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

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development | DASH Data and Specimen Hub

OMB Control Number: 0925-0744
Expiration Date: 06/30/2019

Submitter Information: Submitter Name [Email address]

Submission Start Date: mm/dd/yyyy

- General - Part 1
- General - Part 2
- Policy Compliance
- Study Details
- Study Population
- Data Distribution
- Supporting Documents - Compliance
- Supporting Documents - Descriptive
- Data Preparation
- Review and Submit

General - Part 1

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

NOTE: Be sure to de-identify all your study data prior to submission.

STUDY

Study Name *

Please enter study name (256 characters including spaces).

Abbreviation *

Abbreviation

○ Single Site ○ Multi Site

NICHD Division/Branch/Center *

Please select the Division/Branch/Center from the drop down list. If you are unsure of what to enter, please contact the NICHD Program Officer responsible for this study to obtain this information.

Please select the NICHD Division/Branch/Center Name

NICHD Program/Clinical Research Network Name

Please select the Clinical Research Network Name

POINT OF CONTACT INFORMATION

NOTE: You must include an email address, or this Point of Contact Information section will not be saved.

☐ Use information from my registered account to auto-populate Point of Contact Information and add Institution and Division fields.

Email Address *

Email Address

Title | **First Name** * | **Last Name** * | **M.I.**

Dr. | First Name | Last Name | M.I.

Job Title/Position *

Job Title/Position

Phone

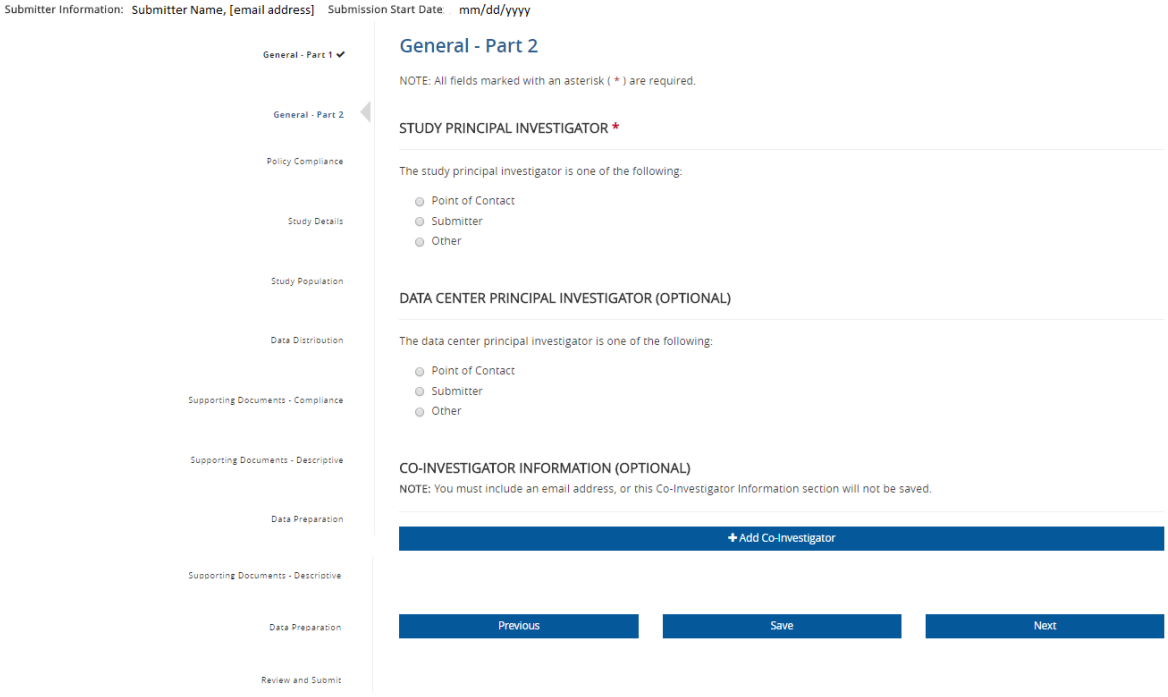
Phone Number

Institution *

Select an Institution...

