

Quick Guide: Overview

LEARN

- From the **Home** page, learn about when and where the available NCS data were collected
- From the **Data & Documentation** tab:
 - View high-level **Public Data** collected under the IVS, ARS, and VS protocols.
 - Download data user manuals, historical study documents, and more.
 - Access IVS and ARS protocol procedures.
- Review a listing of primary NCS publications from the **Publications** tab.
- Under **Sample & Lab Data**, the **Biological and Environmental Sample Repository Inventory** provides a static table view of available samples, while the **Biological and Environmental Sample Datasets** page lists samples that have already undergone a specific process or analysis. The **Sample Explorer** allows you to search for sample types available for conducting your own analyses.

EXPLORE

Use the **Research Tools** to learn more specific information about the Study.

- View and download specific data collection instruments from the **Instrument and Dataset Inventories**, separated by NCS protocol.
- Explore NCS participants by demographic characteristics, study activity, and more using the **Participant Explorer**.
- Using the **Protocol Browser**, you can view the data collection points used during the Study. Filter down from a study protocol to a specific study visit category and data collection event.
- Need more information about a specific topic? Use the **Variable Locator** to search for keywords, view related variables, and even see how many valid responses exist for each variable.

RESEARCH

Use the **Research Request** tab to request access to participant-level NCS data and biological and environmental specimens. Easily submit, track, and manage your research requests using this online submission process.

- To enter a new request, simply complete the fields on the appropriate data or data and sample request form. Don't forget necessary attachments, like proof of funding and IRB approval.
- To view an existing request, navigate to the **My Requests** tab. You can see when the request was created and its current status. Click on a request to take additional action, signing and uploading your Research Materials Distribution Agreement (**RMDA**).

After you have submitted a request, a team will thoroughly review it and vote on whether or not your research should be approved. You may receive results such as:

- **Pending RMDA Signature/Upload:** Your request is being processed. Return to your request to generate the NICHD RMDA. You cannot access data until this is completed.
- **Request Under Review:** The NICHD review team is reviewing your request for scientific merit and will determine whether or not the request should be approved.
- **Request Denied:** Your request has not been approved. You may submit a new request in the future.

Quick Guide: Registration

Create an Account

1. From the **Home** page, click **Log In/Register**.
2. If you have NIH credentials, select the **NIH Network** login option and login using your existing username and password. Then, skip to the **Complete Your Profile** section of this guide.
3. Alternatively, select to **register for a new account using the IMS login service**.
4. Enter your **Profile Information**, including your name, email address, and phone number.
5. Choose a **Username** that is at least three characters long.
6. Create your **Password**. Follow the tips on the screen to ensure your password is secure.
7. Create three **Security Questions** to be used in case you forget your username and password.
8. Click **Continue**.
9. Check your email for instructions for verifying your email address. After your address is verified, you may access the NCS Archive.

Complete Your Profile

***Note:** The first time you access the NCS Archive, you will be prompted to complete your registration by creating a profile and agreeing to the terms of use. You may not take any other actions until these steps are completed.*

1. From the **Home** page, click **Log In/Register**.
2. Select the login service through which you wish to access the site (**NIH Network** or **IMS Login**).
3. Enter your credentials and select **Login**.
4. On the **User Profile** page, some information will be automatically populated with information you provided at registration. Enter your **Institution** and provide an **Address** and **Phone** number.
5. Complete other fields as information is available.
6. Carefully read **The National Children's Study Vanguard Data User Agreement**. Make note of all conditions and requirements of Archive use.
7. Check the **I Agree** box to agree to the terms.
8. Click **Save Changes**. Your registration will be complete and you will have full access to the NCS Archive registered website.

THE NATIONAL CHILDREN'S STUDY VANGUARD DATA USER AGREEMENT

Terms and Conditions

The data owned by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is offered as an information and data resource for scientific research.

Users of The National Children's Study (NCS) Vanguard data agree to comply with all terms and conditions of the NICHD User Agreement during the registration process.

