

## Submit Study to NICHD DASH

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As per the [NICHD DASH Policy](#), data submitted to NICHD DASH must be stripped of the 18 HIPAA identifiers and coded, with keys to the codes retained by the submitting institution(s). NICHD has developed Data and Biospecimen Catalog De-identification Guidance for investigators to utilize when preparing data for submission to NICHD DASH. It is available on the [DASH Submission Resources Page](#). All data submissions to NICHD DASH must be accompanied by the following:

- An Institutional Certification (template is available on the [DASH Submission Resources Page](#)) from responsible institutional official(s) of the submitting institution stating that an Institutional Review Board (IRB) and/or Privacy Board, as applicable, has approved submission of the study to NICHD DASH and that the identities of research participants will not be disclosed to NICHD.
- Required study documentation (study protocol, codebook/variable dictionary, data collection instruments, and de-identification methodology) which ensures meaningful use of the data and prevents misuse, misinterpretation, and confusion.

Submitting study data to NICHD DASH includes the following major steps:

1. **Complete online required information** about the study (such as general information, the investigator(s), policy compliance, and data distribution instructions).
2. **Upload completed Institutional Certification** into NICHD DASH.
3. **Annotate and prepare your study documents and data for submission** to NICHD DASH. You will be provided with a downloadable Data Preparation Tool (DPT) to assist you with offline annotation and preparation of your documents and data for submission to NICHD DASH.
4. **Upload your study submission** to NICHD DASH via the secure and encrypted NICHD DASH system.

### 1. Who May Submit

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All investigators (extramural and intramural) who have studies funded by NICHD are encouraged to submit their studies to NICHD DASH. To submit studies to NICHD DASH, you must be registered and logged into your NICHD DASH account.

### 2. Study Documents for Submission

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Submission of de-identified study data to NICHD DASH must be accompanied by the following documentation:

1. **Institutional Certification:** This is an administrative compliance document for internal use and will not be viewable to all DASH users. Submitters must provide an Institutional Certification from the responsible institutional official(s) of the submitting institution stating that they approve submission to NICHD DASH and that the identities of research participants will not be disclosed to NICHD. The template for the Institutional Certification is available on the [DASH Submission Resources Page](#).

The Institutional Certification must assure that:

- The data submission is consistent with all applicable national, tribal, and state laws and regulations, as well as institutional and study policies
  - Any limitations to the use of data submitted to NICHD DASH are consistent with the informed consent documents and have been delineated during the data submission process
  - The investigator will inform the NICHD DASH if data needs to be removed from NICHD DASH for any reason, such as change in informed consent
  - An IRB and/or Privacy Board (as applicable) has reviewed and verified that:
    - Data sharing via NICHD DASH does not conflict with the informed consent of study participants from whom the data were obtained
    - Data has been de-identified in accordance with [NICHD DASH Policy](#)
    - Data were collected in a manner consistent with [45 CFR Part 46](#)
2. **Study Documents:** These documents ensure meaningful use of the data and are provided to users who are interested in requesting your study data from NICHD DASH. In addition to the Institutional Certification, four document types are required, and other document types are highly encouraged:

- Study Protocol (required)
- Codebook/Variable Dictionary (required)
- Data Collection Instruments (required)
- De-Identification Methodology (required; for guidance on de-identification, see Data and Biospecimen Catalog De-identification Guidance on the [DASH Submission Resources Page](#))
- Data Collection Methodology
- Data Analysis Plan
- Manual of Operations
- Study Manual
- Project Summaries
- Summary Statistics
- List of Publications

### 3. Navigating through NICHD DASH Submission

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Once you have started the submission process, please navigate using the NICHD DASH navigation buttons and **NOT** your browser buttons. There are two ways to navigate among

pages in the NICHD DASH submission process. The figure below shows a sample submission information page. On the left-hand side of the page is a Navigation pane, and at the bottom of the page are blue buttons: Previous, Save, and Next, depending on the section you are in.

**Figure 1: Sample NICHD DASH Submission Page with Navigation**

The screenshot displays a submission page with a navigation pane on the left and a 'Contact Information' form on the right. The navigation pane consists of a vertical list of steps, each with a circular icon: a green checkmark for 'Study Registration', a blue circle with three dots for 'Contact Information', and circles with an 'X' for 'Policy Compliance', 'Study Information', 'Study Schema', 'Study Population', 'Biospecimen Information', 'Data Distribution', 'Institutional Certification', 'Data Preparation', and 'Review and Submit'. The 'Contact Information' form is titled 'Contact Information' and includes a note: 'All fields marked with an asterisk (\*) are required.' Below this is the 'SUBMITTER INFORMATION' section, which contains a table of fields and their values. The fields are: Email Address (gorelik. irina@bah.com), School/Division/Center (SIG), Name (Dr. Irina Gorelik, II), Division Address (One Preserve Pkwy, Rockville, MD, 20852), Job Title/Position (QA Tester), Institution (Geoz Allen Hamilton), Institution Type (For profit), Phone (N/A), and Institution Address (One Preserve Pkwy, Rockville, MD, 20852). At the bottom of the form is the 'NICHD POINT OF CONTACT INFORMATION \*' section, which includes a note: 'This Point of Contact must be the primary NICHD program person responsible for this study. Please enter an NIH email address for this person. The system will auto-populate the information if they are already registered in DASH. Otherwise, please enter their contact information.'

