



National Children's Study Current Status October 21, 2009

Captain Steven Hirschfeld, MD PhD

Eunice Kennedy Shriver National Institute of Child Health and Human
Development
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- The overall goal of the National Children's Study (NCS) is to improve the health and well-being of children.
- The NCS is a Congressionally mandated activity coordinated among Federal agencies including the Environmental Protection Agency, the Centers for Disease Control, and the National Institutes of Health with the National Institute of Environmental Health Sciences contributing and the Eunice Kennedy Shriver National Institute of Child Health and Human Development serving as the program lead.

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- The NCS will examine the multiple effects of environmental influences on the health and development of 100,000 children across the United States, following them from before birth until age 21, by providing high quality data to analyze scientific hypotheses.
- The NCS is a large multicomponent multiyear longitudinal study that is unprecedented in scope and complexity and therefore necessitates a planning process that is systematic, dynamic, flexible, and evidence based.

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- The NCS is being implemented in several phases
- All components and phases together form the NCS
- The Vanguard Study is designed to evaluate the
 - Feasibility (technical performance)
 - acceptability (the impact on participants, study personnel, and infrastructure)
 - Cost (personnel, time, level of effort and money)
- of
 - Study recruitment
 - Logistics and operations
 - Study visits and study visit assessments

Relationship of Vanguard Study to Main Study



Vanguard Study
N = 1000-2000

NCS Main Study
N = 100 000

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- The enrollment target for the Vanguard Study will be determined empirically by two factors
 - Recruitment data indicate a sufficient number of informative events to assess different strategies for scale up to the Main Study
 - An adequate cohort size to evaluate the study visit assessments for the duration of the study

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- The selection of scientific hypotheses for the Main Study will be guided by
 - the empiric data of the Vanguard Study and other NCS funded substudies
 - by the efforts of the various workgroups and interested parties that proposed and vetted candidate hypotheses
 - potential scientific and public health impact
 - a perceived requirement to use the NCS and not another alternative as the data acquisition platform

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- The Main Study will focus on data acquisition related to the interaction of genetics, environment, growth and development on the health of children and the analyses of those data for multiple scientific hypotheses.
- The Vanguard Study and the Main Study have different goals and the assessment types and assessment techniques used in each of the NCS components may be different so there is no intent to categorically merge data among NCS components.
- The Vanguard and Main Study will run in parallel, and together with additional NCS funded substudies, will form the composite National Children's Study.

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- The outcomes of the Vanguard Study will have a continual and major impact on how the Main Study will be executed; thus, it is imperative that the Vanguard Study be planned, implemented, and monitored to a level of precision that enables it to serve as a reliable and valid platform to evaluate recruitment, study procedures, visits, scale up potential, resource requirements and other aspects for the Main Study.

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- Studies that integrate with the Vanguard Study, are funded by the NCS and focus on a limited question with limited duration will be known as substudies
- Studies that integrate with the Vanguard Study and have independent funding will be known as Supplemental Methodological studies
- Studies that integrate with the Main Study and have independent funding will be known as Adjunct Studies

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- Data from the NCS is intended to be shared and will be made accessible through the policies outlined in the Data Access Manual

National Children's Study Advisory Committee Recommendations



- The Study should develop a list of potential adjunct studies to guide investigators interested in adjunct studies. (Janet Currie) *This could be useful for the development of supplemental methodological studies as well.*
- The Study needs to reassess its priorities and optimize the pilot nature of the Vanguard Center activities. *This recommendation was in accordance with the NAS panel's recommendation to implement a discrete Vanguard Phase* (Maria Cancian, John Butenhoff)
- The Study needs to evaluate the methodologies and validity of assessments as it would evaluate the samples themselves. (David Schonfeld)

Leveraging Resources



- As the Program Office has increased in capacity, transfer of activities from NCS Coordinating Center and from Working Groups to Program Office
 - Assure alignment and consistency
 - Responsibility for deliverables is with NCS Program Office
- NCS Scholars Program
 - Details available on NCS and NICDH websites

Optimizing Resources



- NCS Program Office established Planning Committee
- Planning Committee completed analysis of responsibilities and resources with gap analysis
- NCS Program Office is realigning to optimize resources to meet responsibilities
- Filling gaps and augmentation through multiple mechanisms
- Process analysis and evaluation for all study elements including Information Management System
- Dynamic and continuous evaluation of all study components including Study Center and Coordinating Center performance and value

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- The NCS Program Office is committed to
 - Compliance with the highest ethical and scientific standards
 - Complete fiscal responsibility, accountability and transparency
 - Respect for all involved
 - Listen to and work with NCS partners including the Interagency Coordinating Committee, the NCS Advisory Committee, the NCS Steering Committee and all the NCS investigators
 - Engage subject matter experts and other advisors when needed to provide guidance on specific scientific and operational activities
 - Strive that adequate resources are in place in advance for operations
 - Establish performance metrics monitoring and reporting progress Identify potential risks and address them proactively
 - Actively monitor and make adjustments based on empiric evidence and study needs