By accepting the NICHD User Agreement, you agree:

1. to use NCS resources for the purposes of archiving and accessing data obtained from scientific research with the intent of data sharing and reuse, and to notify the NCS Administrator of any breach in use
 2. to use NCS data for scientific research in an institution with an approved assurance from the Department of Health and Human Services Office for Human Research Protections, and to not use the data for commercial purposes (or sell the data obtained from NICHD)
 3. to preserve and protect the confidentiality of, and not attempt to identify, any individuals or households in the data
 4. that archived data are provided without warranty or liability of any kind
 5. to notify the NCS Administrator of any errors discovered in the archived data
 6. to establish safeguards to prevent unauthorized viewing or release of NCS information or data
 7. to comply with any charges that may apply for various services offered by NCS
 8. to ensure that the means of access to NCS (such as passwords) are kept secure and not disclosed to anyone else
 9. that personal data submitted by you are accurate to the best of your knowledge and kept up to date by you
 10. that personal data provided by you may be used for administrative management of NCS and for reporting purposes with the goal of improving services offered by NCS
 11. that any breach of the User Agreement could lead to termination of your access to the services
 12. [Privacy Act Notification] that information collected from the Recipient, as part of the data use agreement or data request forms, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the recipient comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200 (<https://oma.od.nih.gov/forms/Privacy%20Documents/PATfiles/0200.htm>) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate the use of the NCS Archive, as well as to notify interested recipients of updates, corrections or other changes to the NCS data.
- The Federal Privacy Act protects the confidentiality of some NIH records. The NIH and any users that are provided access to the NCS Archive will have access to the information collected by the NIH from the Recipient, as part of the data use agreement or data request forms for the purposes described above. In addition, the Act allows the release of some information without the Recipient's permission; for example, if it is requested by members of Congress or other authorized individuals. The information collection requested is voluntary, but necessary for obtaining access to data and samples in the NCS Archive.
13. to complete NCS Data User Training.

Check the box if you agree to the terms and conditions (required)

I Agree

Save Changes



Quick Guide: Submit a Data Request

The steps below outline the process for requesting participant-level data only. Please see the **Submit a Data & Sample Request** quick guides if you would like to request both data and biological or environmental samples.

- From the **Research Request** tab, select **Submit Data Request**. The data request form will open.
- Enter a name for your request in the **Request Name** field.
- Information from your profile will populate in the **Requesting Investigator Information** section. Name, Institution, and email are not editable. Enter/update all other fields.
- In the **Recipient Information** section, select the type of institution at which the research will be conducted and how many years of experience the lead investigator has. Enter whether or not funding is available, and the source or anticipated source of funding.
- In the **Request Details** section of the form, supply information about your research as follows:
 - Subject Characteristics:** Details about the subjects for whom you wish to access data. Be specific and thorough.
 - Research Plan:** Summary of your rationale, hypothesis, and proposed research aims.
 - Scientific Background and Rationale:** Research protocol background and additional information about hypotheses and objectives.
- Enter the name and email addresses of any **Approved Users** who will assist you with your research.
- Indicate the method by which you will maintain **Information Security** while accessing NCS data.
- Enter any **Comments** about your application.
- Review the **Upload Checklist** and ensure that you have provided the necessary documentation, such as an IRB letter, proof of funding, or your CV. If necessary, **Attach Files**.
- Choose **Submit Request**, or **Save for Later** to return and complete your request at a later time.

The screenshot shows the 'Submit Data Request' form with the following sections and steps:

- Research Request** (Dropdown menu with 'Submit Data Request' selected and highlighted by a red arrow).
- Request Identifier** (Form with 'Request Name (required)' field).
- Requesting Investigator Information** (Form with fields for Name, Title, Institution, Email, Department, Website, Address (required), Phone (required), and Fax).
- Recipient Information** (Form with 'Institution type (required)' radio buttons (Non-Profit, Commercial, Academic), 'Number of years in scientific research' radio buttons (0-5, 5-10, 10+), 'Is funding currently available for this research?' radio buttons (Yes, No), and a dropdown for 'Anticipated primary funding source').
- Request Details** (Form with 'Subject characteristics', 'Research Plan: Describe this request, including a summary of the rationale, main hypothesis and proposed research aims (required)', and 'Scientific background and rationale' text areas).
- Approved Users** (Form with four sections for 'Approved user #1' through '#4', each with Name and Email fields).
- Information Security** (Form with 'Please check the information security practices to be used (required)' checkboxes for: Institute supported, controlled access server; Institute supported, password protected desktop computer; Encrypted, password protected laptop computer; Encrypted portable media (encrypted external hard drive, encrypted thumb drive); and Unencrypted portable media backup (CD, DVD, thumb drive) stored in locked file cabinet).
- Comments** (Text area for user comments).
- Upload checklist** (Form with checkboxes for: 'I have uploaded Institutional sign off or a cover letter approving research' and 'I have uploaded documentation of primary funding').
- Attach Files** (Form with 'You may use this section to upload files relevant to your request. There are no restrictions on file types. If you answered "yes" to the "Is funding currently available for this research?" question above, then please upload documentation of primary funding.' and a table for File Name and Size).
- Attachments** (Form with 'Choose Files' button and 'No file chosen' text).
- Submit Request** and **Save For Later** buttons at the bottom.