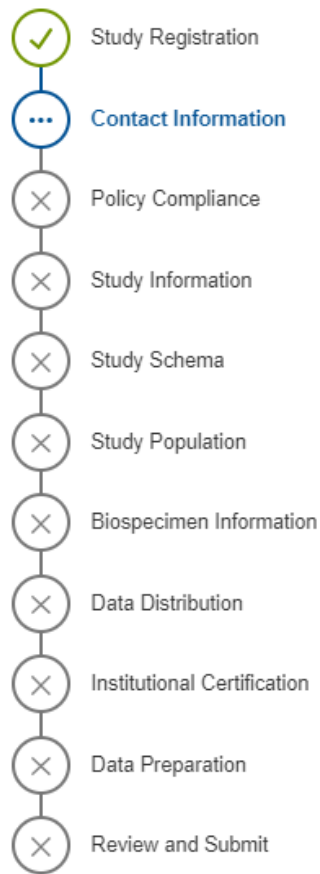
Field	Value
Email Address	gorelik. irina@bah.com
School/Division/Center	SIG
Name	Dr. Irina Gorelik, II
Division Address	One Preserve Pkwy Rockville, MD, 20852
Job Title/Position	QA Tester
Institution	Geoz Allen Hamilton
Institution Type	For profit
Phone	N/A
Institution Address	One Preserve Pkwy Rockville, MD, 20852

**NICHD POINT OF CONTACT INFORMATION \***

This Point of Contact must be the primary NICHD program person responsible for this study. Please enter an NIH email address for this person. The system will auto-populate the information if they are already registered in DASH. Otherwise, please enter their contact information.

**NOTE:** Using your Internet browser's "Back" button will take you out of the NICHD DASH submission process. This will cause you to lose any information that you have not saved. To avoid this, please use the navigation pane/blue buttons provided and click "Save" often.

**Figure 2: Navigation Pane**



The left-hand navigation pane shows each of the major submission steps. If you have not completed a section, it will appear in non-bolded gray text. Sections that are completed are shown in bolded black text with a check mark to the right. The section you are currently working on is shown in bolded blue text with an arrow mark to the right.

You may return to any section that you have already completed by clicking on the section name.

At the bottom of each page, there are blue navigation buttons labeled "Previous", "Save", and "Next."

**Figure 3: Navigation Buttons**

[< PREVIOUS](#)

[SAVE](#)

[NEXT >](#)

Use the blue “Previous” and “Next” buttons to navigate between pages—to move forward to the next page or to return to a previous page to make additions or corrections. Do not use your browser’s “Back” button, or you will exit the submission process and may lose your work. The “Save” button will save completed sections of the page without leaving the current page.

## 4. Start a New Submission

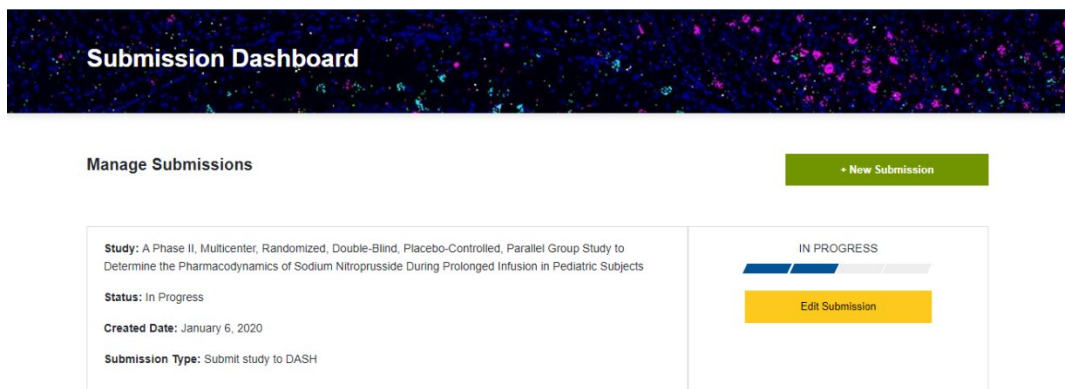
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Follow the instructions below to submit your study to NICHD DASH. You may save your work at any point during the submission process and resume later. Note that only completed sections within a page will be saved. To access ongoing study submissions, click on the “Submit Study” button located on the top bar of the homepage. You will be directed to the “Submission Dashboard” page displaying your study submissions. Click on “Resume” to the right of the study that you wish to continue working on. For more information, see Section “Tracking your Submission via the “Manage Submissions” Dashboard.”

**NOTE:** You must de-identify all your study data prior to initiating submission.

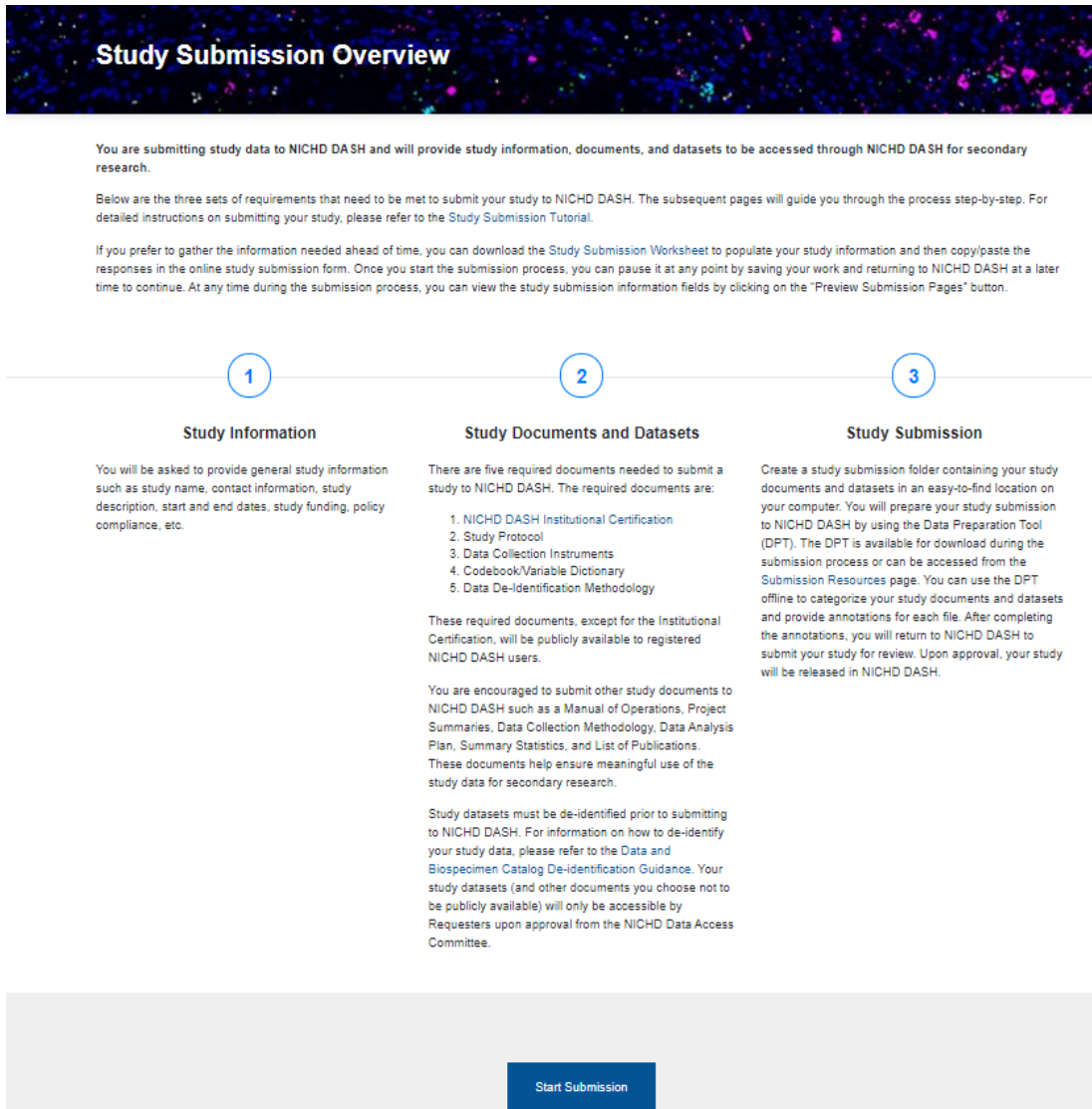
1. Click on the “Submit Study” button on the top menu bar of NICHD DASH and select “+ New Submission”.

