

**National Children's Study
Questions and Answers
March 2007**



What is the National Children's Study?

The National Children's Study is a long-term study of human health conducted in the United States. By following 100,000 children from before birth to age 21, Study researchers hope to better understand how children's genes and their environments interact to affect their health and development. In the Study, "environment" includes factors such as: air, water, and house dust; what children eat; how they are cared for; the safety of their neighborhoods; and how often they see a doctor.

What will we learn from the Study?

The Study will examine important health issues, including: birth defects and pregnancy-related problems, injuries, asthma, obesity and diabetes, and behavior, learning, and mental health disorders. By establishing links between children's environments and their health, and charting their development through infancy, childhood, and early adulthood, the Study hopes to determine the root causes of many childhood and adult diseases. Findings from the Study will benefit all Americans by providing researchers, health care providers, and public health officials with information from which to develop prevention strategies, health and safety guidelines, and possibly new treatments and cures for disease.

How will the Study be conducted?

The Study will be conducted in 105 locations (counties or groups of counties) across the United States. All locations were selected using a probability-based method to ensure that children and families across the nation—from diverse ethnic, racial, economic, religious, geographic, and social groups—are fairly represented in the Study. In these locations, Study teams will work with health care professionals and community leaders to recruit women who are pregnant or are likely to have a child in the near future for participation in the Study. Most families will be recruited door-to-door. Others will join through their local physicians' offices, health clinics, and hospitals.

Initially, researchers will collect information on women's pregnancies, including their diets, environments, chemical exposures, and emotional stress. When the children are born, and periodically thereafter, researchers will collect biologic samples and environmental samples like air, water, and dust from children's environments. Researchers will meet with families in both their homes and in clinical settings, and data also will be collected remotely via telephone, computer, or mail-in questionnaires.

What is the difference between a Study Center and a Study location?

It is important to distinguish between Study Centers and locations. Study Centers are organizations or institutions, often working in collaboration, who are engaged through a federal contract in conducting the Study. Study locations are the previously designated geographic areas, or counties, where the Study will be conducted, and where eligible participants reside.

Who designed the Study and how was it developed?

The U.S. Department of Health and Human Services (including the National Institute of Child Health and Human Development, the National Institute of Environmental Health Sciences, and the Centers for Disease

Control and Prevention) and the U.S. Environmental Protection Agency are leading the Study with the help of researchers around the country. Members of the National Children's Study Federal Advisory Committee—including its working groups of more than 2,400 obstetric, pediatric, and environmental health researchers from federal agencies, the private sector, and non-governmental organizations—completed the groundwork that helped the lead federal agencies design and develop the Study.

What is the source of funding for the National Children's Study, and does funding the Study mean that other NIH research funds will be reduced?

Fiscal years 2000 to 2006, the early development and initial implementation years of the Study, were funded with agency funds from the lead supporting agencies: the U.S. Department of Health and Human Services—through the National Institutes of Health and the Centers for Disease Control and Prevention—and the U.S. Environmental Protection Agency. In fiscal year 2007, NIH received a direct Congressional appropriation of \$69 million specifically for the National Children's Study, which will fund the establishment of additional Study Centers, and allow the Vanguard Centers to begin recruitment of women into the Study. This funding was provided separately from other Congressional funds appropriated for NIH's research activities.

When will the Study begin and when will initial findings be available?

Vanguard Center teams will begin enrolling at least 250 newborns each year for five years beginning as soon as possible over the next year or two. The 15 to 20 new Study Center teams will begin recruitment by 2009. Initial Study results will be available around 2010, according to the current timeline.

Who will participate in the Study and how will they be recruited and retained?

Families who participate in the National Children's Study will come from 105 previously designated locations, which include U.S. counties or groups of counties from across the country, and will be from many different racial, ethnic, and socioeconomic groups. Recruitment efforts for the Study will include community based grassroots campaigns to promote the formation of community partnerships; to build relationships with area obstetricians and other health care providers; and to direct outreach to parenting groups, religious and community institutions, and other organizations offering health information and support to families. Building trusting relationships with community leaders will be critical to the success of the recruitment efforts.

The National Children's Study will seek to retain participants by maintaining strong relationships between Study staff and the children and families involved in the Study, as well as by engaging local community groups and activists. Some tools and activities to promote connection and cohesion among participants may include newsletters, interactive Web sites for the children, periodic get-togethers, public presentations, and birthday greetings. As in most studies of this kind, participants will receive appropriate incentives for their continued participation.

What is the National Children's Study's Plan for Expansion in 2007?

In February the National Children's Study received an appropriation of \$69 million from Congress to support expansion of the Study into additional communities across the country. To carry out this expansion, the National Institute of Child Health and Human Development (NICHD) will award 15 to 20 new Study Centers. These Study Centers will manage Study operations in up to 30 Study locations. A map and list of all Study locations can be found at <http://www.nationalchildrensstudy.gov/about/locations/>.

How will additional Study Centers be selected?

NICHD issued a Request for Proposals (RFP) in March 2007 to award more federal contracts to new Study Centers. Potential offerors included: universities, hospitals, health departments, or collaborations of these or other organizations, that will manage Study operations in each of the Study locations. These

organizations can propose to become Study Centers at up to 3 of the remaining 98 previously designated Study locations as long as they meet requirements put forth in the RFP.

Study Centers will be selected from a pool of interested applicants through a competitive selection process. Applicants must successfully demonstrate advanced clinical research and data collection capabilities, with the ability to collect and manage biologic and environmental specimens; community networks for identifying, recruiting, and retaining eligible mothers and infants; and a commitment to the protection and privacy of data. The Request for Proposals includes all remaining 98 Study locations. Centers will be awarded based on merit, geographic proximity to Study locations, and in accordance with the Study's probability sample. Contract awards are anticipated in September 2007.

How will Study Centers support the Study?

The Study Centers, including the Vanguard Centers, will work within their communities to recruit participants, collect and process data, and pilot new research methods for incorporation into the full Study. Study Centers will manage operations within one or more Study locations and are responsible for reporting to the Study's Program Office.

What Study Centers (Vanguard Centers) are currently operational?

The Vanguard Centers were awarded contracts in 2005, and have been preparing for participant recruitment since then. They are:

- University of California–Irvine with Children's Hospital of Orange County for **Orange County, California**
- Mt. Sinai School of Medicine with Columbia University Mailman School of Public Health, New York City Department of Health and Mental Hygiene, University of Medicine and Dentistry of New Jersey, and Columbia University Department of Obstetrics and Gynecology for **New York City (Queens), New York**
- University of North Carolina at Chapel Hill with Battelle Memorial Institute and Duke University for **Duplin County, North Carolina**
- Children's Hospital of Philadelphia and Drexel University School of Public Health with University of Pennsylvania for **Montgomery County, Pennsylvania**
- South Dakota State University with Children's Medical Center of Cincinnati and the University of Cincinnati for **Brookings County, South Dakota, and Lincoln, Pipestone, and Yellow Medicine Counties, Minnesota**
- University of Utah for **Salt Lake County, Utah**
- University of Wisconsin–Madison and Medical College of Wisconsin with National Opinion Research Center, Marquette University, UW Marine and Freshwater Biomedical Sciences Center/Institute for Environmental Health, and Children's Service Society of Wisconsin for **Waukesha County, Wisconsin**

What is the Coordinating Center?

The Coordinating Center provides scientific, technical, and logistical support to all Study Centers and is responsible for information management, statistical sampling, data collection and analysis, and quality control. Westat, a nationally-known research institution that contracts with federal agencies, staffs the Study Coordinating Center.