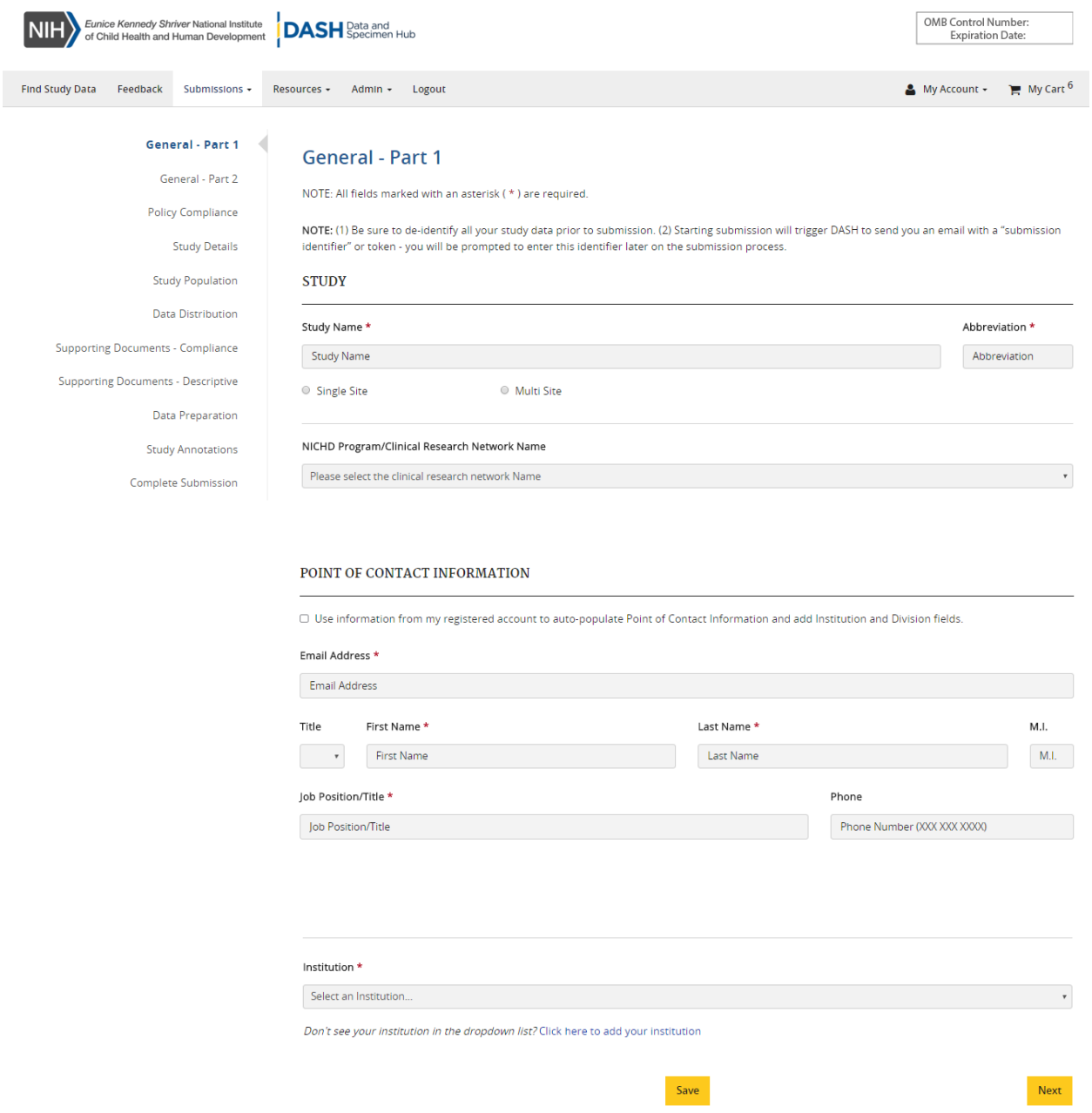
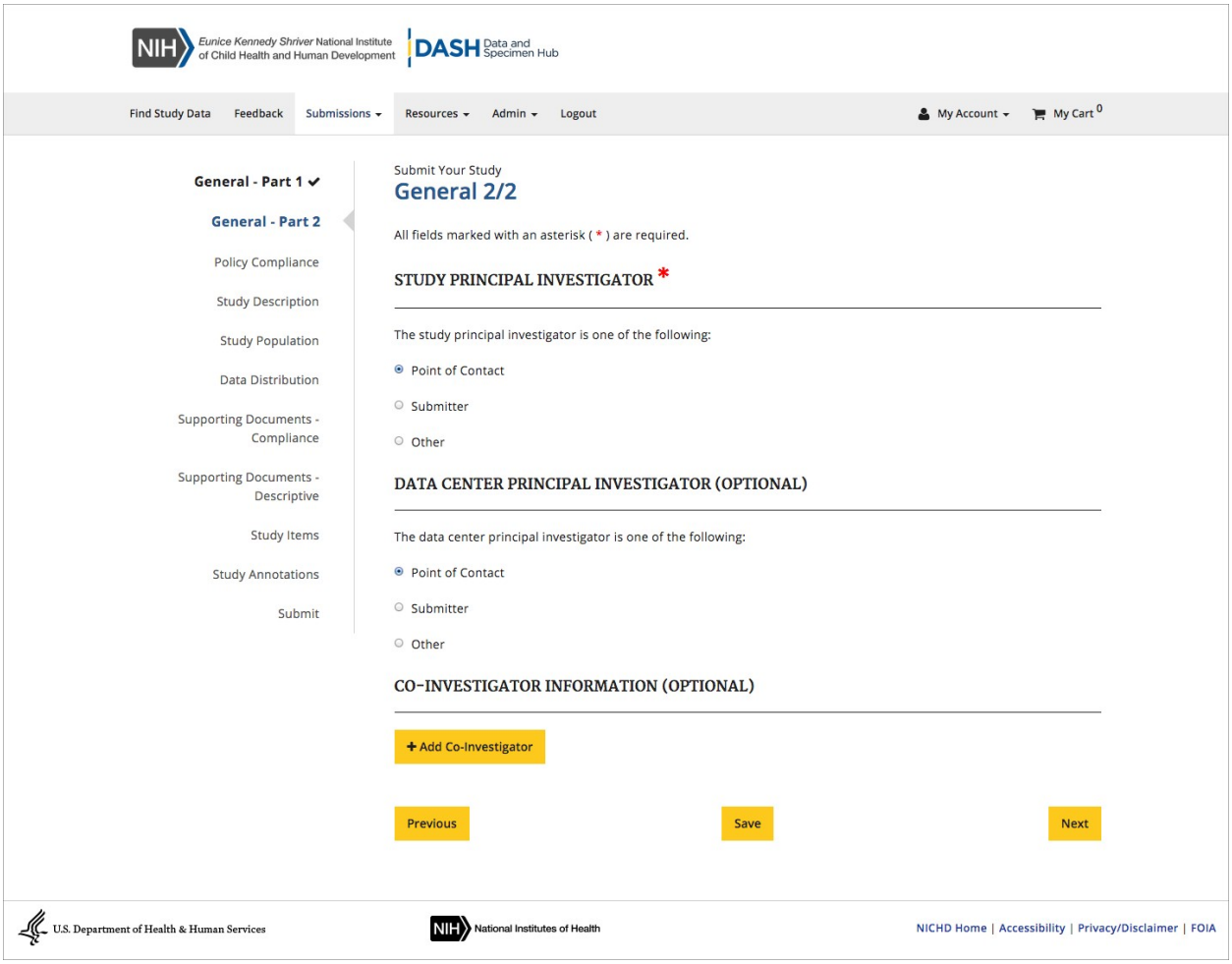
0925-NEW_DASH_ATTACHMENTA.2-2_DATASUBMISSION

