



Why the National Children's Study?

Fifty years ago, most American children walked to school, rode their bikes without helmets, and ate home-cooked dinners each night with their families. Car travel for children—without seat belts—seldom occurred more than a few times a week. Fewer children were overweight—fewer high-fat snack foods, coupled with more physically active lives, helped to keep them at healthy weights.

But 50 years ago, pesticides were used routinely in our yards and kitchens. Pregnant women were not commonly advised to avoid cigarettes or alcohol. Type 2 diabetes was considered an adult disease. The diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) did not exist. Physicians rarely treated asthma. Babies were placed on their stomachs to sleep.

In the years since, research has brought about significant improvements in children's health. Today, caregivers are urged to place infants on their backs to reduce the risk of Sudden Infant Death Syndrome (SIDS). Lead has been removed from house paint and gasoline after being linked to reduced IQ in children.¹ Cribs, high chairs, and playground equipment are now safer, and most parents wouldn't even think of transporting their children without car safety restraints.

But with advancements, new challenges have emerged. Children today make less than one in seven trips to school by walking or biking.² Although this has sharply reduced childhood pedestrian and bicycle injuries, rates of obesity and overweight among children have tripled since the mid-1960s.³ Asthma is now the most common chronic disease of childhood.⁴ ADHD and developmental disorders collectively are estimated to affect 17 percent—nearly one in every five—school-age children.^{4,5} And even though the infant mortality rate in our increasingly diverse society has reached an all-time low, and the proportion of mothers receiving early prenatal care is at a record high, disparities in care and outcomes remain among racial and ethnic groups, presenting a host of challenges for many families.⁶

A CHANGING AMERICA

As many health and safety practices from past generations have been validated or dismissed based on new evidence, we have come to understand that the environments our children live in are profoundly important. From the air they breathe to the food they eat, from where they live to how they live, the

environments in which our children grow affect their lifelong health and well being.

Multiple studies point to associations between air pollution and allergens with asthma, poor diet with obesity, and pesticides with impaired neuro-development. Today, these problems stand among the most pressing public health concerns in the United States. Yet, with the prevalence of these conditions remaining stubbornly persistent, or on the rise, few studies can confirm more definitive links that lead to prevention strategies. In addition, with the threats of terrorism, violence, and other stress-inducers becoming facts of daily life for many families, understanding and protecting our children's health and safety is a national priority.

Everyone is worried about the health and education of our children. Parents and grandparents—we all want to do right by our children. We need a scientific base for what we are doing because our children's future is at stake.

Lynn R. Goldman, M.D., M.P.H., professor, Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health



WHY STUDY CHILDREN?

Compared with adults, children:

- Have a greater vulnerability to environmental exposures;
- Have immature mechanisms for detoxification and protection;
- Have several critical windows of vulnerability, especially before birth;
- Have differences in metabolism that cause different reactions to the same exposures; and
- Spend more time on the ground and put objects in their mouths.



COMMON EXPOSURES

The National Children's Study will measure:

- Living conditions and housing: air quality, dust, pet allergens, lead levels
- Family and social experiences: child care, alcohol use, family resources
- Community characteristics: neighborhood safety, access to health care
- Activity and diet: sports, food additives, in-home versus takeout meals

Children are not simply “little adults.” Because of differences in both physiology and behavior, what we understand about how adults interact with their environments does not necessarily apply to children. For instance, children tend to be more vulnerable to environmental threats because their developing systems cannot effectively resist and break down toxicants.⁷

In response to growing concerns over children's health and development, a partnership of government, community, advocacy, and private organizations is planning this long-term, observational study of how health and development during the first 21 years of life are affected by physical, chemical, biological, and psychosocial environments.

The environment is defined broadly in the National Children's Study to include natural and man-made environmental factors, biologic and chemical factors, physical surroundings, social factors, psychological influences and outcomes, cultural and family influences, and geographic locations.

The National Children's Study will observe approximately 100,000 children in the United States from before birth to their 21st birthdays,

and possibly beyond. The Study seeks to determine not only what is harmful, but what is harmless and helpful to children's health and development. The Study will measure exposures to, and relationships with, an array of environmental factors. Initial research findings will be published soon after the birth of the children. Findings will continue to be published throughout the duration of the Study.

We need to get really basic facts about all these diseases. It all starts in childhood.

