

# The National Children's Study Archive

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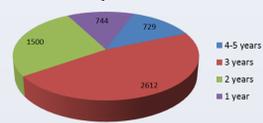


## INTRODUCTION

The National Children's Study (NCS) Vanguard Data Archive and Access System ("NCS Archive") was made available for public use earlier this year at <https://ncsarchive.s-3.net>.

The NCS Vanguard was a pilot for a planned cohort study of environmental influences on child health and development. Starting in 2009, recruitment strategies were tested in 43 counties across 31 states throughout the U.S. The study enrolled over 5,600 birth families and followed them through 2014. At protocol-specified study visits, questionnaires and interviews, neuro-psychosocial and cognitive assessments, and physical examination data were collected, along with nearly 19,000 biological and 5,500 environmental primary samples from which a sample repository of over 250,000 items was created. That information and material is now available through the NCS Archive for approved research projects by qualified investigators. Data release will be complete in early 2017 and includes study visit data from preconception to 42 months post birth. The purpose of the Vanguard Study was to test procedures for use in the larger study, and due to its pilot nature, identical evaluations were not conducted on all participants.

Distribution of children by age at study termination, 2014



## Study Locations by Size and Recruitment



## Study Recruitment

	Initial Vanguard Study	Enhanced Household	Direct Outreach	Provider Based	Provider Based Sampling	Totals
Recruitment period (ending with last baby enrolled)	Jan 2009 – Sep 2010	Nov 2010 - Dec 2012	Nov 2010 - Dec 2012	Nov 2010 - Dec 2012	Dec 2012 – Mar 2014	
Total months of recruiting women (active* months)	36 (18)	16 (13)	16 (13)	16 (13)	7 (7)	
Number of locations	7	10	10	10	3	40
Women identified for contact	35,726	27,840	19,347	3,717	3,256	89,886
Completed Pregnancy Screener	30,960	21,399	17,194	2,998	1,453	74,004
Women eligible for enrollment	3,164	2,482	2,781	1,470	1,268	11,165
Women Enrolled^	1,996	1,648	2,256	1,172	850	7,922
Enrolled mothers	1,297	1,022	1,370	998	733	5,420
New born children Enrolled	1,409	1,039	1,395	1,021	744	5,608
Fathers enrolled	709	74	132	74	13	1,002

\* Active recruitment refers to study center staffs identifying, screening, and recruiting potential study participants through participant outreach and engagement, passive recruitment refers mostly to follow-up of initially screened women.  
 ^ The Initial Vanguard Study and Alternate Recruitment Strategies enrolled both women who were pregnant or trying to become pregnant, whereas the Provider Based Sampling substudy enrolled only pregnant women.

## WHAT'S IT FOR?

The NCS Archive is a web portal application available to interested researchers, designed to facilitate and encourage continued research opportunities using NCS data. The web portal includes a request and tracking system, summaries of available data, data tracking, and management of access to the data.

The request and tracking system allows researchers to request and receive standard and custom datasets, using a web-based request, approval, and data delivery system. User accounts are established via requests for the desired role for each user.

The Research Request system allows researchers to submit novel study ideas that make use of existing NCS data and/or samples. Downloadable de-identified women, father, and child SAS and csv datasets are available for exploratory use.

The NCS Archive web portal includes the following features:

- Research Tools: Designed to promote and cultivate new ideas for further exploration of existing NCS data.
- Data & Documentation: Users download de-identified datasets and dataset documentation, and documents related to the history, structure, and administration of the NCS. Additional datasets will be added over time.
- Research Request: Access data user training, submit data requests, manage requests.
- Sample Inventory: Listing of all stored sample materials.
- Laboratory Data: Biological and environmental sample test data.
- Help: Learn more about the NCS Archive, see responses to frequently asked questions, and submit requests for help.

## WHAT'S THERE?

- Questionnaire Data:** Reproductive and pregnancy history, medical conditions and history, health behaviors, mental health, occupation, hobbies, environmental exposures, and social support.
- Physical Measures and Anthropometric Data:** Weight, height, ulnar length, circumferences of the head, mid-upper arm, waist, and thigh, triceps and subscapular skinfold thickness, heart rate, blood pressure.
- Biospecimens:** Include DNA, RNA, placenta, blood (from venipuncture, umbilical cord, and/or heelprick), meconium, vaginal swab, urine, saliva, hair, nails, breast milk.
- Environmental Samples:** Include dust, air, and water. Study staff also performed observations of the internal and external structure of participant residences.

