



## National Children's Study Introduction

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# National Children's Study



- Congressionally mandated by Children's Health Act of 2000
- An integrated system of activities to examine the relationships between environmental exposures and genetics on growth, development and health
- Environment is broadly defined to include factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status and learning.

# What the law says



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 Principles



- Data driven
- Evidence based
- Community and participant informed

# Examples of Exposure Areas of Interest



- Exposure to industrial chemicals and byproducts in the air, water, soil and commercial products
- Exposure to natural products in the air, water, soil and commercial products
- Exposure to pharmaceuticals used for therapy and in the environment
- Radiation exposure
- Effects of proximity to manufacturing, transportation and processing facilities

# Examples of Exposure Areas of Interest



- Living with animals, insects and plants
- Media and electronic device exposure, noise
- Access to routine and specialty healthcare
- Learning opportunities that are structured and unstructured
- Diet and exercise
- Family and social network dynamics in cultural and geographic context

# Examples of Outcome Areas of Interest



- Interpersonal relationships and bonding
- Inflammatory processes including allergies, asthma and infections
- Genetic and epigenetic status
- Epilepsy and other neurologic disorders
- Cardiovascular screening and function
- Childhood cancer
- Multidisciplinary multidimensional aspects of sensory input, learning and behavior
- Precursors and early signs of chronic diseases such as obesity, asthma, hypertension and diabetes

# Prevalence of Conditions of Potential Interest



- Of 100,000 children, an estimated
  - 30,000 will be overweight; 17,000 with obesity
  - 5,000 with learning disorders
  - 5,000 with asthma
  - 1,000 with autism spectrum disorders
  - 750 with congenital heart disease
  - 320 with childhood cancers
  - 125 with Down syndrome
  - 50 with Fragile X syndrome



# NCS Structure



- The NCS is an integrated system of activities
- All components and phases together form the NCS
- Current major components are the
  - NCS Vanguard Study- pilot phase for methods-runs for 21 years-started in 2009 with 7 centers- expanded in 2010 with 30 additional centers
  - NCS Main Study-exposure response phase- runs for 21 years about 3 years time shifted from Vanguard Study-planned start in 2012
  - NCS Substudies- studies within studies
  - Formative Research-short term limited studies, often methods development, to support and inform the Vanguard and Main Studies

# NCS Activities



Administration

Communications

Dissemination

Planning

Operations

Analysis

Instrument  
Development

Protocol  
Development

*Main Study*

*Vanguard  
Study*

Case  
Management

Data  
Repository

*Formative  
Research*

Central  
Informatics

Data  
Acquisition

Sample &  
Specimen  
Repository



# NCS Vanguard Study Goals



- Vanguard Study designed to evaluate:
  - Feasibility (technical performance)
  - Acceptability (impact on participants, study personnel, and infrastructure)
  - Cost (personnel, time, effort, money)
- of
  - Study recruitment
  - Logistics and operations
  - Study visits and study visit assessments

# Current Sampling Frame (simplified)



- Random selection of about 100 of ~ 3000 counties in the United States
  - Counties = Primary Sampling Unit
- Counties divided into segments that are normalized to have ~ 250 live births per year. Some sparsely populated areas involves merging counties
  - Segments = Secondary Sampling Unit
- Recruitment is restricted to the Secondary Sampling Units

# Alternate Recruitment Substudy



- NCS Vanguard is now at 37 locations across the country with 30 engaged in new recruitment using one of three different strategies
  - Household based- participants learn about the study through field workers walking through neighborhoods
  - Provider based- participants learn about the study through trusted health care providers with a broad definition of provider including physicians, public health nurses, midwives, etc.
  - Direct to the public- participants learn about the study directly through media and community outreach
- The goal is compare strategies to assemble a toolkit for cost effective directed recruitment for the Main Study launch
- Both direct data analysis and predictive modeling employed

# NCS Recruitment Status

-based on data as of 10/06/11



	Provider	Enhanced Household	Direct Outreach	All Alt. Recruitment	Initial Household‡	All Vanguard
Locations	10	10	10	<b>30</b>	7	<b>37</b>
Recruitment Duration, months	10	10	10		18 full + 12 monitoring	
Women Identified	2350	22700	12550	<b>37550</b>	34900	<b>72450</b>
Women Screened	2050	17400	12500	<b>32000</b>	30900	<b>62900</b>
High probability or pregnant Women	1450	2100	1850	<b>5400</b>	3450	<b>8850</b>
Women Enrolled	1150	1300	1500	<b>3950</b>	2000	<b>5950</b>
Babies Enrolled	350	300	150 <sup>^</sup>	<b>800</b>	1000	<b>1800</b>

Person and participant numbers above have been rounded to the nearest 50, following the NCS Rounding policy.

<sup>^</sup> - Implementation of Birth Visit data collection for Low-Intensity women was delayed due to logistical reasons.

‡ - Initial Household includes participants from the initial protocol and the minimal visit protocol

# For further information



- <http://nationalchildrensstudy.gov>
- [ContactNCS@mail.nih.gov](mailto:ContactNCS@mail.nih.gov)