Unable to find your institution in the dropdown list? Click here to add your institution

Save Next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General - Part 2
NOTE: All fields marked with an asterisk (*) are required.
STUDY PRINCIPAL INVESTIGATOR *
The study principal investigator is one of the following:
Point of Contact
Submitter
Other
DATA CENTER PRINCIPAL INVESTIGATOR (OPTIONAL)
The data center principal investigator is one of the following:
Point of Contact
Submitter
Other
CO-INVESTIGATOR INFORMATION (OPTIONAL)
NOTE: You must include an email address, or this Co-Investigator Information section will not be saved.
+ Add Co-Investigator
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Submitter Information: Submitter Name, [email address] Submission Start Date: mm/dd/yyyy

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Policy Compliance

NOTE: 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. ℹ 45 CFR Part 46 Protection of Human Subjects

- ○ Yes
- ○ No

If no, please explain:

Provide an explanation (512 characters including spaces) of why the study is not compliant with this policy.

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. ℹ 21 CFR Parts 50 and 56 FDA Human Subjects Regulations

- ○ Yes
- ○ No

If no, please explain:

Provide an explanation (512 characters including spaces) of why the study is not compliant with this policy.

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. ℹ Information about HIPAA 1996 (PDF-157 KB)

- ○ Yes
- ○ No

If no, please explain:

Provide an explanation (512 characters including spaces) of why the study is not compliant with this policy.

4. Is this Study compliant with the Privacy Act of 1974? *

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. ℹ Information about Privacy Act 1974

- ○ Yes
- ○ No

If no, please explain:

Provide an explanation (512 characters including spaces) of why the study is not compliant with this policy.

