

NATIONAL CHILDREN'S STUDY GLOSSARY*

*Terms as used in the National Children's Study

Acceptability: The impact of each visit and each assessment on the participants, Study personnel, and Study infrastructure.

Address Look-Up Tool (ALT): An information application that allows the user to examine whether a potential participant is geographically eligible to participate in the National Children's Study. The user does not have direct access to address lists; the response generated is "match" or no "match".

Adjunct Studies: Focused studies supporting the Main Study, which are initiated, developed, and funded outside of the Study protocol planning efforts. They utilize National Children's Study participants and/or laboratory materials.

Affidavit of Non-Disclosure (AN-D): A document that is to be completed and notarized by all individuals who access National Children's Study non-public use data (including viewing and data entry). Data Use Agreements (DUAs) must be updated with a Request for Amendment form to include newly completed AN-Ds.

Alternate Recruitment Strategy/Schema: See *Recruitment Strategy/Recruitment Schema*.

Ancillary Study: National Children's Study terminology for these studies during the Vanguard phase is "Supplemental Methodological Study" and during the Main Study is "Adjunct Study."

Authority to Operate (ATO): An Authority to Operate indicates that an information capture and management system has been determined by the NICHD Chief Information Officer as compliant with the Federal Information and Security Management Act of 2002. Authority to Operate is one of the conditions to be met before information collection may begin.

Chunking: A procedure used in a geographic sampling model when a selected segment is as small as physically possible, but is still expected to produce more eligible women and births than needed. To ensure random selection and equal probability of selection for individuals within the geographic area, the selected segment is then divided into two or more "chunks", and recruitment occurs only in the selected "chunks" of the selected segments.

Collaborative Improvement Network (CoIN): The Hi/Lo CoIN began as part of formative research for the National Children's Study. It expanded to include the Enhanced Household-based Recruitment (EHBr) Study Centers in July 2011 with a Technical Directive Memo issued from the Program Office.

Contracting Officer Representative (COR)/Contracting Officer Technical Representative (COTR): See *Project Officer*.

Cost: The time, money, number/type of personnel, resources, and effort required to perform an aspect of the Study.

Enhanced Household-based Recruitment (EHBr): During recruitment, this strategy utilized field workers who entered predefined geographic segments and contacted individuals and families at their residence. This strategy is similar to that used by the initial seven Vanguard Centers, but was enhanced through application of best practices from experience, targeted marketing campaigns, enhancement of additional sources of referral into the Study, such as health care providers, social clubs and organizations, and public events, as well as streamlined enrollment procedures.

EHBr Study Centers:

- Case Western Reserve University School of Medicine (Cuyahoga County, OH)
- Maine Medical Center (Cumberland County, ME)
- Saint Louis University School of Public Health (St. Louis, MO)
- University of Arizona (Pinal County, AZ)
- University of California, Irvine (San Diego County, CA)
- University of Hawai'i at Manoa John A. Burns School of Medicine (Honolulu County, HI)
- University of Iowa (Polk County, IA)
- University of Miami (Baker County, FL)
- University of New Mexico (Valencia County, NM)
- University of Washington (Grant County, WA)

Facilitated Decentralization: Centralized development of specifications, quality controls, and policies with the flexibility of local implementation allowing for adaptation to local skills, resources, and other factors.

Feasibility: Assessment of the technical performance of an aspect of the Study visits or infrastructure.

Federal Advisory Committee (NCSAC): A federally chartered advisory committee, constituted under the Federal Advisory Committee Act, provides advice and recommendations to the NIH Director, the NICHD Director, and the Director of the National Children's Study regarding critical aspects of the Study.

Federated IRB: An Institutional Review Board (IRB) model that provides a mechanism for creating a shared set of principles and processes for review of the National Children's Study and for sharing information across all IRBs reviewing the Study protocol. Institutions can choose to review submissions independently and

share information with other members of the Federation or streamline local IRB review by utilizing a facilitated review mechanism or by relying on the review conducted by the NICHD IRB.

Federal Information and Security Management Act of 2002 (FISMA): The Federal Information Security Management Act of 2002 (“FISMA”, 44 U.S.C. § 3541, et seq.) is a United States federal law enacted in 2002 as Title III of the E-Government Act of 2002 (Pub.L. 107-347, 116 Stat. 2899). The act recognized the importance of information security to the economic and national security interests of the United States. The act requires each federal agency to develop, document, and implement an agency-wide program to provide security for the information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor, or other source.

Formative Research: Focused studies supporting the Vanguard phase, initiated by the Program Office and funded by the National Children’s Study. If they involve National Children’s Study participants and/or laboratory materials, they are referred to as Substudies.

