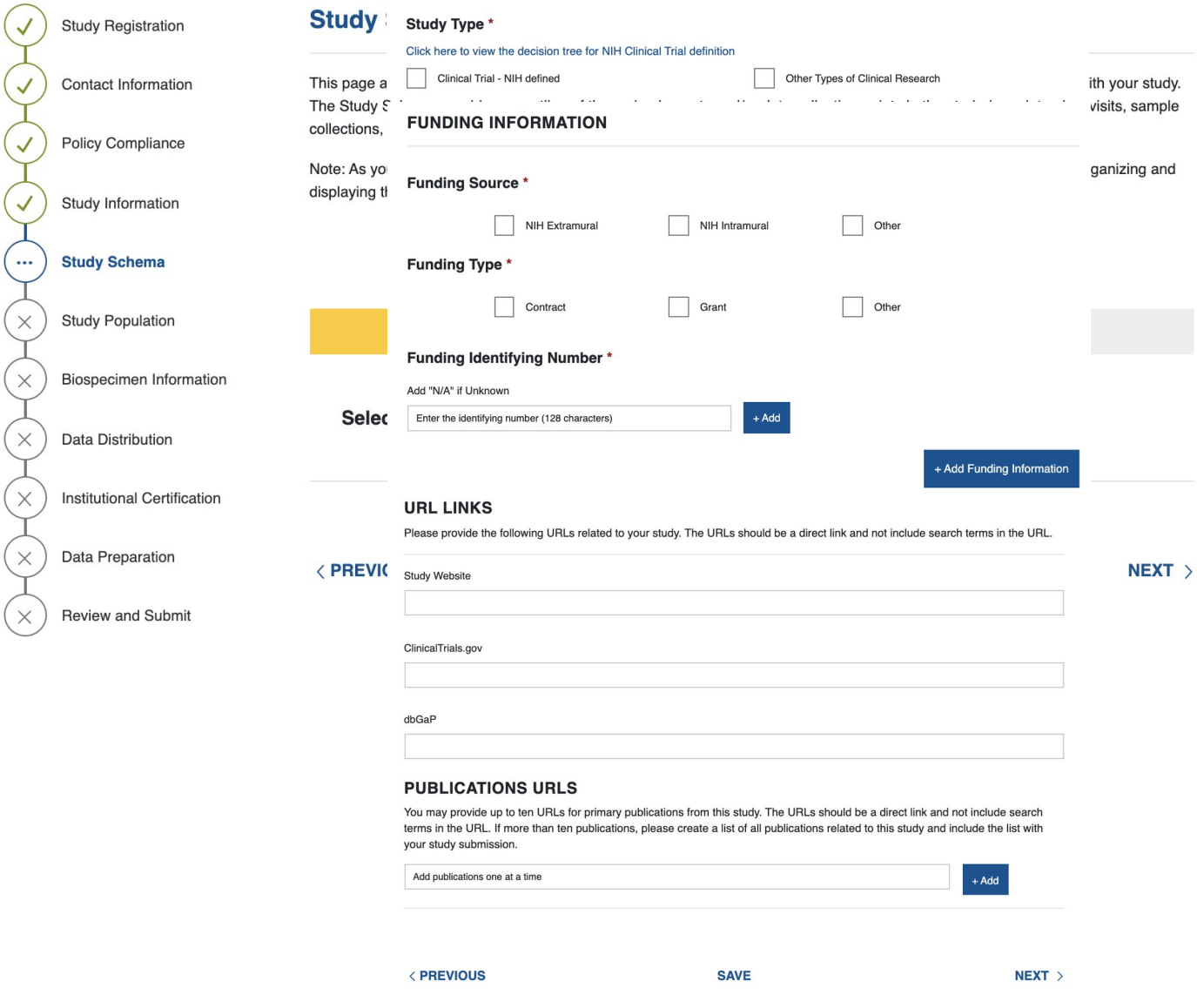
Provide a description of the study being submitted to archive (1024 characters)

Study Timeline *

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

☐ Yes ☐ No

Keywords *


Review and Submit
Topics *
Select and add a topic
+ Add
Study Registration
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Study
Study Type *
Click here to view the decision tree for NIH Clinical Trial definition
Clinical Trial - NIH defined
Other Types of Clinical Research
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ith your study.
The Study S
visits, sample
collections,
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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
Enter the identifying number (128 characters)
+ Add
Selec
+ Add Funding Information
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.
PREVI
NEXT
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
+ Add
PREVIOUS
SAVE
NEXT

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Study Population

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

TOTAL STUDY POPULATION

Total Population *

Enter Total Population

Total Population Description *

Provide a brief description of the aggregate study population being submitted to the archive (256 characters including spaces)

SUBJECTS BY SEX

***NOTE:** Please provide all applicable information*

Males

Enter Total Number

Females

Enter Total Number

Unknown

Enter Total Number

Undifferentiated

Enter Total Number

SUBJECTS BY LIFE STAGE

***NOTE:** Please provide all applicable information*

Infant (0 - 1 yr)

Enter Total Number

Toddler (13 mo - <2 yrs)

Enter Total Number

Early Childhood (2 - 5 yrs)

Enter Total Number

Middle Childhood (6 - 11 yrs)

Enter Total Number

Early Adolescence (12 - 18 yrs)

Enter Total Number

Late Adolescence (19 - 21 yrs)

Enter Total Number

Adults

Enter Total Number

Unknown

Enter Total Number

SUBJECTS BY ETHNICITY

***NOTE:** Please provide all applicable information*

Hispanic

Enter Total Number

Non-Hispanic

Enter Total Number

Unknown

Enter Total Number

SUBJECTS BY RACE

***NOTE:** Please provide all applicable information*

American Indian or Alaska Native

Enter Total Number

Asian

Enter Total Number

Black or African American

Enter Total Number

Native Hawaiian or other Pacific Islander

Enter Total Number

White

Enter Total Number

Multi Race

Enter Total Number

Unknown

Enter Total Number

SUBJECTS BY LOCATION

***NOTE:** Please provide all applicable information*

Select a U.S. Location

+ Add

Select an International Location

+ Add

< PREVIOUS SAVE NEXT >

- ✓ Study Registration
- ✓ Contact Information
- ✓ Policy Compliance
- ✓ Study Information
- ✓ Study Schema
- ✓ Study Population
- ••• **Biospecimen Information**
- × Data Distribution
- × Institutional Certification
- × Data Preparation
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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 *

Upload File

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

Upload File

PREVIOUS SAVE NEXT

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. 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.

DOWNLOAD DATA PREPARATION TOOL

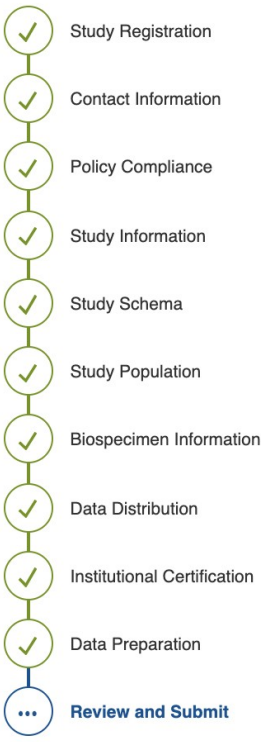
The Data Preparation Tool (DPT), available for download below, will allow you to work offline to prepare your study for upload into DASH.

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]

PREVIOUS NEXT



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.

< PREVIOUS SUBMIT STUDY