Submit Study to NICHD DASH

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

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

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:

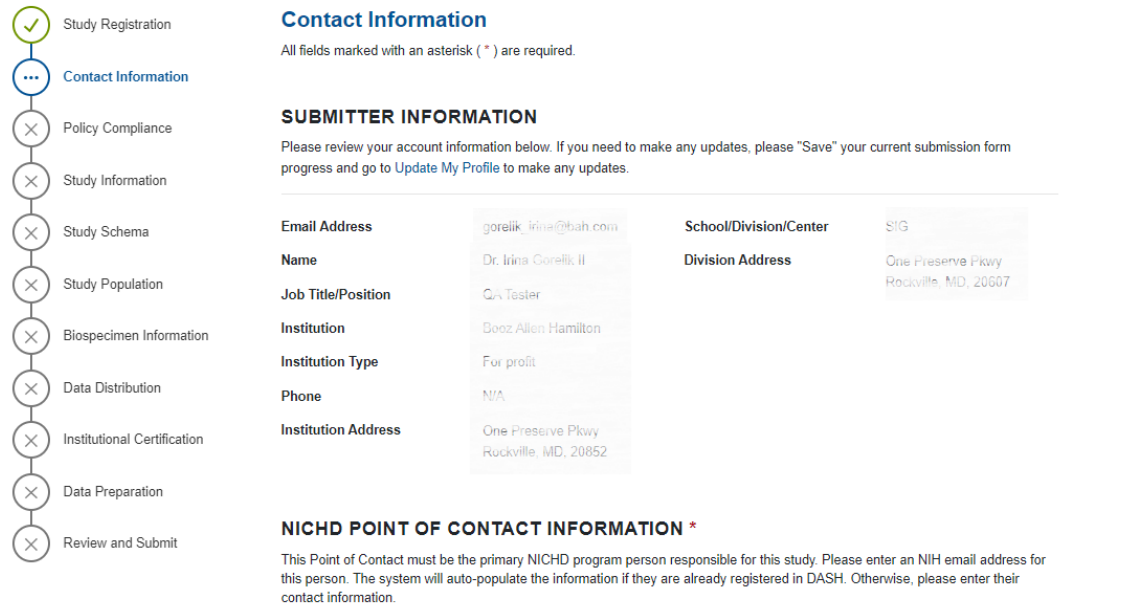
   - Study Protocol (required)
   - Codebook/Variable Dictionary (required)
   - Data Collection Instruments (required)
   - De-Identification Methodology (required; for guidance on de-identification, see Data and Biospecimen Catalog De-identification Guidance on the DASH Submission Resources Page)
   -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

3. Navigating through NICHD DASH Submission

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

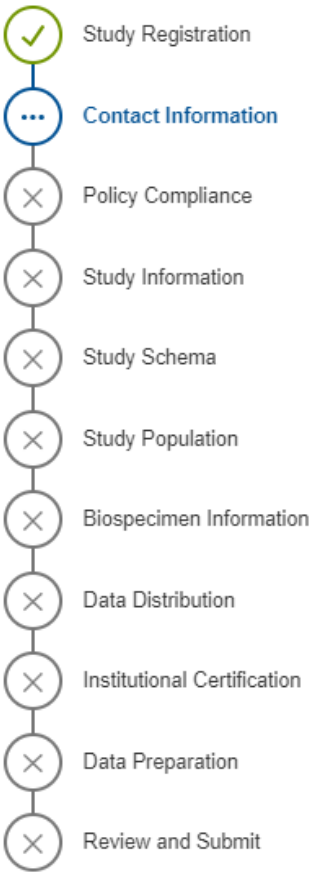
pages in the NICHD DASH submission process. The figure below shows a sample submission information page. On the left-hand side of the page is a Navigation pane, and at the bottom of the page are blue buttons: Previous, Save, and Next, depending on the section you are in.

Figure 1: Sample NICHD DASH Submission Page with Navigation



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

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.

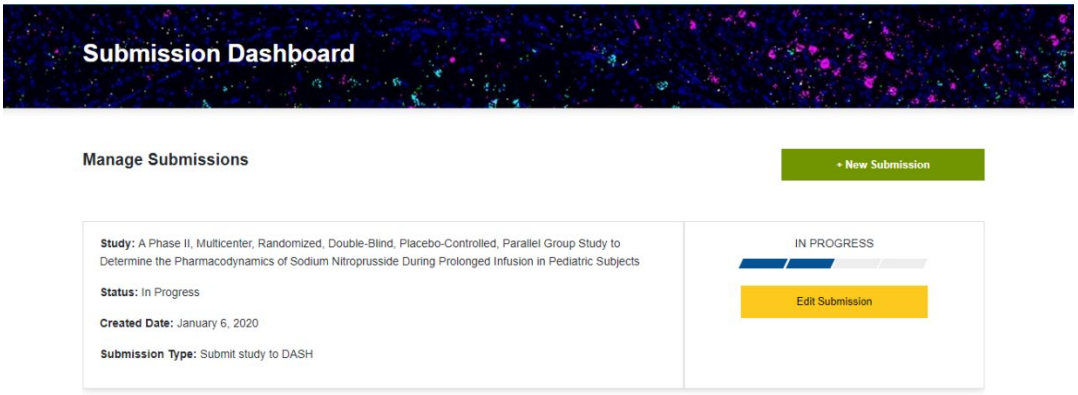
4. Start a New Submission

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.

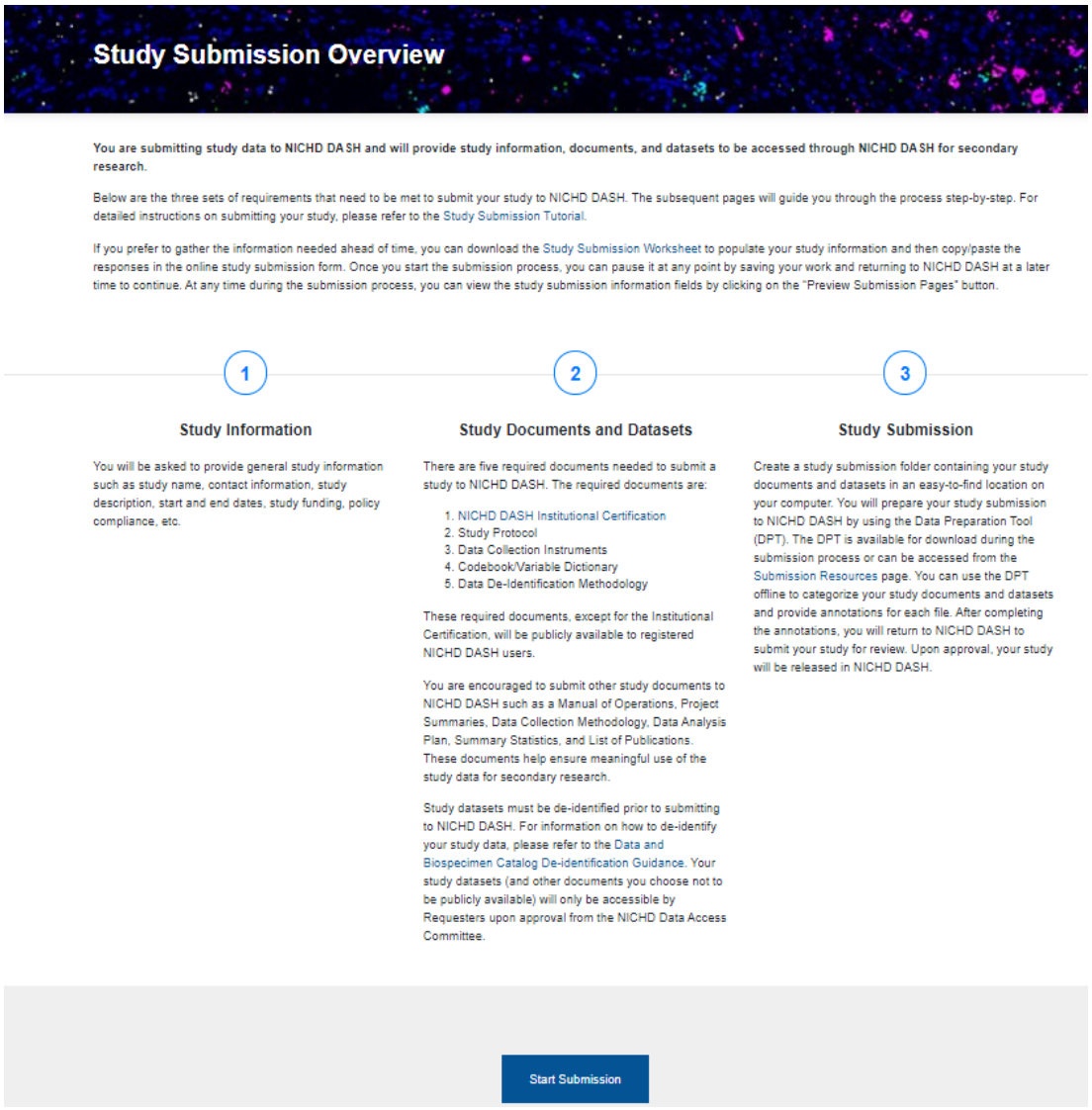
1. Click on the "Submit Study" button on the top menu bar of NICHD DASH and select "+ New Submission".

