

The National Children's Study Archive

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Background of the National Children's Study (NCS)

- With passage of the Children's Health Act of 2000, NICHD was directed to conduct a longitudinal study on children's health.
- The study was to be a nationally representative longitudinal cohort study of 100,000 children from before birth through age 21.
- The purpose was to investigate the effects of environmental exposures (chemical, biological, physical, and psychosocial) as well as gene-environment interactions on pregnancy outcomes, child health and development, and precursors of adult disease.



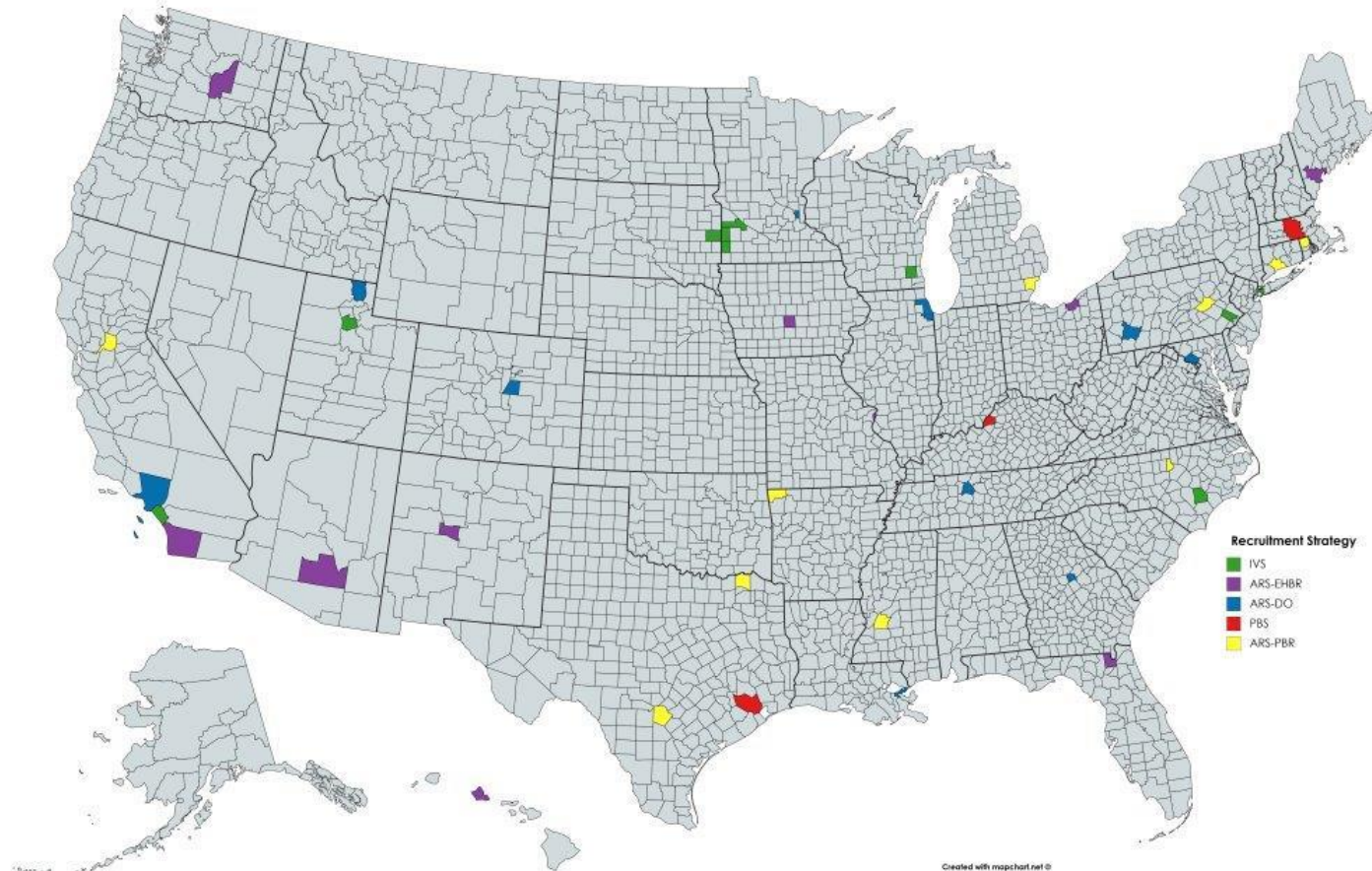
Background of the National Children's Study (NCS)

