Catalog Study in NICHD DASH

To catalog your study in NICHD DASH, you will provide descriptive information about your study and the publicly accessible repository where it is stored. Users will be able to find your study through NICHD DASH, and will be directed to the source repository to obtain access to the datasets and documents for secondary research.

All investigators (extramural and intramural) who have NICHD-funded studies stored in another publicly accessible archive (such as DSDR, BioLINCC) may also catalog their studies in NICHD DASH to promote its discovery and reuse. To catalog a study in NICHD DASH, you must be registered and logged into your NICHD DASH account.

1. NICHD DASH Cataloging Navigation

Once you have started the cataloging process, please navigate using the NICHD DASH navigation buttons and **NOT** your browser buttons.

The figure below shows a sample catalog submission information page. There are two ways to navigate among pages in the NICHD DASH cataloging process. On the left-hand side of the page is a Navigation pane, and at the bottom of the page are navigation options: Previous, Save, and Next, depending on the section you are in.

Figure 1: Sample NICHD DASH Catalog Submission Page with Navigation

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

The left-hand navigation pane shows each of the major catalog submission steps. Sections that are completed are shown with a check mark to the left. The section you are currently working on is shown in bolded blue text with three dotted marks to the left.

Figure 2: Navigation Bar

- ✓ Study Registration
- ••• **Study Information**
- ✕ Study Schema
- ✕ Study Population
- ✕ Review and Submit
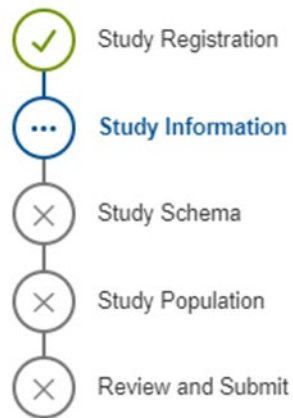
You may return to any section that you have already completed by clicking on the section name.

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

Figure 3: Navigation Options

‹ PREVIOUS   SAVE   NEXT ›

Use the blue text options "Previous" and "Next" to navigate between pages— to return to a previous page to make additions or corrections, or to move forward to the next page, respectively. 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.

## 2. Start a New Catalog Submission

Follow the instructions below to catalog your study in NICHD DASH. You may save your work at any point during the cataloging process and resume later. Note that only completed sections within a page will be saved. To access ongoing study submissions and/or cataloging, click on the "Submit Study" button located on the top menu bar of the NICHD DASH homepage. You will be directed to the "Submission Dashboard" page displaying your study and/or catalog submissions. Click on "Resume" to the right of the study/catalog that you wish to continue

working on. For more information, see the section, "Tracking your Catalog Submission via the "Manage Submissions" Dashboard."

> *NOTE: You will not submit any data or documents to NICHD DASH as part of the catalog submission process. Only information about the study is submitted during the catalog submission process.*

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

Figure 4: Study Catalog Dashboard
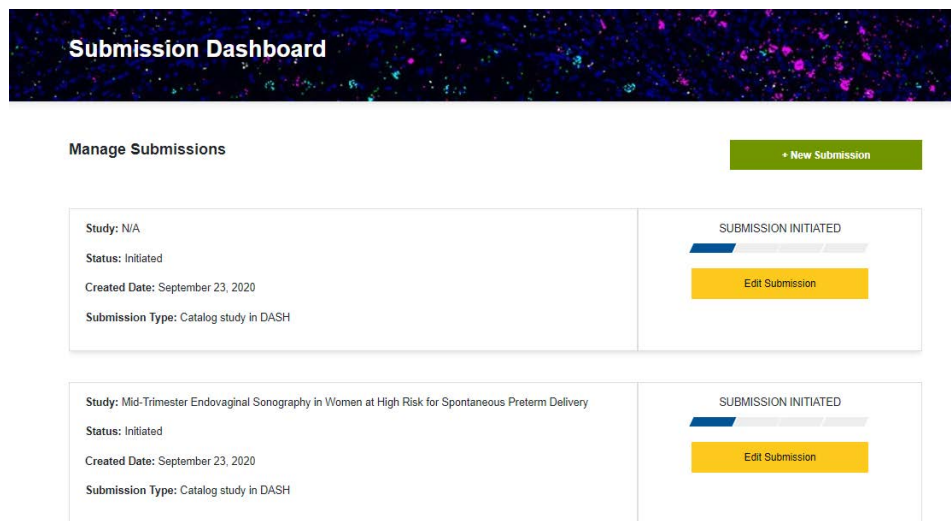
2. The system will present a modal asking you to choose between Study Submission and Study Cataloging. You can hover over the information icon to learn more about the difference between submitting a study or cataloging a study in NICHD DASH.

