User Tutorial for Data and Biospecimen Request

Request Data

You must have an active NICHD DASH account and be logged into the system to request data from the NICHD DASH. You may request data from any study archived in NICHD DASH. Please consult the <u>Data Request Checklist</u> before requesting Data. You will be required to submit the following:

- 1. Data Request Form signed by the Data Requester
- NICHD DASH Data Use Agreement signed by the Data Recipient and the Authorized Organization Representative (AOR) from your institution. Please see the <u>NICHD DASH</u> <u>FAQs</u> for additional information on the AOR.
- 3. Institutional Review Board (IRB) approval, if required for the requested study data (as shown on the Study Overview page)

Note: If you are interested in obtaining datasets from multiple studies, you will need to submit a separate Data Request Form, NICHD DASH Data Use Agreement, and IRB approval (if applicable) for each study.

Add to Your Cart

You can add data to your cart in a number of different ways.

Option 1: "Explore Studies" Page

From the "Explore Studies" page (outlined in "Explore Study" section) you can click the yellow "Add to Cart" button located on the right on each study. This will add all items associated with that study to your cart.

Genomic and Proteomic Network for Preterm Birth Research Expression Profiling Study (GPN-PBR EP) O Adrenal Gland Disorders (1) NICHD Division/Branch/Center: DER - Pregnancy and Perinatology Branch (PPB) O Amenorrhea (1 O Autism Spectrum Disorder (ASD) ☐ Bacterial Vaginosis ඬ ☐ Birth Defects ② ☐ Bullying **⑤** Hide Details Cerebral Palsy 2 Study Type: Other Types of Clinical Research Subjects By Sex O Females (19 O Males @ Requires IRB approval to obtain data: No O Undifferentiated @ Study data availability in DASH: All data for the study is available in DASH

Figure 1: "Add Study to Cart" from the "Explore Studies" Page

From the "Explore Datasets" page (outlined in "Browse/Search Datasets" section) you can click the circle to the left of each dataset to select it. You can click "Select all items on Page" to select all of the items displayed on the page. Then you can click the yellow "Add [Number] of items to Cart" button to add the selected items to your cart.

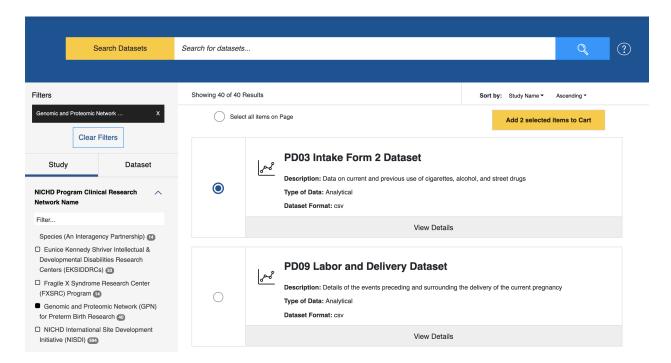
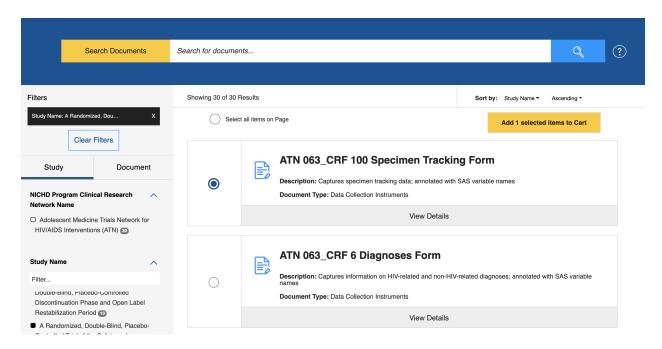


Figure 2: "Add Study to Cart" from the "Explore Datasets" Page

Option 3: From "Explore Documents" Page

From the "Explore Documents" page (outlined in "Browse/Search Documents" section) you can click the circle to the left of each document to select it. You can click "Select all items on Page" to select all of the items displayed on the page. Then you can click the yellow "Add [Number] of items to your cart" button to add the selected items to your cart.

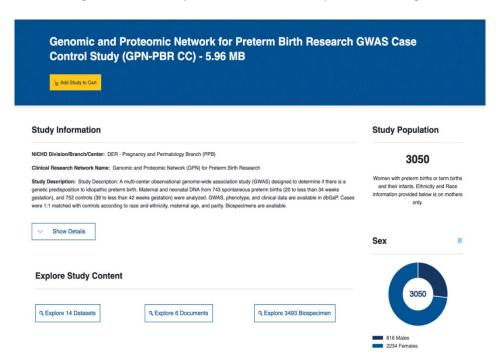
Figure 3: "Add Study to Cart" from the "Explore Documents" Page



Option 4: From the "Study Overview" Page

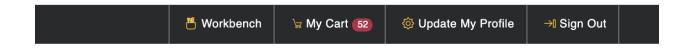
Each study has a "Study Overview" page, which is accessible from any of the Browse/Search methods outlined in "Browse Studies/Search Data" Section. When you are on the "Study Overview" page, click on "Add Study to Cart" located below the study name. This will add all items associated with that study to your cart.