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

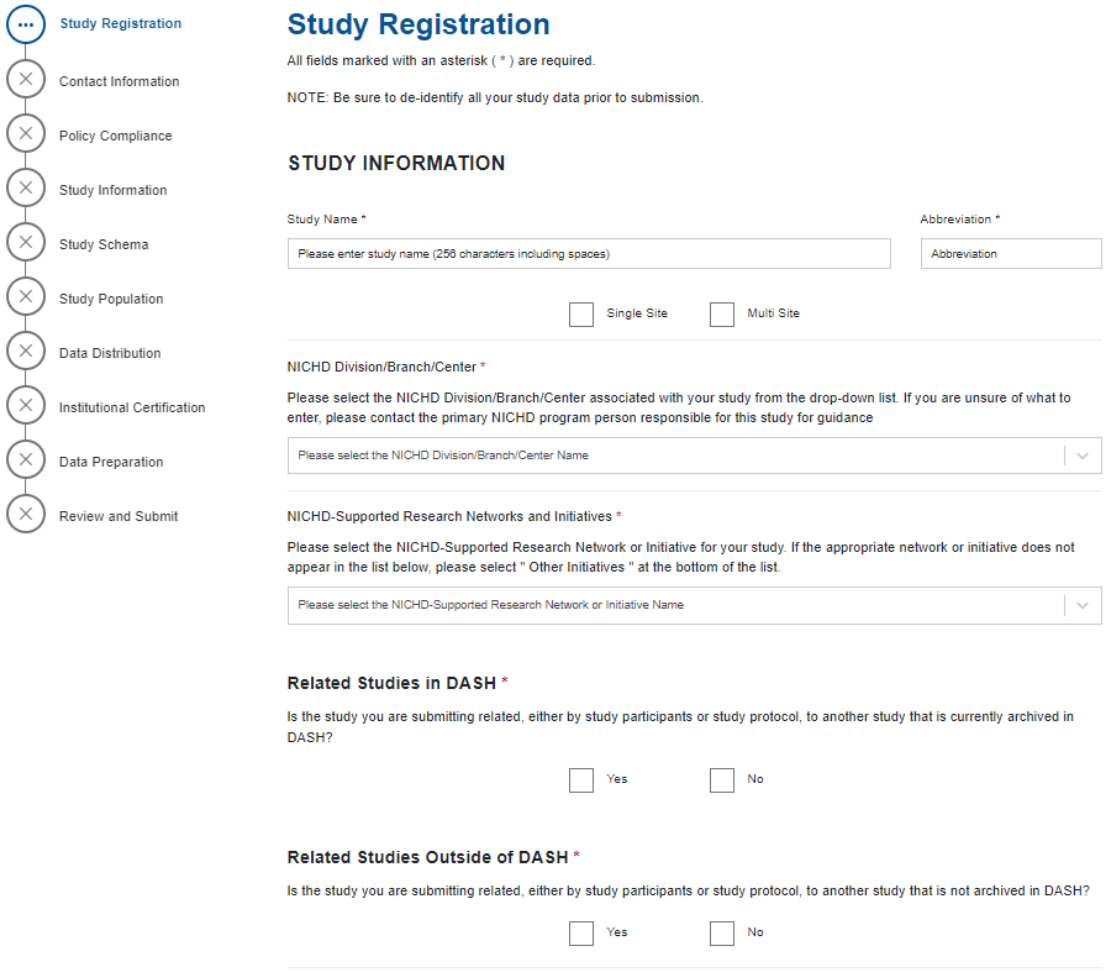


3. Click the "Start Submission" button. You will be directed to the "Study Registration" page.

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



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.

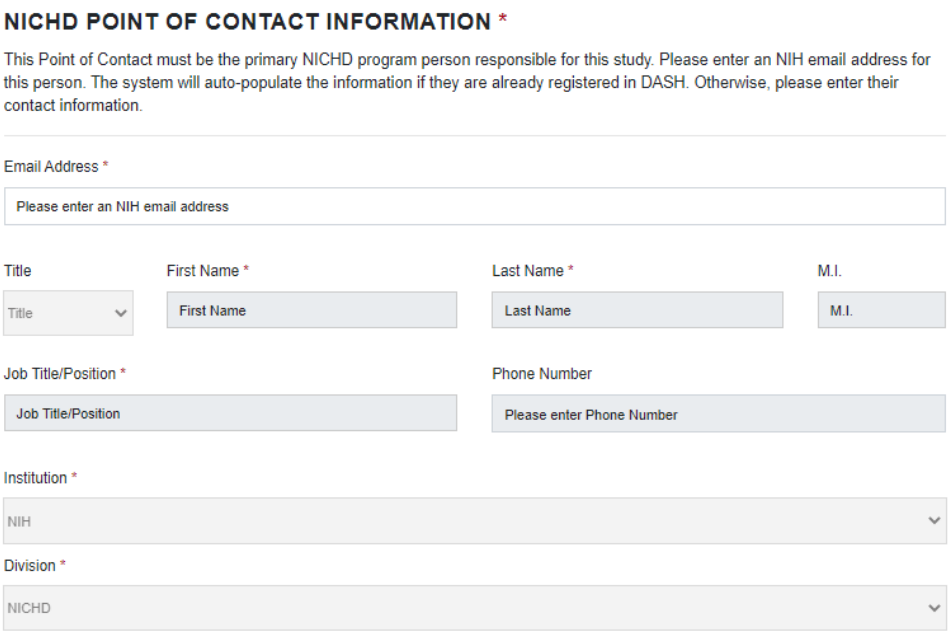
6. Submission – Contact Information

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.

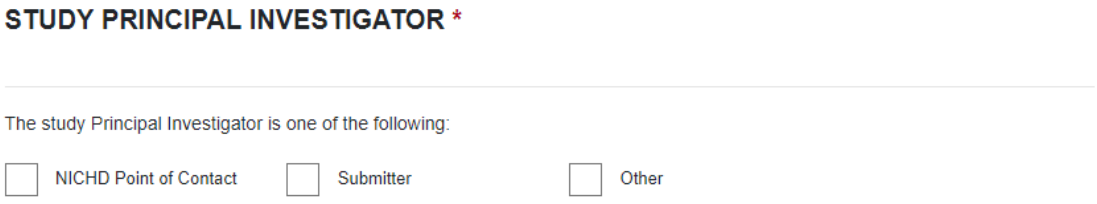
Figure 7: NICHD Point of Contact Information



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.

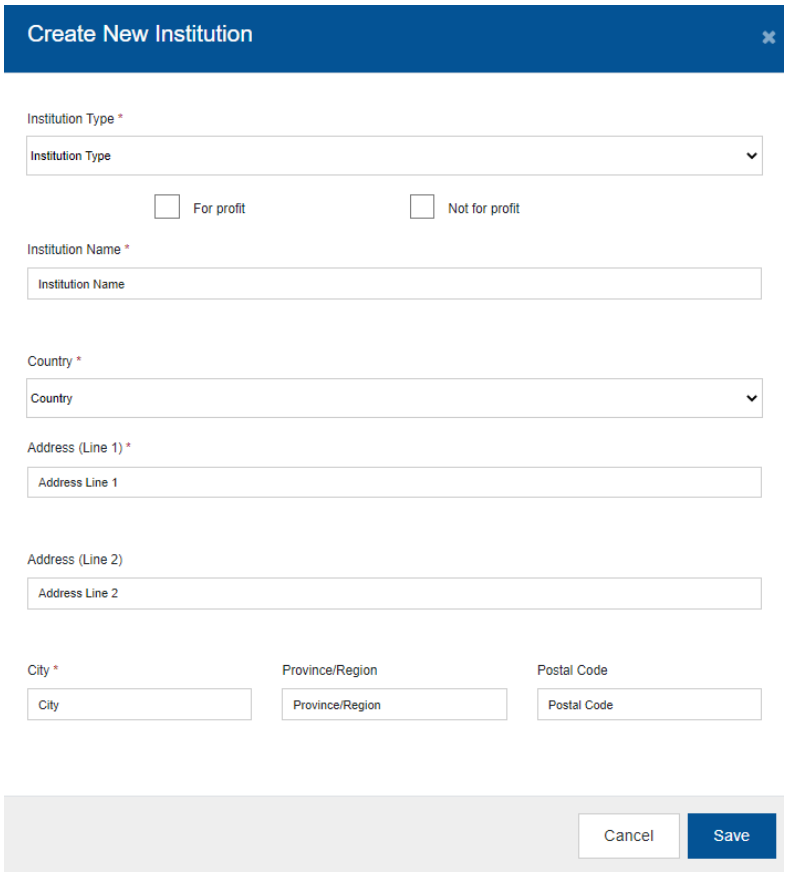
Figure 8: Study PI Information



- 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.

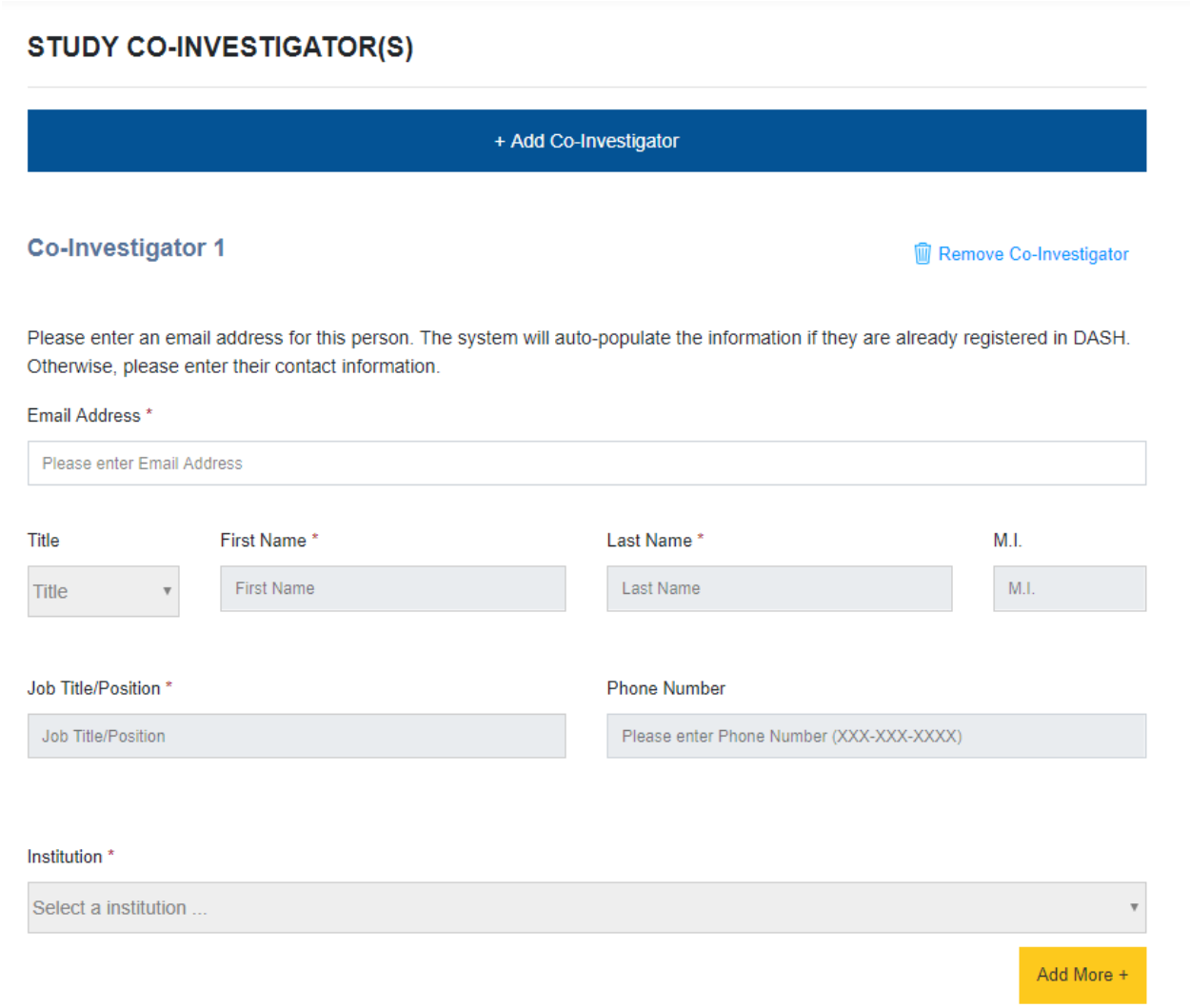
- To add the institution, complete all the required fields denoted by an asterisk for the institution and division. This will make this institution available for future submissions.
- Select "For Profit" or "Not For Profit".