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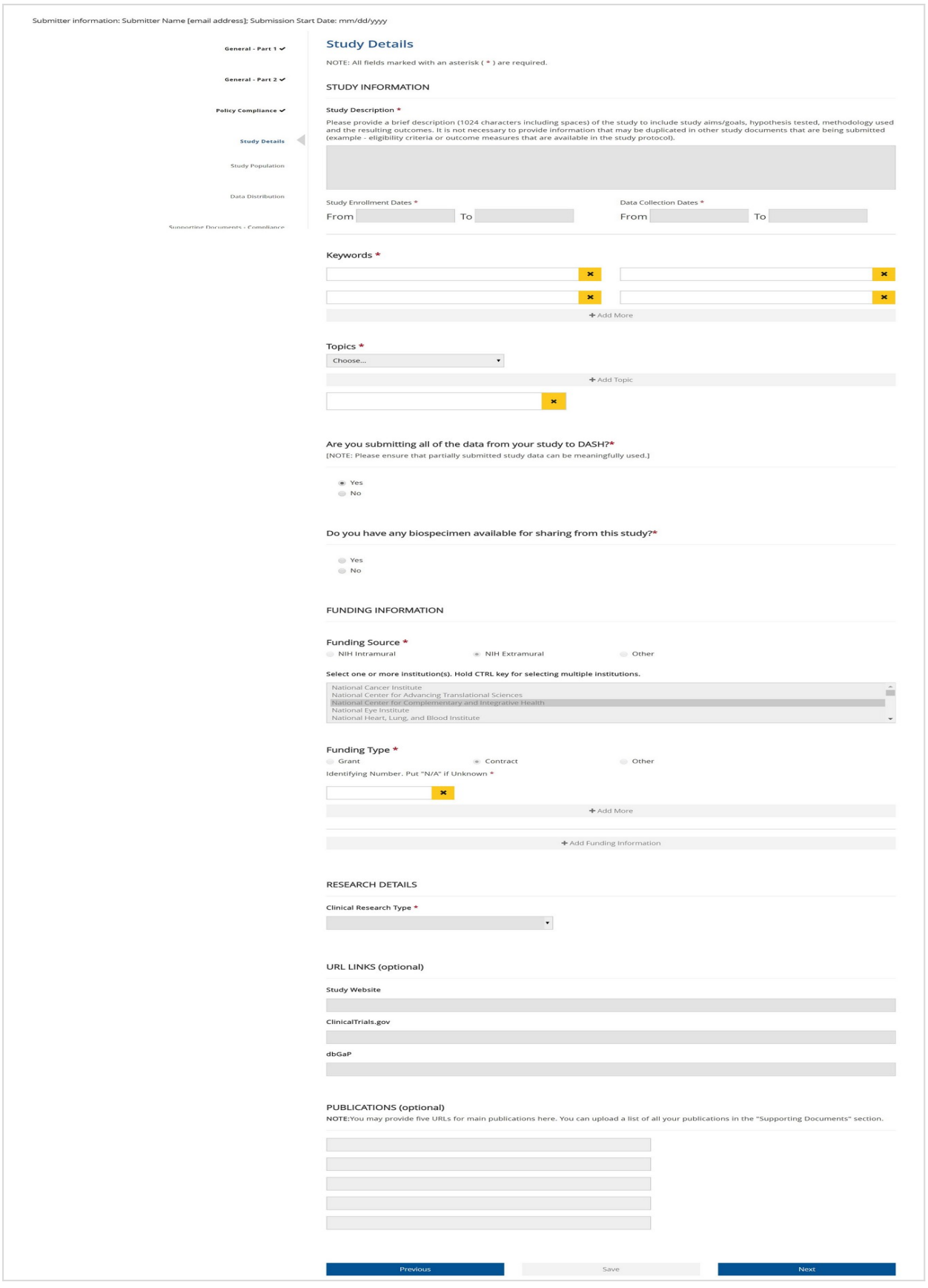
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Study Details
NOTE: All fields marked with an asterisk (*) are required.
STUDY INFORMATION
Study Description *
Please provide a brief description (1024 characters including spaces) of the study to include study aims/goals, hypothesis tested, methodology 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).
Study Enrollment Dates *
From To
Data Collection Dates *
From To
Keywords *
+ Add More
Topics *
Choose...
+ Add Topic
Are you submitting all of the data from your study to DASH?*
[NOTE: Please ensure that partially submitted study data can be meaningfully used.]
Yes
No
Do you have any biospecimen available for sharing from this study?*
Yes
No
FUNDING INFORMATION
Funding Source *
NIH Intramural
NIH Extramural
Other
Select one or more institution(s). Hold CTRL key for selecting multiple institutions.
National Cancer Institute
National Center for Advancing Translational Sciences
National Center for Complementary and Integrative Health
National Eye Institute
National Heart, Lung, and Blood Institute
Funding Type *
Grant
Contract
Other
Identifying Number. Put "N/A" if Unknown *
+ Add More
+ Add Funding Information
RESEARCH DETAILS
Clinical Research Type *
URL LINKS (optional)
Study Website
ClinicalTrials.gov
dbGaP
PUBLICATIONS (optional)