Figure 4: Submit Study



2. You will be directed to the “Study Submission Overview” page, where you can download a DASH Study Submission Worksheet (also available on the [DASH Submission Resources Page](#)) to help you gather all the information you will need for your study submission.

Figure 5: "Study Submission Overview" Page



The image shows a screenshot of the "Study Submission Overview" page. At the top, there is a dark blue header with the title "Study Submission Overview" in white. Below the header, there is a paragraph of introductory text. This is followed by three numbered steps, each with a title and a detailed description. Step 1 is "Study Information", Step 2 is "Study Documents and Datasets", and Step 3 is "Study Submission". At the bottom of the page, there is a large grey button labeled "Start Submission".

## Study Submission Overview

You are submitting study data to NICHD DASH and will provide study information, documents, and datasets to be accessed through NICHD DASH for secondary research.

Below are the three sets of requirements that need to be met to submit your study to NICHD DASH. The subsequent pages will guide you through the process step-by-step. For detailed instructions on submitting your study, please refer to the Study Submission Tutorial.

If you prefer to gather the information needed ahead of time, you can download the Study Submission Worksheet to populate your study information and then copy/paste the responses in the online study submission form. Once you start the submission process, you can pause it at any point by saving your work and returning to NICHD DASH at a later time to continue. At any time during the submission process, you can view the study submission information fields by clicking on the "Preview Submission Pages" button.

- 1 Study Information**

You will be asked to provide general study information such as study name, contact information, study description, start and end dates, study funding, policy compliance, etc.
- 2 Study Documents and Datasets**

There are five required documents needed to submit a study to NICHD DASH. The required documents are:

  1. NICHD DASH Institutional Certification
  2. Study Protocol
  3. Data Collection Instruments
  4. Codebook/Variable Dictionary
  5. Data De-identification Methodology

These required documents, except for the Institutional Certification, will be publicly available to registered NICHD DASH users.

You are encouraged to submit other study documents to NICHD DASH such as a Manual of Operations, Project Summaries, Data Collection Methodology, Data Analysis Plan, Summary Statistics, and List of Publications. These documents help ensure meaningful use of the study data for secondary research.

Study datasets must be de-identified prior to submitting to NICHD DASH. For information on how to de-identify your study data, please refer to the Data and Biospecimen Catalog De-identification Guidance. Your study datasets (and other documents you choose not to be publicly available) will only be accessible by Requesters upon approval from the NICHD Data Access Committee.
- 3 Study Submission**

Create a study submission folder containing your study documents and datasets in an easy-to-find location on your computer. You will prepare your study submission to NICHD DASH by using the Data Preparation Tool (DPT). The DPT is available for download during the submission process or can be accessed from the Submission Resources page. You can use the DPT offline to categorize your study documents and datasets and provide annotations for each file. After completing the annotations, you will return to NICHD DASH to submit your study for review. Upon approval, your study will be released in NICHD DASH.

[Start Submission](#)

3. Click the "Start Submission" button. You will be directed to the "Study Registration" page.

## 5. Submission – Study Registration

In the following steps, you will provide information on the “Study Registration” page regarding the study you are submitting.

Figure 6: “Study Registration” Page

The screenshot shows the 'Study Registration' page. On the left is a vertical navigation menu with ten items: 'Study Registration' (active, with a blue circle and three dots), 'Contact Information', 'Policy Compliance', 'Study Information', 'Study Schema', 'Study Population', 'Data Distribution', 'Institutional Certification', 'Data Preparation', and 'Review and Submit' (all with a grey circle and an 'X'). The main content area is titled 'Study Registration' and includes a note: 'All fields marked with an asterisk ( \* ) are required.' and a 'NOTE: Be sure to de-identify all your study data prior to submission.' The 'STUDY INFORMATION' section contains a 'Study Name \*' field (with placeholder text 'Please enter study name (256 characters including spaces)') and an 'Abbreviation \*' field (with placeholder text 'Abbreviation'). Below these are two radio buttons: 'Single Site' and 'Multi Site'. The 'NICHD Division/Branch/Center \*' section has a note: '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' and a dropdown menu with placeholder text 'Please select the NICHD Division/Branch/Center Name'. The 'NICHD-Supported Research Networks and Initiatives \*' section has a note: 'Please select the NICHD-Supported 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.' and a dropdown menu with placeholder text 'Please select the NICHD-Supported Research Network or Initiative Name'. The 'Related Studies in DASH \*' section asks 'Is the study you are submitting related, either by study participants or study protocol, to another study that is currently archived in DASH?' with 'Yes' and 'No' radio buttons. The 'Related Studies Outside of DASH \*' section asks 'Is the study you are submitting related, either by study participants or study protocol, to another study that is not archived in DASH?' with 'Yes' and 'No' radio buttons.