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General 2/2
All fields marked with an asterisk (*) are required.
STUDY PRINCIPAL INVESTIGATOR *
The study principal investigator is one of the following:
Point of Contact
Submitter
Other
DATA CENTER PRINCIPAL INVESTIGATOR (OPTIONAL)
The data center principal investigator is one of the following:
Point of Contact
Submitter
Other
CO-INVESTIGATOR INFORMATION (OPTIONAL)
+ Add Co-Investigator
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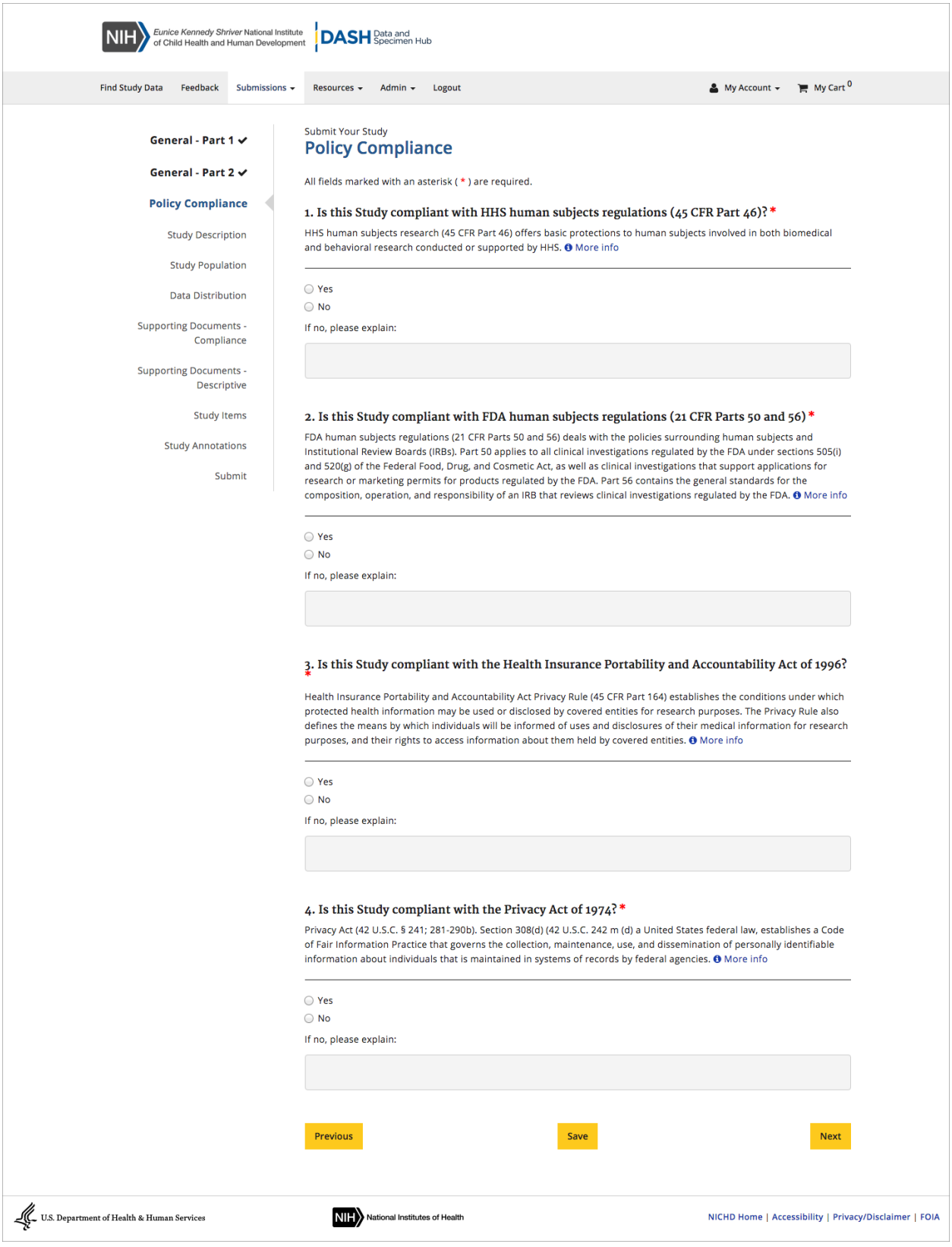
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Policy Compliance
All fields marked with an asterisk (*) are required.
1. Is this Study compliant with HHS human subjects regulations (45 CFR Part 46)? *
HHS human subjects research (45 CFR Part 46) offers basic protections to human subjects involved in both biomedical and behavioral research conducted or supported by HHS. More info
Yes
No
If no, please explain:
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. More info
Yes
No
If no, please explain:
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. More info
Yes
No
If no, please explain:
4. Is this Study compliant with the Privacy Act of 1974? *