William Castelli, M.D., former director, the Framingham Heart Study

The Study will be uniquely positioned to examine and assess a multitude of elements and aspects of participating children's lives, from the constructed world of neighborhoods and schools, to chemical exposures linked to the atmosphere, water supplies, or food, to the interactions of birth history, family patterns, and the frequency and severity of specific diseases. This ability to examine multiple exposures and link them in cause-effect relationships with multiple outcomes is the defining characteristic of the National Children's Study. The Study's trajectory will encompass pregnancy-related influences, including latent or unrecognized prenatal infections, the impact

of maternal diabetes, the interplay of individual genetic inclinations with subsequent behavior patterns, school performance, and the development of conditions such as asthma, diabetes, or obesity.

In the broadest sense, the National Children's Study will provide new insights into human growth and development. Incorporating the powerful reach of the human genome, genetic assays, and new computing technologies will further enhance the Study's power. By implementing various tools of connection and collaboration among biologic, physical, engineering, computer, and clinical sciences, the Study's outcomes promise to be of fundamental importance not only for medical diagnostics and health care, but also for educational strategies, city planning, public policy, and environmental regulation.

**PRIORITY FOR OUR TIMES:
A STUDY OF HEALTH OUTCOMES
AND EXPOSURES**

The rationale for the National Children's Study stems from a consensus within the research community that new and reliable data on factors responsible for child health are needed. Previous studies established vital scientific foundations, including some information

The National Children's Study has relied on many of the world's foremost scientists in designing and developing the plan of research.

about genetic susceptibility to certain diseases. But no study to date has been broad enough or long enough to draw definitive conclusions to many outstanding child health and development questions.

In formulating the National Children's Study's key areas of emphasis, hundreds of scientists and representatives from community and professional organizations helped to identify and articulate important children's environmental health questions. These core hypotheses encompass many important child health outcomes and exposures that are best studied for long-term follow-up and this particular research design. They establish both a scientific framework as well as a "public identity" for the National Children's Study.

The National Children's Study Interagency Coordinating Committee used the findings from 20 National Children's Study working groups, as well as reviews of children's environmental health literature

With its emphasis on multiple health outcomes and environmental exposures among a cohort of 100,000 children, the National Children's Study combines scientific power and cost-effectiveness. By evaluating data across exposures, the Study will help create a complete picture of what actually causes diseases and influences health.



The National Children's Study will help public health practitioners develop effective prevention and intervention strategies to improve the health of children and adults, and will assist doctors and health care professionals in better diagnosing and treating diseases in the future.

and comments from a broad-based Study Assembly to develop initial hypotheses. Although the hypotheses ensure that specific research areas will be included in the Study, they do not, by themselves, convey its true breadth. The full scope of the Study encompasses these hypotheses in tandem with the priority outcomes and exposures outlined below. Together, they represent an approach to addressing the nation's most urgent public health concerns.

PRIORITY HEALTH OUTCOME THEMES

Pregnancy-Related Outcomes. Can good nutrition help overcome potential risks from other environmental exposures that can affect the fetus? How does infection at various times over the course of pregnancy impact the fetus?

Injury. What are the links between childhood injuries and risk-taking behaviors? How do city and neighborhood planning and construction encourage or discourage injuries? How do genes and the environment interact to promote or prevent violent behavior in teenagers? How do innate characteristics, parenting, and peer relationships influence risk taking, persistent aggression, and risk of injury?

Asthma. What really causes asthma and how can it be prevented? Can very early exposure to some allergens actually help children remain asthma-free? How do the multiple factors contributing to asthma interact to result in the disease?

Obesity, Diabetes, and Physical Development. Are lack of exercise and poor diet the only reasons many children are overweight? How do genes and the environment interact to encourage obesity? How do social, behavioral, and family factors that affect the development of dietary preferences and physical activity patterns in early childhood determine the risk of childhood obesity?

Child Development and Mental Health. How are exposures to environmental toxicants, stress, pre-natal nutrition, and other factors, such as genes, linked to a child's risk of autism, ADHD, and other developmental disorders?

