



**NATIONAL CHILDREN'S STUDY (NCS)  
PROGRAM PLANNING**

**EXECUTIVE BRIEFING  
SUBMITTED TO THE NCS ADVISORY COMMITTEE**

*Prepared by  
The National Children's Study Program Office*

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## **NATIONAL CHILDREN'S STUDY PROGRAM PLANNING**

The National Children's Study (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. This planning process includes both a strategic component and a tactical (or operational) component. Strategic planning produces the goals and objectives and a high level plan for achieving them. The tactical plan will be derived from the strategic plan and provides details on the major activities, timelines and resource requirements for implementation of the strategic goals.

The NCS is being implemented in several phases. The Vanguard Study is designed to evaluate the feasibility (technical performance), acceptability (the impact on participants, study personnel, and infrastructure), and cost (staff, time, level of effort and money) of study recruitment, procedures and visits. 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. Both the Vanguard and Main Study will run in parallel, and together with additional substudies, will form the composite National Children's Study. The outcomes from 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 is 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.

The Vanguard Study was launched in January 2009 at selected Study Centers. Initial analysis of the operations and data collected from these Centers by the NCS Program Office resulted in the recognition that additional strategies, including new and innovative approaches to recruitment, study visits and measurements are necessary to reach study goals. The analysis highlights the need for a robust planning process that can accommodate changes based on empiric evidence.

To streamline and integrate innovation and evidence-based changes throughout the multi-year span of the study, the NCS Program Office has established a new Planning Team. The primary responsibilities of the Team will be to set new program goals, define objectives, develop recommendations and plans for implementation, and monitor progress (Exhibit 1).



**Exhibit 1: An Overview of NCS Program Planning**

The Team will generate at least two levels of plans— a Strategic Plan that will provide an overview of the Study integrating long term goals and objectives and Operational Plan that will address specific objectives. The Team will ensure the following:

- Compliance with the highest ethical and scientific standards
- Respect for all involved
- Adequate resources are in place in advance for operations
- Performance metrics are established for monitoring and reporting progress
- Potential risks are identified and addressed proactively
- Engage subject matter experts and other advisors when needed to provide guidance on specific scientific and operational activities
- Active monitoring and adjustment based on empiric evidence and study needs

The Team became operational in September 2009 and is currently engaged in developing a Strategic Plan for the overall Study and Operational Plans for the Vanguard Study. A notional draft Process Map that will be adjusted and elaborated for the Vanguard Study is shown in Appendix A. The Team is currently refining the Vanguard Study Process Map and then will develop analogous Process Maps for the other Study components. These Process Maps will support setting long term goals, objectives, and resource requirements for the Strategic Plan and for defining specific activities, timelines and resource requirements for the Operational Plans.

The Team will provide regular updates to the NCS Advisory Committee on NCS plans and progress and looks forward to receiving feedback and comments from the Committee.

# APPENDIX A: A High Level View of a Sample Draft Business Process Map for the Vanguard Study