Privacy Act (42 U.S.C. § 241; 281-290b). Section 308(d) (42 U.S.C. 242 m (d) a United States federal law, establishes a Code of Fair Information Practice that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by federal agencies. More info
Yes
No
If no, please explain:
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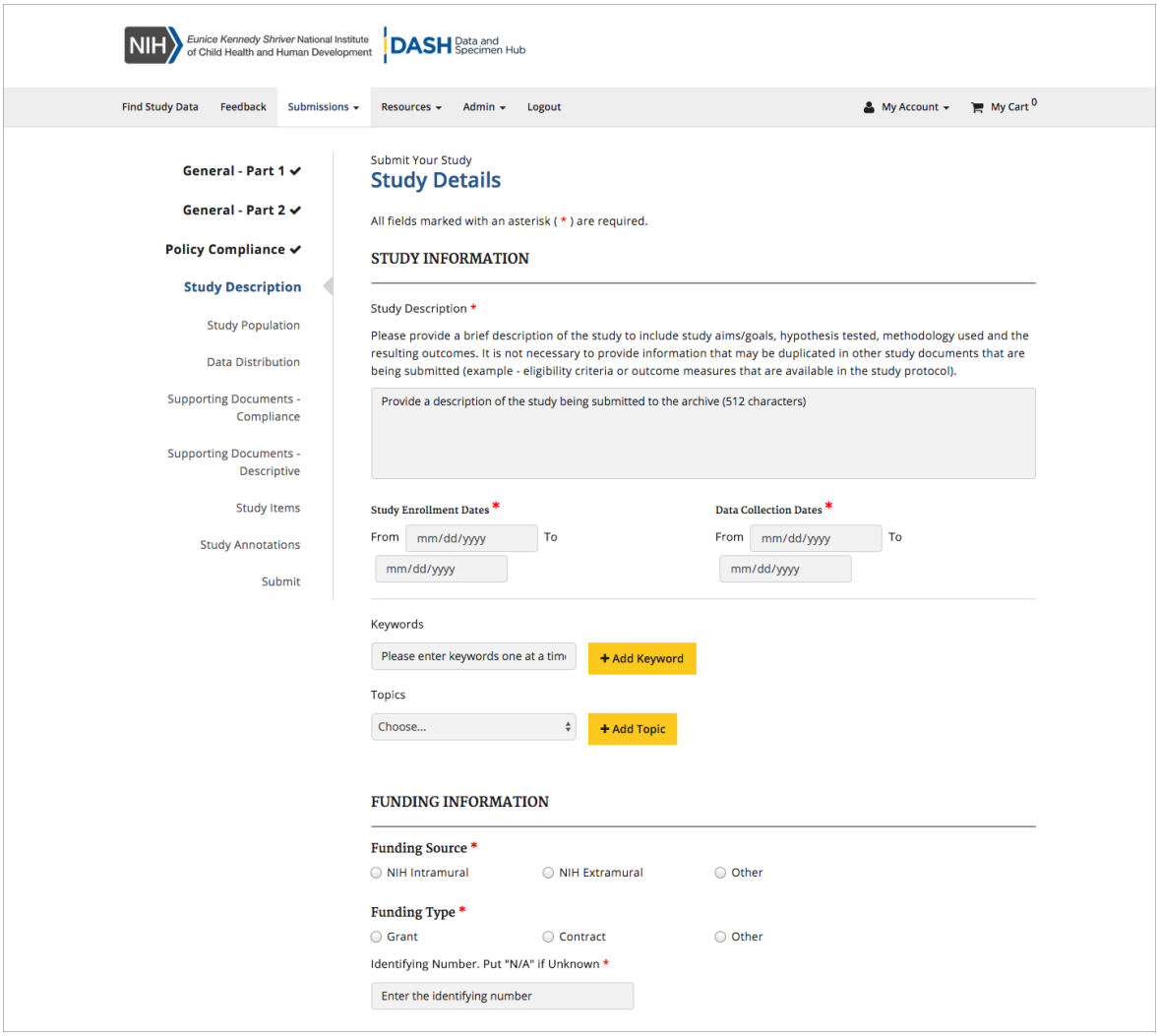
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Study Details
All fields marked with an asterisk (*) are required.
STUDY INFORMATION
Study Description *
Please provide a brief description of the study to include study aims/goals, hypothesis tested, methodology used and the resulting outcomes. It is not necessary to provide information that may be duplicated in other study documents that are being submitted (example - eligibility criteria or outcome measures that are available in the study protocol).
Provide a description of the study being submitted to the archive (512 characters)
Study Enrollment Dates *
From mm/dd/yyyy To mm/dd/yyyy
Data Collection Dates *
From mm/dd/yyyy To mm/dd/yyyy
Keywords
Please enter keywords one at a tim
+ Add Keyword
Topics
Choose...
+ Add Topic
FUNDING INFORMATION
Funding Source *
NIH Intramural
NIH Extramural
Other
Funding Type *
Grant
Contract
Other
Identifying Number. Put "N/A" if Unknown *
Enter the identifying number