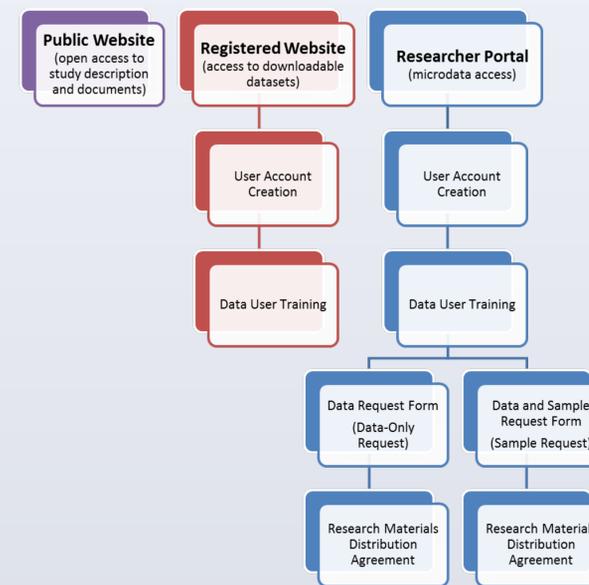
- K-BIT2
- BSI
- Major Life Events
- Rothbart IBQ
- ASQ
- M-CHAT
- SWAN

## HOW DOES IT WORK?

The NCS Archive has three components:

- NCS public webpages, a
- Registered Website, and a
- Secure Researcher Portal.

The public website provides basic Study information. Users may register to obtain additional Study information, download available data files, and submit proposals to request access to more study data and stored materials.



All requests are reviewed by a NICHD data access committee to determine that the proposed research use is scientifically and ethically appropriate and consistent with the informed consent. Criteria for sample request approval include sample availability and technical suitability with adequate funding, facilities, and expertise to perform the proposed research. Descriptions of approved proposals are viewable by all registered website users.

Once approved, the researcher is given access to a secure virtual workstation in the Researcher Portal. Archive support is provided to make available the requested data. NCS Archive staff can help bring in laboratory result data or extant data as needed. The researcher can work with NCS data in the secure environment using provided statistical software (SAS and R). When analysis is complete and prior to release of any information from the Researcher Portal, a data reviewer will help assure that any information to be transferred meets disclosure standards.

## WHAT DOES IT COST?

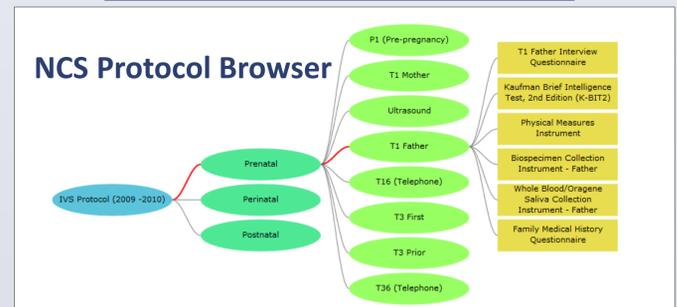
There is **no cost** to researchers to use the NCS Archive and data. Handling and shipping costs may apply for biological or environmental sample requests.

## STEP-BY-STEP

### Register and Request NCS Vanguard Data:

- Go to the Registered Website at [NCSArchive.s-3.net](https://ncsarchive.s-3.net)
  - Create an account
  - Complete your profile
  - Accept the data user agreement
- Develop a Research Plan using the Archive tools:
  - Downloadable Operational Datasets
  - Protocol Browser (example below)
  - Variable Locator
  - Instrument and Dataset Inventory
  - Participant Explorer
  - Sample Explorer (example below)
- Complete and submit a Data Request or Data and Sample Request form which includes:
  - Title of Research Plan
  - Requesting investigator information
  - Investigator's institution information
  - Request Details-rationale, hypothesis, research aims
- Complete the NCS Data User Training
  - Privacy protection and data security (20 min)
- Receive notification of approval or disapproval of the request at the email address specified in the request

## DATA EXPLORATION TOOL EXAMPLES



## NCS Sample Explorer

## TO CONTACT

NICHD website <https://www.nichd.nih.gov/research/NCS/>  
 NCS Archive website <http://ncsarchive.s-3.net/>  
 Archive Email [ncsarchive.s-3.net](mailto:ncsarchive.s-3.net)  
 NCS General Email [vanguardncs@mail.nih.gov](mailto:vanguardncs@mail.nih.gov)