NOTE:You may provide five URLs for main publications here. You can upload a list of all your publications in the "Supporting Documents" section.
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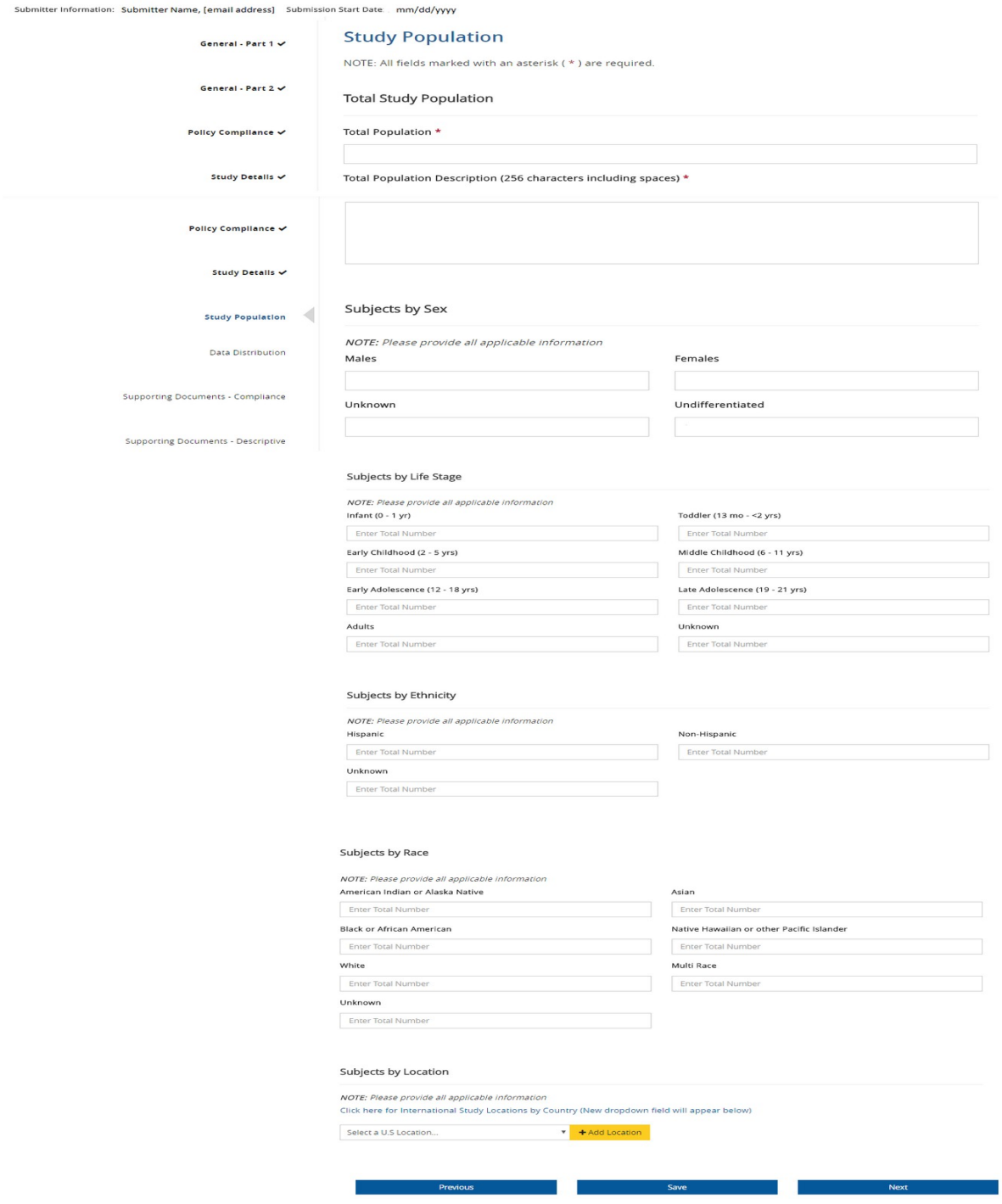
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Supporting Documents - Descriptive
Study Population
NOTE: All fields marked with an asterisk (*) are required.
Total Study Population
Total Population *
Total Population Description (256 characters including spaces) *
Subjects by Sex
NOTE: Please provide all applicable information
Males
Females
Unknown
Undifferentiated
Subjects by Life Stage
NOTE: Please provide all applicable information
Infant (0 - 1 yr)
Toddler (13 mo - <2 yrs)
Early Childhood (2 - 5 yrs)
Middle Childhood (6 - 11 yrs)
Early Adolescence (12 - 18 yrs)
Late Adolescence (19 - 21 yrs)
Adults
Unknown
Enter Total Number
Subjects by Ethnicity
NOTE: Please provide all applicable information
Hispanic
Non-Hispanic
Unknown
Subjects by Race
NOTE: Please provide all applicable information
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White
Multi Race
Unknown
Subjects by Location
NOTE: Please provide all applicable information
Click here for International Study Locations by Country (New dropdown field will appear below)
Select a U.S Location...
+ Add Location
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Data Distribution