Figure 9: Add Institution



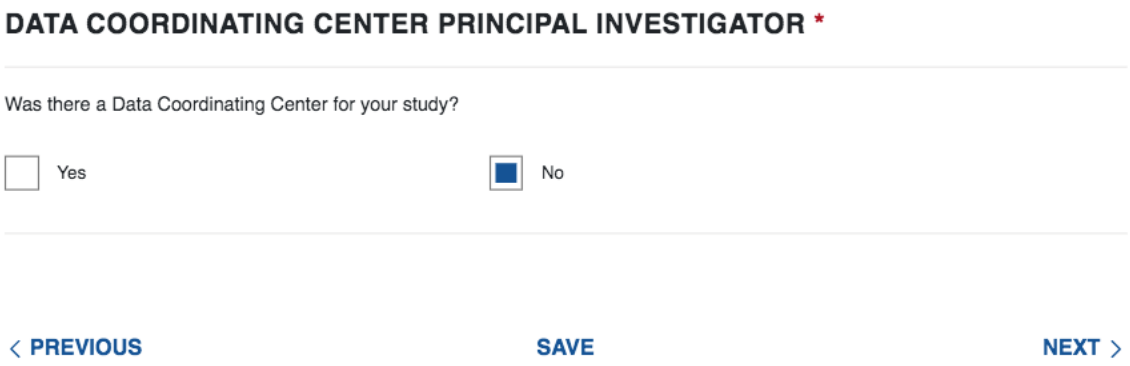
3. Add contact information for one or more Study Co-investigator(s). Click on "+Add co-investigator" to add each of them . Click on "Remove Co-investigator" to remove an entry.

Figure 10: Add Study Co-investigator Contact Information



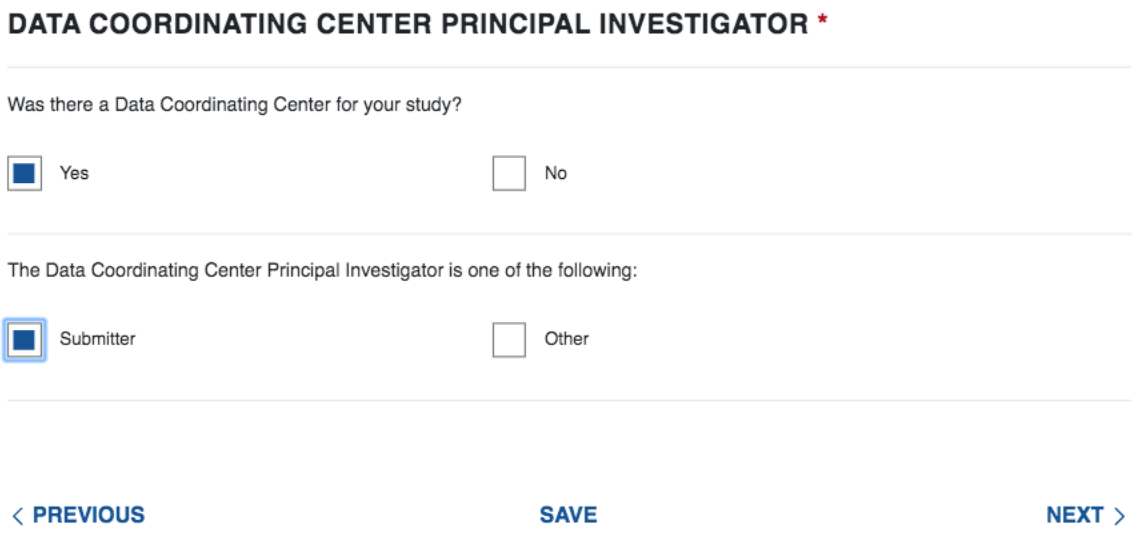
4. For the "Was there a Data Coordinating Center for your Study" question, answer the question by selecting "Yes" or "No." Select "No" only if there was no Data Coordinating Center for this study.

Figure 11: No Data Coordinating Center for the study



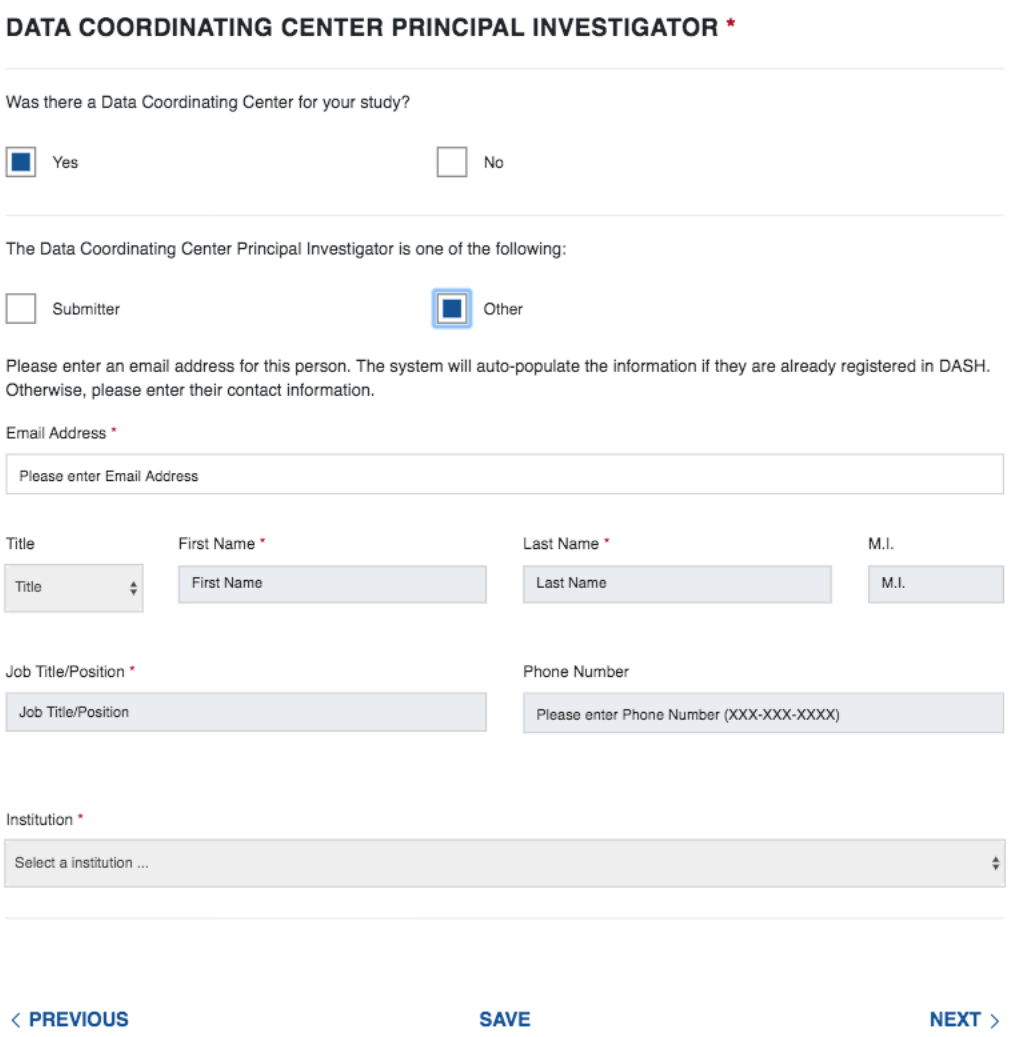
- If you select "Yes", new fields will appear. Indicate if the Data Coordinating Center Principal Investigator is either the "Submitter" or "Other".

