

Cover

Be Part of the National

Children's Study

Together We Can Change the Course of Children's Health

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The National Children's Study is a national response to the need for new knowledge in the area of children's health. This landmark study is being conducted in your community, and your hospital's participation is vital.

Inside

The National Children's Study is the most comprehensive study of the effects of the environment on children's health ever done in the United States. In the Study, the "environment" includes not only air, water, and dust, but also what children eat, how they are cared for, the safety of their neighborhoods, and how often they see a health care provider.

National Children's Study

The National Children's Study will follow 100,000 children from before birth through their 21st birthday. The Study is observational—no interventions, such as drugs or treatment, will be involved. By collecting certain biological and environmental samples from participants, researchers will analyze how different factors interact with each other and what helpful or harmful effects they have on children's health. Some of these factors include the following:

- Natural and man-made environmental factors, such as air quality and building safety
- Biological and chemical factors, such as infections and exposure to chemicals
- Social factors, such as community services and support systems
- Behavioral influences, such as response to stress
- Genetics
- Cultural and family influences, such as family structure and ethnicity

The Study's key scientific questions address some of the most pressing health and development concerns for today's children:

- Diabetes
- Injuries
- Asthma
- Obesity

- Autism
- Learning and behavioral problems
- Many others

Just as the Framingham Heart Study provided new insights into the determinants of heart disease in adults, the National Children's Study hopes to provide new findings related to genetic and environmental influences on child health. These insights may form the basis of child health guidance, interventions, and policy for generations to come. The National Children's Study is led by a consortium of federal agency partners: the U.S. Department of Health and Human Services (including the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences within the National Institutes of Health, and the Centers for Disease Control and Prevention) and the U.S. Environmental Protection Agency.

Where is the National Children's Study being conducted?

The National Children's Study has selected hundreds of communities and, in some cases, certain neighborhoods across the United States to take part in the Study. By using a scientific selection method, the Study ensures that participants represent the diversity of U.S. births. The Study will recruit pregnant women and women of childbearing age who may soon become pregnant. Participation in the Study is voluntary. Researchers will collect data from participants in their homes, in clinical settings, and via telephone, computer, and mail-in questionnaires. Recruitment will begin in some communities in 2008.

What is the role of the hospital or birthing center in the Study?

The success of the National Children's Study relies on the help of hospitals and birthing centers to collect critical data. Much of the data is time-sensitive, meaning that information must be collected at the time of delivery or shortly after the infants are born. Local Study staff will work with the staff at hospitals and birthing centers to determine how best to collect the data based on each facility's needs and resources, while minimizing the burden on staff and without interfering with the delivery of care.

The Study plans to collect the following information for every birth:

- An abstraction of birth records
- An observational exam of the infant
- Basic size and weight measures of the infant
- Biological specimen collections from the mother and the infant
- A brief neurological, sensory, and motor functioning exam of the infant

The Study's ability to assess pregnancy outcomes depends on collaboration among hospitals, birthing centers, and local Study staff. The Study promises to yield valuable data that will contribute to the improvement of maternal and child health.

How will the hospital or birthing center know who is enrolled in the Study?

Because local Study Center staff will visit potential participants in their homes to enroll eligible women during their first trimester, or even before they are pregnant, the women will know they are part of the Study when they arrive at the hospital for care. The Study will ask participants to identify themselves to hospital staff when they register or when they are admitted and to present National Children's Study identification.

It is possible that some recruitment will take place at hospitals or birthing centers to ensure that all eligible women within a defined geographic area have the opportunity to participate in the Study. In these cases, local Study staff will work with hospital and birthing center staff to determine the best approach for handling recruitment and enrollment.

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How will the Study handle informed consent and medical records release authorizations?

Every woman enrolled in the National Children's Study will provide her informed consent to participate. Prior to the birth of her child, she will have to sign a form authorizing her providers to release medical information to Study staff. This form will be Health Insurance Portability and Accountability Act (HIPAA) compliant, and each facility will get a copy of the patient's signed authorization form at or before delivery. If additional facility-specific authorization forms are required, local Study staff will ask participants to sign these forms too.

What safeguards are in place to protect participants' confidentiality?

The National Children's Study will meet and exceed all laws, regulations, and guidelines related to strict protection of participant confidentiality. Data collected for the Study will be used only for research purposes. The Study will use unique identification numbers, carefully designed computer-management systems that protect personal identifying information, and staff trained on issues related to privacy and confidentiality.

Before enrollment begins, the National Children's Study will obtain a Certificate of Confidentiality from the National Institutes of Health to protect identifiable research data from forced disclosure. The Study leaders will also secure relevant Institutional Review Board approvals prior to the first data collection to ensure that the risk of participation in the Study is understood and minimal.

For more information about The National Children's Study, visit the
Web site at

<http://www.NationalChildrensStudy.gov> or contact your local
Study Center.