1. Fill in the “Study Name” and “Abbreviation” fields with your study name and abbreviation, respectively.
2. Select whether the study is a “Single Site” or “Multi Site.”
3. From the dropdown menu, select the “NICHD Division/Branch/Center” that was associated with your study. If you are unsure, please contact the primary NICHD program person responsible for your study for guidance.

4. From the dropdown menu, select the “NICHD-Supported Research Networks & Initiatives” used for your study. For reference see the [NICHD-Supported Research Networks & Initiatives](#) page. If the appropriate network or initiative does not appear in the list, select “Other Initiatives.”
5. For the “Related studies in DASH” question, answer the question by selecting “Yes” or “No.” If you select “Yes”:
  - Identify the relationship from the dropdown list:
    - the Main Study of
    - a Sub-Study of
    - a Mother/Child Follow-Up Study of
    - an Outcome Follow-Up Study of
    - Related to
  - Select study from the list of studies in DASH
6. For the “Related Studies Outside of DASH” question, answer the question by selecting “Yes” or “No.” If you select “Yes”, enter the study name (study abbreviation), brief description of study, and a link to the study website.
7. Click “Next” to save your work and continue to the “Contact Information” page.

## 6. Submission – Contact Information

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In the following steps, you will provide contact information for the key individuals related to your study.

1. Provide NICHD Point of Contact (POC) information. This is the primary NICHD program person responsible for your study.
  - Enter the NICHD POC’s NIH email address (e.g., john.doe@nih.gov)
  - If the NICHD POC is a registered user, NICHD DASH will auto-populate the POC information associated with that NIH email address.
  - If you enter an email address and the fields do not auto-populate, fill in the remaining fields.
  - The institution field will be auto-populated.



Figure 7: NICHD Point of Contact Information

**NICHD POINT OF CONTACT INFORMATION \***

This Point of Contact must be the primary NICHD program person responsible for this study. Please enter an NIH email address for this person. The system will auto-populate the information if they are already registered in DASH. Otherwise, please enter their contact information.

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Email Address \*

Title	First Name *	Last Name *	M.I.
<input type="text" value="Title"/>	<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	<input type="text" value="M.I."/>

Job Title/Position *	Phone Number
<input type="text" value="Job Title/Position"/>	<input type="text" value="Please enter Phone Number"/>

Institution \*

Division \*

2. Select who was the Study Principal Investigator (PI), select from: NICHD Point of Contact, Submitter, or Other.
  - For the first two options, NICHD DASH will auto-populate this section with the NICHD POC or Submitters' information, respectively, associated with their email address.
  - If you select "Other", enter the Study PI's email address
    - If the Study PI is a registered user, NICHD DASH will auto-populate the contact information associated with that email address.
    - If you enter an email address and the fields do not auto-populate, fill in the remaining fields. NICHD DASH will store this information, based on the email address, for future submissions.

Figure 8: Study PI Information

**STUDY PRINCIPAL INVESTIGATOR \***

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The study Principal Investigator is one of the following:

NICHD Point of Contact     Submitter     Other

- Select the Study PI's institution from the dropdown list. If you are unable to find the institution, select the "Click here to add institution" link, and fields will appear for you to add the institution name.

- To add the institution, complete all the required fields denoted by an asterisk for the institution and division. This will make this institution available for future submissions.
- Select “For Profit” or “Not For Profit”.

**Figure 9: Add Institution**

**Create New Institution** ✕

Institution Type \*

Institution Type ▾

For profit  Not for profit

Institution Name \*

Institution Name

Country \*

Country ▾

Address (Line 1) \*

Address Line 1

Address (Line 2)

Address Line 2

City \* Province/Region Postal Code

City Province/Region Postal Code

Cancel Save

3. Add contact information for one or more Study Co-investigator(s). Click on “+Add co-investigator” to add each of them . Click on “Remove Co-investigator” to remove an entry.

Figure 10: Add Study Co-investigator Contact Information

## STUDY CO-INVESTIGATOR(S)

+ Add Co-Investigator

### Co-Investigator 1

 Remove Co-Investigator

Please enter an email address for this person. The system will auto-populate the information if they are already registered in DASH. Otherwise, please enter their contact information.

Email Address \*

Please enter Email Address

Title

Title

First Name \*

First Name

Last Name \*

Last Name

M.I.

M.I.

Job Title/Position \*

Job Title/Position

Phone Number

Please enter Phone Number (XXX-XXX-XXXX)

Institution \*

Select a institution ...

Add More +

4. For the "Was there a Data Coordinating Center for your Study" question, answer the question by selecting "Yes" or "No." Select "No" only if there was no Data Coordinating Center for this study.

Figure 11: No Data Coordinating Center for the study

### DATA COORDINATING CENTER PRINCIPAL INVESTIGATOR \*

Was there a Data Coordinating Center for your study?

Yes  No

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[SAVE](#)

[NEXT >](#)

- If you select "Yes", new fields will appear. Indicate if the Data Coordinating Center Principal Investigator is either the "Submitter" or "Other".

Figure 12: Data Coordinating Center Principal Investigator is Submitter

### DATA COORDINATING CENTER PRINCIPAL INVESTIGATOR \*

Was there a Data Coordinating Center for your study?

Yes  No

The Data Coordinating Center Principal Investigator is one of the following:

Submitter  Other

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- If you select "Other", you will be prompted to enter the Data Coordinating Center Principal Investigator's email address.
- If you enter the email address of a registered user in the "Email Address" field, NICHD DASH will auto-populate the Data Coordinating Center Principal Investigator's information associated with that email address.
- If you enter an email address and the fields do not auto-populate, fill in the remaining fields. NICHD DASH will store this information, based on the email address, for future submissions.