Figure 12: Data Coordinating Center Principal Investigator is Submitter



- 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



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

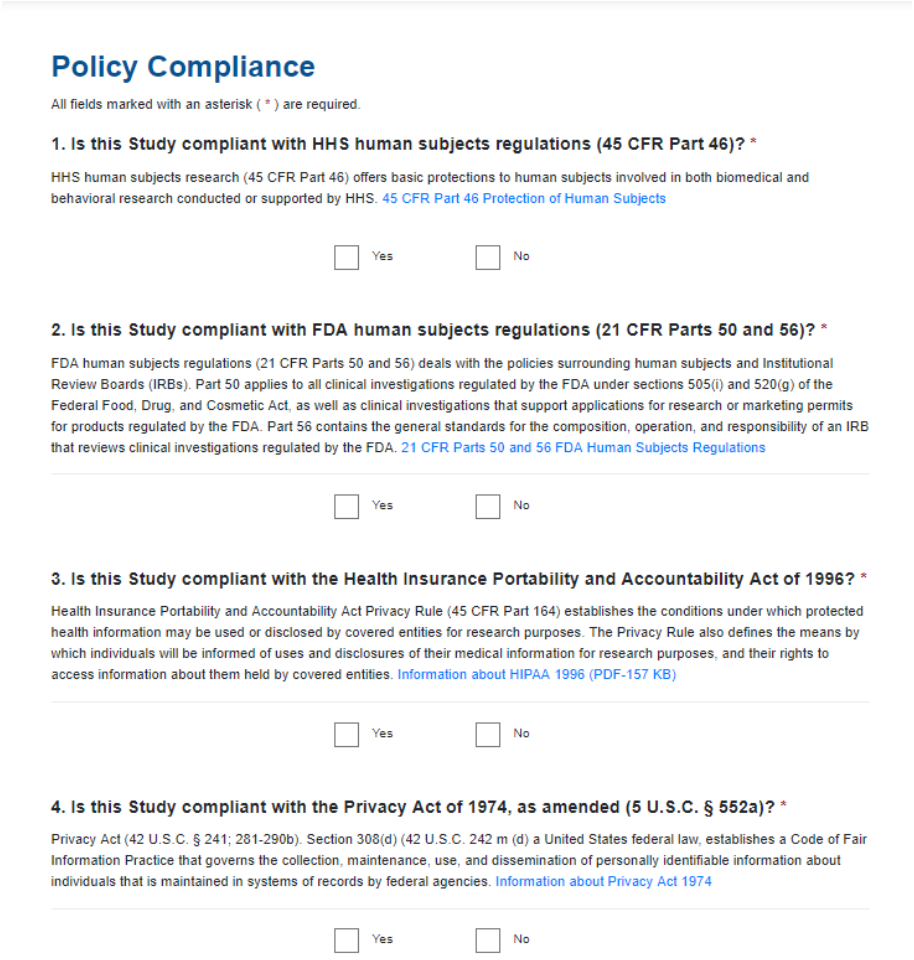
7. Submission – Policy Compliance

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.

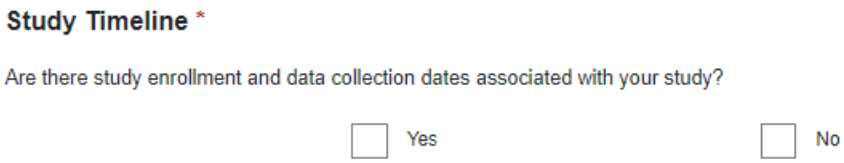
Study Details

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."

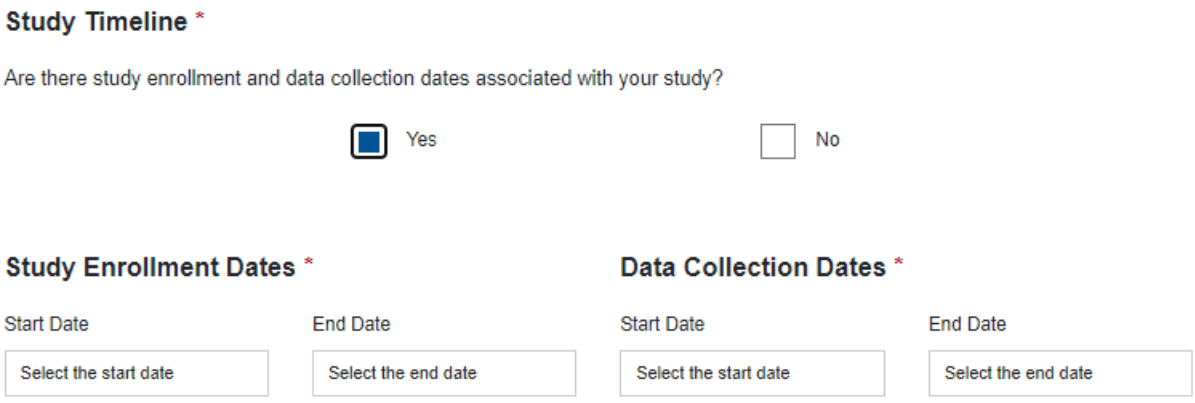
Figure 15: Study Dates



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

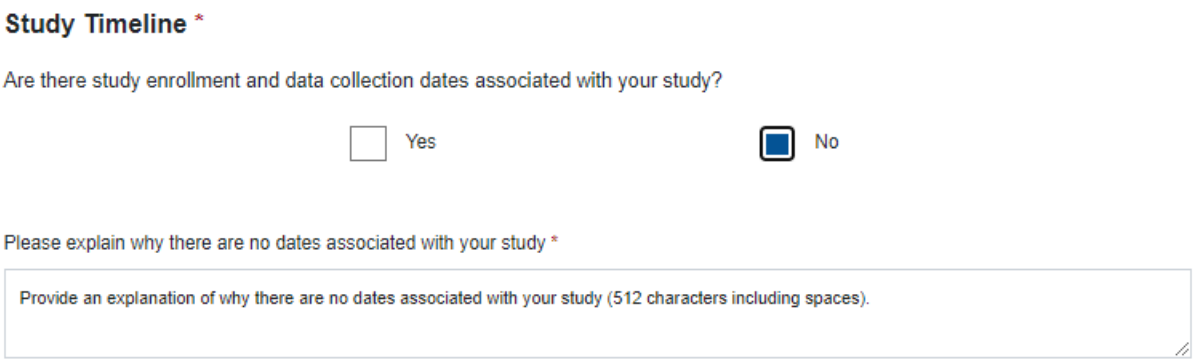
Figure 16: Study Enrollment and Data Collection Dates



NOTE: DASH cannot accept any missing date elements.

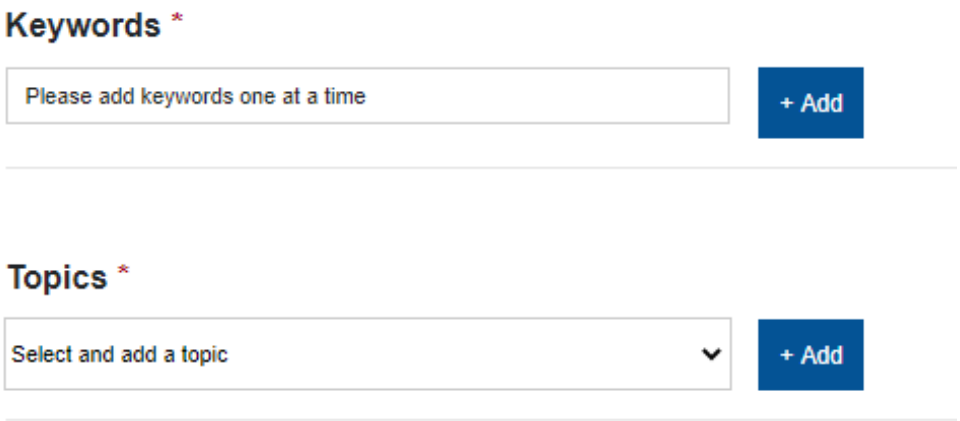
If you select "No", please provide an explanation of why there are no dates associated with your study (limit to 512 characters including spaces).

Figure 17: Explanation of No Study Dates



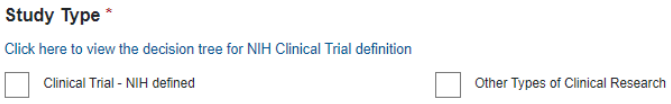
3. Enter keywords by typing in the keyword one at a time and clicking "Add Keyword" after each entry.
4. Add topics by selecting a topic from the dropdown list and clicking "Add Topic". This list is generated from the NICHD A to Z Topics Index.
5. To remove keyword(s) or topic(s), click on the "X" next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

