

## 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.

**Adjunct Studies:** Modular, focused studies that leverage the National Children's Study infrastructure, and occur during and integrate with the Main Study. They are initiated, developed and implemented from outside the National Children's Study Program Office and funded by other than the Study appropriation. They may be initiated by a variety of sources, such as federal agencies, Study Centers, independent investigators, industry, and research advocacy organizations.

**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.

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

**Ancillary Study:** National Children's Study terminology for these 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.

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

**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 committee operating under the Federal Advisory Committee Act that provides advice and recommendations to the Directors of NIH, NICHD, and the National Children's Study on scientific and policy matters regarding the Study.

**Federated IRB:** The Federation of National Children's Study IRBs is an 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.

**FISMA: Federal Information and Security Management Act of 2002:** 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 information 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:** Research addressing acceptability, feasibility, and/or cost related to methods and process, performed during the Vanguard Study. May or may not be “integrated” with the Vanguard Study (that is, may or may not utilize Study participants and/or Study laboratory materials). If it is integrated, it is termed a Substudy. Formative research is initiated by the National Children’s Study Program Office (for example, via request for Letters of Interest) and funded by the Study appropriation. Its purpose is to inform the Main Study.

**Information Management System (IMS):** An integrated system of hardware, software, and connectivity that provides administrative, computational, and telecommunications support for the Study. The IMS securely connects all Study Centers and associated locations, the National Children’s Study Program Office, various support contractors, and participating laboratories and repositories to support all Study operational activities and protect the privacy and integrity of the data.

**Independent Study Monitoring and Oversight Committee:** 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.

**Interagency Coordinating Committee (ICC):** A committee of staff and scientists from federal agencies that support the development and planning of the National Children’s Study. The ICC provides strategic advice and advises regarding Study alignment with the missions of the respective federal agencies.

**Letters of Interest:** Documents acknowledging interest by a current contractor to perform a specific activity in response to invitation by the Program Office, such as Formative Research projects.

**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 (MOP):** Details all procedures to be used throughout the conduct of 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 Elements/MDES:** A set of data specifications describing the format of information files Study Centers transmit to the Vanguard Data Repository. The specifications for the MDES are updated as instruments are added to the protocol and questions are revised. The MDES includes operational and Study visit measure data specifications. The MDES is a method to establish uniform data formats for information collected using different capture systems.

**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 serve as liaison to the Study Centers and advise Contracting Officers regarding technical aspects of the Study; the Contracting Officer Technical Representative (COTR).

**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
- Two-Tiered Recruitment Strategy (High Intensity/Low Intensity).

**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 Study contracted Study Centers to provide, to the National Children’s Study Director, advice regarding Study implementation.

**Study Centers:** Contracted organizations responsible for participant recruitment 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 Sites:** The segments that were selected in the second stage of sampling, within the Study locations. The Study Sites correspond roughly to neighborhoods, and will be the areas from which Study participants are recruited and in which most of the community level data collections will occur.

**Substudies:** Focused clinical research studies, on a portion of the cohort, which “integrate” with the Vanguard (and later the Main) Study; that is, they involve a portion of the cohort and/or laboratory materials. During the Vanguard phase, a type of formative research, pertaining to scientific, operational, or methodological questions of limited scope. Initiated by the National Children’s Study Program Office and funded through the Study appropriation.

**Supplemental Methodological Studies:** Focused methodological studies initiated, developed, and implemented from outside the National Children’s Study Program Office, and funded with other than National Children’s Study funds. Supplemental Methodological Studies occur during and integrate with the Vanguard phase (that is, they utilize National Children’s Study participants and laboratory materials). Their purpose is to inform the Main Study by assessing feasibility, acceptability, and/or cost of logistic, methodological and operational activities, recruitment-related activities, or specific Study visit assessments.

**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 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 actively recruiting for and participating in the Vanguard Study.

**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.

**Vanguard Recruitment Pilot:** A substudy of the Vanguard Study, assessing alternate recruitment strategies.

**Visit Assessments:** The various functions performed at Study visits, including tests, measurements, interviews, questionnaires, 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.