Figure 4: "Add Study to Cart" from the "Study Overview" Page



You can continue exploring data after adding items to your cart. You can click "My Cart" at the top navigation bar to view all the items you have added to your cart, or click "View in Cart" from either the "Explore Studies" or "Study Overview" page for the items you have added.

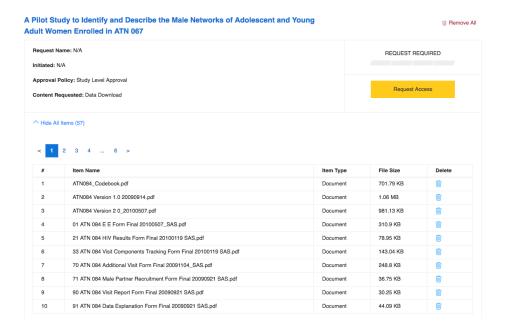
Figure 5: "My Cart" Button



From the "My Cart" page, you can remove items previously added to your cart. You can either:

- Remove individual items by expanding the "Show All Items" option and clicking on the bin icon to the right of the item name.
- Remove the whole study from the cart by clicking on the 'Remove all' button located above the status bar.

Figure 6: "Delete from Cart" button

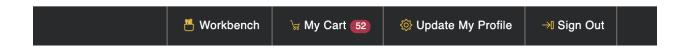


Complete a Data Request

After you have added study items (datasets or documents) to your cart, you can start the data request process by following the instructions below. The status of each study request is also displayed in "My Cart" (i.e. 'request required', 'request initiated', and 'request submitted'), which you can check at any time during the approval period. You will be unable to edit or delete a request after your request has been submitted.

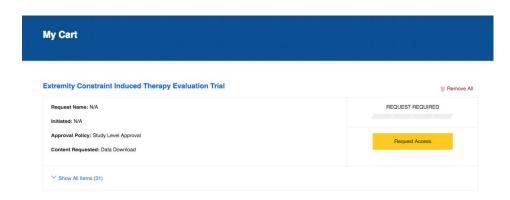
1. Click on "My Cart" located at the top right of the menu bar.

Figure 7: "My Cart" Location on Menu Bar



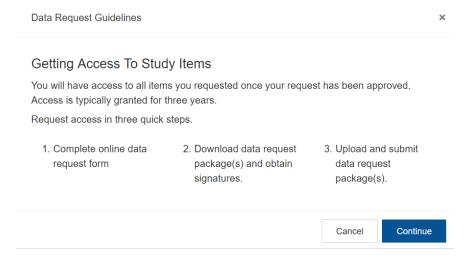
2. Under the "Data Requests" tab, the study items in your cart are grouped by study. Click on "Request Access" to initiate the data request.

Figure 8: Requesting Access through the "My Cart" Page



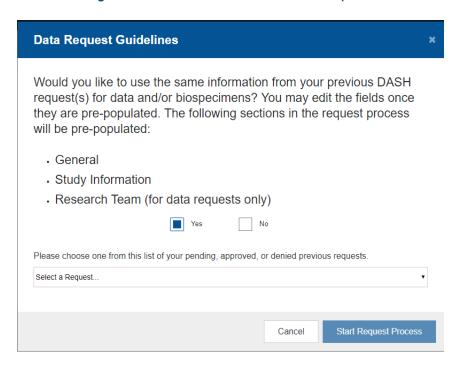
3. "Data Request Guidelines" pop-up window will provide guidance on how to access Study Items. Click on "Continue" in the pop-up.

Figure 9: "Getting Access to Study Items" Pop-Up Window



4. If you have previously submitted a request, you will see a pop-up that asks if you would like to use information from previous requests. If you select "Yes", the "General", "Request Information", and "Research Team" sections will be prepopulated with the information you provided from the previous request you select from the dropdown list.

Figure 10: Use Information from Previous Requests



5. Complete the Data Request Form. The left-hand navigation pane will show you the various sections you will need to complete to request data from NICHD DASH. All fields marked with an asterisk (*) are required and must be completed to move on to the next page. The General page of the online Data Request Form will be prepopulated with the information you provided when you created your NICHD DASH account. Review the information and then click "Next".

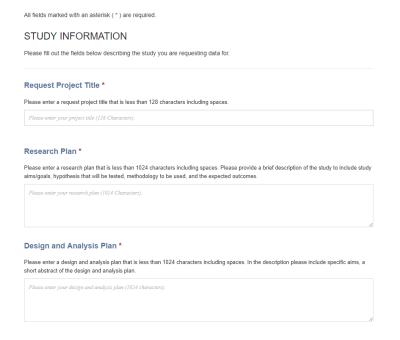
Note: You may start and stop this process at any time, and resume at the section where you left off. Be sure to click "Save" at the bottom of the window you are working on so your work is available when you return.