Figure 18: Add Keywords or Topics



6. Select your Study Type from the dropdown list. Refer to the Decision Tree for NIH Clinical Trial Definition.

Figure 19: Study Type

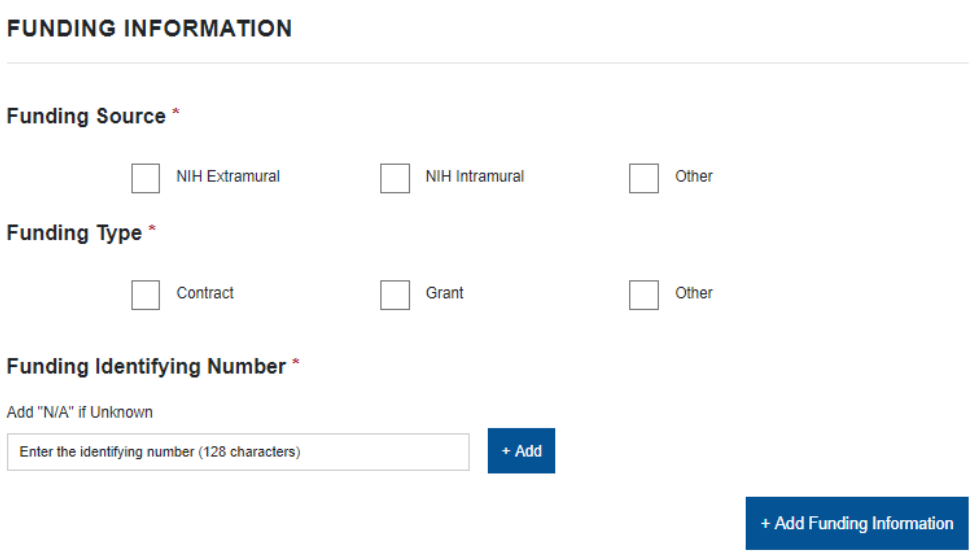


Funding Information

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

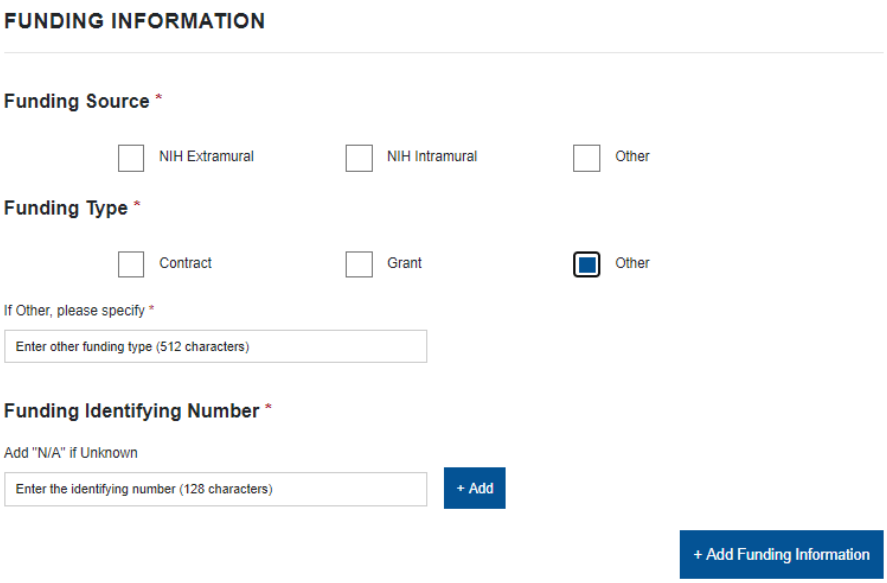
1. First, select "Funding Source." If you select "NIH Intramural" or "NIH Extramural", you will see a dropdown list of NIH institutions.
2. Select your institution from the dropdown list. If your funding institution is not "NIH Intramural" or "NIH Extramural", select "Other" and then select from the 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



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

Figure 21: Other Funding Type

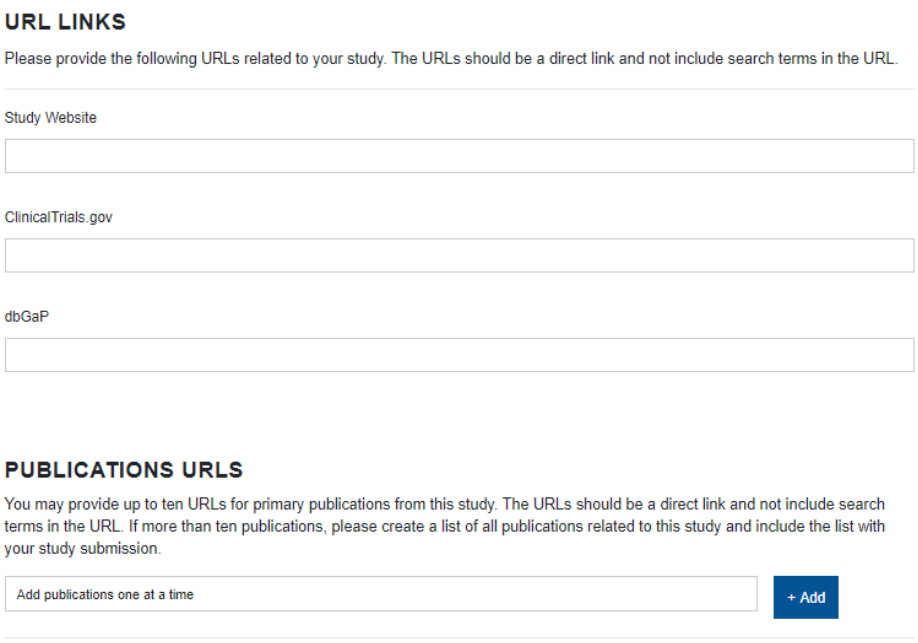


4. If you need to add additional funding information, click "+ Add Funding Information". If you wish to delete additional funding information, click on the "X".

URL Links

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



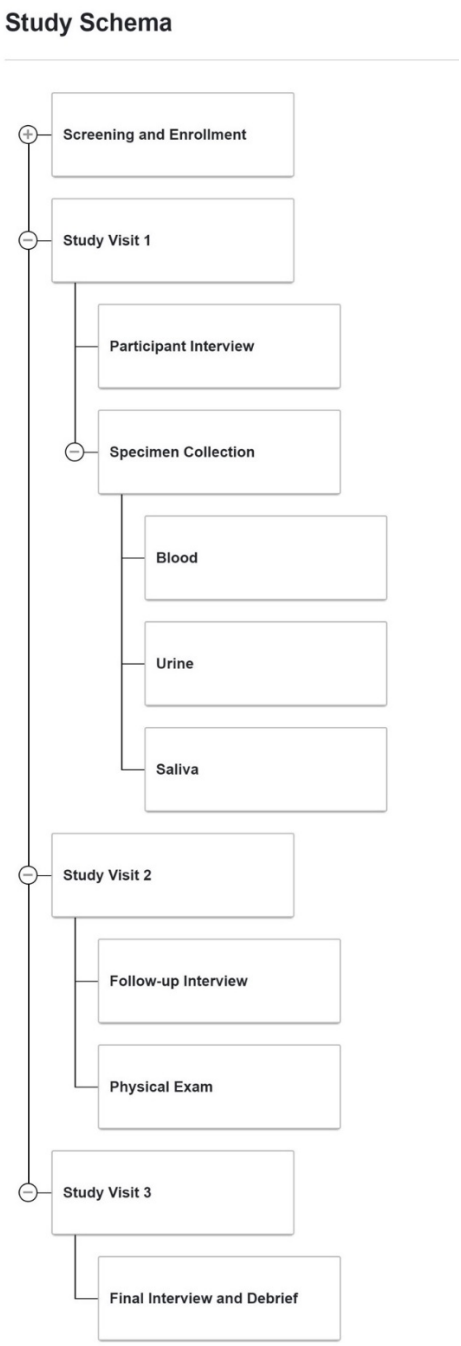
2. Click on "Next." You will be taken to the "Study Schema" page.

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

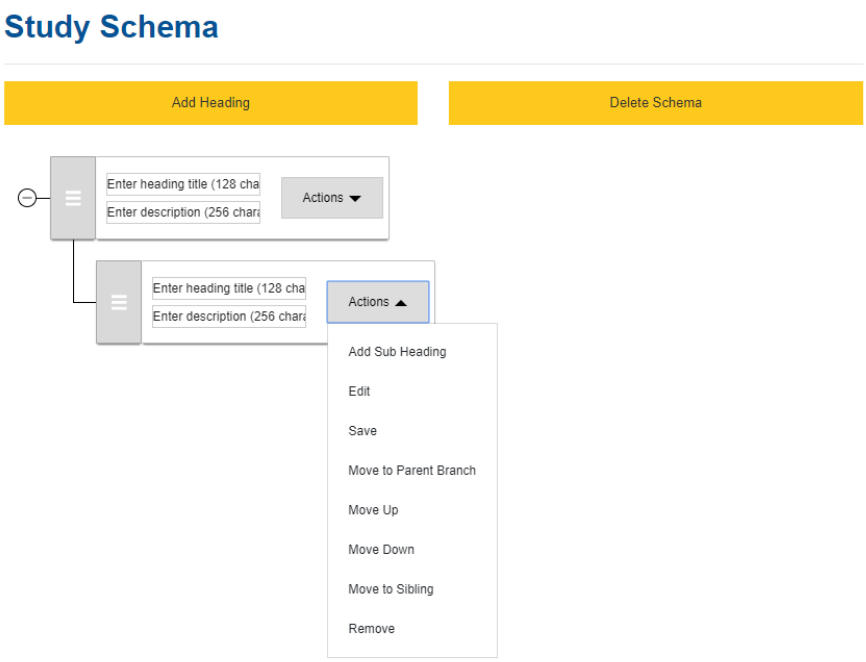


3. You are encouraged to create a study schema in a Word document in order to copy/paste the information into the schema building tool

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 decription
- 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 decription
- Continue to add headings and sub headings as needed to complete your study schema

Figure 24: Adding Headings and Sub Headings

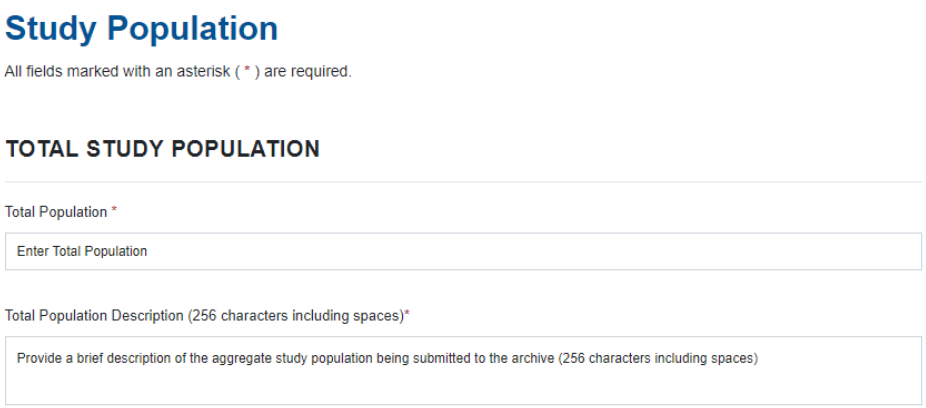


5. Click on “Next.” You will be taken to the “Study Population” page.

10. Submission – Study Population

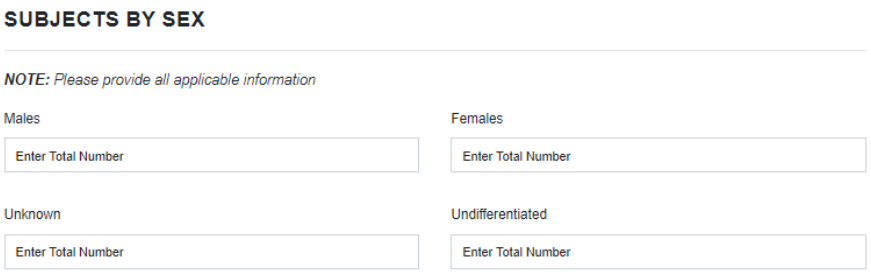
The "Study Population" page will allow you to enter information about the different population groups of your study. Not all population information is required, but you are encouraged to be as specific as possible so that others can better understand your study.