Figure 13: Data Coordinating Center Principal Investigator as Other

**DATA COORDINATING CENTER PRINCIPAL INVESTIGATOR \***

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Was there a Data Coordinating Center for your study?

Yes  No

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The Data Coordinating Center Principal Investigator is one of the following:

Submitter  Other

Please enter an email address for this person. The system will auto-populate the information if they are already registered in DASH. Otherwise, please enter their contact information.

Email Address \*

Please enter Email Address

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

Title First Name Last Name M.I.

Job Title/Position \* Phone Number

Job Title/Position Please enter Phone Number (XXX-XXX-XXXX)

Institution \*

Select a institution ...

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[< PREVIOUS](#) [SAVE](#) [NEXT >](#)

5. Click "Next" to save your work and continue to the "Policy Compliance" page.

## 7. Submission – Policy Compliance

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The Policy Compliance page contains regulatory compliance questions regarding your study. These fields are all required, and you may provide a narrative explanation if necessary.

1. On the Policy Compliance page, answer the regulatory compliance questions by selecting "Yes" or "No" for each question. If you select "No", provide an explanation in the space provided.
2. Click "Next". You will be taken to the "Study Information" page.

Figure 14: Policy Compliance

## 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

## 8. Submission – Study Information

In the following steps, you will enter a study description that includes a narrative description, dates, keywords, funding information, and additional details. Secondary researchers will be able to use this description to get a better idea of your study and ensure that it is the correct one for them to request.

### Study Details

The Study Details section requires you to enter a narrative description of your study, enrollment start and end dates, data collection start and end dates, and the type of study.

1. Provide a narrative study description of the study, including study aims/goals, hypothesis tested, methodology used, and the resulting outcomes (limit to 1024 characters including spaces).

2. In the “Study Timeline” section, answer the question, “Are there study enrollment and data collection dates associated with your study?” by selecting “Yes” or “No.”

Figure 15: Study Dates

**Study Timeline \***

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

Yes  No

If you select “Yes”, enter enrollment start and end dates and data collection start and end dates in MM-DD-YYYY format. For dates that are missing one or two elements, follow these rules:

- If day is missing, assign as the 15th
- If month is missing, assign as July
- If month and day are missing, assign as July 1st
- In the unlikely event that the year is missing, a reasonable year should be agreed upon with input from study stakeholders

Figure 16: Study Enrollment and Data Collection Dates

**Study Timeline \***

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

Yes  No

**Study Enrollment Dates \***

Start Date

Select the start date

End Date

Select the end date

**Data Collection Dates \***

Start Date

Select the start date

End Date

Select the end date

**NOTE: DASH cannot accept any missing date elements.**

If you select “No”, please provide an explanation of why there are no dates associated with your study (limit to 512 characters including spaces).

Figure 17: Explanation of No Study Dates

**Study Timeline \***

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

Yes

No

Please explain why there are no dates associated with your study \*

Provide an explanation of why there are no dates associated with your study (512 characters including spaces).

3. Enter keywords by typing in the keyword one at a time and clicking “Add Keyword” after each entry.
4. Add topics by selecting a topic from the dropdown list and clicking “Add Topic”. This list is generated from the [NICHD A to Z Topics Index](#).
5. To remove keyword(s) or topic(s), click on the “X” next to the keyword or topic.

Figure 18: Add Keywords or Topics

**Keywords \***

Please add keywords one at a time

+ Add

**Topics \***

Select and add a topic

+ Add

6. Select your Study Type from the dropdown list. Refer to the [Decision Tree for NIH Clinical Trial Definition](#).

Figure 19: Study Type

**Study Type \***

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

Clinical Trial - NIH defined

Other Types of Clinical Research



## Funding Information

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In the “Funding Information” section, identify the funding source and additional identifying information.

1. First, select “Funding Source.” If you select “NIH Intramural” or “NIH Extramural”, you will see a dropdown list of NIH institutions.
2. Select your institution from the dropdown list. If your funding institution is not “NIH Intramural” or “NIH Extramural”, select “Other” and then select from the dropdown or click on the corresponding link to add the institution.
3. Select your funding type.
  - If you select “Grant” or “Contract,” provide the grant or contract identifying number in the “Identifying Number” field. Then click on “+ Add Identifying Numbers”.
  - To add another identifying number for the same funding type and funding source, click on “+Add Identifying Numbers.”
  - If you need to remove a number, click on the “X” next to the number you wish to remove.

**Figure 20: Funding Information**

### FUNDING INFORMATION

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#### 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

+ Add Funding Information

- If you select “Other”, you must provide information in the “Please specify” input field, which will appear.

Figure 21: Other Funding Type

**FUNDING INFORMATION**

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**Funding Source \***

NIH Extramural       NIH Intramural       Other

**Funding Type \***

Contract       Grant       Other

If Other, please specify \*

Enter other funding type (512 characters)

**Funding Identifying Number \***

Add "N/A" if Unknown

Enter the identifying number (128 characters)

+ Add

+ Add Funding Information

4. If you need to add additional funding information, click "+ Add Funding Information". If you wish to delete additional funding information, click on the "X".

## URL Links

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1. Enter URL links for your study website, ClinicalTrials.gov entry, and/or dbGaP entry, as applicable. The URLs should be a direct link and not include search terms in the URL. You may also provide up to ten links to primary publications associated with your study. If there are additional study publications you would like to provide, you are encouraged to upload a list of publications at a later step in the submission process.

**Figure 22: URL Links**

**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.

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.