+ Add Funding Information

DATA INFORMATION

Clinical Research Type *

Please select the clinical research type

URL LINKS

Study Website

ClinicalTrials.gov

dbGaP

PUBLICATIONS (optional)

NOTE: Please provide no more than five URLs for main publications at this time. You will be able to upload the entire list of publications in the 'Supporting Documents' section.

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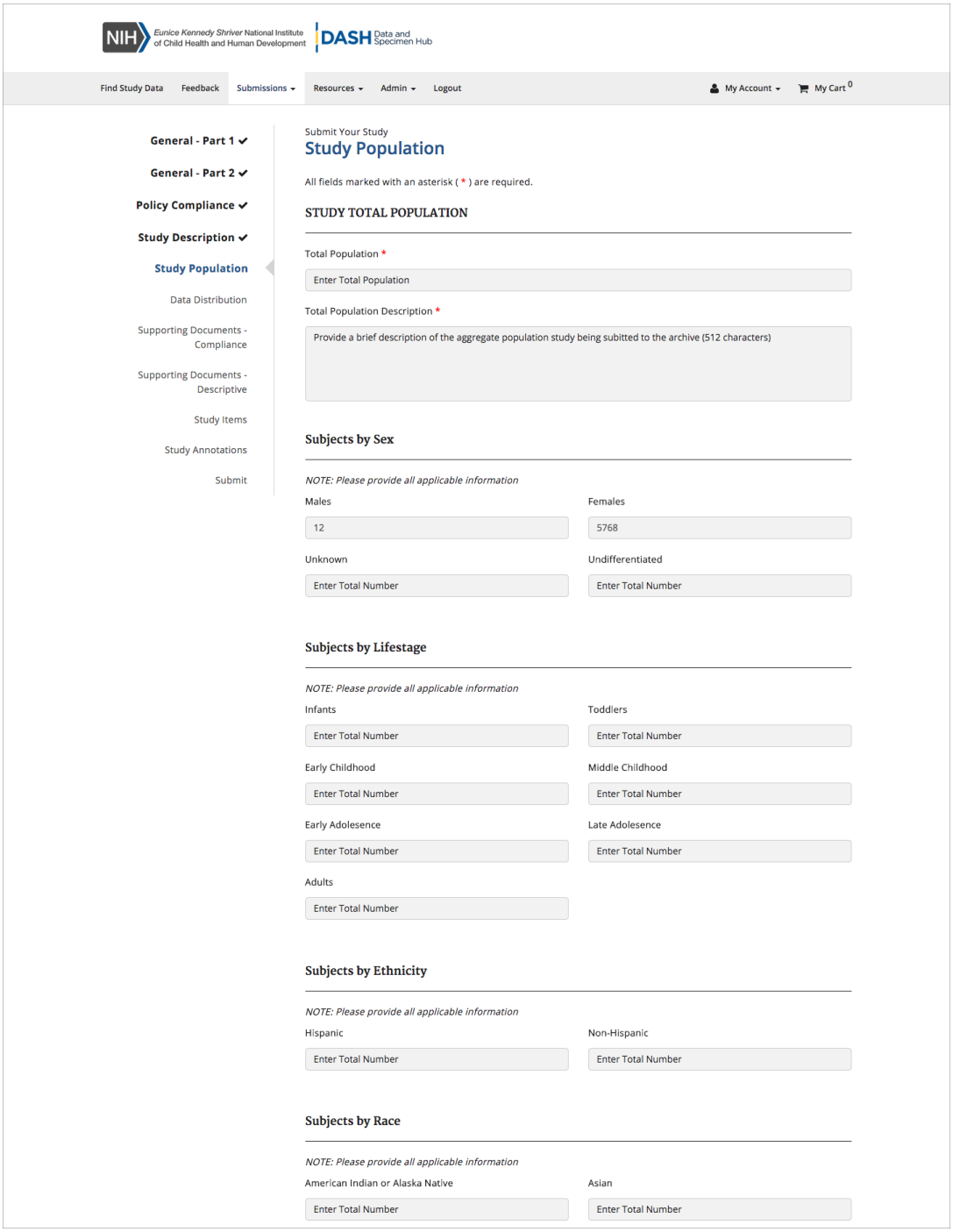
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Study Population
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STUDY TOTAL POPULATION
Total Population *
Enter Total Population
Total Population Description *
Provide a brief description of the aggregate population study being subitted to the archive (512 characters)
Subjects by Sex
NOTE: Please provide all applicable information
Males
12
Females
5768
Unknown
Enter Total Number
Undifferentiated
Enter Total Number
Subjects by Lifestage
NOTE: Please provide all applicable information
Infants
Enter Total Number
Toddlers
Enter Total Number
Early Childhood
Enter Total Number
Middle Childhood
Enter Total Number
Early Adolesence
Enter Total Number
Late Adolesence
Enter Total Number
Adults
Enter Total Number
Subjects by Ethnicity
NOTE: Please provide all applicable information
Hispanic
Enter Total Number
Non-Hispanic
Enter Total Number
Subjects by Race
NOTE: Please provide all applicable information
American Indian or Alaska Native
Enter Total Number
Asian
Enter Total Number