3. Select the "Catalog study in DASH" option and press "Continue".

Figure 5: Submission Types
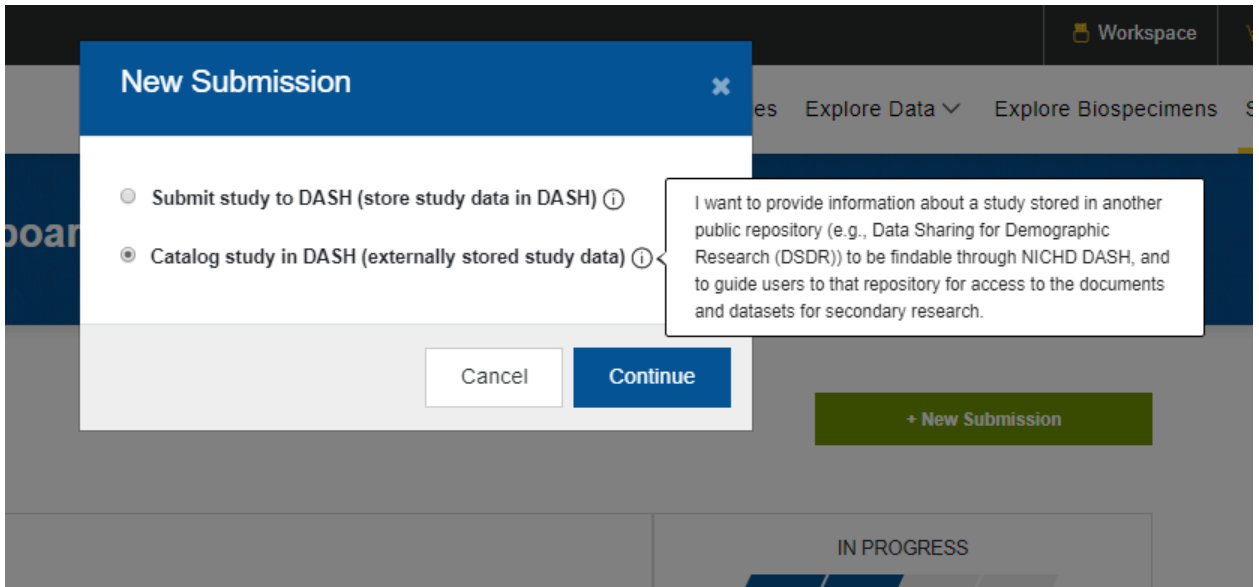
4. You will be directed to the "Study Cataloging Overview" page, where you can download a DASH Study Cataloging Worksheet to help you gather all the information you will need ahead of time for study cataloging. This worksheet can also be found in the "Submission Resources" page under the "Resources" tab in NICHD DASH.

Figure 6: "Study Cataloging Overview " Page
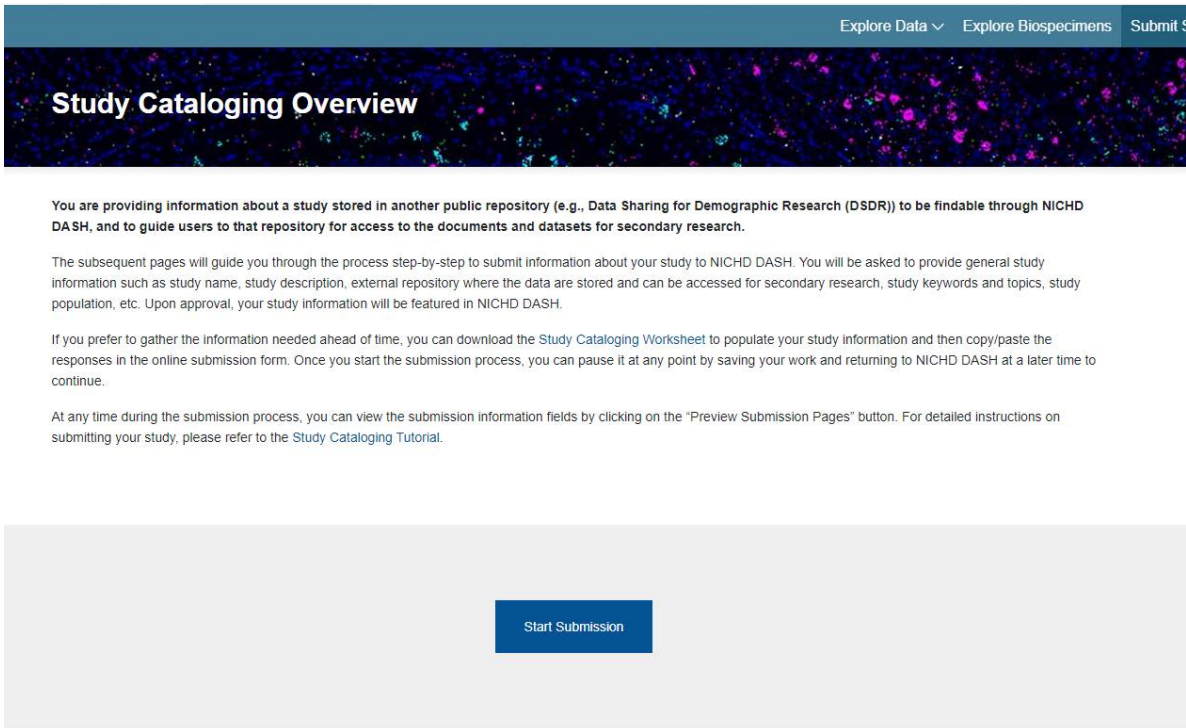
5. Click the "Start Submission" button. You will be directed to the "Study Registration" page.