- The NCS as initially planned consisted of two distinct but related studies:
 - NCS Vanguard (Pilot) Study
 - NCS Main Study
- All study procedures could be tested within the Vanguard Study prior to being considered for inclusion with the Main study.
- Both studies would run for 21 years.
- NCS Vanguard Study was active from 2009–2014 enrolling nearly 6,000 children and their parents (mostly mothers) from 40 locations throughout the US.
- In December 2014, NIH decided not to launch the Main Study and stopped data collection for the Vanguard Study.



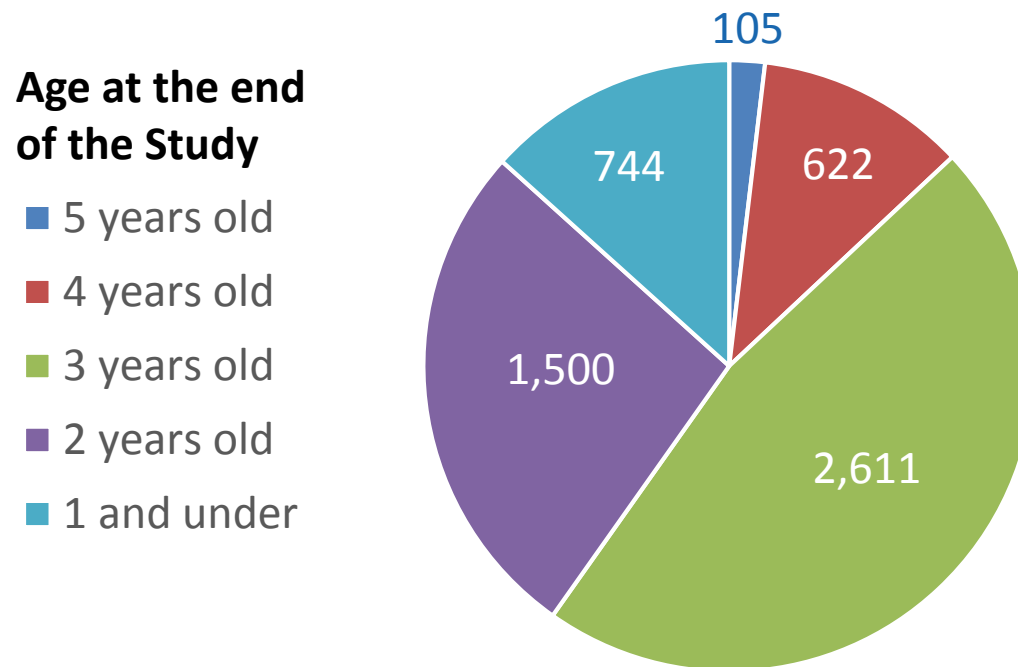
Study Center Locations Map

The data was collected from 40 Study Center Locations through the U.S. Five different recruitment strategies were used throughout the Vanguard Study at various times, with each location assigned one strategy.



NCS Participant Demographics

- 5,608 children – over 1,800 with biological samples



- 1,009 fathers – over 400 with biological samples

Interview Data — Women

- Interviews
 - pre-conception, pregnancy, birth visit, and post natal visits
- Some topics covered:
 - reproductive and pregnancy history
 - medical conditions and history
 - health behaviors
 - mental health
 - occupation
 - hobbies
 - environmental exposures
 - social support



Interview Data — Children

- Interviews
 - Birth visit, 3, 6, 9, 12, 18, 24, 30, 36, and 42 months
- Some topics covered:
 - Infant feeding, crying patterns, and sleep
 - Well baby care, immunizations, medical conditions
 - Child care arrangements
 - Child development
 - Pets and in-home exposures