Figure 11: "General" Page of Data Request Form



6. The "Study Information" page of the online Data Request Form requests information about the research study for which you will be using the data. Complete required fields marked by an asterisk (*).

Figure 12: "Study Information" Page of Data Request Form



7. The "Funding Information" section of the "Study Information" page asks you to indicate your funding source, which can be NIH intramural, NIH extramural, or other. You will also be asked to include the Funding Institution, Funding Type and the Identifying Number attached to that Funding Type.

Select your funding source. A dropdown list appears to select the funding institution. If the funding institution for this project is not listed, click "Click here to add an institution" and complete the required fields.

Select the funding type, and enter the Identifying Number for your funding.

If you select "Other" for the funding source or funding type you must specify the type of funding source or funding type in the required field.

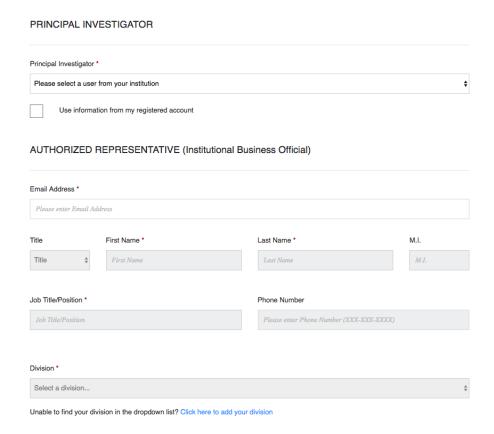
If your study has multiple funding sources and/or multiple identifying numbers, please make a new funding information entry for each funding source by clicking on "Add Funding Information".

Figure 13: "Funding Information" Page of Data Request Form

FUNDING INFORMATION	
Funding Source *	
NIH Extramural NIH Intra	mural Other
Select one or more institutions. Hold Ctrl key for selecting multiple institu-	utions *
Attain, LLC Ballet company Bill & Melinda Gates Foundation Birds Cage Booz Allen Hamilton	
Unable to find your institution in the dropdown list? Click here to add an	institution
Funding Type *	
Contract Grant	Other
If Other, please specify *	Identifying Number. Put "N/A" if Unknown *
Enter other funding type	Enter the identifying number
	Add Funding Information

- 8. The Principal Investigator (PI) section asks information about the PI for your study. If you are the PI, click on "Use information from my registered account". The PI must register as a user in NICHD DASH. They must also be registered under the same institution as the person requesting NICHD DASH data for a study. If you are not the PI, select a registered user from your institution from the dropdown list. If the PI has not already created an NICHD DASH account, please ask him or her to do so, and return to this section to complete your request. There is a "Save" button located at the bottom of every page so that you can return to your request and edit it.
- 9. The Authorized Representative (Institutional Business Official) section requests the name and contact information for the Authorized Organization Representative from your institution. NIH defines the Authorized Organization Representative as, "the individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards". Please see the NIH Grants Glossary page for additional details. This is the person from your institution with the authority to sign your Data Use Agreement. The Authorized Organization Representative does not need to be registered in DASH. However if they are a registered user and you enter their registered email address, the system will automatically populate the appropriate user information.

Figure 14: Principal Investigator and Authorized Representative



10. Click "Next" when complete. This will save your work and move to the next page. You may also click on "Save" to save completed sections without leaving the page.

Figure 15: Navigation Buttons



- 11.The "Research Team" page asks for information about Affiliates, Associates, and Collaborators.
 - Affiliates are individuals within your institution, for whom access to Data is required to carry out the Research Plan. Affiliates are permitted to access and download Data directly from NICHD DASH. Note: All listed affiliates must be registered DASH users.
 - Associates are individuals employed by other institutions that will be allowed
 to access data and will be covered under your institution's Data Use
 Agreement. They will not be permitted by the DASH system to access or
 download Data directly; instead, they must access Data only within your data
 platform and must not download Data from your data platform to their own
 local data platform or devices.

 Collaborators are individuals at other institution under the supervision of other Principal Investigators working collaboratively on the same research plan.
 Note that Collaborators must submit a separate Data Request Form and sign a separate DUA with NICHD.