Figure 25: Study Total Population and Description



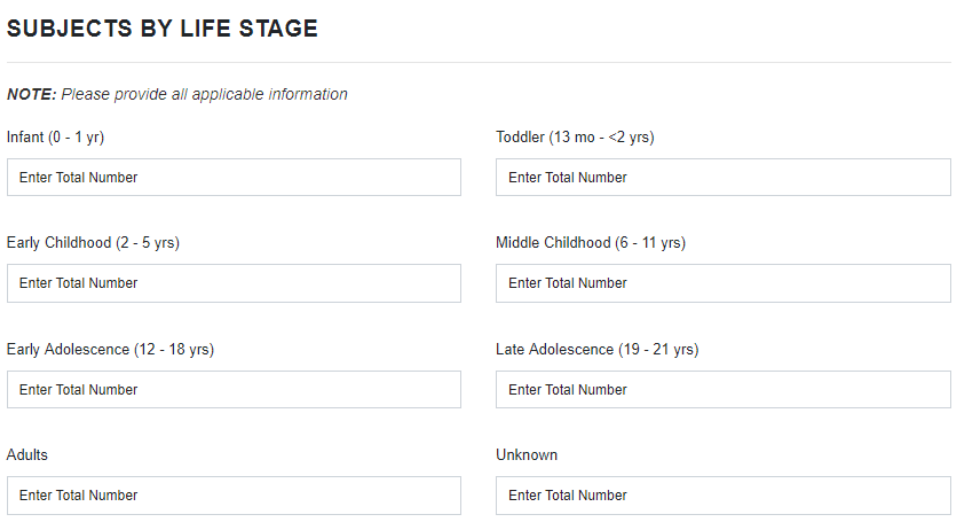
1. Enter the total number of research participants from your study into the "Total Population" field.
2. Add a description of your total population into the "Total Population Description" field (limit: 256 characters including spaces).
3. Provide a breakdown of study participants by sex. Enter the population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

Figure 26: Study Population by Sex



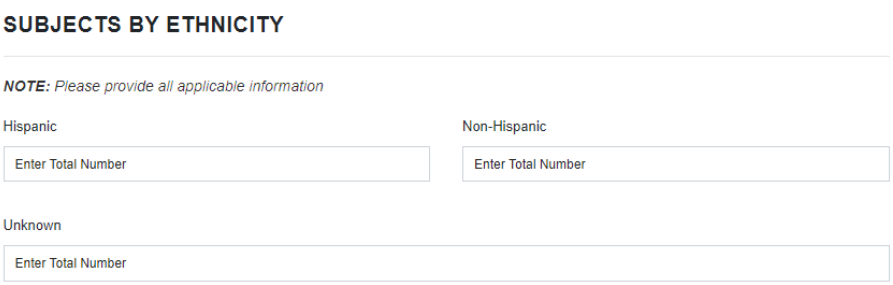
4. Provide a breakdown of study participants by "Life Stage".

Figure 27: Study Population by Life Stage



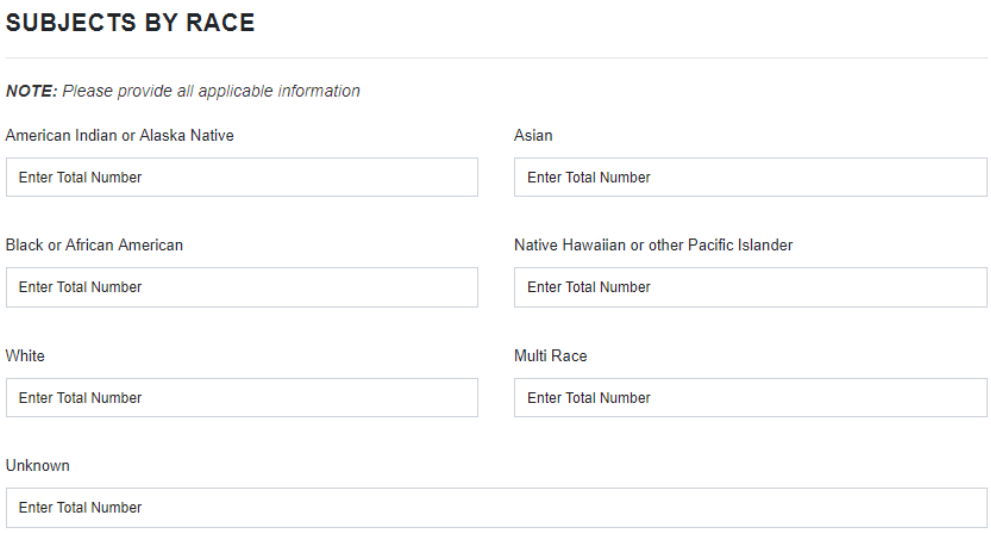
5. Provide a breakdown of study participants by ethnicity.

Figure 28: Study Population by Ethnicity



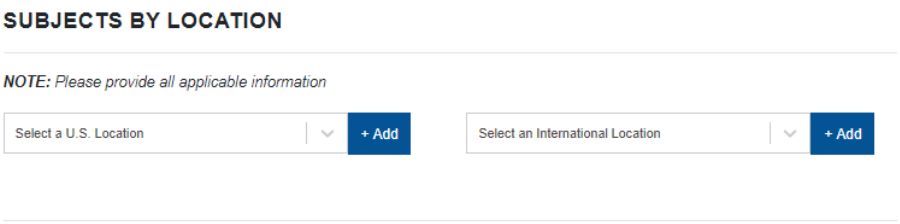
6. Provide a breakdown of study participants by race.

Figure 29: Study Population by Race



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

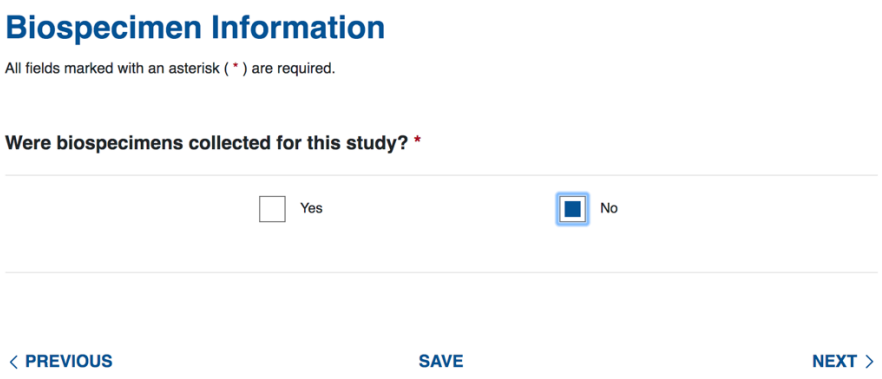


8. Click on "Next." You will be taken to the "Biospecimen Information" page.

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.

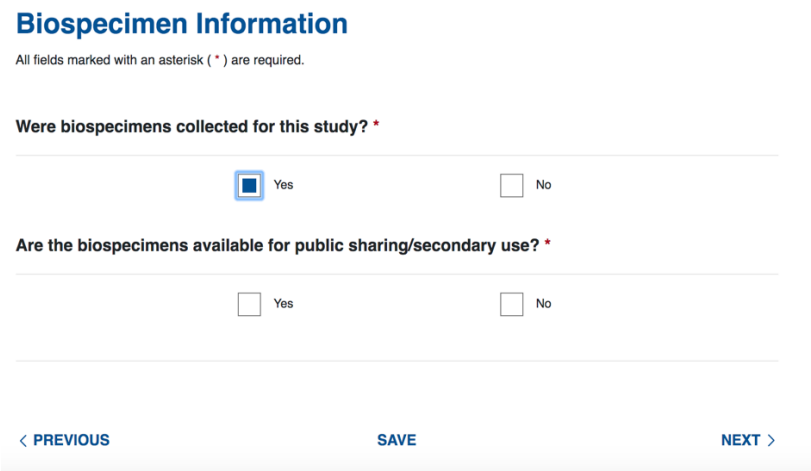
Figure 31: Biospecimen Information



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

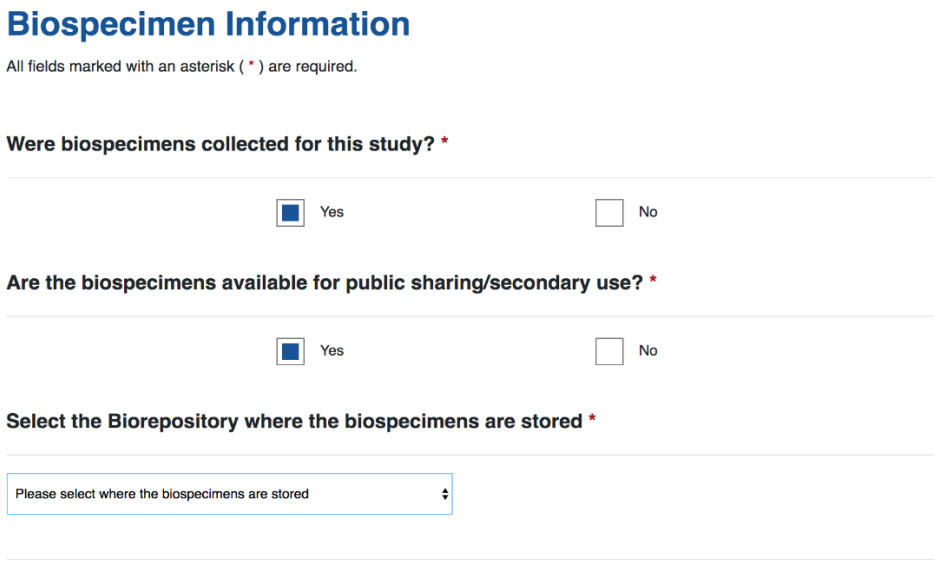
  If you select "Yes", a new field will appear for details. Indicate if the biospecimens are available for public sharing/secondary use.