2. Click on "Next." You will be taken to the "Study Schema" page.

## 9. Study Schema

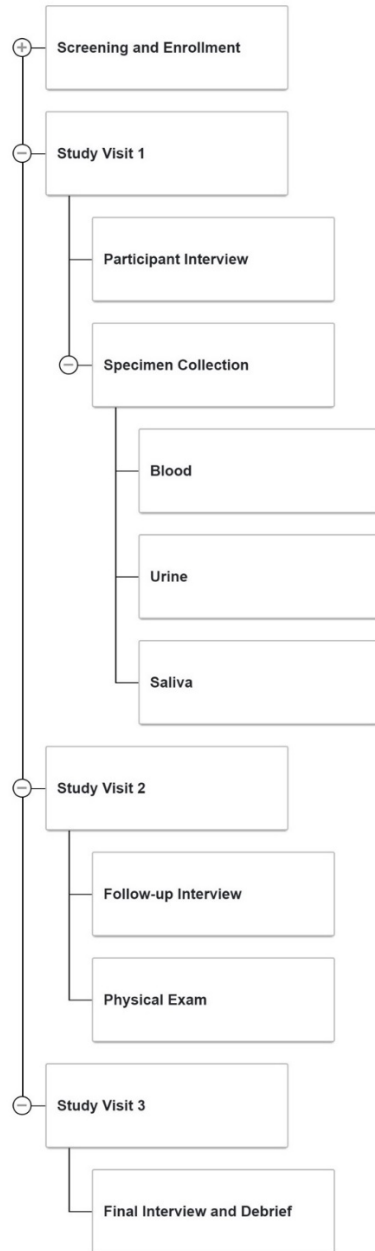
---

1. This page allows you to build a Study Schema that will be displayed on the DASH Study Overview page associated with your study. The Study Schema provides an outline of the main headings and/or data collection points in the study (e.g., interview visits, sample collections, laboratory tests). These will be organized hierarchically, much like a decision tree with various nodes or subcomponents. There can be as many levels as necessary in the hierarchy.
2. The goal is to provide a schematic representation of the main elements of your study as outlined in your study protocol. You can decide what events, levels, and/or headings, data collection points, etc., work best to describe your study.

**Figure 23: Sample Schema**

### Study Schema

---

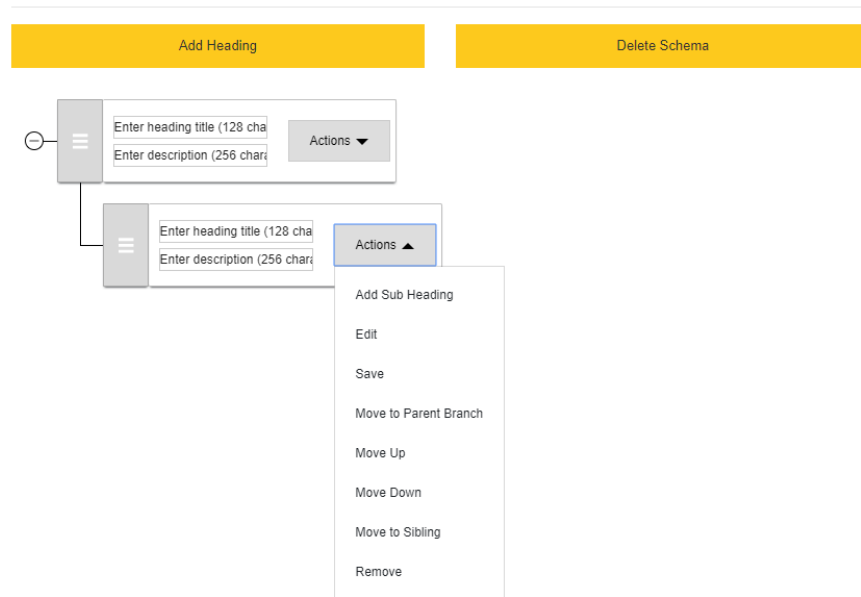


3. You are encouraged to create a study schema in a Word document in order to copy/paste the information into the schema building tool
4. To create the schema:

- Click “Add Heading” to create a heading; a box appears with two fields where you can enter/paste the heading text in the top field and an optional description
- Using the “Actions” dropdown on the right provides eight options:
  - Add Sub Heading
  - Edit
  - Save
  - Move to Parent Branch
  - Move Up
  - Move Down
  - Move to Sibling
  - Remove
- Click “Add Sub Heading” to add a sub heading under the selected heading; a box appears with two fields where you can enter/paste the sub heading text in the top field and an optional description
- Continue to add headings and sub headings as needed to complete your study schema

**Figure 24: Adding Headings and Sub Headings**

## Study Schema



5. Click on “Next.” You will be taken to the “Study Population” page.

## 10. Submission – Study Population

---

The “Study Population” page will allow you to enter information about the different population groups of your study. Not all population information is required, but you are encouraged to be as specific as possible so that others can better understand your study.

**Figure 25: Study Total Population and Description**

### Study Population

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

#### TOTAL STUDY POPULATION

Total Population \*

Total Population Description (256 characters including spaces)\*

1. Enter the total number of research participants from your study into the “Total Population” field.
2. Add a description of your total population into the “Total Population Description” field (limit: 256 characters including spaces).
3. Provide a breakdown of study participants by sex. Enter the population by sex in the “Males”, “Females”, “Unknown”, and “Undifferentiated” fields.

**Figure 26: Study Population by Sex**

#### SUBJECTS BY SEX

*NOTE: Please provide all applicable information*

Males

Females

Unknown

Undifferentiated

4. Provide a breakdown of study participants by "Life Stage".

**Figure 27: Study Population by Life Stage**

### 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

5. Provide a breakdown of study participants by ethnicity.

**Figure 28: Study Population by Ethnicity**

### SUBJECTS BY ETHNICITY

---

*NOTE: Please provide all applicable information*

Hispanic

Enter Total Number

Non-Hispanic

Enter Total Number

Unknown

Enter Total Number

6. Provide a breakdown of study participants by race.

**Figure 29: Study Population by Race**

### 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

7. Provide a breakdown of study participants by location either within the United States or for international countries. Select a location from the dropdown list and click on "+Add Location". A second data entry box will appear, and you will then be able to add subjects by U.S. or International locations, using the appropriate data entry box.

**Figure 30: Add Subjects by U.S. or International Location**

### SUBJECTS BY LOCATION

*NOTE: Please provide all applicable information*

 |  | 

8. Click on "Next." You will be taken to the "Biospecimen Information" page.

## 11. Submission – Biospecimen Information

In the following steps, you will provide information about any study-associated biospecimens. If your study collected biospecimens, provide information about whether they can be shared and where the biospecimens are stored.