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

1. All data requests will be reviewed by the DASH Data Access Committee. Do you require additional approval from a study-specific approving entity based on the study protocol and/or consent form? *

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

- ○ Yes
- ◉ No

3. Do you require data requesters to submit IRB approval for obtaining your study data from DASH? *

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

- ○ Yes
- ◉ No

4. Did you use any proprietary data collection instruments in your study?*

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

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

Acknowledgment Instructions

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

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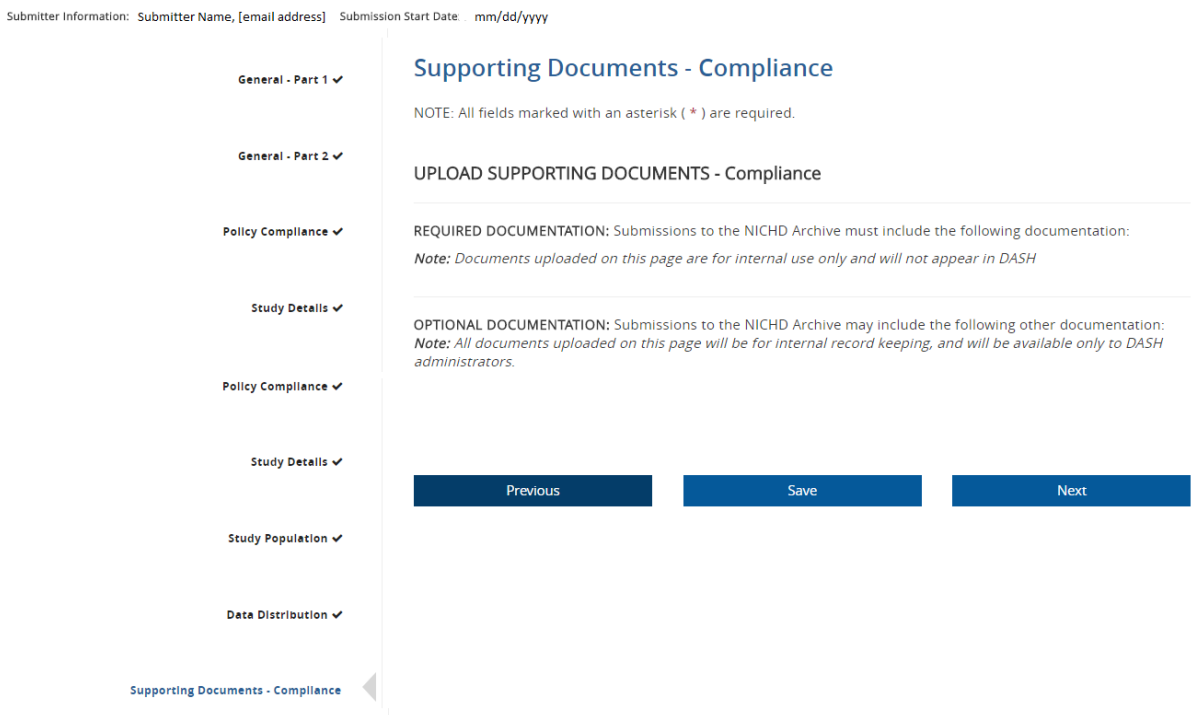
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Policy Compliance ✔
Study Details ✔
Study Population ✔
Data Distribution ✔
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Supporting Documents - Compliance
NOTE: All fields marked with an asterisk (*) are required.
UPLOAD SUPPORTING DOCUMENTS - Compliance
REQUIRED DOCUMENTATION: Submissions to the NICHD Archive must include the following documentation:
Note: Documents uploaded on this page are for internal use only and will not appear in DASH
OPTIONAL DOCUMENTATION: Submissions to the NICHD Archive may include the following other documentation:
Note: All documents uploaded on this page will be for internal record keeping, and will be available only to DASH administrators.