Figure 16: "Research Team" Page of Data Request

All fields marked with an asterisk (*) are required.		
AFFILIATES		
Will you have Affiliates as part of this Data Use Agreement? Affiliates are individuals within your institution, for whom access to Data is required to carry out the Research Plan. Affiliates are permitted to access and download Data directly from NICHD DASH. *		
Note: All listed affiliates must be registered DASH users.		
Yes No		
Please select your affiliates from the dropdown list and click the "Add an Affiliate" button. This list includes registered DASH users from your institution. If you are unable to find your affiliates in the list, please ask them to register and activate an account in DASH. When their accounts are active, you will be able to find them in the list and add them to your list of affiliates. Please do not proceed to the next step until you have added all of your affiliates who will have access to the requested data.*		
Select a user from your institution		
Add Affiliate		
ASSOCIATES		
Will you have Associates as part of this Data Use Agreement? Associates are individuals employed by other institutions that will be allowed to access data and will be covered under your institution's Data Use Agreement. They will not be permitted by the DASH system to access or download Data directly; instead, they must access Data only within your data platform and must not download Data from your data platform to their own local data platform or devices. *		
Yes No		
COLLABORATORS		
Will you have Collaborators? Collaborators are individuals at other institution under the supervision of other Principal Investigators working collaboratively on the same research plan? *		
Note: Collaborators must submit a separate Data Request Form and sign a separate DUA with NICHD.		
Yes No		

12. If no additional Research Team members require access, select "No" and then click "Next". Otherwise select "Yes" to add the appropriate Research Team members.

- If affiliates from your institution will be using the data, select your affiliates from the dropdown list and click on the "Add Affiliate" button. You may select more than one affiliate. Affiliate names will appear below in the dropdown list. To remove an Affiliate, click on the "X" to the right of the name.
- To add Associates and Collaborators, enter their institution and fill in the required information.

Note: All affiliates must be pre-registered in DASH for their name to appear in the dropdown list. If you are unable to select an affiliate, save your work by clicking on the "Save" button and return to this page when your affiliates have registered. Do not continue to the "Generate Package" section until you have completed this section, as you will not be able to add affiliates to this request once your package is generated.

- 13 When you have finished adding Research Team members names, click "Next."
- 14 Read the information on the "Generate Package" page, and then click "Confirm and Generate Package". The system will generate a data request package and send it to you via email. This package includes your NICHD DASH Data Request Form and Data Use Agreement that require signatures from you and your Authorized Organization Representative.

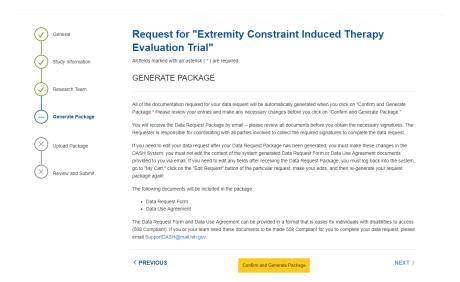
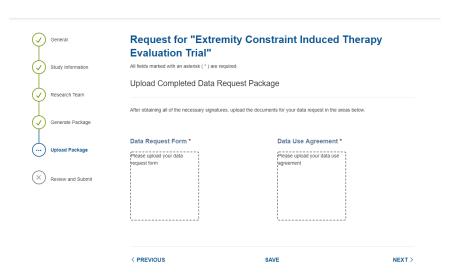


Figure 17: "Generate Package" Page

Note: Do not make changes to or add information in the Data Request Package you receive. If you make any changes to your data request (e.g. adding or removing affiliates) after the system has generated the package, your request package will be invalidated, and you will need to generate your request package again. If there are changes to the request, login to NICHS DASH, make the changes to your Data Request and generate a new Data Request Package.

- 15. Please review all documents in the Data Request Package prior to requesting appropriate signatures from your institution. The requester is responsible for coordinating with all parties involved and collecting all signatures required to complete the data request.
- 16. To upload the package after obtaining all necessary signatures, scan your documents and log back in to the NICHD DASH system. Click on "My Cart" at the top of the NICHD DASH homepage to begin. Next to the requested study, click "Edit Request". You will be directed to the "Upload" page.
- 17. Click the dashed boxes and select the appropriate file from your computer to upload each required file. Each required file must be uploaded separately. In the example below, two of the three required documents have been uploaded.

Figure 18: "Upload Completed Data Request Package" Page of the Data Request Form



- Once you have uploaded your documents, click "Next" to move to the "Review & Submit" page. This page shows all of the information you have entered thus far; please carefully review this page for accuracy and completeness. Then click the "Submit" button to submit your request.
- 19 Your data request will be reviewed by the NICHD DASH Data Access Committee and possibly by a study-specific approval entity such as the Steering Committee of the study you requested. You will be notified via email if any updates or additional information are needed for your request. You will also be notified by email if your request is approved or not approved. You may check on the status of your data request at any point from your cart.

Request Biospecimens

You must be registered, have an active NICHD DASH account and be logged in to the system to request biospecimens. You will be required to submit the following:

- 1. Biospecimen Request Form signed by the biospecimen requester
- 2. NICHD DASH Material Transfer Agreement signed by the Biospecimen Recipient and the Authorized Organization Representative (AOR) from the Recipient's institution. Please see the NICHD DASH FAQs for information on the AOR.
- 3. Proof of funding to obtain the biospecimens: Note that if you do not have funding for shipping and handling of the biospecimens you are requesting, you can obtain a Letter of Biospecimen Availability from DASH to apply for funding.