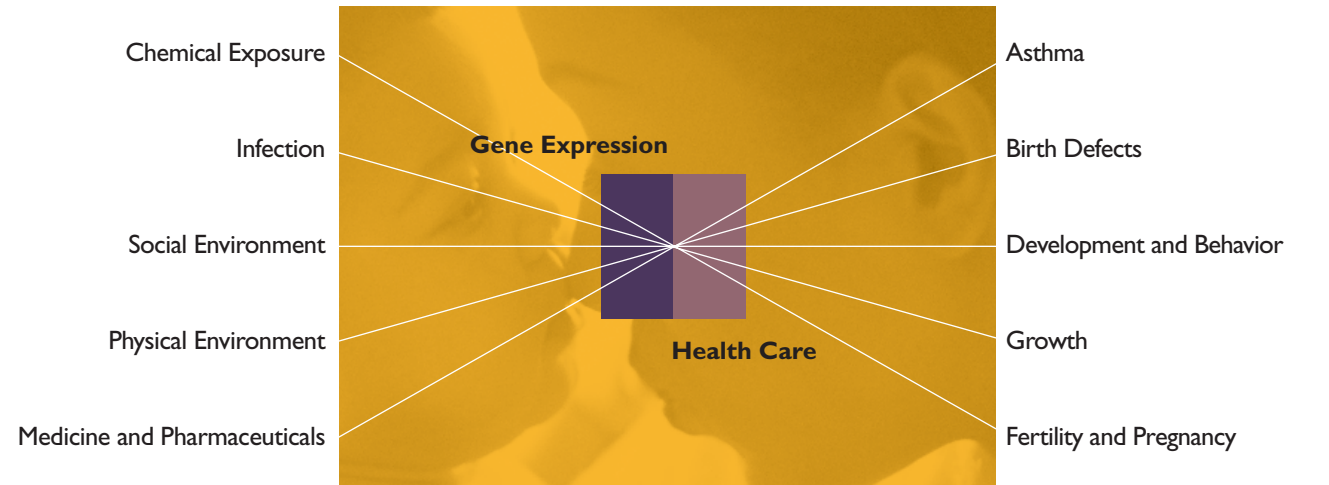
We are pleased that the goals of the proposed national study will encompass our basic mission of understanding the complex components of adverse birth outcomes, including birth defects, prematurity, and low birth weight, as a critical route to improving child health.

Nancy Green, M.D., medical director,
March of Dimes

FROM EXPOSURE TO OUTCOME

Understanding Complex Interactions in a Child's Environment

POSSIBLE EXPOSURES



A broad range of possible exposures must be examined to pinpoint causes of the potential outcomes. The National Children's Study is uniquely positioned to uncover these complex interactions to address today's health concerns and also those of tomorrow.

GENETICS

In what ways do environmental factors intersect with genes? How do mutations and variations in genes affect the development of diseases?

exposure to chemicals, pesticides, and herbicides? What are the health effects associated with complex low-level exposures?

PRIORITY EXPOSURES

The five priority environmental exposure groups discussed below may have a profound influence (either beneficial or deleterious) on child health and development.

Psychosocial Environment. How do school environments, emotional stress, family conflict, and personal relationships affect the physical and mental health of children?

Physical Environment. Do aspects of the physical environment, such as housing quality and neighborhood and community conditions, affect child health and development? What about the influence of physical factors, such as radiation (e.g., electromagnetic, ultrasound, microwave, X-ray), as well as light and noise?

Biologic Environment. How do bacteria, viruses, toxins, and diet influence immunity, inflammation, and diseases, such as diabetes? Do infections impact developmental progress, asthma, obesity, and heart disease? How do molecular and genetic mechanisms interact with viruses and bacteria in the expression of disease?

If the Study finds significant effects of chemicals on health, we can enhance our risk management of chemicals and other environmental influences and make changes.

Lee Salamone, director, Public Health Team, American Chemistry Council

Chemical Environment. What happens to the human organism after long periods of low-dose

STUDY MODEL—THE NATIONAL CHILDREN'S STUDY IS:

<p>The largest proposed longitudinal study of U.S. children, their families, and their environment</p>	<p>A study of children's physical, social, cultural, behavioral, and chemical environments</p>	<p>Hypothesis-driven: focusing on causes of obesity, injury, developmental disorders, asthma, and pregnancy-related outcomes</p>
<p>National in scope: involving children from diverse ethnicities and socioeconomic backgrounds</p>	<p>Large enough to identify causes of important, but less common diseases and conditions</p>	
	<p>The first nationwide children's study to benefit from human genome mapping</p>	<p>Using state-of-the-art technology to capture data and track developments</p>
<p>A national resource for future studies</p>	<p>A public-private partnership of government, private industry, and community organizations</p>	<p>Scheduled to announce first findings in 2008–2009</p>

INTEGRATING PRIORITY OUTCOMES AND EXPOSURES

The outcome themes and exposures will define the Study's parameters over time. The interplay of these factors will help link exposure data to a broad range of health and disease measures. The overall goal is to build a rich source of data to answer the critical public health questions confronting Americans today and in the future.

