

Quick Guide: Overview

LEARN

- From the overview on the **Home** page, learn about when and where the available NCS data were collected
- From the **Data & Documentation** tab, view **IVS Datasets** that provide high-level data related to NCS women, children, and fathers. Visit the **Study Documents** tab to view historical NCS documents.
- View the **Sample Inventory** to learn about the biological and environmental samples collected for NCS. These samples are not currently available to researchers.

EXPLORE

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

- Using the **Protocol Browser**, you can view the data collection points used during the Study.
- View specific data collection instruments from the **Instrument and Dataset Inventory**.
- 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. Easily submit, track, and manage your research requests using this online submission process.

- To enter a new request, simply complete the fields on the **Submit Data Request** tab. Don't forget any 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.
- **Pending Requestor Form Update:** The approvers require edits to your request before they can approve or deny. Update your request based on their feedback.
- **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, 289I-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

- 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.

Research Request -

1

DUA Training
Submit Data Request ←
My Requests

2

Request Identifier

Request Name (required)
Create a brief title for your research plan

3

Requesting Investigator Information

<p>Name</p> <p>Title</p> <p>Institution</p> <p>Email</p> <p>Department</p> <p>Website</p>	<p>Address (required)</p> <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div> <p>Phone (required)</p> <p>Fax</p>
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Recipient Information

Institution type (required)

Non-Profit Organization
 Commercial Organization
 Academic

Number of years in scientific research
Approximately how many years has the lead investigator been involved in scientific research?

0-5
 5-10
 10+

Is funding currently available for this research? (required)
If yes, please upload documentation of primary funding

Yes
 No

If no and funding is not yet available, please indicate anticipated primary funding source

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Request Details

Subject characteristics
Describe the characteristics of the subjects to be searched for available data. Criteria might include gender, age, disease status, genotype, etc. Be as specific as possible

Research Plan: Describe this request, including a summary of the rationale, main hypothesis and proposed research aims (required)
A brief overview of your research needs

Scientific background and rationale
Provide the research protocol background, objectives and hypothesis

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Approved Users

Approved user #1

Name	Email
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>

Approved user #2

Name	Email
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>

Approved user #3

Name	Email
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>

Approved user #4

Name	Email
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>

7

Information Security: Please check the information security practices to be used (required)
Study data must be maintained in a secure and controlled environment

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)
 Unencrypted portable media backup (CD, DVD, thumb drive) stored in locked file cabinet

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Comments

9

Upload checklist

I have uploaded Institutional sign off or a cover letter approving research
 I have uploaded documentation of primary funding

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Attach Files

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.

File	Size

Attachments

No file chosen

Note: You may also download a PDF version of this form from the **Submit Request** tab for your convenience.

Quick Guide: Manage a Data 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.