Note: If you are interested in obtaining biospecimens from multiple studies, you will need to submit a separate Biospecimen Request Form and Material Transfer Agreement for each study.

Add to Your Cart

You can add biospecimens to your cart from the "Explore Biospecimens" page, from the table view or the list view (outlined in "Browse/Search for Biospecimens" section).

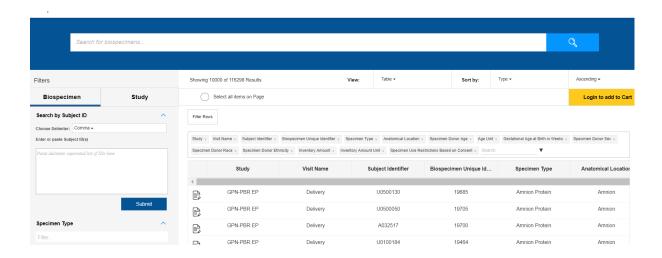
• Option 1: From Table View

• Option 2: From List View

Option 1: From Table View

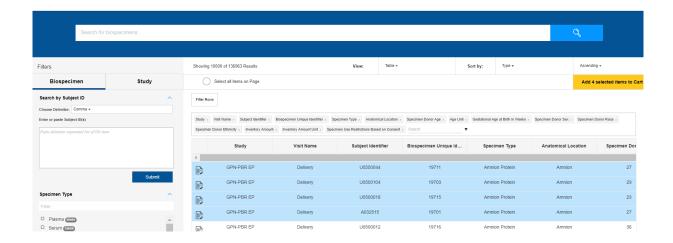
1. Click the yellow "Login to add to Cart" button located on the top right of the page.

Figure 19: Login to Add Biospecimen(s) to Cart, Table View



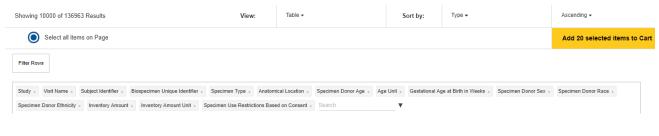
- 2. Enter your credentials to log in if you are not already logged in. Once you enter your credentials, you will be redirected back to the "Explore Biospecimens" page.
- 3. Click on biospecimens (rows) in the table and they will be highlighted in blue. Click the yellow "Add selected items to Cart" button to add your selection to your cart.

Figure 20: Add Selected Biospecimens to Cart, Table View



4. You also may want to use the "Select all items on Page" button to quickly select all items on that page.

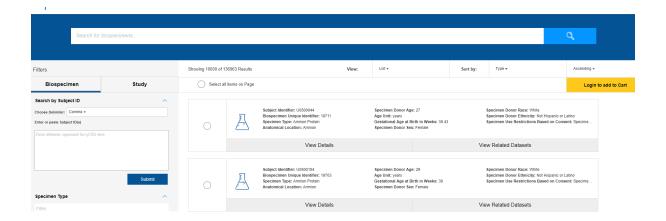
Figure 21: Select All Items on Page, Table View



Option 2: From List View

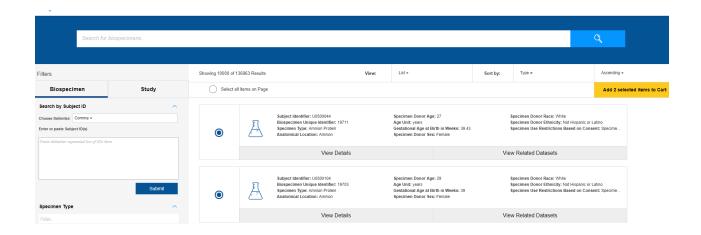
1. Click the yellow "Login to add to Cart" button located on the top right of the page.

Figure 22: Login to Add Biospecimen(s) to Cart, List View



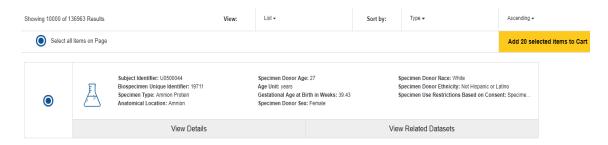
- 2. Enter your credentials to log in. You will be redirected back to the "Explore Biospecimens" page.
- 3. Click the circle on the left of each biospecimen to select it. Click the yellow "Add selected items to Cart" button to add your selection to your cart.

