



The National Children's Study

U.S. Department of Health and Human Services
National Institutes of Health
Centers for Disease Control and Prevention
U.S. Environmental Protection Agency

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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.

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

Rationale for the National Children's Study



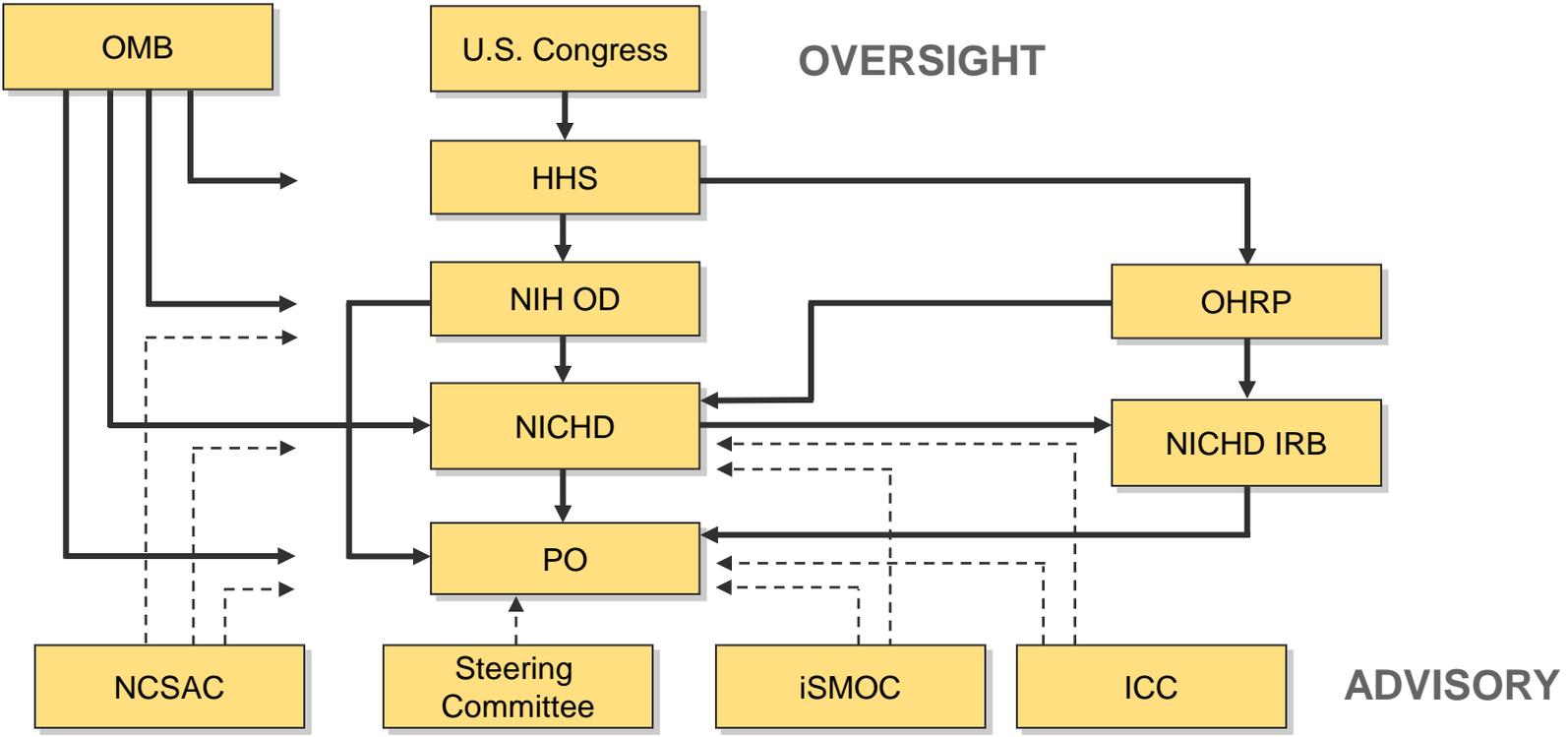
From The President's Task Force on Environmental Health and Safety Risks to Children, 1997*

- 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



National Children's Study Governance



Abbreviations

OMB = Office of Management and Budget
 HHS = U.S. Department of Health and Human Services
 NIH OD = National Institutes of Health Office of the Director
 OHRP = Office of Human Research Protections
 NICHD = Eunice Kennedy Shriver National Institute of Child Health and Human Development

NICHD IRB = NICHD Institutional Review Board
 PO = Program Office
 NCSAC = National Children's Study Federal Advisory Committee
 iSMOC = Independent Study Monitoring and Oversight Committee
 ICC = Interagency Coordinating Committee



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

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

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.