Quick Guide: Submit a Data & Sample Request (1)

168497
Samples

| | | | | | | | | | | | | | | |
|-------|-------|---------------|------|-------|--------|----------|----------------|-------------|------------|----------|---------|-----|-------|------|
| 79495 | 67890 | 3677 | 1075 | 842 | 7334 | 3186 | 0 | 0 | 0 | 454 | 133 | 329 | 1330 | 2752 |
| Blood | Urine | Vaginal Swabs | Hair | Nails | Saliva | Placenta | Umbilical Cord | Breast Milk | Cord Blood | Meconium | Formula | Air | Water | Dust |

Sub Types (Static)

Select a sample to see available sub types.

Participant

Woman

Father

Child

Mother / Child

Race/Ethnicity

Hispanic

White

Black

AI/AN

Asian

NH/PI

Multiple Races

Other Races

Time Point

Pre-Pregnancy

Early Pregnancy

Late Pregnancy

Birth

1 Month

6 Months

36 Months

Date

IVS Protocol (2009 - 2010)

ARS Protocol (2011 - 2014)

[Create Pending Request](#)

[Clear Filters](#)

[Need Help?](#)

Related Publications

Select a sample type to view related publications.

Sorry, There are no related publications for the sample you selected.

1. From the **Sample & Lab Data** tab, select the **Sample Explorer**.
2. Select one or more **Sample Types** from the ribbon, and if appropriate, one or more subsample types from the list on the right. Note that when you select a sample type, any related publications display on the right.
3. Use one or more search filters to locate samples meeting your requirements:
 - **Participant:** The type of participant from which the sample was obtained. Use the **Mother/Child** option to locate a familial pairing for samples available for both a mother and her child.
 - **Time Point:** The pregnancy stage of the mother or age of child at which the samples were collected.
 - **Date:** The NCS Protocol under which the samples were collected.
 - **Race/Ethnicity:** The race/ethnicity identified by the participant from whom samples were collected, or for children, the race/ethnicity of the mother.
 - **Genetic Consent:** Consent for genetic testing obtained for the participant from which samples were obtained.
4. The number of available samples matching your search will display in the top portion of the Explorer. Note that if you searched for Mother/Child samples, the number displayed will reflect the number of *samples*, not the number of dyads.
5. If you determine that sufficient samples meeting your criteria exist and you wish to proceed with your research request, click **Create Pending Request**. The sample types you selected will be transferred to the **Data and Sample Request** form.
6. Follow the steps on the second page of this guide to complete your research request.

Quick Guide: Submit a Data & Sample Request (2)

| | |
|---|--|
| <p>Specimen Shipping Information</p> <p>Will the results be used for a commercial purpose? (required)</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>Shipping Address <small>Note: All specimens will be shipped to the account holder's address unless specified below. Specimens cannot be shipped to a post office box.</small></p> <p>FedEx Acct. #</p> <p>Shipping PO #</p> <p>Lab Contact Name Lab Contact Email Lab Contact Phone Number</p> <p>Request Details</p> <p>Number of Specimens (required) <small>Approximate count of specimens required for your study.</small></p> <p>Material Type (required)</p> <p>Minimum volume (or mass if requesting DNA) (required) <small>Please include units.</small></p> <p>Optimum volume (or mass if requesting DNA) (required) <small>Please include units.</small></p> <p>Specimen requirements <small>Describe any additional requirements pertaining to the biospecimens themselves, such as aliquotting used, additional preservation, etc.</small></p> | <p>Subject characteristics <small>Describe the characteristics of the subjects to be searched for available specimens. Criteria might include gender, age, disease status, genotype, etc. Be as specific as possible.</small></p> <p>Research Plan: Describe this request, including a summary of the rationale, main hypothesis and proposed research aims (required) <small>A brief overview of your research needs.</small></p> <p>Scientific background and rationale <small>Provide the research protocol background, objectives and hypothesis.</small></p> <p>Analyte(s) or parameter(s) to be tested (required) <small>Describe the assay(s) to be performed and include any test volume requirements.</small></p> <p>Type of assay(s)/ platform(s) to be used (required) <small>Describe the assay kit(s)/platform(s) to be used, if applicable.</small></p> <p>Rationale for number of biospecimens requested, including power calculations, and describe the use of covariates, if applicable (required) <small>Also describe your intended use of covariates from study datasets, if applicable.</small></p> |
|---|--|