High Intensity/Low Intensity Dynamic Model (Hi/Lo): Also known as Two-tiered Recruitment Strategy. During recruitment, this strategy used marketing, direct mail, and other referral techniques to enroll a broad based population in larger geographic areas, such as complete zip codes, beyond the predefined geographic segments into a Low Intensity National Children’s Study. The approach is similar in concept to the U.S. Census Short Form and Long Form or the Canadian Longitudinal Study on Aging. The Low Intensity National Children’s Study provides participants with Web-based, mail-in, or telephone-based brief questionnaires on a periodic basis. The interval between questionnaires is currently projected to be every 6 months, but different options are plausible. From the pool of participants in the Low Intensity National Children’s Study, those living in the predefined geographic segments are invited to participate in the High Intensity National Children’s Study, which follows the protocol-based planned Study visit schedule that includes home and clinic visits. If participants leave the High Intensity National Children’s Study or decline further participation, new participants from the Low Intensity pool can be added dynamically. In addition, subpopulations that may have higher attrition rates or have other characteristics of interest may be oversampled. Projecting toward the Main Study, the sample size target for the High Intensity participants remains the same as for the other recruitment strategies of 100,000. Thus, if this model were to be scaled up, the total pool of participants in the National Children’s Study would be in excess of 100,000.

Hi/Lo Study Centers:

- Emory University (Baldwin County, GA)
- Johns Hopkins University Bloomberg School of Public Health (Montgomery County, MD)
- Northwestern University (Cook County, IL)
- Tulane University School of Public Health and Tropical Medicine, Center for Applied Environmental Public Health (New Orleans, LA)
- University of California, Los Angeles (Los Angeles County, CA)
- University of Colorado (Douglas County, CO)
- University of Minnesota (Ramsey County, MN)
- University of Pittsburgh (Westmoreland County, PA)
- University of Utah School of Medicine, Department of Pediatrics (Cache County, UT)
- Vanderbilt University Medical Center (Davidson County, TN)

Hidden Dwelling Unit (DU): A Hidden Dwelling Unit is in free standing houses, a basement, apartment, or garage apartment that has a separate legal address. These Hidden DUs may be discovered during the processes of listing or household enumeration.

Hybrid Sampling Model: A sampling model that uses one or more probability or non-probability techniques to select the Study population from one or more sampling frames.

Independent Study Monitoring and Oversight Committee (iSMOC): A committee of independent experts that provides advice to the Director of NICHD and to the Study Director regarding participant and data safety and integrity, and matters related to confidentiality and privacy.

Information Management System (IMS): An integrated system or set of systems consisting of hardware, software, connectivity, and business rules that provides administrative, computational, telecommunications, and data collection and transmission in a secure fashion for the Study.

Institutional Review Board (IRB): Present in every institution that engages in research, the IRB reviews research plans to ensure that research is conducted in an ethical manner that respects and protects the rights of Study participants. All scripts/plans/instruments must be approved by the IRB before a Study Center can start working with participants.

Interagency Coordinating Committee (ICC): A committee of staff and scientists from federal agencies that have supported the development and planning of the National Children’s Study since 2000. The ICC provides strategic advice and assures that the Study is aligned with the missions of the respective federal agencies.

Letters of Interest/Intent (LOI): Research proposals submitted by a current contractor to perform a specific activity in response to an invitation by the National Children’s Study Program Office.

Listing: Listing, traditionally, is sending out walkers or drivers to identify and verify all physical addresses that exist in a particular segment or other geographic area. Where there are apartment buildings, this usually means walking through each floor and area of the building if possible to identify all dwelling units.

Main Study: The longitudinal National Children’s Study, measuring exposures and outcomes from before birth to age 21, to assess effects of the environment on child health and development. Environment is defined broadly, to include the biological, physical, chemical, and psycho-social cultural environments. Gene-environment interaction is a key factor as well.

Manual of Operating Procedures (MOPs): Details all procedures to be used throughout the Study. In addition to detailing what is collected in greater depth than the Study Protocol, it also details the multiple aspects of how samples and information are gathered and submitted for processing and storage.

Master Data Element Specifications (MDES): The collection of documentation and specifications that describe the operational and instrument data items collected in the Vanguard Study. The MDES describe a common set of data elements that are collected at each of the active locations in Vanguard Study. The common format allows independent implementations of Study informatics at each location, but preserves the ability to merge these data.

Micro Data: Micro data are data files in record format such that each variable has a coded value. Micro data files can be analyzed using statistical software to generate statistical information, or “summary data”, such as frequency distributions (that is, count data), proportions, percentages, measures of central tendency, variance, and association. Typically, micro data include individual level participant data, such as the participant identification numbers and item specific responses to questionnaires.

National Children’s Study (NCS): A 21 year longitudinal study that seeks to examine the effects of the environment, broadly defined, and gene-environment interaction on the growth, development, and health of children across the United States, following them from before birth until age 21 years.