Black or African American

Enter Total Number

Native Hawaiian or other Pacific Islander

Enter Total Number

White

Enter Total Number

Multi Race

Enter Total Number

Subjects by Location

NOTE: Please provide all applicable information

Alabama, United States

Enter Total Number

Arkansas, United States

Enter Total Number

California, United States

Enter Total Number

Connecticut, United States

Enter Total Number

Florida, United States

Enter Total Number

Illinois, United States

Enter Total Number

Kentucky, United States

Enter Total Number

Maryland, United States

Enter Total Number

Michigan, United States

Enter Total Number

New Jersey, United States

Enter Total Number

New York, United States

Enter Total Number

North Carolina, United States

Enter Total Number

Ohio, United States

Enter Total Number

Oklahoma, United States

Enter Total Number

Pennsylvania, United States

Enter Total Number

Rhode Island, United States

Enter Total Number

South Carolina, United States

Enter Total Number

Tennessee, United States

Enter Total Number

Texas, United States

Enter Total Number

Utah, United States

Enter Total Number

Virginia, United States

Enter Total Number

West Virginia, United States

Enter Total Number

United States

Enter Total Number

Argentina

Enter Total Number

Bahamas

Enter Total Number

Brazil

Enter Total Number

Jamaica

Enter Total Number

Mexico

Enter Total Number

Peru

Enter Total Number

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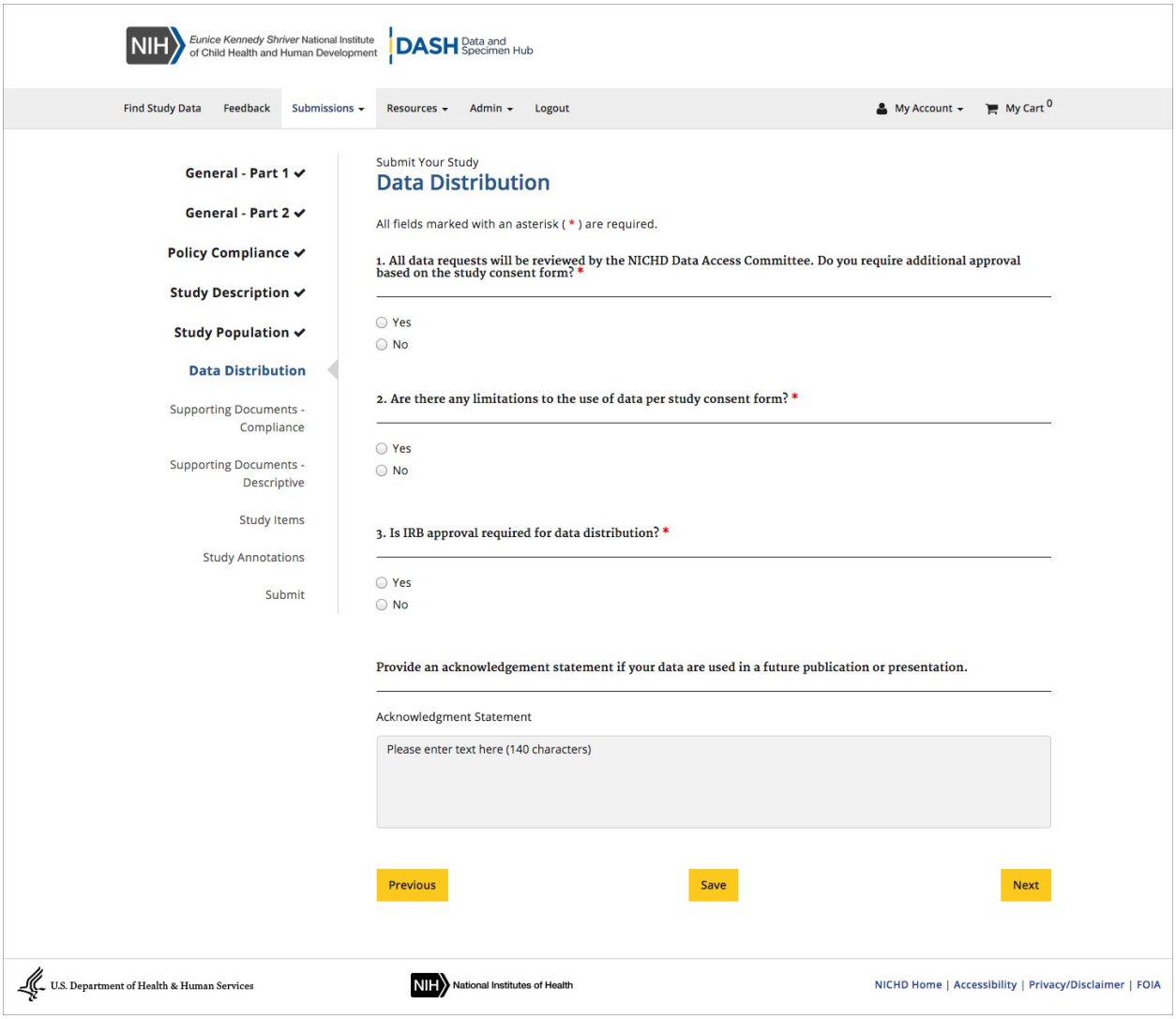
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Data Distribution
All fields marked with an asterisk (*) are required.
1. All data requests will be reviewed by the NICHD Data Access Committee. Do you require additional approval based on the study consent form? *
Yes
No
2. Are there any limitations to the use of data per study consent form? *
Yes
No
3. Is IRB approval required for data distribution? *
Yes
No
Provide an acknowledgement statement if your data are used in a future publication or presentation.
Acknowledgment Statement
Please enter text here (140 characters)
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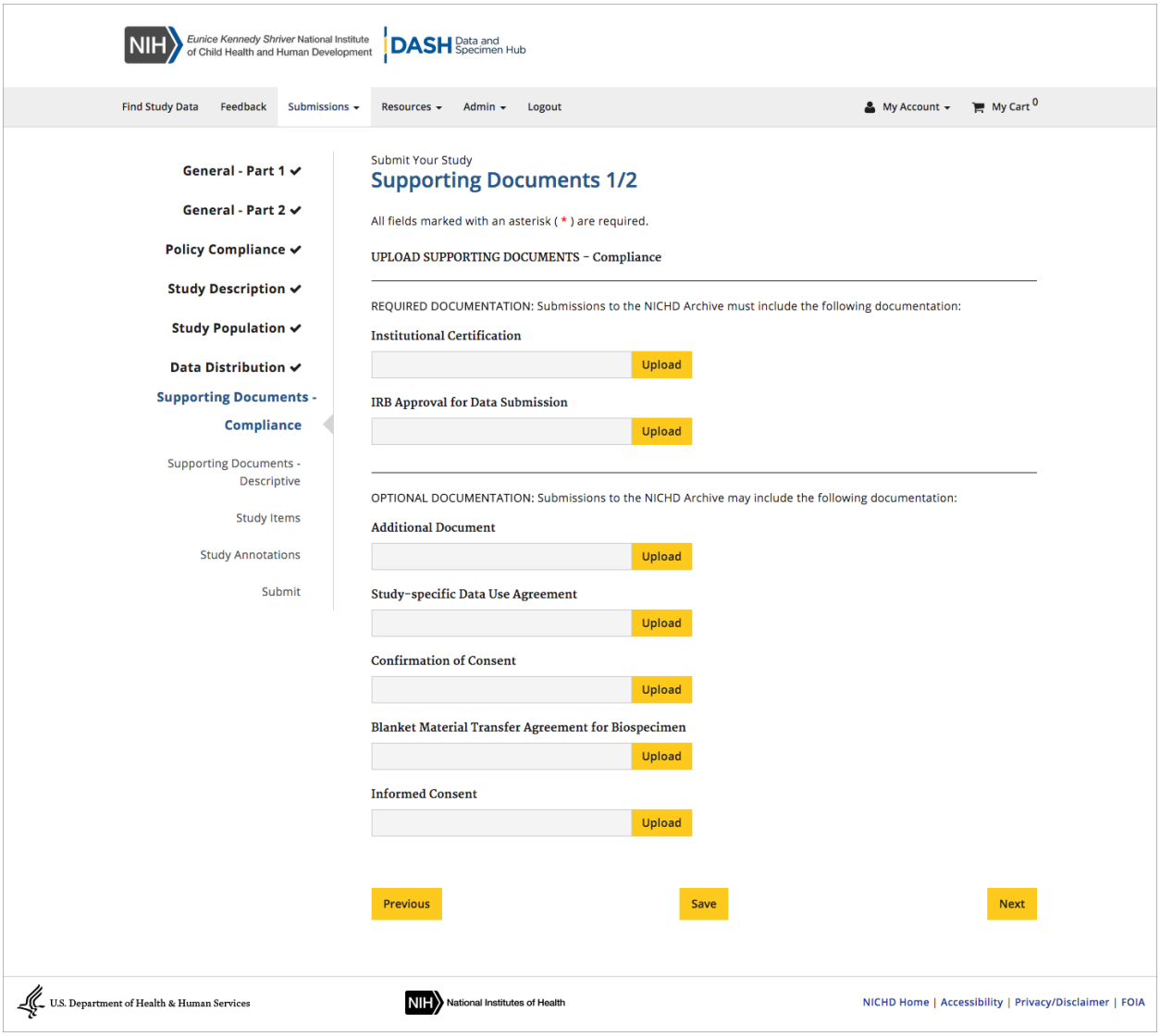
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Supporting Documents 1/2
All fields marked with an asterisk (*) are required.
UPLOAD SUPPORTING DOCUMENTS - Compliance
REQUIRED DOCUMENTATION: Submissions to the NICHD Archive must include the following documentation:
Institutional Certification
Upload
IRB Approval for Data Submission
