



## The National Children's Study Introduction and Harmonization Efforts

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## The National Children's Study



- The National Children's Study (NCS) is mandated by the U.S. Congress and implemented by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) with input from a consortium of federal partners.
- The NCS is a multi-year study that will examine the effects of environmental influences on the health and development of 100,000 children across the United States from before birth until 21 years of age.
- The goal of the NCS is to improve the health and well-being of children and contribute to the understanding of how various factors influence health and disease.



## What the law (Children's Health Act of 2000 Public Law 106-310 Title X Section 1004) 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



## An Integrated System



- The NCS is an integrated system of activities that include:
  - a Pilot or Vanguard Study which began in January 2009 with the goal of determining the feasibility, acceptability and cost of Study activities,
  - a Main Study targeted to begin recruitment following a scientific review process to investigate exposure-response relationships and
  - various sub-studies and formative research projects to examine specific methodological questions



## NCS Vanguard Study Objectives



- Feasibility-technical performance
- Acceptability- impact on participants and infrastructure
- Cost- personnel, supplies, time and money of
  - Recruitment
  - Study Visits
  - Logistics and Operations



## Evolution of Design



- 2009: a multi-stage, modified national probability sample using selected geographic areas as primary and secondary sampling units and door-to-door household recruitment
- Vanguard data demonstrated divergence between expected and observed experience, which led to re-examination of options
- In examining options, NCS was informed by pilot data supplemented by participant, community, and expert input



## Alternate Recruitment Substudy



- **Provider-based:** participants learn about and are referred to the Study through healthcare providers (broadly defined, including pediatricians, obstetricians, public health nurses, midwives, etc.)
- **Direct outreach:** participants learn directly about the Study through media and community outreach and are invited to self-refer and enroll
- **Enhanced household-based:** contact is through NCS field contractors going door to door in selected neighborhoods, augmented by additional outreach activities and healthcare provider referrals



## NCS Vanguard Study Recruitment



	Household Based Recruitment	Provider Based Recruitment	Direct Outreach Recruitment
Number of Sites	17	13	10
Eligible women	62750	6100	19350
Contacted for pregnancy screen (% of eligible)	56400 (90%)	4970 (81%)	19300 (99%)
Completed screen (% of contacted)	51350 (91%)	3400 (68%)	15850 (82%)
Pregnant or trying to become pregnant (% of screened)	5700 (11%)	2650 (78%)	2800 (18%)
Women enrolled (% of pregnant or trying)	3650 (64%)	1950 (74%)	2300 (82%)
Women contacted for each woman enrolled	<b>15.5</b>	<b>2.5</b>	<b>8.4</b>
Newborns enrolled	2450	1150+ *	1100
Women contacted for each newborn enrolled	<b>23.0</b>	<b>*</b>	<b>17.6</b>

## Examples of Potential Exposures and Health Outcomes of Interest

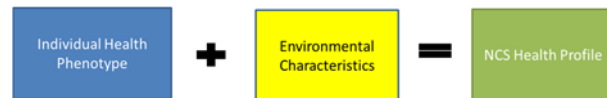


Exposures	Examples	Health Outcomes	Examples
Physical Environment	Housing quality, neighborhood	Pregnancy Outcomes	Preterm, Birth defects
Chemical Exposures	Pesticides, phthalates, heavy metals, BPA	Neurodevelopment & Behavior	Autism, learning disabilities, schizophrenia, conduct and behavior problems
Biologic Environment	Infectious agents, endotoxins, diet		Injury
Genetics	Interaction between genes and environment	Asthma	Asthma incidence and exacerbation
Psychosocial milieu	Family structure, socio-economic status, parenting style, social networks, exposure to media and violence	Obesity & Physical Development	Obesity, diabetes, altered puberty

## Health Phenotype Framework



- Framework for data collection is grounded in a concept of health characterized by several inter-related dimensions
- The composite of assessments describes a health phenotype
- Phenotype is defined in this context as the observable characteristics of the whole person
- Phenotype is the result of the interactions of genotype and environment and development



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## General Design Principles



- Anchored in a national probability sample
- Recruitment through health care providers
  - Birth stratum: via selected hospitals and birthing centers
  - Prenatal stratum: via community based prenatal providers and clinics that refer to the selected hospitals and birthing centers
- Sample size of 100,000
  - Birth and prenatal strata to total about 90,000
  - Additional convenience sample to total up to 10,000 for preconception and additional targeted populations

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## Front Loaded Visit Schedule



Prenatal and infancy	Childhood	Youth
Pregnancy before 20 weeks*	18 months	7 years
Pregnancy after 20 weeks*	24 months	9 years
Birth	30 months	11 years
3 months	36 months	13 years
6 months	42 months	15 years
9 months	48 months	17 years
12 months	54 months	19 years
	60 months	21 years

## Data Access Guiding Principles



The general principles that guide the NCS approach to data access and confidentiality include:

- Provide Quality Data
- Task-Driven Access
- Maximize Scientific Access
- Shared Responsibility
- Maintain Transparency of Process
- Ensure Compliance

## Collaborative Activities on Harmonization



- Metadata- structural and descriptive
- Operational Data Elements/Paradata
- Health Measurements Network
- Harmonized terminology
- Ancillary Studies (NCS Infrastructure- non-NCS funding)
  - Supplemental Methodological Studies for Vanguard
  - Adjunct Studies for Main Study
- Data analysis
- Formative Research



## Further information



<http://www.nationalchildrensstudy.gov>

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