Official National Children’s Study Web site: <http://www.nationalchildrensstudy.gov>

National Institutes of Health (NIH): Located in Bethesda, MD, NIH is the umbrella federal organization that houses the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), which is the lead agency for the National Children’s Study.

Office for Human Research Protections (OHRP): OHRP provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP maintains regulatory oversight and provides guidance regarding ethical and regulatory issues in biomedical and social-behavioral research.

Office of Management and Budget (OMB): The largest component of the Executive Office of the President. It reports directly to the President. The *Office of Information and Regulatory Affairs* (OIRA) within OMB oversees and coordinates information collection and regulatory policy in the federal government; coordinates statistical policies, budgets, standards, long-range plans, and international activities; and develops and oversees government-wide information policy and information technology policy. One information management activity administered by OIRA is the *Paperwork Reduction Act (PRA)*^[1], 44USC 3501, which assesses and approves information collection requests by federal agencies, to improve the quality and utility of information required by the federal government, and reduce paperwork burden on the public. This approval is mandatory prior to all National Children’s Study information collection activities.

Original Vanguard Centers: There are seven Original Vanguard Centers around the country. They received funding in 2003/2004, and went into the field in 2009. Their data collection and recruitment methods consisted of household recruitment. They served as a test-bed for the later Vanguard Centers and to inform the planning of the National Children’s Study Main Study.

P1: In the Original Vanguard data collection model, this was the designation code for the pre-conception data collection visit.

Plan-Do-Study-Act (PDSA): A systematic method of testing ideas for quality improvement.

[1] <http://www.archives.gov/federal-register/laws/paperwork-reduction/3501.html>

Principal Investigator (PI): Refers to Study Center staff members who lead the National Children’s Study effort on behalf of a Study Center.

Pledge of Confidentiality: Affirmation by an individual to keep confidential Study non-public use data, to be used for the intended scientific purpose only.

Probability Sampling: A sampling scheme where every person in the target population has a chance of being selected into the Study, and this probability can be calculated. Examples of probability sampling schemes are simple random sampling, systematic sampling, stratified sampling, sampling with probability proportionate to size, and multi-stage sampling.

Program Office (PO): Refers to the National Children’s Study Program Office, located at NICHD in Bethesda, MD.

Primary Sampling Units (PSUs): Individual components into which the target population is divided for the first sampling stage. In the National Children’s Study, the PSUs roughly correspond to U.S. counties.

Project Officer: Program Office staff who serves as a liaison to the Study Centers and advises Contracting Officers regarding technical aspects of the Study; the Contracting Officer’s Representative or the Contracting Officer Technical Representative (COR/COTR).

The COR/COTR does not have the authority to take any action, directly or indirectly, that will change the pricing, quantity, or delivery schedule, nor can the COR/COTR direct the accomplishment of effort that goes beyond the scope of the contract.

Provider-based Recruitment: For recruitment, this strategy utilized health care providers that are in contact with women who are or may become pregnant. Options included placing Study-related personnel in health care delivery locations, training health care providers in recruitment approaches, installing informational material, or combinations or other additional methods.

Provider-based Recruitment Study Centers:

- Arkansas Children’s Hospital Research Institute (Benton County, AR)
- Brown University (Providence County, RI)
- Children’s Hospital of Philadelphia (Schuylkill County, PA)
- Michigan State University (Wayne County, MI)
- University of California, Davis (Sacramento County, CA)
- University of Mississippi (Hinds County, MS)
- University of North Carolina at Chapel Hill, Carolina Population Center (Durham County, NC)
- University of Texas Health Science Center San Antonio (Bexar County, TX)

- University of Texas Southwestern Medical Center at Dallas (Lamar County, TX)
- Yale University (New Haven County, CT)

Provider-based Sampling: This sampling strategy involves developing a list frame of all prenatal care providers that provide services to women residing in a selected primary sampling unit (generally a county). Provider offices are then selected with probability proportionate to size with the number of first prenatal care visits of women residing in the sample PSU intended to serve as the measure of size. A systematic random sample of women, within selected provider offices, are approached for eligibility screening and enrollment. Recruitment is comparable to the provider-based recruitment strategy in that options may include placing Study Center-related personnel in the selected health care delivery locations, obtaining contact information and calling potentially eligible women after their first prenatal care visit, installing informational material, or combinations or other additional methods.

Provider-based Sampling Study Centers:

- Baylor College of Medicine (Harris County, TX)
- University of Louisville (Jefferson County, KY)
- University of Massachusetts (Worcester County, MA)

Provider-based Sampling Feasibility Study: An arm of the Vanguard Study. Briefly, the Provider-based Sampling arm includes:

- County as the Primary Sampling Unit (PSU)
- Three counties are participating in this feasibility study
- Providers of prenatal care as the Secondary Sampling Units (SSUs)
- Recruitment of participants from selected providers with eligibility criteria based on confirmed pregnancy, age, and residence in the sampled PSU.