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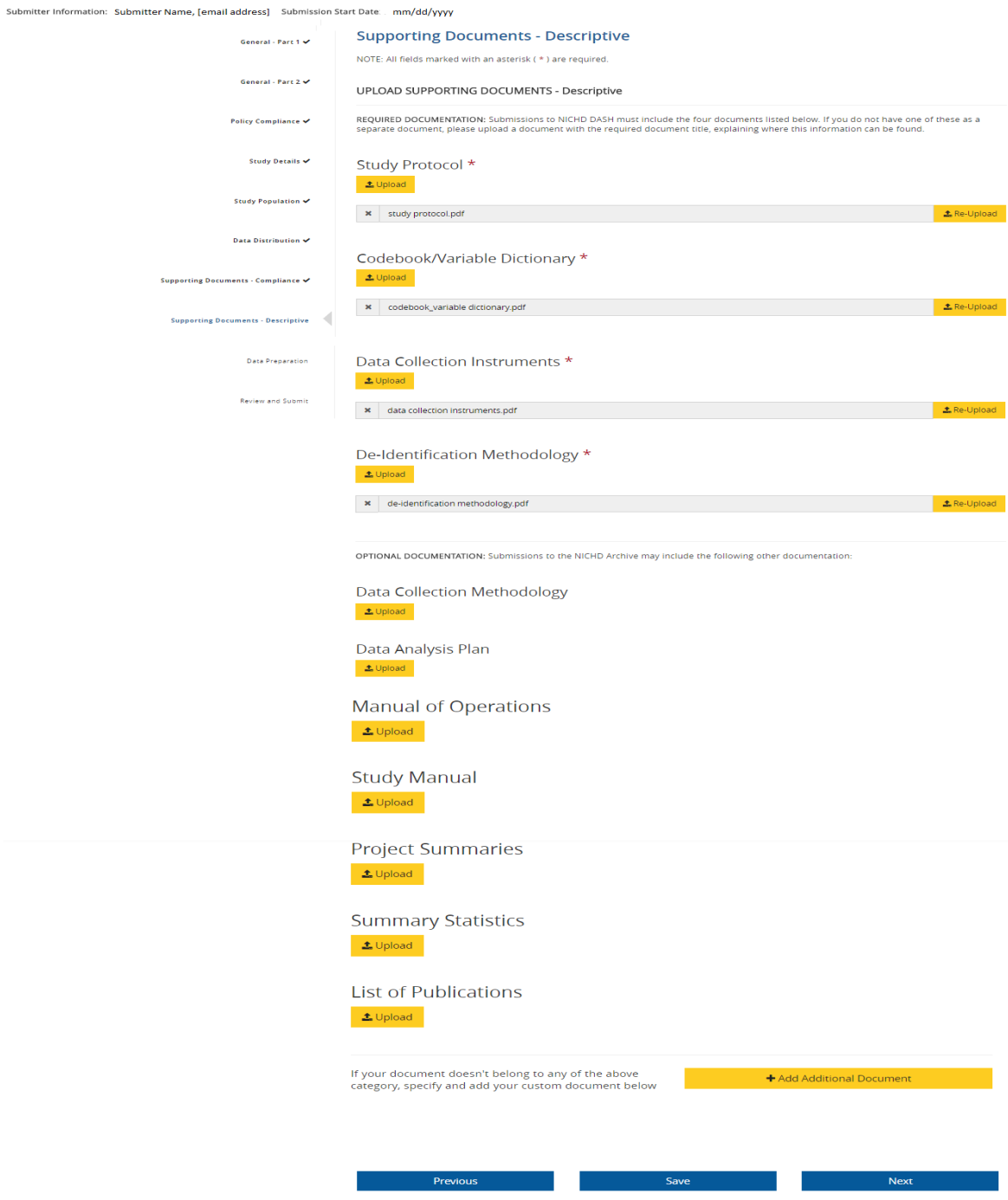
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NOTE: All fields marked with an asterisk (*) are required.
UPLOAD SUPPORTING DOCUMENTS - Descriptive
REQUIRED DOCUMENTATION: Submissions to NICHD DASH must include the four documents listed below. If you do not have one of these as a separate document, please upload a document with the required document title, explaining where this information can be found.
Study Protocol *
Upload
study protocol.pdf
Re-Upload
Codebook/Variable Dictionary *
Upload
codebook_variable dictionary.pdf
Re-Upload
Data Collection Instruments *
Upload
data collection instruments.pdf
Re-Upload
De-Identification Methodology *
Upload
de-identification methodology.pdf
Re-Upload
OPTIONAL DOCUMENTATION: Submissions to the NICHD Archive may include the following other documentation:
Data Collection Methodology
Upload
Data Analysis Plan
Upload
Manual of Operations
Upload
Study Manual
Upload
Project Summaries
Upload
Summary Statistics
Upload
List of Publications
Upload
If your document doesn't belong to any of the above category, specify and add your custom document below
+ Add Additional Document
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Supporting Documents - Compliance ✔

Supporting Documents - Descriptive ✔

Data Preparation

Review and Submit

Data Preparation

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

PREPARING YOUR DATA

Currently, DASH will accept datasets and documents but not images. So, 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 Guidelines for Data De-identification and Coding.