WHAT PARTICIPANTS WILL BE ASKED TO DO

The National Children's Study will recruit women who are pregnant, or who may soon become pregnant, to assess fetal and maternal health. It will also observe participating children and their families as they grow and live.

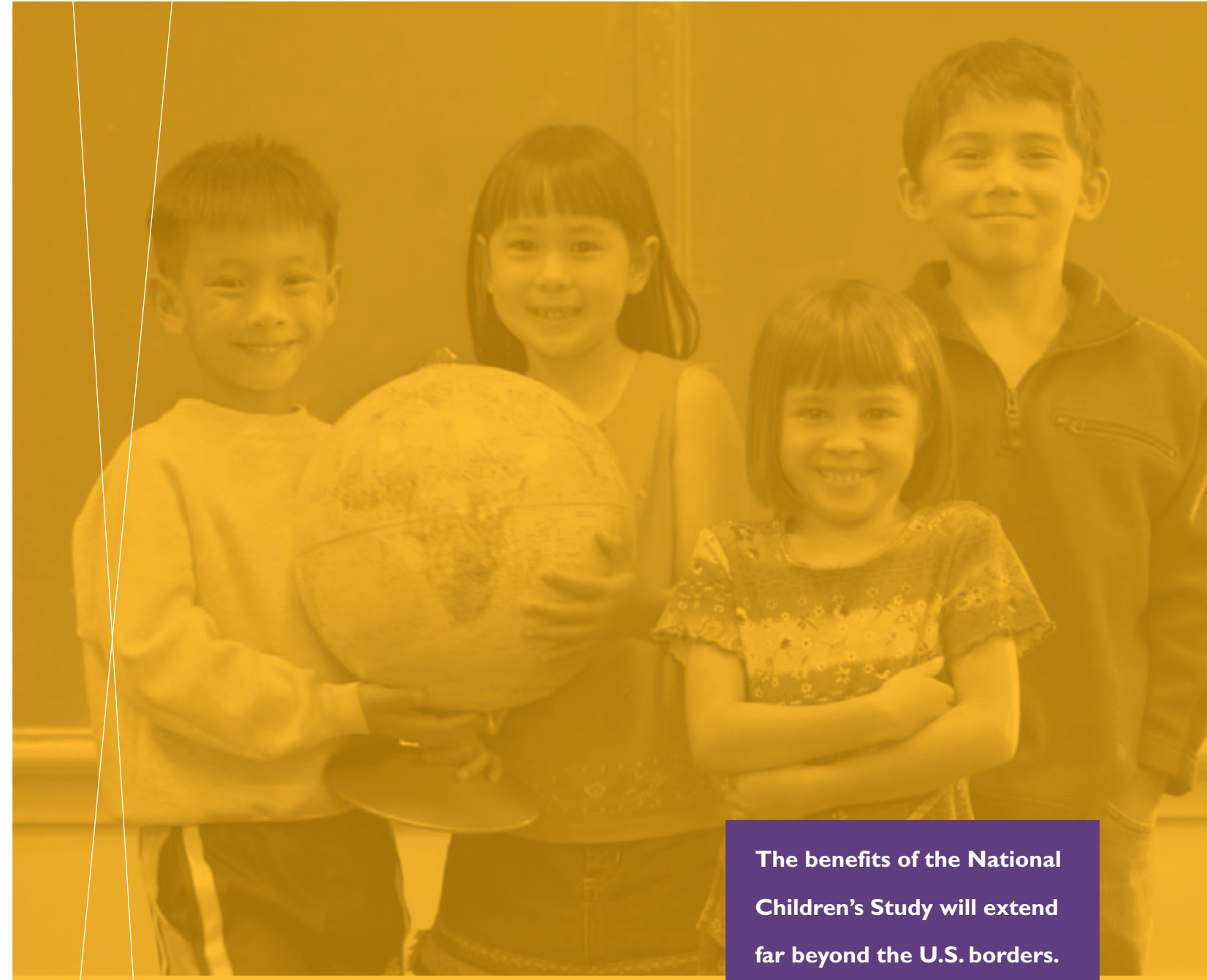
Unlike a clinical trial, in which participants take medication or engage in a prevention or treatment activity, an observational study like the National Children's Study collects information about participants' lifestyles in the home, at school, and at play. Families will visit a participating Study site on a few occasions during the baby's first year of life and less frequently in subsequent years. During the visits, health professionals will collect samples such as urine, blood, hair, DNA from parents and grandparents, and other information regarding the child's environment and health status. Families can expect to receive information about the research findings from Study coordinators by phone, mail, and the Internet, and through home visits. In home visits, a nurse or health research assistant will confer with the parents or caregivers to collect samples of indoor and outdoor air, water, or other environmental components.