Relationship of Vanguard Study to Main Study



Vanguard Study
N = estimated 6,000

Main Study
N = 100,000

Examples of Priority Health Exposures, Outcomes



Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood
Chemical Exposures	Pesticides, phthalates, heavy metals, BPA
Biologic Environment	Infectious agents, endotoxins, diet
Genetics	Interaction between genes and environment
Psychosocial Milieu	Family structure, socioeconomic status, parenting style, social networks, exposure to media and violence



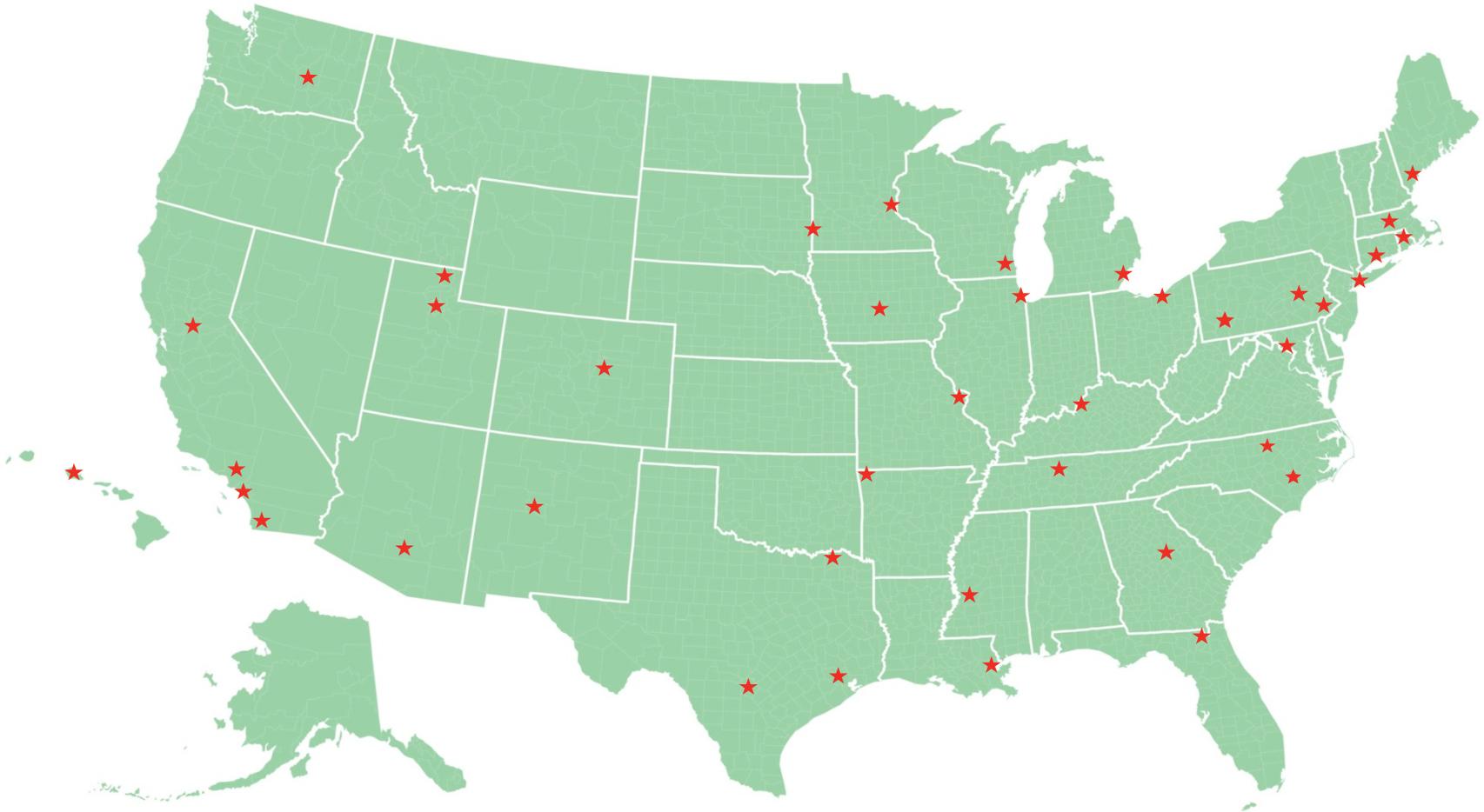
Priority Health Outcomes	Examples
Pregnancy Outcomes	Preterm, birth defects
Neurodevelopment and Behavior	Autism, learning disabilities, schizophrenia, conduct and behavior problems
Injury	Head trauma, injuries requiring hospitalizations
Asthma	Asthma incidence and exacerbation
Obesity and Physical Development	Obesity, diabetes, altered puberty