Portion of fields required on the **Data and Sample Request form**

- Follow the steps on page 1 of this guide to select appropriate samples. The Data and Sample Request form will open.
- Follow the instructions on the Submit a Data Request quick guide to complete the Request Identifier, Requesting Investigator Information, and Recipient Information sections of this form.
- In the Specimen Shipping Information section:
 - Enter specimen **Shipping Address**, if different from the address associated with your account.
 - Enter your **FedEx Acct. #** and complete the **Shipping PO #** if applicable.
- In the Request Details section of the form, supply information about your research as follows:
 - Number of Specimens:** Number of specimens requested to perform research.
 - Material Type:** Type of sample(s) being requested
 - Minimum Volume:** Minimum volume required to perform your analyses
 - Optimum Volume:** Ideal volume to perform analyses
 - Specimen Requirements:** Note any additional requirements pertaining to the specimens
 - Subject Characteristics:** This field will be populated with data from the Sample Explorer.
 - Research Plan:** Summary of your rationale, hypothesis, and proposed research aims.
 - Scientific Background and Rationale:** Research protocol background and additional information about hypotheses and objectives.
 - Analyte(s) or parameter(s) to be tested:** The assay(s) to be performed and include any test volume requirements.
 - Type of assay(s)/ platform(s) to be used:** The assay kit(s)/platform(s) to be used, if applicable
 - Rationale for number of biospecimens requested, including power calculations, and describe the use of covariates, if applicable:** Include use of covariates from study data sets, if applicable.
- Enter the name and email addresses of any Approved Users who will assist you with your research.
- Indicate the method by which you will maintain Information Security while accessing NCS data.
- Enter any Comments about your application.
- Review the Upload Checklist and ensure that you have provided the necessary documentation, such as an IRB letter, proof of funding, or your CV. If necessary, Attach Files.
- Choose Submit Request, or Save for Later to return and complete your request at a later time.

Quick Guide: Manage a Data or Data and Sample Request

Monitor Request Status

1. From the **Research Request** tab, click **My Requests** to view your submitted or saved data requests.
2. Click on the **Request Name** to open a request.
3. View the current status of your request and information about when the request was last modified in the request header.
4. From the **Comments** tab, view comments left for you by the review committee or add comments yourself.
5. From the **View Request** tab, review your submitted request.
6. Click the **More** menu to view additional options. From this menu, you can choose to:
 - **Edit Request** and supply additional details
 - **Watch** or **Unwatch** the request, to choose whether or not you receive notifications for each update to the request.

Complete the Research Materials Distribution Agreement

After you have prepared your data request for submission, you will be required to complete the **Research Materials Distribution Agreement**, or **RMDA**. The RMDA is a contract between you, your institution, and NICHD. It ensures that you are aware of and have agreed to the terms for accessing participant-level NCS data. The RMDA is not available until your request has reached an appropriate stage of completion (all required information has been submitted, and a high-level review has been conducted to ensure that the request is feasible). Access to the RMDA does not indicate that your request has been approved. You may complete the RMDA while your request is being evaluated. After being notified that the RMDA is available to you, to complete and submit the form:

1. From the **Research Request** tab, click **My Requests** to view your submitted data request.
2. Click on the **Request Name** to open the request.
3. Click the **RMDA** tab, and from the **Generate Agreement** menu, select **RMDA** to produce an RMDA populated with your request information.
4. Review the generated RMDA and make any necessary changes to the title of the research plan, name and email address for the principal investigator, and name of any other approved users. Indicate whether or not the **Research Plan Includes a Commercial Purpose**.
5. Click **Generate RMDA**. An RMDA will be listed with your name in the **Generated By** field, and the current date and time indicated in the **Date Created** field.
6. Choose **View Unsigned RMDA** to open the generated PDF.
7. Print or download the form and complete all fields, including gathering all appropriate institutional sign-offs. Then, scan the completed form and save it to your computer.
8. Return to your request, and select the **RMDA** tab again.
9. Select **Upload Signed RMDA**. On the displayed screen, select **Choose File** to navigate to your saved RMDA. Highlight the appropriate file and click **Open**.
10. Click **Upload Signed RMDA** to upload your file.
11. Your RMDA will be uploaded, and your request status will automatically change to **Pending NIH Review**. You will be notified when this review has concluded and your request status has changed.

Note: Before you are approved to access any data, you will be required to complete Data User Training and pass the associated quiz. The training can be accessed via the **Research Request** tab. View the multimedia training and complete your quiz online, or read the accessible text alternative and email quiz responses to ncsarchive@s-3.net.