Figure 31: Biospecimen Information

## Biospecimen Information

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

Were biospecimens collected for this study? \*

Yes

No

< PREVIOUS

SAVE

NEXT >

- Answer Yes/No to “Were biospecimens collected for this study?”:

If you select “Yes”, a new field will appear for details. Indicate if the biospecimens are available for public sharing/secondary use.

Figure 32: Biospecimen collected question

## Biospecimen Information

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

Were biospecimens collected for this study? \*

Yes

No

Are the biospecimens available for public sharing/secondary use? \*

Yes

No

< PREVIOUS

SAVE

NEXT >

- If you select “Yes”, a new field will appear for details. Select the biorepository where the biospecimes are stored.

Figure 33: Biospecimen available question

## Biospecimen Information

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

Were biospecimens collected for this study? \*

 Yes No

Are the biospecimens available for public sharing/secondary use? \*

 Yes No

Select the Biorepository where the biospecimens are stored \*

Please select where the biospecimens are stored

- From the dropdown list, select if the biospecimens are stored in “NICHD Contracted (Fisher) Biorepository, or “Other”. The default option is “NICHD Contracted (Fisher) Biorepository”.

Figure 34: Biorepository selection

## Biospecimen Information

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

Were biospecimens collected for this study? \*

 Yes No

Are the biospecimens available for public sharing/secondary use? \*

 Yes No

Select the Biorepository where the biospecimens are stored \*

✓ NICHD Contracted (Fisher) Biorepository  
Other

< PREVIOUS

SAVE

NEXT >

- If you select “Other”, new fields will appear for details. Indicate the location of the biospecimens and indicate the point of contact for the biospecimens. To indicate the POC, include a name, email address or phone number.

Figure 35: Biorepository Details

Select the Biorepository where the biospecimens are stored \*

Other

Please indicate the location(s) where the biospecimens are stored.\*

Enter the location(s) where the biospecimens are stored (256 characters)

Please indicate a point of contact for the biospecimens (include a name and an email address or phone number).\*

Enter the point of contact information for the biospecimens (256 characters)

- Click on “Next.” You will be taken to the “Data Distribution” page.

## 12.Submission – Data Distribution

In the following steps, you will enter data distribution information, including acknowledgement instructions for users of your study data.

Figure 36: Data Distribution Instructions

### Data Distribution

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

1. 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

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

1. Answer all the Yes/No questions related to study data distribution (please note that all fields are mandatory):

- In Question 1, please mark whether you are submitting all the data from your study to DASH.

If you answer “No”, additional fields will open asking you to provide details about the study data not being submitted to DASH and how other researchers can obtain the data not being submitted.

**Figure 37: Data Availability Information**

**1. 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

Describe study data not being submitted to DASH\*

Enter description of data not submitted to DASH but available for use by other investigators (1024 characters)

Please indicate how other researchers can obtain data not being submitted to DASH (Example: Genomics data are in dbGaP or provide contact information, etc.)\*

Enter description of how other researchers can obtain data not being submitted to DASH (1024 characters)

- In Question 2, please mark whether you require additional approvals for access to your data beyond the approvals made by the NICHD Data Access Committee. If you select “Yes”, a new field will appear for details. You can select “Steering Committee” or “Other” for a study-specific approving entity. If you select “Other”, you will need to indicate the “Approving Entity”, “POC Name” and “Email Address”.

Figure 38: Study-specific Approving Entity Information

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

Select a study-specific approving entity \*

Steering Committee  Other

Approving Entity \*

Enter the approving entity

POC Name \* Email Address \*

Enter point of contact name Enter email address

- In Question 3, please mark whether there are any limitations to the use of the data. If you select "Yes", a new field will appear for details to specify the limitations.

Figure 39: Data Use Limitations

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

Yes  No

If yes, please specify limitations\*

Enter data use limitations (512 characters)

- In Question 4, please mark whether the informed consent requires the data requesters to submit IRB approval to obtain the study data.
- In Question 5, please mark whether you used any proprietary data collection instrument(s) in your study. If you select "Yes", a new field will appear for details regarding the name of the proprietary instrument and a URL/contact information for the instrument.
- In Question 6, please mark whether you used any licensed coding standards (e.g., SNOMED, MedDRA) to code any of your study data. If you select "Yes", a new field will appear for details.

**Figure 40: Proprietary instruments and Licensed Coding Standards Information**

**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

Please add the name(s) of proprietary instrument(s) and the corresponding URL or contact information to assist users who may be interested in using the instruments. Note: Proprietary data collection instruments should not be uploaded to DASH.

Name of proprietary instrument

URL or contact information

Enter name of proprietary instrument (128 characters)

Enter URL or contact information (256 characters)

+ Add

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

Yes  No

Please add the name(s) of the licensed coding standard(s). Note: If licensed coding standards were used, data requesters will be required to comply with any licensing or subscription requirements to use your coded data stored in DASH. \*

Licensed coding standard

Enter licensed coding standard (256 characters)

+ Add

2. Provide instructions for how you wish your study to be acknowledged by researchers who use your study data in future presentations or publications. These acknowledgements will be in addition to those required by the [Data Use Agreement](#).

**Figure 41: Data Distribution Acknowledgment Instructions**

**Acknowledgment Instructions**

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

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

3. Click on "Next." You will be taken to the "Institutional Certification" page.

## 13. Submission – Institutional Certification

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. In the following steps, you will upload the required Institutional Certification.

You must use the DASH Institutional Certification template. You can find it on the [DASH Submission Resources Page](#).

**Figure 42: Institutional Certification**

The screenshot shows a web form titled "Institutional Certification". Below the title, it states: "All fields marked with an asterisk ( \* ) are required." and "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." It also notes: "You must use the DASH Institutional Certification template." There are two main sections for file uploads: "Institutional Certification \*" and "Biospecimen Catalog Institutional Certification". Each section has a yellow "Upload File" button and a text input field. At the bottom of the form, there are three navigation buttons: "< PREVIOUS", "SAVE", and "NEXT >".

1. Upload your completed and signed Institutional Certification. This is required to submit to DASH.
2. Click on the "Upload File" button, and then select the signed Institutional Certification saved on your computer. Your document title will appear on the page to verify it has been uploaded.