Study Locations vs. Study Centers



- Study Locations — the counties (or in sparsely populated areas, groups of contiguous counties) that were selected as primary sampling units in the first stage of sampling
- Study Centers — entities or institutions that will carry out Study at the locations
 - Selected by a competitive process
 - Each will cover more than one location

Active National Children's Study Locations



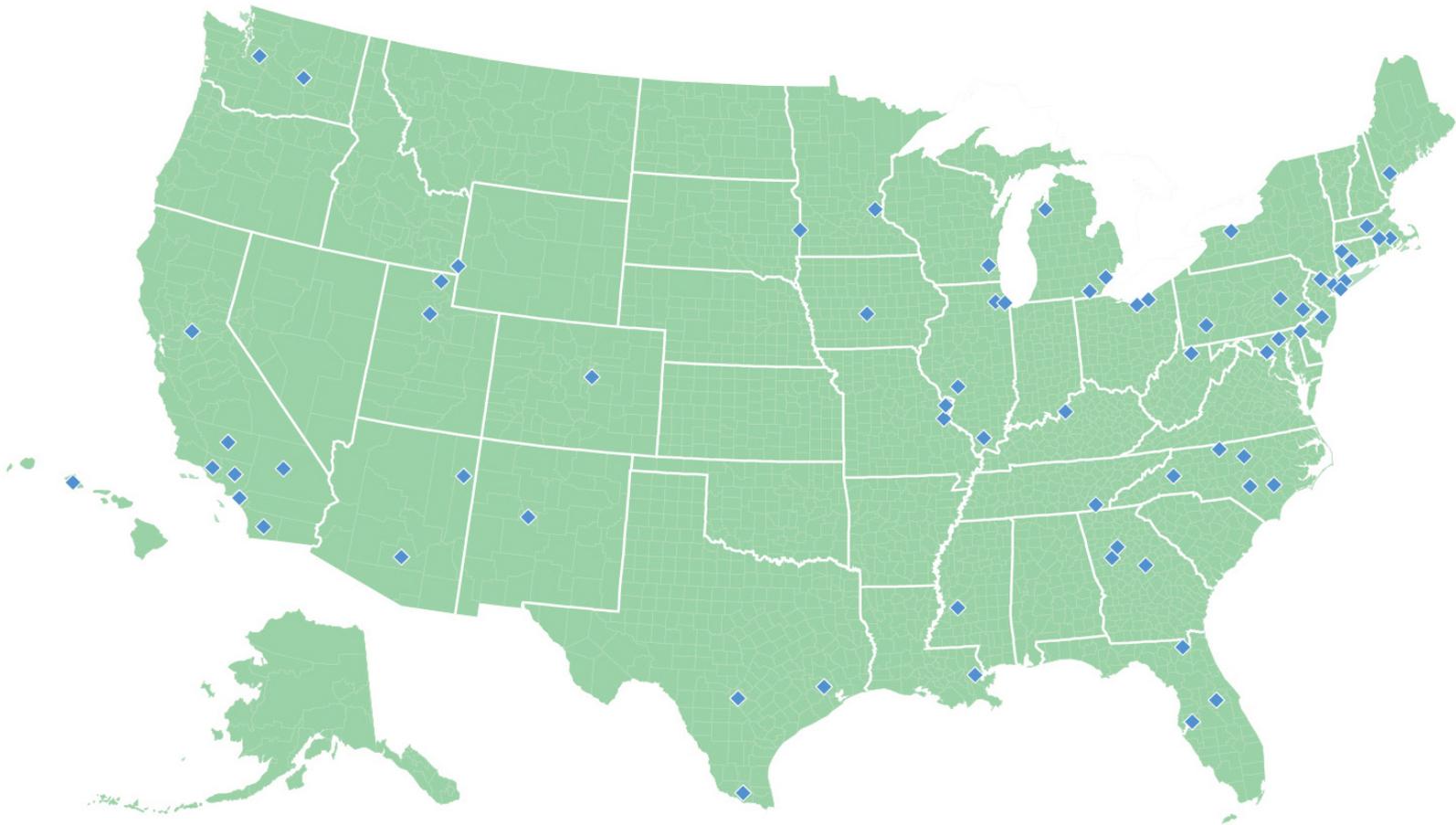
Active National Children's Study Locations