Figure 23: Add Selected Biospecimens to Cart, List View



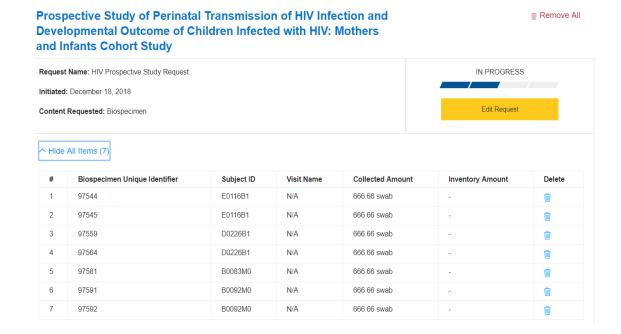
4. You also may want to use the "Select all items on Page" button to quickly select all items on that page.

Figure 24: Select All Items on Page, List View



- 5. From the "My Cart" page, you can remove biospecimens previously added to your cart. You can either:
 - Remove individual items by expanding the 'Show All Items' option and clicking on the bin icon to the right of the item name.
 - Remove the whole study from the cart by clicking on the 'Remove All' button located above the status bar.

Figure 25: Remove Biospecimens from Cart



Complete a Biospecimen Request

After you have added biospecimens to your cart, you can start the data request process by following the instructions below.

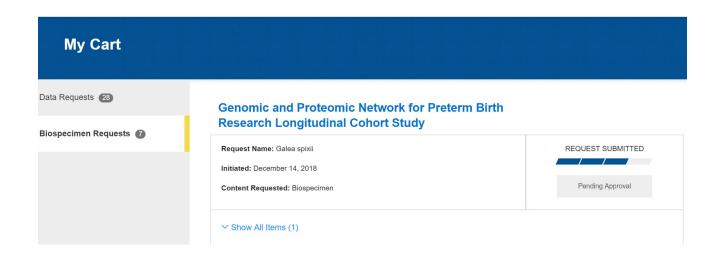
1. Click on "My Cart" located at the top right of the NICHD DASH homepage.

Figure 26: My Cart



2. Click on "Biospecimen Requests" in the left hand navigation pane.

Figure 27: Biospecimen Requests Tab



3. The biospecimens you have added to your cart will be grouped by study. Click on "Request Access".

Figure 28: Initiate Biospecimen Request

Remove All

NISDI Pediatric Latin American Countries Epidemiological Study: A Prospective, Observational Study of HIV-infected Children at **Clinical Sites in Latin American Countries** Request Name: N/A REQUEST REQUIRED Initiated: N/A Request Access Content Requested: Biospecimen ✓ Show All Items (4)

4. The "Biospecimen Request Guidelines" pop-up window will provide guidance on the steps required to complete your biospecimen request. Click on "Continue" in the popup.

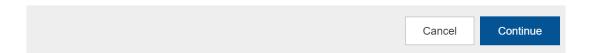
Figure 29: Biospecimen Request Guidelines

Biospecimen Request Guidelines

- 1

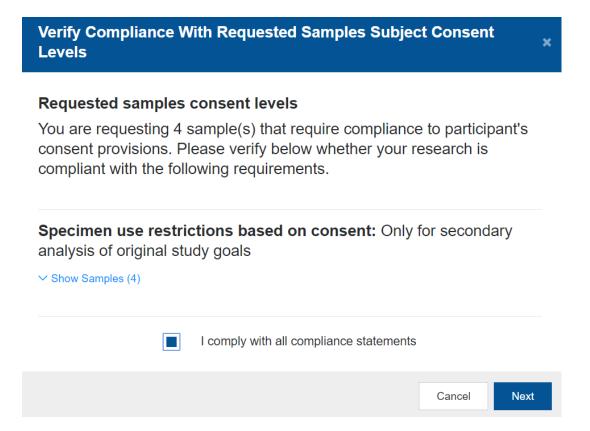
Request biospecimens in four quick steps:

- 1. Verify that your research is compliant with participants' consent provisions (if any).
- 2. Complete online biospecimen request form.
- 3. Download biospecimen request package and obtain signatures.
- 4. Upload and submit biospecimen request package.
- * Note that once your request is approved, the biospecimen repository will contact you to arrange shipping.



5. You will then see a pop-up window that says "Verify Compliance with Requested Samples Subject Consent Levels". Some specimens have use restrictions based on consent; if applicable, you will be asked to verify that your research is compliant. Then click "Next".

Figure 30: Verify Compliance with Requested Samples Subject Consent Levels



6. If you have previously submitted a request, you will see a pop-up that asks if you would like to use information from previous requests. If you select "Yes", the "General" and "Study Information" sections will be prepopulated with the information you provided from the previous request you select from the dropdown list.

Figure 31: Use Information from Previous Requests

Would you like to use the same information from your previous DASH request(s) for data and/or biospecimens? You may edit the fields once they are pre-populated. The following sections in the request process will be pre-populated: • General • Study Information • Research Team (for data requests only) Please choose one from this list of your pending, approved, or denied previous requests. Select a Request...