Figure 32: Biospecimen collected question



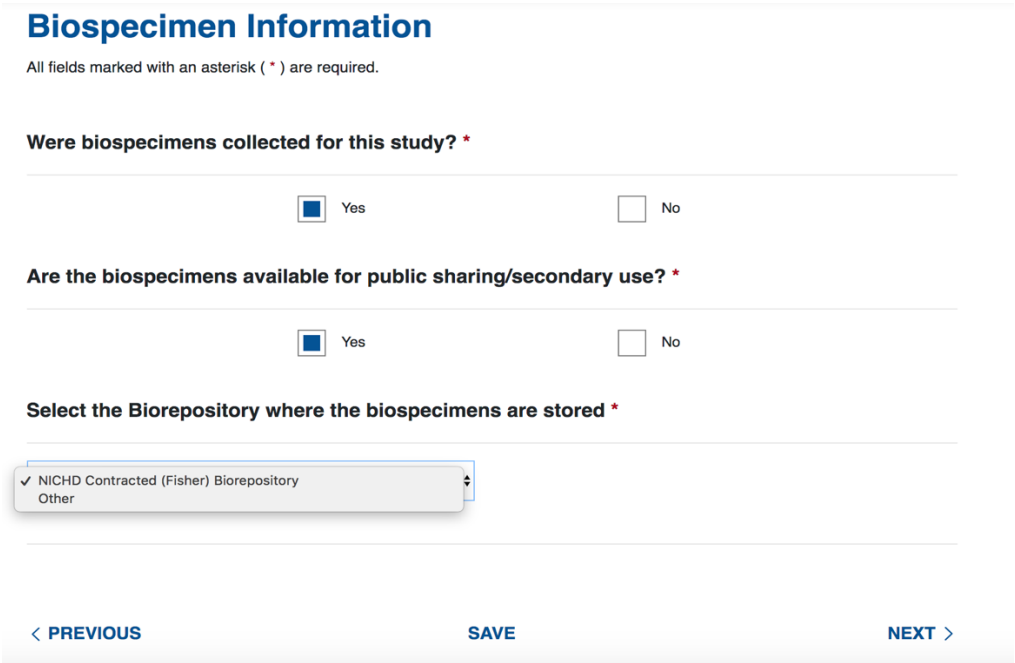
- If you select "Yes", a new field will appear for details. Select the biorepository where the biospecimes are stored.

Figure 33: Biospecimen available question



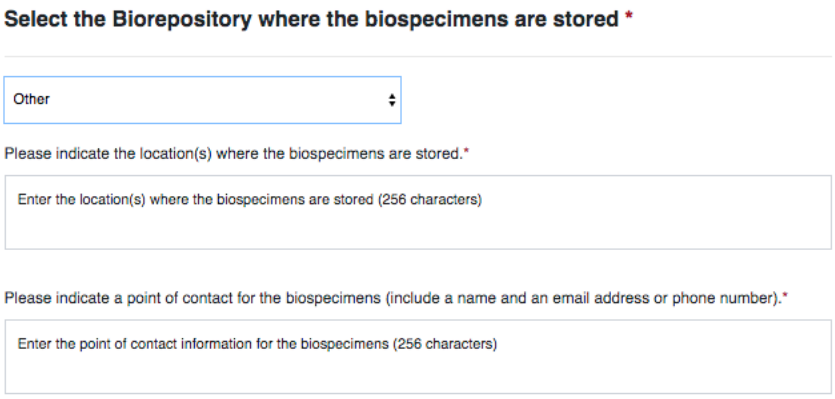
- From the dropdown list, select if the bioscpecimes are stored in "NICHD Contracted (Fisher) Biorepository, or "Other". The default option is "NICHD Contracted (Fisher) Biorepository.

Figure 34: Biorepository selection



- 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

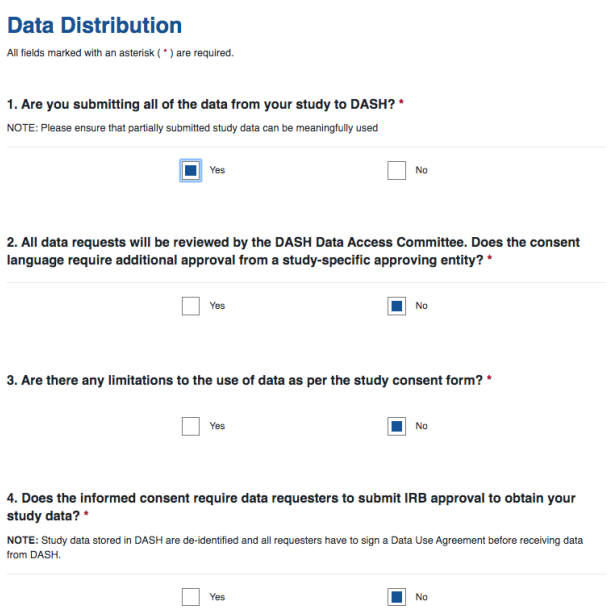


- Click on "Next." You will be taken to the "Data Distribution" page.

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

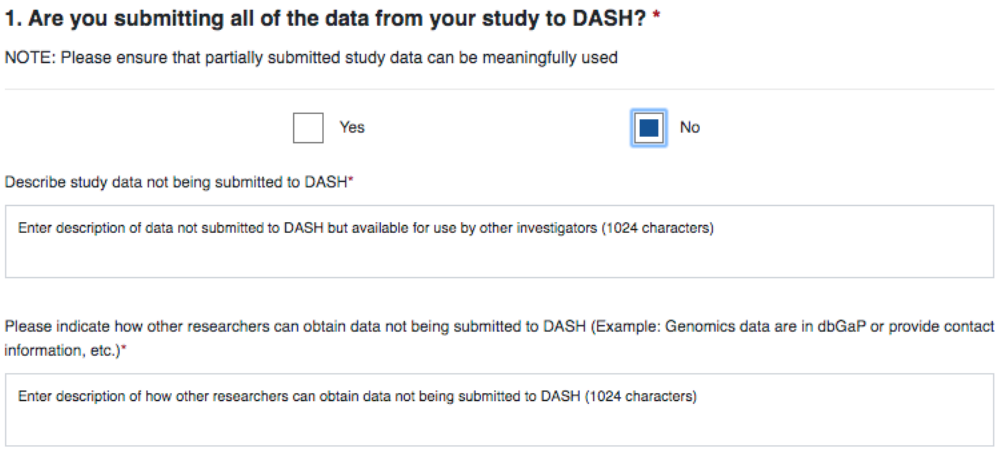


1. Answer all the Yes/No questions related to study data distribution (please note that all fields are mandatory):

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

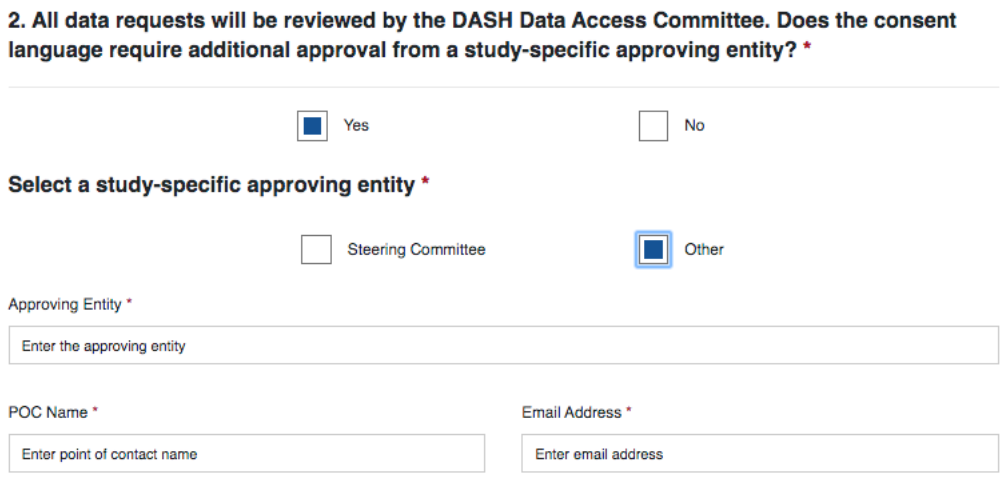
   If you answer "No", additional fields will open asking you to provide details about the study data not being submitted to DASH and how other researchers can obtain the data not being submitted.

igure 37: Data Availability Information



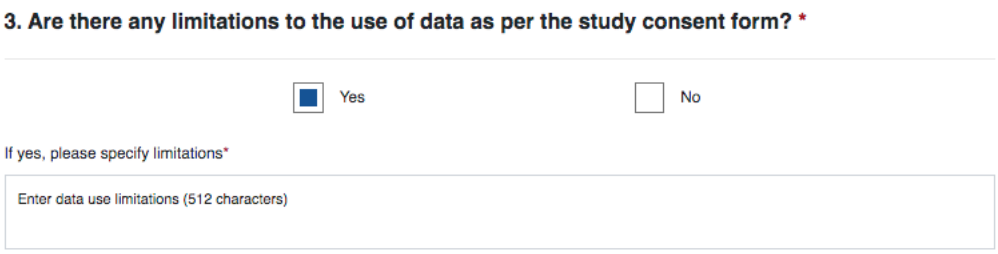
   - In Question 2, please mark whether you require additional approvals for access to your data beyond the approvals made by the NICHD Data Access Committee. If you select "Yes", a new field will appear for details. You can select "Steering Committee" or "Other" for a study-specific approving entity. If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