*Note: The Institutional Certification is an administrative requirement for submitting studies to NICHD DASH and is not made available to other users.*

3. 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 and upload the DASH Biospecimen Catalog Institutional Certification. You can find it on the [DASH Submission Resources Page](#).
4. Click "Next". You will be taken to the "Data Preparation" page.

## 14. Submission – Data Preparation

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The NICHD DASH system allows researchers to search for study documents and data based on annotated study content. The Data Preparation Tool (DPT) is a downloadable application that

you can use offline to prepare your study documents and data for submission. It allows you to organize and annotate your study documents and datasets . When using the DPT offline, you can save your work and return to it later.

*Note: All your study documents and data must be de-identified prior to performing annotation (for de-identification guidance, see “Data and Biospecimen Catalog De-identification Guidance” on the [DASH Submission Resources Page](#)).*

All studies submitted to NICHD DASH must be accompanied by proper documentation to ensure meaningful use of the research data and to prevent misuse, misinterpretation, and confusion. Documentation provides information about the methodology and procedures used to collect your study data, details about your data variable codes, definitions of variables, variable field locations, frequencies, etc. The precise content of documentation for each study will vary by scientific area, study design, type of research data collected, and characteristics of the research data. Four study documents types are required when submitting a study to NICHD DASH:

- Study Protocol
- Codebook/Variable Dictionary
- Data Collection Instruments
- De-identification Methodology

*You are encouraged to upload additional study documents to ensure meaningful use of your study data and to prevent misuse, misinterpretation, and confusion. Examples of additional study documents include: Data Collection Methodology, Data Analysis Plan, Manual of Operations, Study Manual, Project Summaries, Summary Statistics, List of Publications, and additional documents as appropriate. Note: PDF documents are preferred over .DOC or .DOCX; however, all are accepted, including .RTF and .TXT files.*

Your study documentation uploaded through the DPT will be available and viewable by any registered NICHD DASH user without approval from the NICHD DASH Data Access Committee. Verify that all of your study documents have been properly de-identified before uploading into NICHD DASH through the DPT.

The following steps walk you through preparing your study documents and data, and uploading them using the DPT.

1. Ensure all your study documents and data are de-identified and saved in a single, easy-to-find location on your computer.



Figure 43: Download Data Preparation Tool

## 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 Guidelines for [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 \[109.2 MB\]](#)

2. Download DPT for Windows or for Mac OS X by clicking the appropriate download button.
3. Open and install DPT. For step-by-step instructions on how to use DPT for preparing your study documents and data, annotating these files and uploading them to DASH, see DPT Section.
  - Guidelines for de-identifying your data are available [here](#).
  - Datasets should be in a format that can be easily accessed by others. For example, if your datasets were created using a statistical software package such as SAS, please also provide your datasets as .CSV files.
  - You are required to include a “De-identification Methodology” document that explains how your datasets were de-identified.
  - For documents, .PDF files are preferred but all formats are accepted including .DOC, .DOCX, .RTF, and .TXT.
4. If you are logged out of NICHD DASH at this stage, you can return to this step of your study submission by logging into NICHD DASH and clicking on the “Submit Study” button located on the top bar of the homepage. You will be directed to the “Submission Dashboard” page displaying your study submissions. Click on “Resume” to the right of the study that you wish to annotate and navigate to the “Data Preparation” page.

## 15.Submission – Review and Submit

---

You are now ready to review and complete the submission of your study.

Figure 44: Review and Submit page

**Submission: NISDI Pediatric Latin American Countries Epidemiological Study: A Prospective, Observational Study of HIV-infected Children at Clinical Sites in Latin American Countries (NISDI PLACES)**

Preview Submission Pages

**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 you have made 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

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

1. First, verify the completeness and accuracy of your submission. Click "Preview Study Overview Page" button. If you need to make changes, use the navigation bar on the left or the "Previous" button to return to a previous section.
2. After verifying the accuracy and completeness of the information provided on the "Study Overview" page, click "Submit".
3. You have submitted your study. You will receive an email confirmation from the NICHD DASH Administrator that your submission has been received.

## 16.Tracking your Submission via the "Manage Submissions" Dashboard

---

You are not required to submit your study in one session; you can save your work and resume it later. To access your ongoing study submission, log into NICHD DASH, click on the "Submit Study" button on the top menu bar of the NICHD DASH homepage. You will be directed to the "Submission Dashboard" page.

A list of your study submissions will appear, along with a status column and "action" buttons.

The studies you have started to submit or have already submitted will be displayed under one of the following statuses:

**Figure 45: Submission Status**

Status	Definition	Description
<b>Initiated</b>	The Submitter has initiated a new submission.	You have started a submission but have not clicked "Next" for the first time in the submission process. <i>Actions you can take:</i> You can resume your submission by clicking on the "Resume" button from the "Manage Submissions" dashboard at any time while your study is in the "Initiated" status.
<b>In Progress</b>	The Submitter is in the process of entering information in the submission steps.	You started a submission and are in the process of submitting but have not completed the submission. <i>Actions you can take:</i> You can resume your submission by clicking on the "Resume" button from the "Manage Submissions" dashboard at any time while your study is in the "In Progress" status.
<b>Submitted</b>	The Submitter has clicked "Submit" in the Complete Submission step.	You have submitted all documents, datasets, and information for the study. <i>Actions you can take:</i> None. You can no longer make changes to your submission; it is now under review by a NICHD DASH Curator.
<b>Approved</b>	The appropriate NICHD Division/Center Director or Branch Chief has approved the study submission.	Your study has been approved and loaded into NICHD DASH. It is now available in NICHD DASH for other researchers to perform searches and request data from your study. <i>Actions you can take:</i> None.
<b>Not Approved</b>	The submission was not approved.	You should have received an email from the NICHD DASH Administrator stating the reason why your study was not approved. <i>Actions you can take:</i> You can click on the "Edit Submission" button in the "Manage Submissions" dashboard to revise your submission by entering correct information or replacing documentation and/or data.

To resume working on your ongoing study submission, click "Resume" to the right of the study status for the appropriate study name.