The Study will be implemented through a group of university hospitals, community hospitals, local health clinics, or physicians' offices across the country. Participants will be recruited by local members of the Study team and will participate in or near their hometowns. Study planners are designing a careful recruitment strategy and follow-up plan to keep families actively engaged in the Study for more than two decades—no small challenge in today's mobile society. The National Children's Study will promote its research results through scientific journal articles, Web site postings, and media outreach activities.

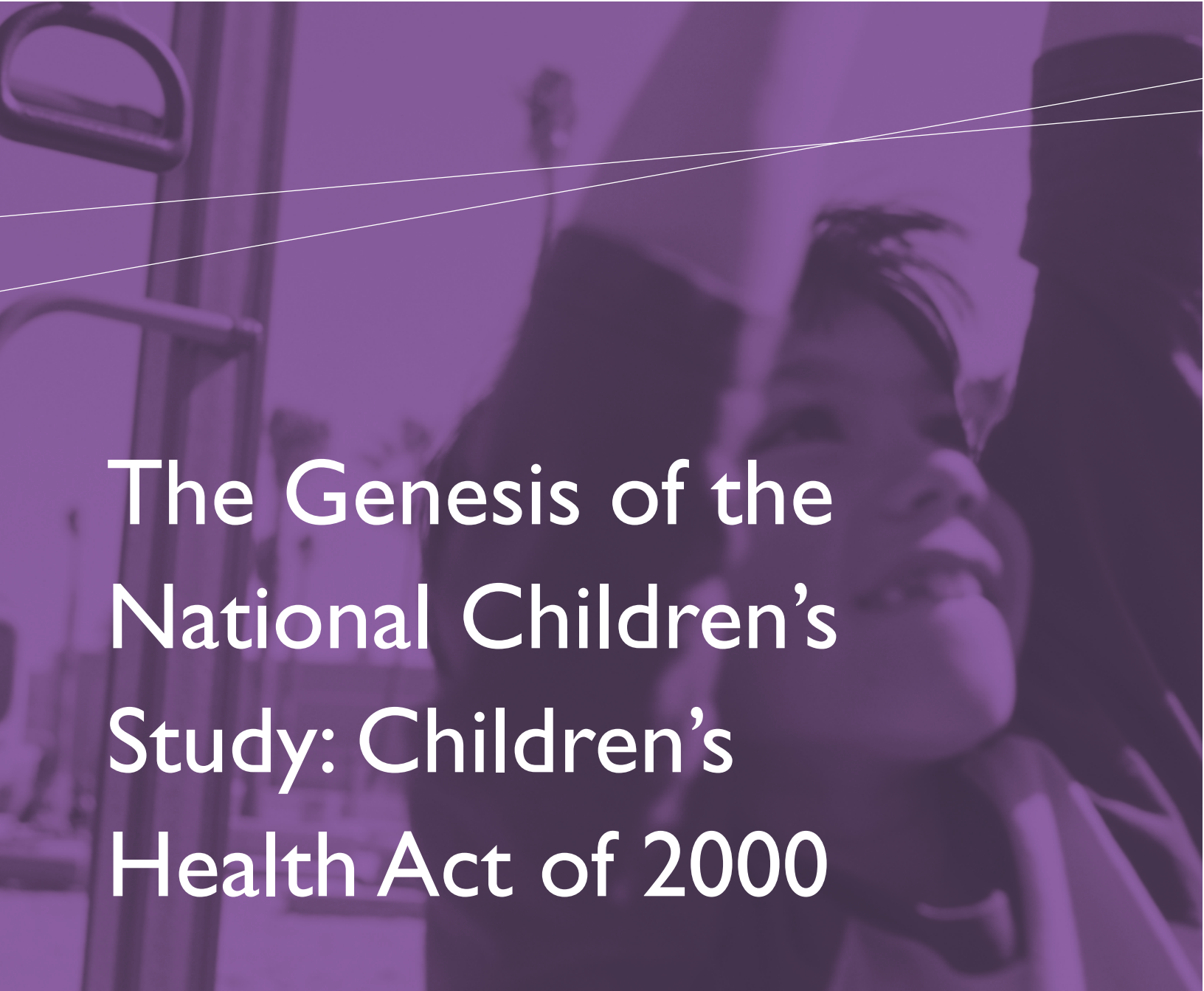
A UNIQUE PARTNERSHIP

The National Children's Study is a collaborative effort led by the U.S. Department of Health and Human Services (HHS)—through the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC)—and the U.S. Environmental Protection Agency (EPA). Operating through the NIH's National Institute of Child Health and Human Development (NICHD), the Study benefits from the input of more than 40 other federal agencies and departments. Study planners hope to build partnerships among local communities, health care providers, and federal and non-federal scientists, as well as parent, advocacy, and private industry groups that will inform the Study throughout its duration and will ensure the greatest benefit to the nation's children.

The National Children's Study has the potential to fill knowledge gaps, make a positive impact on the lives of children and adults, and generate the knowledge to find cures and maintain healthy lives. Everyone involved—families, researchers, policy makers, and the children themselves—will offer a gift to future generations through their support of and participation in the Study.



The benefits of the National Children's Study will extend far beyond the U.S. borders. What is learned about American children and their environments can help people around the world.



The Genesis of the National Children's Study: Children's Health Act of 2000

By the late 1990s, numerous experts in science and medicine were calling for new data on children's health and development. The last major study of children's health, the Collaborative Perinatal Project (1959–1974), offered information that reflected very different physical environments and social settings, and a far less diverse population of children. Studies conducted since, although offering important insights, have been too small or too specific to analyze the wide range of environmental factors and relationships that the National Children's Study will address.