This approach eliminates the recruitment limitation of requiring participants to reside within small geographic SSUs, and instead bases the geographic eligibility on residing within the PSU.

Recruitment Strategy/Recruitment Schema: A description of a recruitment methodology that will be subjected to analysis regarding feasibility, acceptability, and cost. The three alternate recruitment strategies undergoing assessment are: Provider-based Recruitment Strategy, Enhanced Household-based Recruitment Strategy, and Two-tiered Recruitment Strategy (High Intensity/Low Intensity).

Rounded Summary Data: Refers to the required manipulation of National Children’s Study frequency data that is being presented to audiences who have not signed a National Children’s Study affidavit of nondisclosure, as described in the National Children’s Study Rounding Rules.

Sampling: The selection of a subset of individuals from a population to estimate selected characteristics of the target population.

Sampling Frame: A listing of the target population that a sample can be drawn from.

Secondary Sampling Units (SSUs): Units sampled directly within primary sampling units in a multi-stage sample.

Segments: In a multi-stage probability sample, primary sampling units (PSUs) are divided into smaller geographic areas called secondary sampling units or segments. In the National Children’s Study, the boundaries for these segments correspond to “neighborhoods or communities”.

Statistically Valid Sample: A participant population whose results are generalizable to the U.S. population.

Steering Committee: A committee with representation from the federal staff and from contracted Study Centers to provide advice regarding Study implementation to the National Children’s Study Director.

Study Centers (SCs): Contracted organizations responsible for participant retention and data collection within the given Study locations.

Study Locations: The counties (or in sparsely populated areas, groups of contiguous counties) that were selected as primary sampling units in the first stage of sampling.

Study Population: The individuals that are selected from the target population for participation in the Study. The selected individuals may then choose whether or not they wish to participate.

Study Sites: The segments that were selected in the second stage of sampling within the Study locations. The Study Sites correspond roughly to neighborhoods, the areas from which Study participants are recruited and in which most of the community level data collections occur.

Study Visits: Encounters of Study participants with Study personnel for the purpose of collecting data and/or laboratory materials.

Substudies: Focused clinical research studies that integrate with the Vanguard Study (that is, they involve a portion of the Vanguard Study cohort and/or laboratory materials). A type of formative research, they pertain to scientific, operational, or methodological questions of limited scope during the Vanguard phase. Initiated by the National Children’s Study Program Office and funded through the National Children’s Study appropriation. (The Main Study will incorporate Substudies as well).

Summary Data: Refers to the aggregate results from an analysis of the micro data, such as the frequencies, percentage frequencies, rates, measures of central tendency or variation for measures of community outreach contacts, completed pregnancy screeners, completed consents and questionnaires, or reporting of census data for population characteristics for segments or a location.

Supplemental Methodological Studies: Focused studies that take place during the Vanguard (pilot) phase of the National Children’s Study. They are geared to inform the Main Study as to the feasibility, acceptability, and/or cost of items pertaining to recruitment, operational and logistic issues, and Study visit assessments. Supplemental Methodological Studies are initiated from outside of the Program Office and are developed outside the Study protocol planning process. They are funded externally; that is, not with the National Children’s Study appropriation.

T1 First: Designation code in the Original Vanguard data collection model for the first trimester visit among enrolled women.

T3 First: Designation code in the Original Vanguard data collection model for the third trimester visit among women who have *not* previously received a first trimester visit.

T3 Prior: Designation code in the Original Vanguard data collection model for the third trimester visit among women who *have* previously received a first trimester visit.

Target Population: The population of interest for the Study. This population is the group of individuals that need to be enumerated or listed in order to construct a sampling frame.

Vanguard Data Repository (VDR): A central information system that receives information transmitted from Study Centers active in the Vanguard Study, including data collected in the Alternate Recruitment Substudy. Data received through the Vanguard Data Repository are transferred securely to a National Children’s Study Support Contractor for data cleaning, transformation, and further distribution to analysts and organizations upon Program Office direction.

Vanguard Locations: The Study locations that participate in the Vanguard Study

Vanguard Recruitment Pilot: A substudy of the Vanguard Study that assessed alternate recruitment strategies.

Vanguard Study/Vanguard Phase: The pilot phase of the National Children's Study that is designed to study the feasibility, acceptability, and cost of methodological, operational, and logistic activities, recruitment-related activities, and Study visit assessment measurements, for the purpose of informing the Main Study. Refers to all Vanguard Study locations.

Visit Assessment: The various functions performed at Study visits, including tests, measurements, and collection of laboratory materials (biospecimens and environmental samples).

Visit Choreography: The process of designing the order and flow of individual components within Study visits, whether they are at home or at National Children's Study clinics.