


## The National Children's Study

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## The National Children's Study




- The National Children's Study will examine the effects of the environment, as broadly defined to include factors such as air, water, diet, sound, family dynamics, community and cultural influences, and genetics on the growth, development, and health of children across the United States, following them from before birth until 21 years of age.
- The goal of the Study is to improve the health and well-being of children and contribute to understanding the role various factors have on health and disease.
- Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible.

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## The National Children's Study




- Largest long-term study of children's health and development ever to be conducted in the U.S.
- Longitudinal study of children, their families, and their environment
- Approximately 100,000 children enables study of important but less common outcomes

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## Rationale for the National Children's Study




From The President's Task Force on Environmental Health and Safety Risks to Children, 1997\*

- Compared to adults, children are especially vulnerable to environmental exposures – metabolism, behavior
- Exposures to some agents demonstrate potential for serious developmental effects – lead, prenatal alcohol
- Current known exposures of high frequency – pesticides, violence, media
- Numerous high burden conditions with suspected environmental contribution – learning disabilities, autism, diabetes, asthma, birth defects, premature birth
- Existing research too limited in size and scope to answer the questions
- Life-course (longitudinal) design needed to correctly link with multiple exposures and multiple outcomes

\* Reappointed 2001 and 2003

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## What Will the National Children's Study Mean to Our Children's Well-Being?



- Identification of environmental factors that cause or contribute to health, development, and behavior problems
  - Examples include: asthma, injury, obesity, autism, attention deficit hyperactivity disorder (ADHD), prematurity
- Understanding the biology and genetics of health, development, and behavior
- Evidence-based information on which to base decisions about practice and policy regarding children's physical and mental health
- Economic benefits
- Resource for future research



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## National Children's Study Sample



- National probability sample – known chance of inclusion
- Drawn by National Center for Health Statistics
- 105 locations – corresponding to counties/clusters; 79 metro, 26 rural
- 13 very large counties; other counties placed into strata based on:
  - Metropolitan status
  - Geography
  - Average number of births per year
  - Race, ethnicity, percent low birth weight



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## National Children's Study Structure



- The National Children's Study is being implemented in several phases.
- All components and phases together form the National Children's Study.
- Current major components are the:
  - Vanguard Study
  - Main Study
  - Substudies



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## NCS Principles



- Data Driven
- Evidence based
- Community and participant informed



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## Facilitated Decentralization



- NCS Program Office sets specifications, central data repository and analysis
- Study Center field locations establish case management, data acquisition systems and communications based on specifications
- Allows for local tailoring, innovation, sharing, and evaluation of multiple alternatives
- Biweekly progress reports and data submission

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## Vanguard Study Goals



- The Vanguard Study is 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

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## Main Study

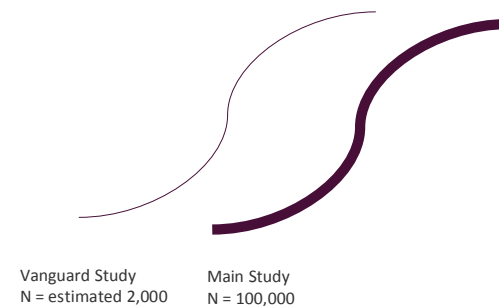


- The Main Study will focus on data acquisition related to the interaction of genetics, environment, growth, and development on the health of children and the analyses of those data for multiple scientific hypothesis.
- The Vanguard Study and the Main Study have different goals and the assessment types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

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## Relationship of Vanguard Study to Main Study



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## Current Study Eligibility



- Recruit women who live in designated geographic areas based on sampling strategy to generate an unbiased statistically valid generalizable population
- Ages 18- 49 or pregnant
- A woman may be eligible more than once if she is pregnant multiple times during the enrollment period

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## Initial Recruitment at 7 Sites



- 86% of identified Dwelling Units contacted
- 92% of women determined to be eligible for screening completed the pregnancy screener
- 2,425 women determined to be Study eligible (meeting geographic, age, and pregnancy status criteria)
  - 23% of these women identified during telephone follow-up calls
- 63% of eligible women enrolled
  - 70% pregnant; 30% "high tryers"
- ~ 600 babies born into the NCS

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## Alternate Recruitment Strategies



- Three Recruitment Strategies
  1. Enhanced household-based
  2. Provider-based
  3. Two-tier, high intensity/low intensity
- Each strategy will:
  - Occur in 10 locations that are geographically and demographically diverse
    - No attempt to have a population that can be generalized to the U.S. for any of the strategies
    - Specific interest in examining potential bias
  - Be approximately equally resourced
  - Have a specific communications theme

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## Enhanced Household-based Model



- Professionally trained enumerators recruit from households in selected neighborhoods
  - Best practices from established population-based studies
- Maximizes coverage
  - May reach people who do not normally participate in studies
  - Identifies population-based "pre-pregnancy" cohort
- Time and resource intensive