Figure 38: Study-specific Approving Entity Information



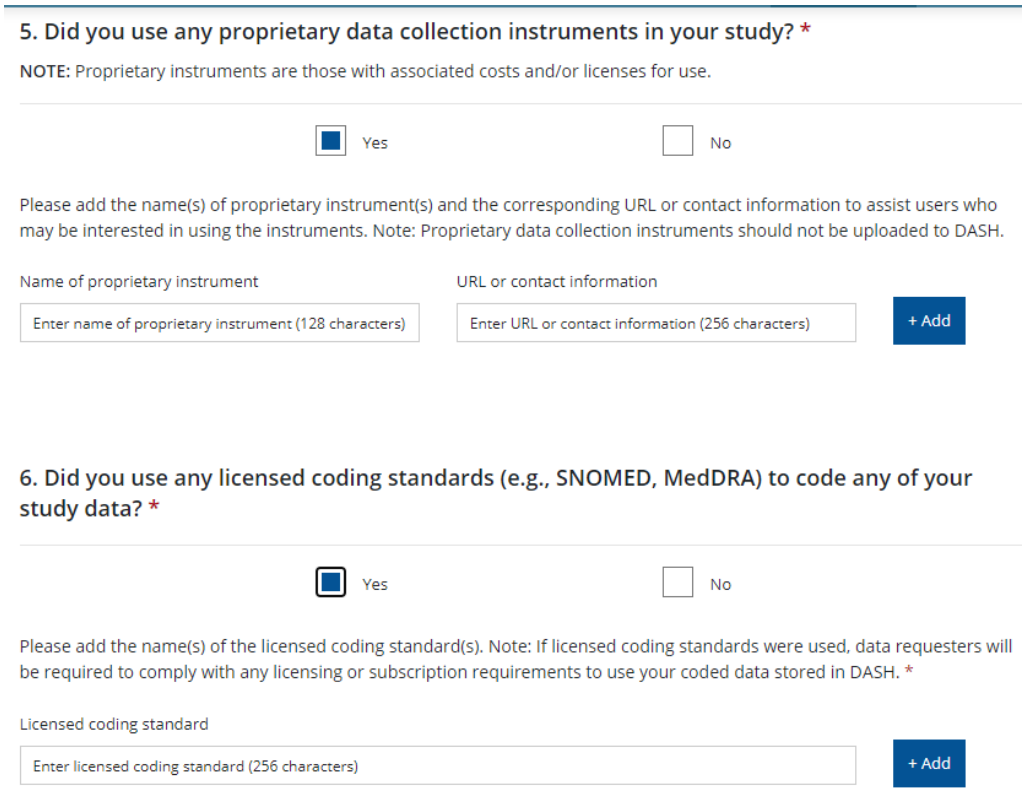
- In Question 3, please mark whether there are any limitations to the use of the data. If you select "Yes", a new field will appear for details to specify the limitations.

Figure 39: Data Use Limitations



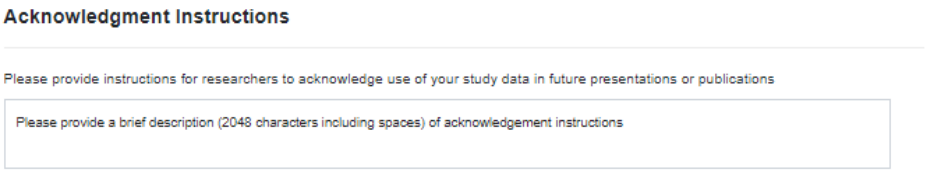
- In Question 4, please mark whether the informed consent requires the data requesters to submit IRB approval to obtain the study data.
- In Question 5, please mark whether you used any proprietary data collection instrument(s) in your study. If you select "Yes", a new field will appear for details regarding 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



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



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

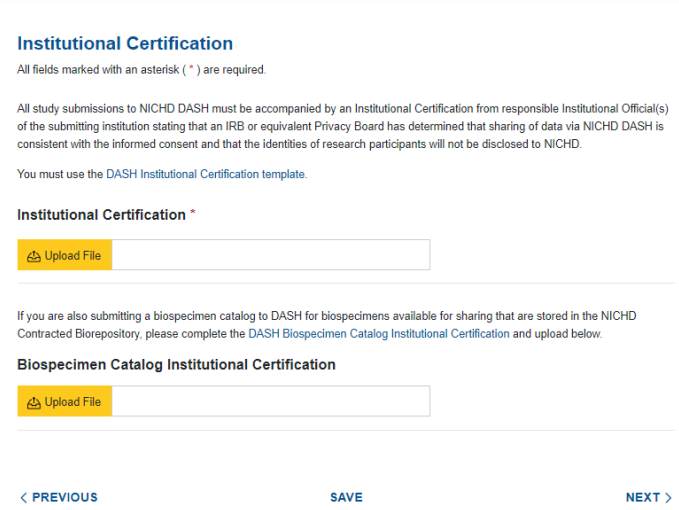
13. Submission – Institutional Certification

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



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

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

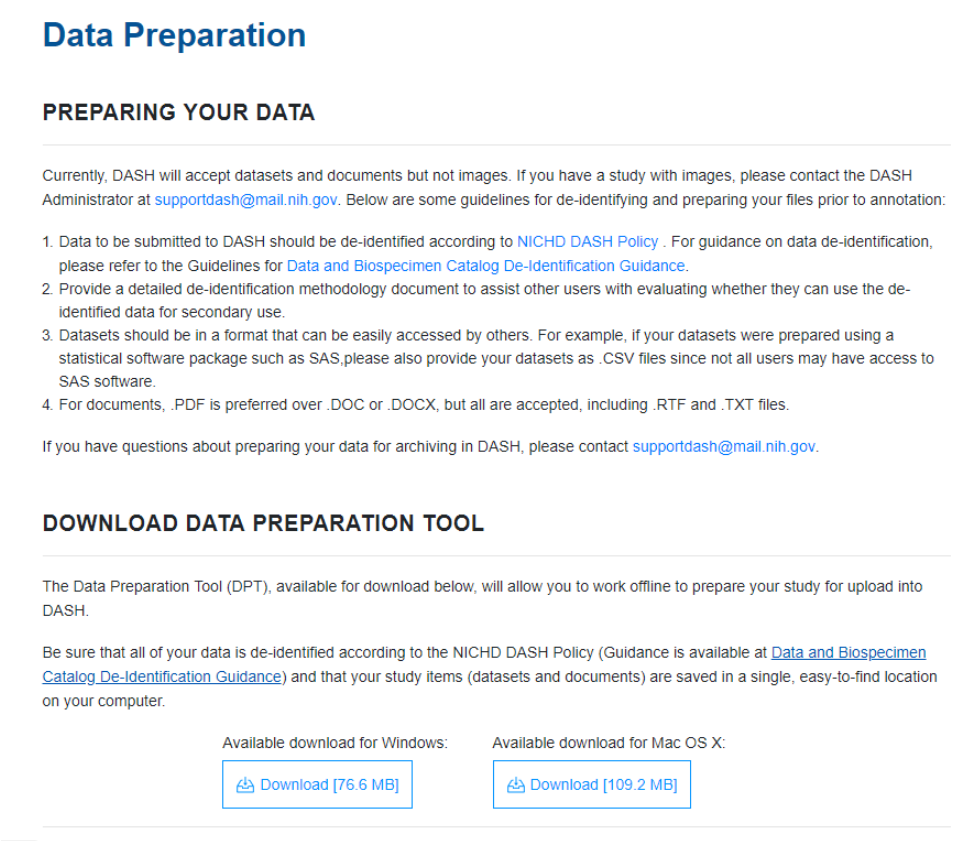
> *You are encouraged to upload additional study documents to ensure meaningful use of your study data and to prevent misuse, misinterpretation, and confusion. Examples of additional study documents include: Data Collection Methodology, Data Analysis Plan, Manual of Operations, Study Manual, Project 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 though 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



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.

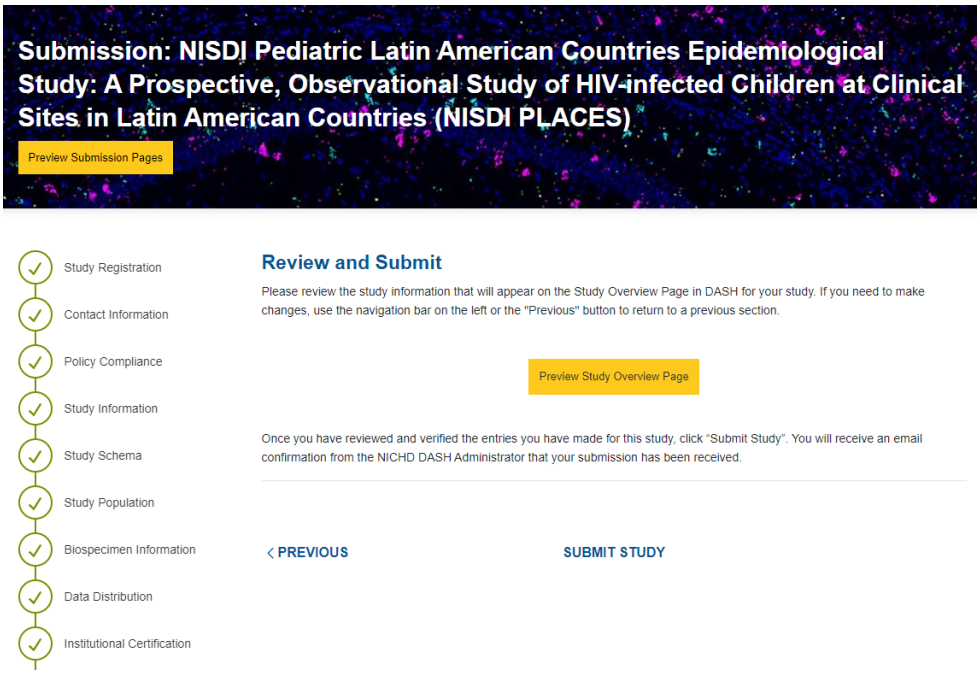
    - Guidelines for de-identifying your data are available here.
    - Datasets should be in a format that can be easily accessed by others. For example, if your datasets were created using a statistical software package such as SAS, please also provide your datasets as .CSV files.
    - You are required 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



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
Initiated	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. *Actions you can take:* 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.
In Progress	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. *Actions you can take:* 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.
Submitted	The Submitter has clicked "Submit" in the Complete Submission step.	You have submitted all documents, datasets, and information for the study. *Actions you can take:* None. You can no longer make changes to your submission; it is now under review by a NICHD DASH Curator.
Approved	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. *Actions you can take:* None.
Not Approved	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. *Actions you can take:* 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.