Benton County, AR
Pinal County, AZ
Los Angeles County, CA
Orange County, CA
Sacramento County, CA
San Diego County, CA
Douglas County, CO
New Haven County, CT
Baker County, FL
Baldwin County, GA
Honolulu County, HI
Polk County, IA
Cook County, IL
Jefferson County, KY
New Orleans, LA
Worcester County, MA
Montgomery County, MD
Cumberland County, ME
Wayne County, MI
Ramsey County, MN
Lincoln, Pipestone, and Yellow Medicine
Counties, MN, and Brookings County, SD

St. Louis, MO
Hinds County, MS
Duplin County, NC
Durham County, NC
Valencia County, NM
New York City (Queens, NY)
Cuyahoga County, OH
Montgomery County, PA
Schuylkill County, PA
Westmoreland County, PA
Providence County, RI
Davidson County, TN
Bexar County, TX
Harris County, TX
Lamar County, TX
Cache County, UT
Salt Lake County, UT
Waukesha County, WI
Grant County, WA



Locations Engaged in National Children's Study Related Research



Locations Engaged in National Children's Study Related Research

Apache County, AZ
Pinal County, AZ
Kern County, CA
Los Angeles County, CA
Orange County, CA
Sacramento County, CA
San Bernardino County, CA
San Diego County, CA
Ventura County, CA
Douglas County, CO
Litchfield County, CT
New Haven County, CT
New Castle County, DE
Baker County, FL
Hillsborough County, FL
Orange County, FL
Baldwin County, GA
DeKalb County, GA
Fayette County, GA
Honolulu County, HI
Polk County, IA
Bear Lake County, ID, and Lincoln
and Uinta Counties, WY
Cook County, IL
DuPage County, IL
Johnson, Union, and Williamson
Counties, IL
Macoupin County, IL
Jefferson County, KY
New Orleans, LA
Bristol County, MA
Worcester County, MA
Baltimore County, MD
Montgomery County, MD
Cumberland County, ME
Grand Traverse County, MI
Lenawee County, MI
Wayne County, MI
Lincoln, Pipestone, and Yellow
Medicine Counties, MN, and
Brookings County, SD
Ramsey County, MN
Jefferson County, MO
St. Louis, MO
Hinds County, MS
Burke County, NC
Cumberland County, NC
Duplin County, NC
Durham County, NC
Rockingham County, NC
Burlington County, NJ
Passaic County, NJ
Valencia County, NM
Monroe County, NY
Nassau County, NY
New York City (Manhattan), NY
New York City (Queens), NY
Cuyahoga County, OH
Lorain County, OH
Montgomery County, PA
Schuylkill County, PA
Westmoreland County, PA
Providence County, RI
Bradley County, TN
Bexar County, TX
Harris County, TX
Hidalgo County, TX
Cache County, UT
Salt Lake County, UT
Grant County, WA
King County, WA
Waukesha County, WI
Marion County, WV

Formative Research



- The National Children's Study has initiated several formative research projects that are limited in scope and duration and are intended to augment the Vanguard Study to address specific technical questions and provide information on the acceptability, feasibility, and cost of the research.
- These formative research projects will provide data to explore new and potentially cost-effective approaches in many areas, including genetic, cognitive, and environmental assessments, that have not previously been evaluated from an operational perspective.
- Based on the results of these formative research projects, the National Children's Study can evaluate the types of research questions that would be feasible for the Main Study.

Examples of Formative Research Topic Areas



- Real-time or Near-time Analysis of Study Samples, Specimens and Measurements
- Study Logistical Analysis and Improvements
- Biospecimen Collection and Processing
- Environmental Sample Collection and Processing
- Physical Measures
- Questionnaire Development and Validation
- Study Infrastructure Development

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

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

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

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.

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

Contact Information



- Check the Web site:
<http://www.nationalchildrensstudy.gov>
- Contact us at ContactNCS@mail.nih.gov
or 1-877-865-2619