Upload
OPTIONAL DOCUMENTATION: Submissions to the NICHD Archive may include the following documentation:
Additional Document
Upload
Study-specific Data Use Agreement
Upload
Confirmation of Consent
Upload
Blanket Material Transfer Agreement for Biospecimen
Upload
Informed Consent
Upload
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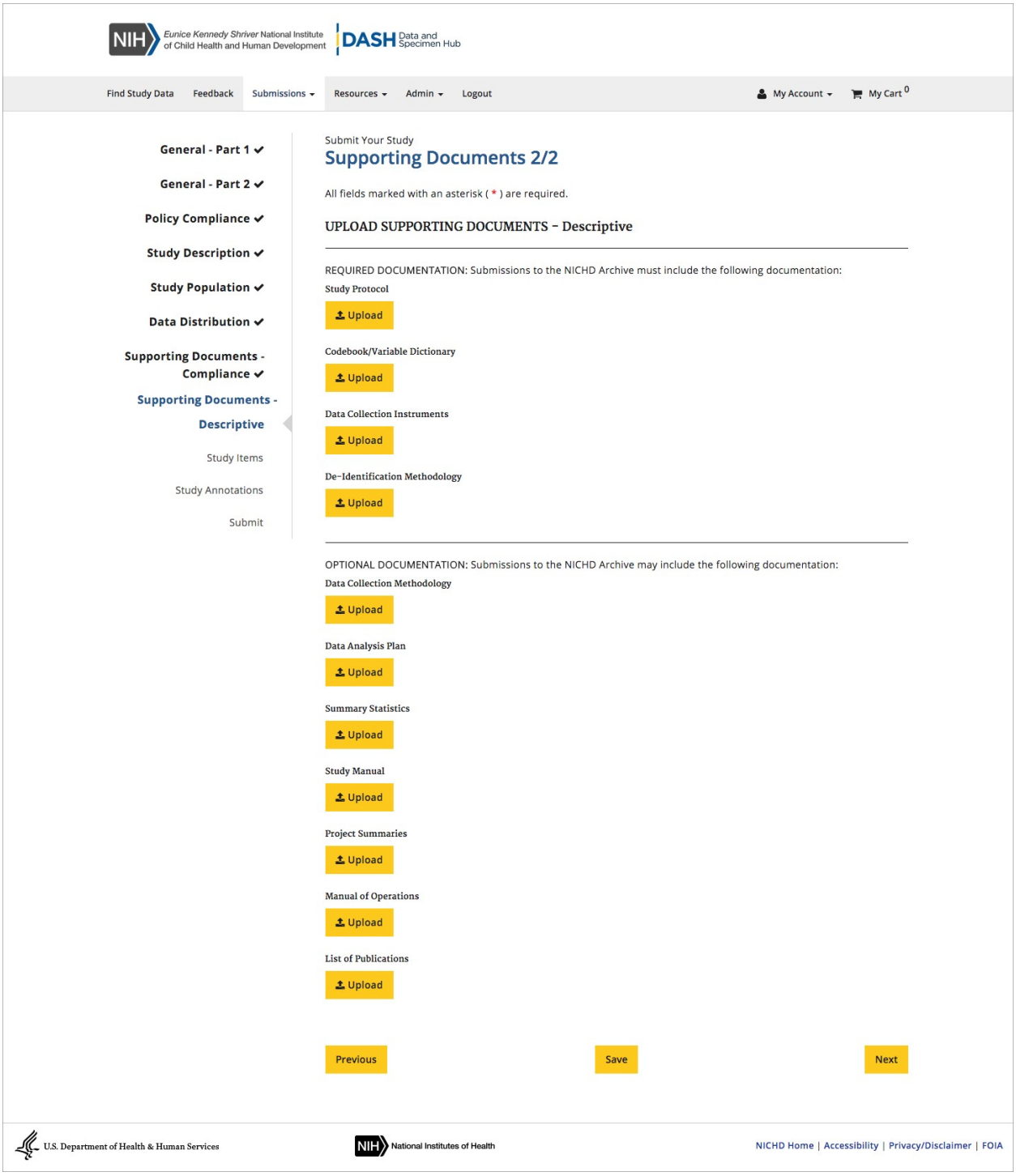
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Supporting Documents 2/2
All fields marked with an asterisk (*) are required.
UPLOAD SUPPORTING DOCUMENTS – Descriptive
REQUIRED DOCUMENTATION: Submissions to the NICHD Archive must include the following documentation:
Study Protocol
Upload
Codebook/Variable Dictionary
Upload
Data Collection Instruments
Upload
De-Identification Methodology
Upload
OPTIONAL DOCUMENTATION: Submissions to the NICHD Archive may include the following documentation:
Data Collection Methodology
Upload
Data Analysis Plan
Upload
Summary Statistics
Upload
Study Manual
Upload
Project Summaries
Upload
Manual of Operations
Upload
List of Publications
Upload
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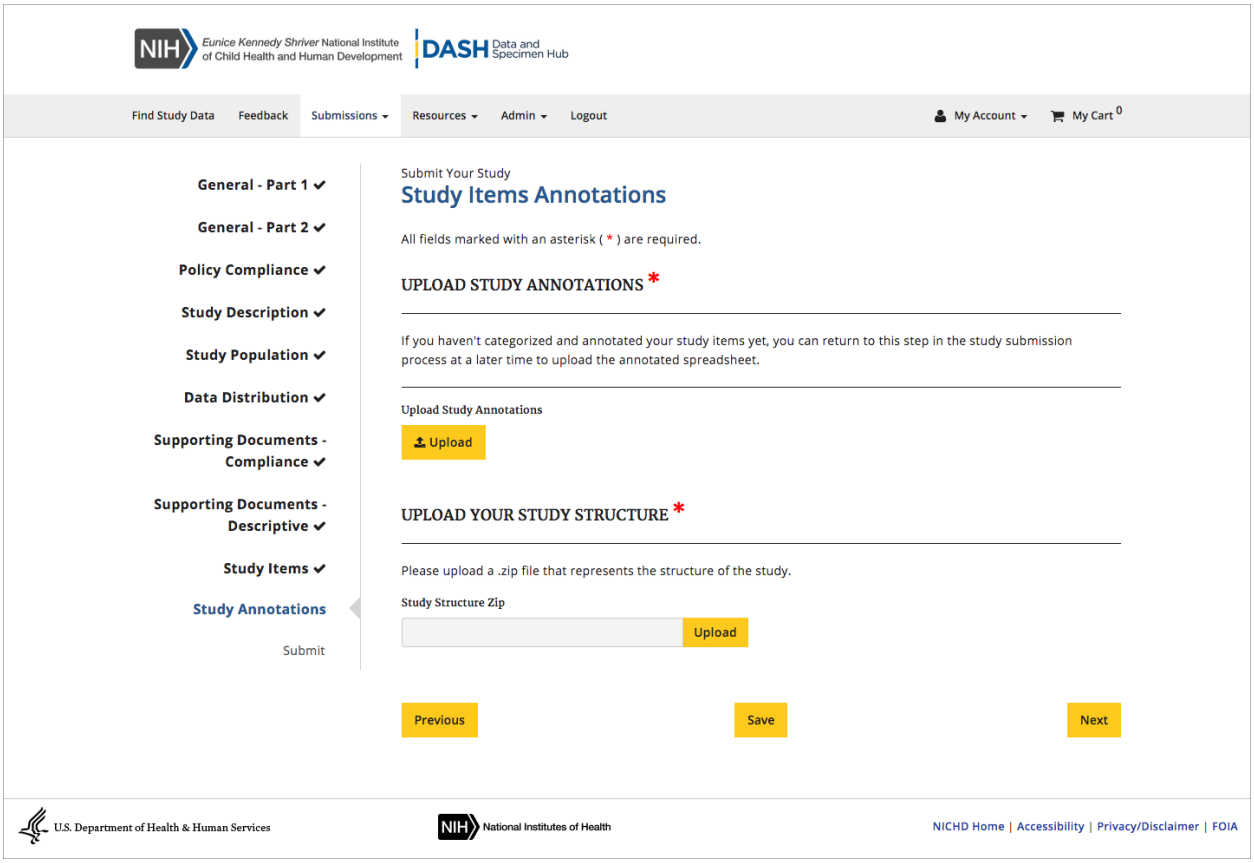
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Study Items ✔