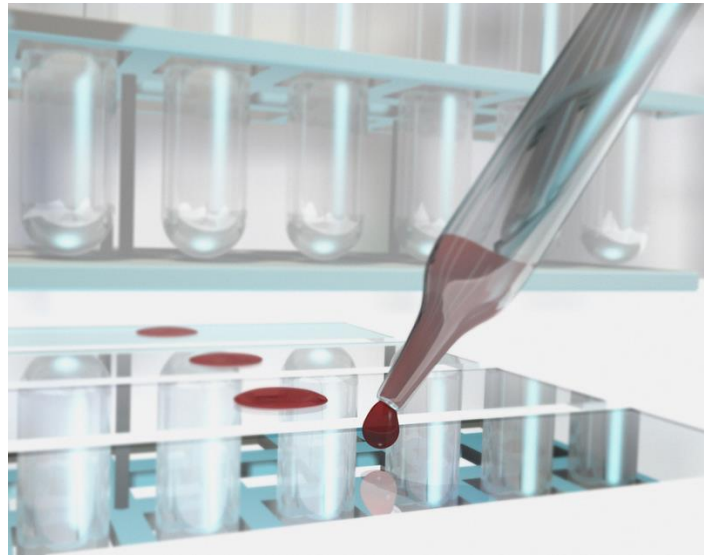
Assessments

Neuro-psychosocial and cognitive assessments.

- Kaufman Brief Intelligence Test, 2nd Edition (K-BIT2)
- Ages & Stages Questionnaires®, Third Edition (ASQ-3™)
- Brief Infant Toddler Social Emotional Assessment (BITSEA)
- Brief Symptom Inventory (BSI)
- Infant & Toddler Sensory Profile (ITSP)
- Modified Checklist for Autism in Toddlers (M-CHAT)
- Strengths and Weaknesses of Attention-Deficit/Hyperactivity-symptoms and Normal-behaviors (SWAN)
- Major Life Event



Samples Collected



Sample Inventory — Biological

Samples in inventory (number of sampled participants) by sample type and visit

Study Event Type and Participant	Prenatal					Perinatal		Postnatal					
	Pre-Pregnancy	Early Pregnancy	Late Pregnancy	Pregnancy (undefined)		Birth		3 Months	6 Months	12 Months	36 Months		
	Woman and Mother	Mother	Mother	Mother	Father	Child	Mother	Mother	Child	Child	Child	Mother	Father
Blood	8089 (238)	14038 (385)	35191 (833)	2892 (205)	6373 (342)	863 (495)	3687 (513)			268 (35)	1969 (154)	4232 (222)	37 (*)
Urine	5551 (279)	8995 (478)	20192 (1015)	1448 (109)	8347 (426)		1143 (66)		978 (133)	1188 (149)	8259 (585)	11314 (651)	54 (*)
Vaginal Swabs	750 (251)	874 (343)	1915 (544)	132 (43)									
Hair	275 (275)		506 (506)	14 (14)	279 (279)								
Nails			433 (433)	10 (10)	399 (399)								
Saliva	57 (29)	1665 (293)	3303 (477)	254 (44)	149 (75)					520 (278)	623 (622)	773 (650)	*
Placenta							3186 (424)						
Umbilical cord							774 (373)						
Cord Blood						49153 (918)							
Breast Milk							4152 (273)	509 (25)					
Meconium						454 (451)							

* Fewer than 10 samples available

Sample Inventory — Environmental

Samples in inventory (number of sample collections) by sample type and visit

	Prenatal				Perinatal	Postnatal
Study Event Type and Participant	Pre-Pregnancy	Early Pregnancy	Late Pregnancy	Pregnancy (undefined)	Birth	6 Months
	Woman	Mother	Mother	Mother	Mother	Mother
Formula - Infant					133 (131)	
Air	251 (248)					73 (72)
Water - Pesticides		147 (62)	307 (135)	42 (19)		
Water - Pharmaceuticals		268 (73)	501 (139)	58 (18)		
Dust - Plates			227 (227)	*		
Dust - Vacuum		866 (414)	1082 (443)	131 (63)		94 (92)
Dust - Wipes	275 (274)	10 (*)	*	*		*