3. Cataloging – Study Registration

In the following steps, you will provide information on the "Study Registration" page regarding the study you are cataloging.

Figure 7: "Study Registration" Page

1. Fill in the "Study Name" and "Abbreviation" fields with your study name and abbreviation, respectively.

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

3. From the dropdown menu, select the Source Repository Name. If you are unable to locate the Source Repository Name for your study in the dropdown list, please select the "Other" option from the dropdown list. Then enter the Source Repository Name in the text field box.

4. Please enter the link to the Study URL in the Source Repository (such as a link to the study overview page). The URL should be a direct link and not include search terms in the URL.

5. For the "Related Studies in DASH" question, answer the question by selecting either "Yes" or "No." If you select "Yes":

   - Identify the relationship from the dropdown list:

     o the Main Study of

     o a Sub-Study of

     o a Mother/Child Follow-Up Study of

     o an Outcome Follow-Up Study of

     o Related to

   - Then select the study from the list of studies in DASH

6. For the "Related Studies Outside of DASH" question, answer the question by selecting either "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. Please provide any comments about the study you are cataloging in NICHD DASH.

8. Under the comments field, you will see the Submitter Information section populated with your information. If you need to make any updates, please click "Save" to save your work and navigate to "Update My Profile" page to make necessary changes.

9. Click "Next" to save your work and continue to the "Study Information" page.

4. Cataloging – Study Information

In the following steps, you will provide information on the "Study Information" page that includes data collection dates, biospecimen information, keywords, topics, and additional information.

1. Enter data collection start and end dates. For dates that are missing one or two elements, follow these rules:

   - If day is missing from any date, assign as the 15th of month

   - If month is missing, assign as July

   - If the month and day elements are missing, assign them as July 1st

   - In the unlikely event that the year element is missing, a reasonable year should be agreed upon with input from study stakeholders

Figure 8: Data Collection Dates

2. 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 9: Biospecimen Information

3. Enter keywords by typing in the keyword one at a time and clicking "+Add" after each entry.

4. Add topics by selecting a topic from the dropdown list and clicking "+Add". This list is generated from the NICHD A to Z Topics Index (https://www.nichd.nih.gov/health/topics).

5. To remove keyword(s) or topic(s), click on the "X" next to the keyword or topic.

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. If unsure which option to select, refer to the Decision Tree for NIH Clinical Trial Definition.

Figure 11: Study Type

Study Type * ⓘ Decision Tree for NIH Clinical Trial Definition

| Please select the study type ▾ |

Clinical Trial - NIH defined
Other Types of Clinical Research

7. Enter funding ID numbers one at a time by typing in the Funding ID number and clicking "+Add" after each entry. To remove a funding ID, click on the "X" next to the ID number.

Figure 12: Funding Identifying Number

Funding Identifying Number

| Enter the funding identifying number (128 characters) | + Add |

8. 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.

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

5. Cataloging – Study Schema

1. This page allows you to build a Study Schema that will be displayed on the NICHD DASH Study Overview page associated with your cataloged 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, headings, data collection points, etc., work best to describe your study.
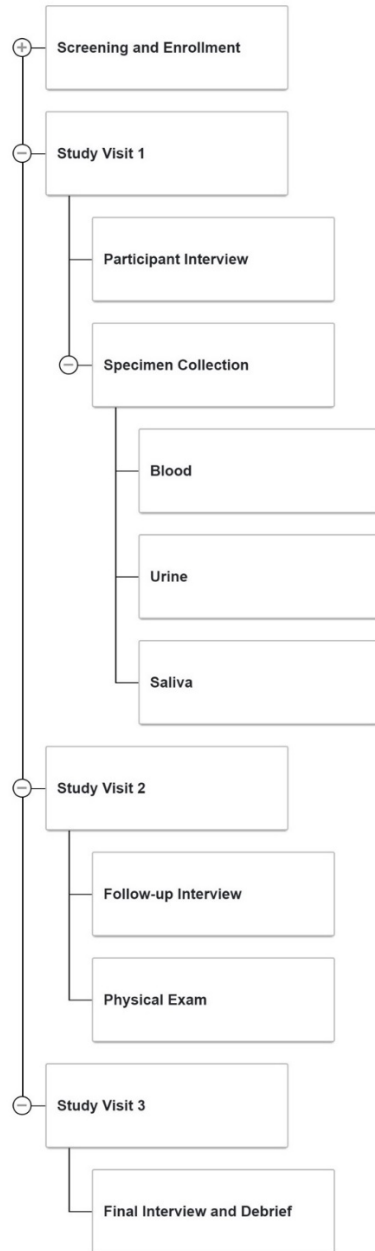
Study Schema