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Submit Your Study
Study Items Annotations
All fields marked with an asterisk (*) are required.
UPLOAD STUDY ANNOTATIONS *
If you haven't categorized and annotated your study items yet, you can return to this step in the study submission process at a later time to upload the annotated spreadsheet.
Upload Study Annotations
Upload
UPLOAD YOUR STUDY STRUCTURE *
Please upload a .zip file that represents the structure of the study.
Study Structure Zip
Upload
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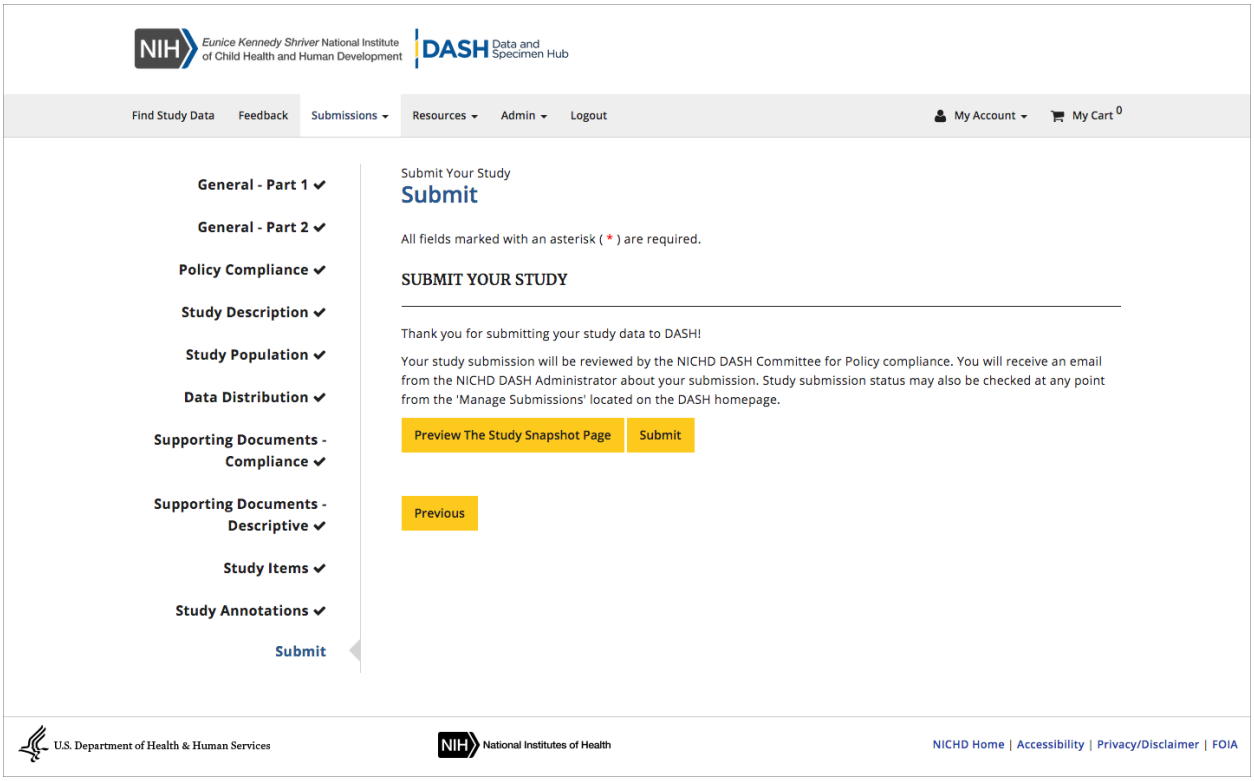
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Supporting Documents - Descriptive ✔
Study Items ✔
Study Annotations ✔
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Submit Your Study
Submit
All fields marked with an asterisk (*) are required.
SUBMIT YOUR STUDY
Thank you for submitting your study data to DASH!
Your study submission will be reviewed by the NICHD DASH Committee for Policy compliance. You will receive an email from the NICHD DASH Administrator about your submission. Study submission status may also be checked at any point from the 'Manage Submissions' located on the DASH homepage.
Preview The Study Snapshot Page
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