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 it as .CSV files since not all users may have access to SAS software.

4. If you provide .SAS files, consider providing them as .SAS transport files (.XPT files) so that SAS users working in different environments can import your files into their SAS application. You will need to encode .XPT files using utf-8.

5. In your study documentation, provide the version of the statistical software package that you used to prepare your datasets.

6. 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 Guidance for Data De-Identification and Coding) and that your study items (datasets and documents) are saved in a single, easy-to-find location on your computer.

Download DPT for Windows

Download DPT for Mac OS X

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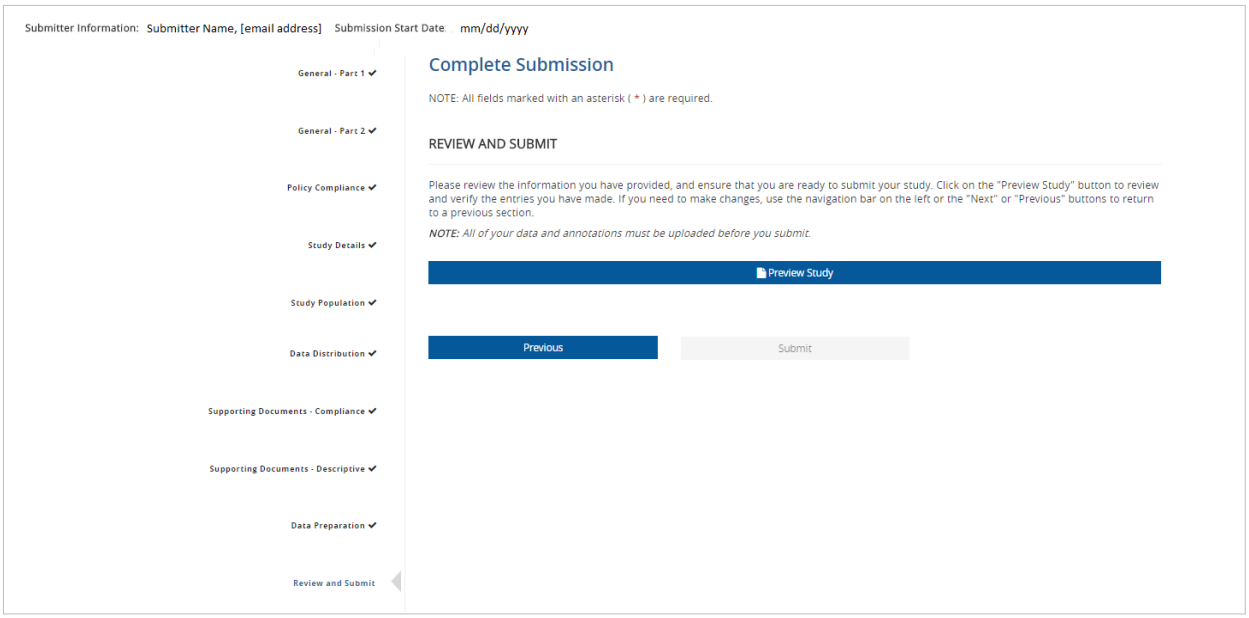
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Review and Submit
Complete Submission
NOTE: All fields marked with an asterisk (*) are required.
REVIEW AND SUBMIT
Please review the information you have provided, and ensure that you are ready to submit your study. Click on the "Preview Study" button to review and verify the entries you have made. If you need to make changes, use the navigation bar on the left or the "Next" or "Previous" buttons to return to a previous section.
NOTE: All of your data and annotations must be uploaded before you submit.
Preview Study
Previous
Submit