7. Complete the Biospecimen Request Form. The left-hand navigation pane will show you the various sections you will need to complete to request biospecimens from DASH. All fields marked with an asterisk (*) are required and must be completed to move on to the next page. The General page of the online Biospecimen Request Form will be prepopulated with the information you provided when you created your DASH account. Review the information and then click "Next".

Cancel

Start Request Process

Figure 32: Provide General Information for Biospecimen Request



8. The "Study Information" page of the online Biospecimen Request Form requests information about the research study for which you will be using the biospecimens. Complete required fields marked by an asterisk (*).

Figure 33: Provide Study Information for Biospecimen Request

All fields marked with an asterisk (*) are required.
STUDY INFORMATION
Please fill out the fields below describing the study you are requesting biospecimens for.
Request Project Title *
Please enter a request project title that is less than 128 characters including spaces.
Please enter your project title (128 Characters).
Research Plan *
Please enter a research plan that is less than 1024 characters including spaces.
Please enter your research plan (1024 Characters).
Design and Analysis Plan *
Please enter a design and analysis plan that is less than 1024 characters including spaces. In the description please include specific aims, a short abstract of the design and analysis plan.
Please enter your design and analysis plan (1024 characters).

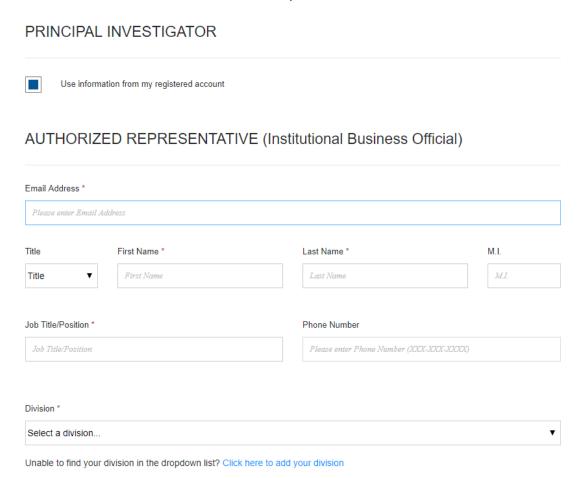
9. The "Funding Information" section of the "Study Information" page asks you to select your funding status, indicating whether you have funding to pay for biospecimen shipping and handling, or if you are applying for funding for this biospecimen request. If you have funding, you will be prompted to enter additional details about your funding source and funding type. If your study has multiple funding sources and/or multiple identifying numbers, please make a new funding information entry for each funding source by clicking on "Add Funding Information".

Figure 34: Provide Funding Information for Biospecimen Request

Funding Status * I have funding to pay for biospecimens shipping and handling I am applying for funding for this biospecimen request Funding Source * NIH Extramural NIH Intramural Other Funding Type * Contract Grant Other Identifying Number. Put "N/A" if Unknown * Enter the Identifying number

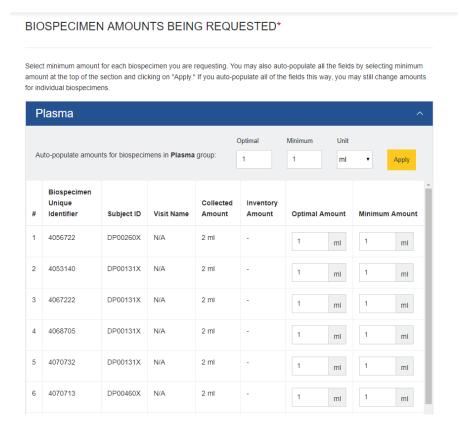
- 10. Principal Investigator (PI) section asks information about the PI for your study. If you are the PI, click on "Use information from my registered account". The PI must register as a user in NICHD DASH. They must also be registered under the same institution as the person requesting NICHD DASH biospecimens for amm study. If you are not the PI, select a registered user from your institution from the dropdown list. If the PI has not already created an NICHD DASH account, please ask him or her to do so, and then you can return to this section to complete your request. There is a "Save" button located at the bottom of every page so that you can return to your request and edit it.
- 11. The Authorized Representative (Institutional Business Official) section require you to provide the name and contact information for the Authorized Organization Representative (AOR) from your institution. NIH defines the Authorized Organization Representative as, "the individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards". Please see the NIH Grants Glossary page for additional details. This is the person from your institution with the authority to sign your Material Transfer Agreement. The Authorized Organization Representative does not need to be registered in DASH. However, if they are a registered user and you enter their registered email address, the system will automatically populate the appropriate user information.

Figure 35: Provide Principal Investigator and Authorized Representative Information for Biospecimen
Request



12. On the "Selected Biospecimens" page you must fill in the amounts of biospecimens you are requesting. You must select minimum amounts for each biospecimen. You may also specify an optimal amount; if you leave optimal amount blank, it will be populated with the minimal amount. You may also auto-populate all the fields by selecting minimum amount at the top of the section and clicking on "Apply". If you auto-populate all of the fields this way, you may still change amounts for individual biospecimens.

