



## NCS Sampling Discussion May 29, 2012

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# NCS Legislation

## Children's Health Act of 2000



- “(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development;*
- (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.”*

The Study is required to:

- “(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;*
- (2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and*
- (3) Consider health disparities among children, which may include the consideration of prenatal exposures.”*

# NCS Structure



- Multi-component system
  - Vanguard Study
    - 40 locations with goals of feasibility, acceptability and cost of recruitment, logistics and operations and study visits
    - Field operations began in January 2009
  - Main Study
    - Goals of exposure-response relationships: growth, development and health of children
  - Formative Research

# NCS Main Study Objectives



- The primary objective of the National Children's Study Main Study is to collect information on and investigate the factors that determine children's health and development. These factors include genetic context and environmental exposures with a broad definition of environment.
- The National Children's Study is not a study in a conventional sense. It will function as a high quality data collection platform for researchers to access and analyze data, biospecimens, and environmental samples.

# Core Physical Environmental Exposure



Analysis of

- heavy metals
- pesticide residues
- semi-volatile organic compounds

in

- household dust
- blood
- urine

as general surrogates for more specific exposures.

# Core Biological Assessments



- Linear growth rate and body mass as a surrogate for general health
- Metabolic screen of serum total protein, blood urea nitrogen, cholesterol, iron, and calcium for nutrition and dietary exposure
- Frequency and duration of health system encounters for respiratory illness for pulmonary health
- Timing of standard neurodevelopmental landmarks for any deviation from adjusted trajectory for cognitive and social development.

# NCS Main Study Framework



## Recruitment of

- 100 000 children through > 100 000 pregnant women

## How

- Healthcare providers

## Where

- To be determined
- How could women who move out of the geographic area be retained?

# Terms to distinguish



- Sample -a subset of individuals from within a population to estimate characteristics of the whole population.
- Sample frame- set or list of items or people that can be measured
- Probability sample- selection of a sample where every unit in the population has a chance greater than zero of being selected
- Recruitment strategy- mechanism to enroll participants

# Proposal to discuss



- Probability sample frame with 3 stages
  - Area sample
  - Provider sample
  - Participant sample
- Supplemental recruitment
  - Populations that may be underrepresented on the basis of factors such as demographics, exposures, access to health care

# Discussion Expectations for Today



- Today is one of a series of opportunities to receive input
- Individual input and perspective is encouraged
- No expectation for consensus
- Additional discussions are scheduled and will occur prior to any decisions
- Draft proposal will be presented to NCS Advisory Committee on July 24, 2012