3. If preferred, you can create your study schema in a Word document and then 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 in the bottom field

- Using the "Actions" dropdown on the right provides eight options:

    o   Add Sub Heading

    o   Edit

    o   Save

    o   Move to Parent Branch

    o   Move Up

    o   Move Down

    o   Move to Sibling

    o   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 in the bottom field

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

Study Schema
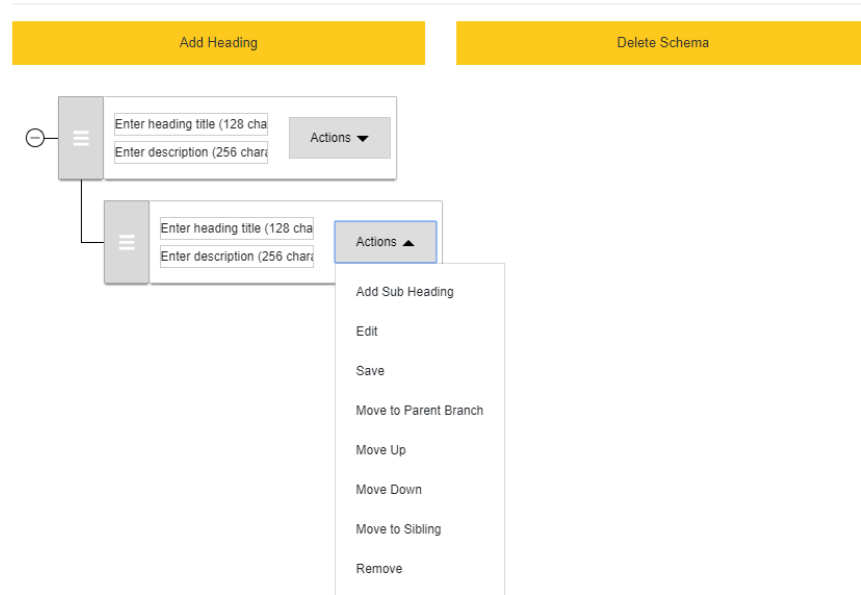
5. Click on "Next." You will then be taken to the "Study Population" page.

6. Cataloging – 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 16: 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 17: Study Population by Sex

SUBJECTS BY SEX *

NOTE: Please provide all applicable information

Males	Females
Enter Total Number	Enter Total Number

Unknown	Undifferentiated
Enter Total Number	Enter Total Number

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

Figure 18: Study Population by Life Stage

SUBJECTS BY LIFE STAGE

NOTE: Please provide all applicable information

Infant (0 - 1 yr)	Toddler (13 mo - <2 yrs)
Enter Total Number	Enter Total Number

Early Childhood (2 - 5 yrs)	Middle Childhood (6 - 11 yrs)
Enter Total Number	Enter Total Number

Early Adolescence (12 - 18 yrs)	Late Adolescence (19 - 21 yrs)
Enter Total Number	Enter Total Number

Adults	Unknown
Enter Total Number	Enter Total Number

5. Provide a breakdown of study participants by ethnicity.

Figure 19: 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 20: Study Population by Race

SUBJECTS BY RACE

NOTE: Please provide all applicable information

American Indian or Alaska Native

> Enter Total Number

Asian

> Enter Total Number

Black or African American

> Enter Total Number

Native Hawaiian or other Pacific Islander

> Enter Total Number

White

> Enter Total Number

Multi Race

> Enter Total Number

Unknown

> Enter Total Number

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 21: Add Subjects by U.S. or International Locations

8. Click on "Next." You will then be taken to the "Review and Submit" page.

7. Cataloging – Review and Submit

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

Figure 22: "Review and Submit" Page

1. First, verify the completeness and accuracy of your catalog submission by clicking on the "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 catalog. You will receive an email confirmation from the NICHD DASH Administrator that your catalog submission has been received.

8. Tracking your Catalog Submission via the "Manage Submissions" Dashboard

You are not required to submit your study catalog in one session; you can save your work and resume it later. To access your in progress catalog submission, log into NICHD DASH, and 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 displaying your catalog submissions. To resume working on your catalog submission, click on "Resume" to the right of the study catalog that is in progress to continue working.