* Fewer than 10 samples available

Sample Analytic Laboratory Results



Sample Analytic Laboratory Results

Existing laboratory results are stored in several datasets classified into three groups:

Biological specimens

consisting of blood, urine, saliva, breast milk, vaginal swabs

- Pre-pregnancy, pregnancy, and birth
- 6-, 12-, and 36-months

Environmental specimens collected 2009–2010

consisting of air, surface dust wipes, and water

- pre-pregnancy, pregnancy, and 6 months

Environmental specimens collected 2011–2012

consisting of household vacuum bag dust samples

- pregnancy

Sample Analytic Laboratory Results

- The documentation for each group includes a full description of the collection and storage, laboratory analysis methodology, and data set content.
- These datasets are structured at the result-level and one participant may have multiple results for multiple sample types.
- https://ncsarchive.s-3.net/bioshare/sample_datasets/



The NCS Archive

The NCS Archive is the data and sample repository of the Vanguard Study.

The NCS Archive is comprised of three components:

- **NCS Webpages – Public Website**
- **Registered Website – Requires creating an account**
- **Secure Researcher Portal – Access available upon approval of a research request**



The NCS Archive Overview

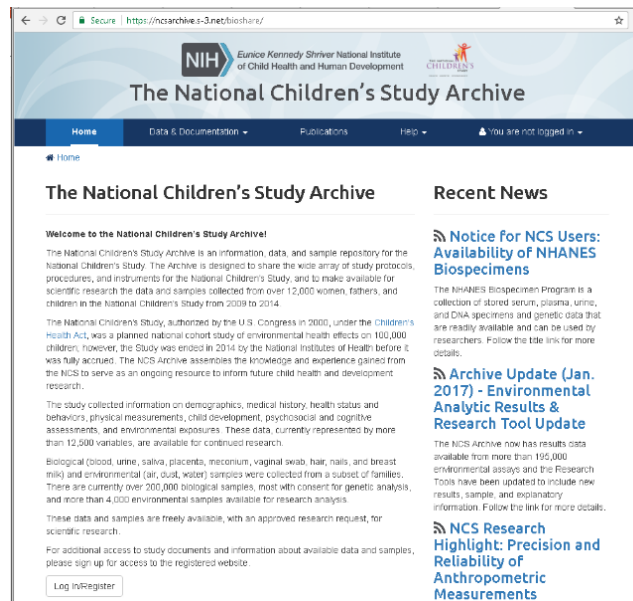
- **NCS Webpages** (<https://ncsarchive.s-3.net>)
- **Registered Website.** Registered users will be able to:
 - Access exploratory tools, downloadable, restricted-use datasets and supporting documentation, and other documents related to data collection.
 - Access reports generated by the NCS on topics specifically relevant to collecting data on children's health.
 - Communicate with NCS Archive staff.
 - Propose new research projects in which to use NCS data and samples.
- **Secure Researcher Portal**
 - Accessing requires submission of a research plan and other information to ensure that NCS data are protected and used in accordance with the terms of participant consent.
 - Researchers with approved projects will be able to analyze NCS data on secure virtual workstations within a supported Researcher Portal, and have access to operational data files, instrument data files, codebooks, and analyte files.
 - Contains analysis software and a virtual data enclave of detailed participant data.

Helpful Links

- **National Children's Study Archive: Study Description and Guide** contains a detailed summary of the scientific basis and operations of the NCS Vanguard Study —
https://www.nichd.nih.gov/research/NCS/Documents/NCS_Archive_Study_Description.pdf
- For complete overview on using the NCS Archive refer to **The NCS Archive Quick Guide: Overview** —
https://www.nichd.nih.gov/research/NCS/Documents/NCSArchive_QuickGuides_2016.pdf

NCS Archive Demonstration

Website: <https://ncsarchive.s-3.net>



Thank You

For more information, please contact:

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