Figure 36: Biospecimen Amounts to be Requested



Note: Please read the Biospecimen Availability Disclaimer and the Price Estimate Disclaimer carefully.

13. Read the information on the "Generate Package" page, and then click "Confirm and Generate Package". The system will generate a biospecimen request package and send it to you via email. This package includes your NICHD DASH Biospecimen Request Form and Material Transfer Agreement that require signatures from you and your Authorized Organization Representative. Note that if you do not have funding, the DASH administrator will separately email you the Letter of Biospecimen Availability

Figure 37: Confirm and Generate Package for Biospecimen Request

Request for biospecimens from "NISDI Pediatric Latin American Countries Epidemiological Study: A Prospective, Observational Study of HIV-infected Children at Clinical Sites in Latin American Countries"

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

GENERATE PACKAGE

All of the documentation required for your biospecimen request will be automatically generated when you click on "Confirm and Generate Package." Please review your entries and make any necessary changes before you click on "Confirm and Generate Package."

You will receive the Biospecimen Request Package by email – please review all documents before you obtain the necessary signatures. The Requester is responsible for coordinating with all parties involved to collect the required signatures to complete the biospecimen request.

If you need to edit your biospecimen request after your Biospecimen Request Package has been generated, you must make these changes in the DASH System; you must not edit the content of the system generated Biospecimen Request Form or Material Transfer Agreement documents provided to you via email. If you need to edit any fields after receiving the Biospecimen Request Package, you must log back into the system, go to "My Cart," click on the "Edit Request" button of the particular request, make your edits, and then re-generate your request package again.

The following documents will be included in the package:

- · Biospecimen Request Form
- · Material Transfer Agreement

Note that if you indicated your funding is not yet available, you will receive a Letter of Availability for the requested biospecimen within 24 hours. This letter will be signed by the DASH Administrator so that you may apply for funding.

The Biospecimen Request Form, Material Transfer Agreement, and Letter of Availability can be provided in a format that is easier for people with disabilities to access (508 Compliant). If you or your team need these documents to be made 508 Compliant for you to complete your data request, please email SupportDASH@mail.nih.gov.

< PREVIOUS Confirm and Generate Package NEXT >

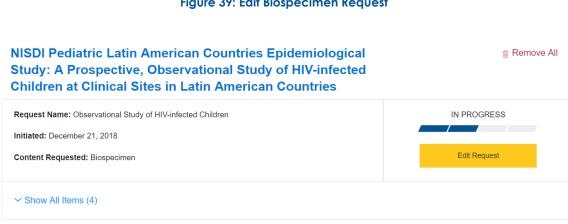
Note: Do not make changes to or add information in the Biospecimen Request Package you receive. If you make any changes to your biospecimen request after the system has generated the package, your request package will be invalidated, and you will need to generate your request package again. If there are changes to the request, login to NICHD DASH, make the changes to your Biospecimen Request and generate a new Biospecimen Request Package.

- 14. Please review all documents in the Biospecimen Request Package prior to requesting appropriate signatures from your institution. The requester is responsible for coordinating with all parties involved and collecting all signatures required to complete the biospecimen request.
- 15. To upload the package after obtaining all necessary signatures, scan your documents and log back in to the DASH system. Click on "My Cart" at the top of the DASH homepage to begin. Click on "Biospecimen Requests". Next to the requested study, click "Edit Request". You will be directed to the "Upload" page.

Figure 38: My Cart

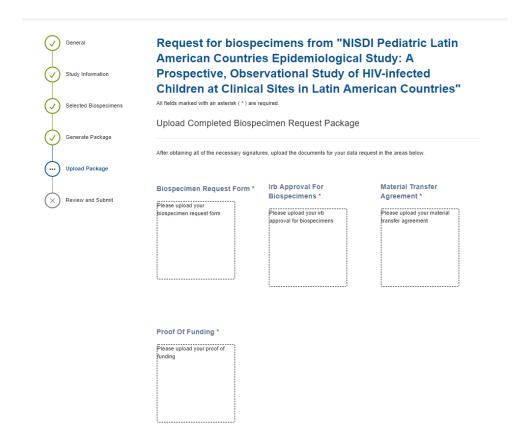


Figure 39: Edit Biospecimen Request



16. Click the dashed boxes and select the appropriate file from your computer to upload each required file. Each required file must be uploaded separately.

Figure 40: Upload Packages for Biospecimen Request



- 17. Once you have uploaded your documents, click "Next" to move to the "Review & Submit" page. This page shows all of the information you have entered thus far; please carefully review this page for accuracy and completeness. Then click the "Submit" button to submit your request.
- 18. Your biospecimen request will be reviewed by the Biospecimen Access Committee. You will be notified via email if any updates or additional information are needed for your request. You will also be notified by email if your request is approved or not approved. You may check on the status of your biospecimen request at any point from your cart.