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## Provider-based Recruitment Model



- Recruit women through health care providers
  - Prenatal, general practitioner, clinic, or other providers
- Participant eligibility criterion remains
  - Must reside in selected neighborhood
- Potential advantages
  - Initial introduction by a trusted source
  - Most likely to enrich sample with higher percentage pregnant women (Willie Sutton Principle)

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## Two-tier, High Intensity/Low Intensity Recruitment Model



- Modeled after U.S. Census with short and long forms
- Improves ability to estimate form/magnitude of selection bias among women choosing to participate in a high and low intensity data collection
- Improves ability to estimate the optimal size of sampling units to achieve enrollment targets
- High intensity participation with visits — same as enhanced household and provider-based
- Low intensity participation with survey instruments
  - May improve community tolerance for Study
  - Decreases immediate privacy issues associated with enumeration and enrollment
  - Allows increased opportunity for testing items

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## Two-tier, High Intensity/Low Intensity Model Low Intensity Group



- Enrollment of women residing in roughly 3 times as large geographic areas
- Recruitment relies on self-referral through marketing, direct mail, and other techniques
- Participants receive Web-based, mail-in, or telephone-based brief questionnaires on a periodic basis

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## Two-tier, High Intensity/Low Intensity Model High Intensity Group



- Low intensity participants are invited to participate in higher intensity data collection if they live in a subset of neighborhoods defined by the sampling frame
- Low intensity participants can choose to decline the high intensity data collection and remain in the low intensity data effort
- Data collections follow the planned visit schedule used in the other recruitment strategies

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## Recruitment Parameters



- The primary outcome measure is a description of recruitment rates and retention among three proposed recruitment strategies.
- Key rates associated with recruitment include:
  - The number of women identified for contact by the Study, per month
  - The number of women successfully contacted by the Study, per month
  - The number of women determined to be eligible for the Study, per month
  - The number of eligible women consented into the Study, per month

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## Retention Parameters



- Key proportions associated with retention include:
  - The proportion of age- and geographically-eligible women initially contacted when not pregnant who join the Study when subsequently becoming pregnant
  - The proportion of consented women who participate in at least one data collection Study visit
  - The proportion of women consented during pregnancy, who participate in all data collection visits through the birth of a child
  - The proportion of women who receive an antepartum data collection visit who also receive a birth visit

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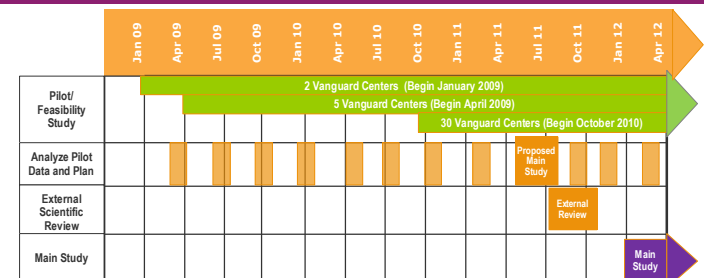
## Secondary Outcomes



- The distribution of key characteristics of recruited women among the three recruitment schema will be analyzed, which will include:
  - Distribution of women enrolled prior to pregnancy (preconception), during pregnancy, or perinatally
  - For pregnant women, distribution of gestational age at enrollment and at the first Study visit
  - The monthly enrollment rate of infants among consented women with due date within that month
  - Distribution of the primary source of entry into the Study for the women, such as self-referral, provider referral, household enumeration, community outreach events, and other possibilities
  - Distribution of the ways and number of ways women heard about the Study, such as friends, mailings, community members, and other possibilities

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## National Children's Study Projected Timeline



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## A Learning Community



- Except for the focus of the Study remaining on the health of children, all other aspects of the National Children's Study are potentially subject to re-evaluation and change.
- The concurrent deployment of three different recruitment strategies plus a formative research program provides an exceptional opportunity for launching a learning community with structured and systematic training, feedback, process maps, process improvement, modeling, and simulations.
- The National Children's Study has adapted these approaches both centrally and in the field to build an effective learning community.

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## Current NCS Program Office Priorities



- Launch of alternate recruitment strategies/Vanguard Study
- Analysis of legacy data
- Design of data management system
- Evaluation of case management and data acquisition platforms
- Evaluation of data acquisition technologies
- Prioritization of environmental assessments
- Biobank solutions



Framing of  
Main Study  
parameters

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## Contact Information



- Check the Web site:  
<http://NationalChildrensStudy.gov>
- Join the listserv (via the Web site) for news and communication
- Contact us at [ContactNCS@mail.nih.gov](mailto:ContactNCS@mail.nih.gov) or 1-877-865-2619

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