With many childhood diseases and unhealthy conditions on the rise over the past two decades, support has grown for a broad partnership of agencies to join forces in conducting an extensive study of children's health. Such a study would develop an important data resource and would yield powerful clinical and research tools at a substantial cost savings over separate studies conducted by individual agencies.

CONGRESSIONAL COMMITMENT

In 1999, the President's Task Force on Environmental Health and Safety Risks to Children recommended a large, new longitudinal study of children to fill large gaps in knowledge about environmental effects and children's health and about how to address these effects. The Task Force's recommendation to initiate a new study was quickly followed by congressional passage of the Children's Health Act of 2000 (Public Law 106-310). Among other provisions, this act authorized the development of the National Children's Study. President George W. Bush has twice reauthorized the Task Force, and Congress has demonstrated continued interest in the National Children's Study by requesting briefings on Study plans and expected outcomes.

The President's Task Force on Environmental Health and Safety Risks to Children was established in 1997 by executive order. The Task Force was instrumental in highlighting the need for the National Children's Study, and its members from 16 departments and White House offices continue to be a strong source of support.

The Children's Health Act called for the Study to be directed by a consortium of agencies led by the NICHD in partnership with CDC and EPA. The National Institute of Environmental Health Sciences (NIEHS) and many other federal partners concerned about children's health and the environment have joined these three lead agencies.

Congress has demonstrated continued support for the National Children's Study since passing the Children's Health Act of 2000.

An Interagency Coordinating Committee, comprising scientists from each lead agency with oversight by the NICHD director, was formed to guide the Study's planning and implementation. A federal advisory committee and 20 working groups composed of federal and non-federal scientists and other representatives have made substantial progress informing various aspects of the Study.

Initial funds for fiscal years 2000 through 2004 were contributed by the lead agencies. Congress has also remained supportive, as reflected by language in appropriations committee reports. Numerous interagency partnerships have been established to plan the components of this ambitious long-term study and to conduct pilot studies.

