



# Another Day in the Life of The National Children's Study

By Marion Balsam, M.D.

Five years ago, the editor of *Exceptional Parent Magazine* requested that I provide an account of a day in the life of the National Children's Study, an ambitious study by the federal government, the aim of which is to find out how our environment affects child health and development. Now, five years later, I'm excited to provide follow-up - as we've come so far during this time.

To provide background for readers who may not have read the first article, some of the following is adapted from the July 2004 article. The National Children's Study, conceived in 1998 by the President's Task Force on Environmental Health Risks and Safety Risks to Children, was authorized by Congress in the Children's Health Act of 2000. The Study plans to follow 100,000 children from many locations across the United States, from before birth, through pregnancy, to age 21. We plan to measure numerous environmental influences (exposures) and numerous health conditions (outcomes), to discover which exposures influence health and developmental outcomes. The Study's ultimate goal is to enable healthier, safer, happier lives for children and their families.

The National Children's Study defines environment very broadly, to include the biological, chemical, physical and psychosocial-cultural environments. As an example of the biological environment,

there are concerns that during pregnancy, a mother's diet or certain other exposures in the unborn baby's environment may predispose the child to developmental or physical disabilities which may become evident during childhood or even later in life. The Study plans to look as well at the influence of the physical environment such as differences in neighborhoods, housing, and climate. We also plan to study psychosocial-cultural influences such as family and community structure and behaviors, economic status and media exposure. And last but not least, we plan to study the chemical environment: whether exposure to certain chemicals either before birth, or during early life, causes problems with child health and development. In addition to looking at direct effects of the environment, we plan to assess the way in which the environment affects how our genes express themselves. It may be that two people inherit similar genes which predispose them to various problems, but just one of those persons is exposed to "triggers" in the environment which enable those genes to express themselves and actually cause those health problems to appear. The National Children's Study is designed to find out just what those "triggers" are, and how we can avoid or influence them for a better outcome. We hope to discover not just the harmful factors which cause ill health, but also the protective or

helpful factors which enable some individuals to be more resistant or resilient than others. The data should provide answers to assist healthcare providers in improving healthcare delivery, and also help policy makers take appropriate action to avoid negative environmental impacts on child health and development.

**That brings us to ANOTHER Day in the Life of the National Children's Study.**

Planning and implementation of the National Children's Study has seen great progress during the past 5 years. In January 2009 we started recruiting participants for the pilot phase of the Study, testing the protocol, the plan that determines how to collect data, in the seven Vanguard locations—Orange County, CA; Duplin County, NC; Queens County, NY; Montgomery County, PA; Salt Lake County, UT; Waukesha County, WI; Lincoln, Pipestone, and Yellow Medicine Counties, MN; and Brookings County, SD. This is called the Vanguard pilot phase. Given the expected "bumps in the road," the challenges of starting new procedures in several very diverse locations, enrollment and initial data collection are proceeding well, a tribute to the strong partnerships forming the infrastructure of this great Study. Results of the pilot study will be used to frame proposals for the Main Study.

The Eunice Kennedy Shriver National Institute of Child Health and Human



Development (NICHD)/NIH is the lead federal agency for this project, working in close collaboration with the Centers for Disease Control and Prevention, the United States Environmental Protection Agency and the National Institute of Environmental Health Sciences. The Program Office (the main site of the Study planning) has expanded its staff and moved forward in many arenas. Thirty-six Study Centers have been activated across the nation, to oversee and collect data for the already awarded 72 Study Locations. Program Office staff lead and work with their respective Study Centers in fulfilling these complex contracts. Numerous Working Teams, led by Program Office scientists and including scientists from the various Study Centers, are refining and developing the protocol as the Study moves forward. Operational aspects of this complex Study will largely be carried out by a Data Coordinating Center.

The protocol has been drafted for the Vanguard pilot phase for the period of pregnancy through the first 2 years of life. Because of the length of this Study and the changing science as time goes on, the protocol will be developed sequentially for a few years at a time. Policies and procedures have been developed regarding researcher and community access to the data and confidentiality of the data, an important function to assure privacy, security and confidentiality of the data

which will be collected. A bioethicist leads the way in addressing the challenging ethical issues which arise with a study of this breadth and depth. Adjunct studies are expected to significantly enhance the NCS, by enabling Study Centers and other investigators to leverage on the NCS with modular, focused research which may be on a topic of their scientific expertise or one of community interest. Our Laboratory Medical Officer and environmental scientists lead the development of contracts and plans regarding the collection, storage and analysis of bio-specimens and environmental samples. Our geneticist contributes to those aspects of the study which pertain to gene expression under the influence of the various environmental exposures. Various staff members focus on such areas as health disparities, neurodevelopment, community engagement, and communications and outreach. The latter is of the utmost importance in a study which proposes to recruit such a large number of diverse participants, and then retain them throughout the entire period of childhood. Many Study Centers have engaged and gotten ideas from their local community members to help them plan the study in their specific locations. The Information Management Systems, or computer systems that will manage the data and the logistics of the study, are continuously being developed and refined, in order to collect, manage, and link the

enormous amount of varied data which we expect to collect over the years. The Interagency Coordinating Committee, which includes scientists from the National Institute of Child Health and Human Development, the Centers for Disease Control and Prevention, the U. S. Environmental Protection Agency, and the National Institute of Environmental Health Sciences continue their oversight to assure that the mission of the NCS is adhered to during this complex planning process. A Federal Advisory Committee provides advice and recommendations regarding many aspects of the Study. A Federal Consortium meets every few years to continue engagement of leaders in various government agencies whose work interfaces with the broad areas of the NCS.

A typical day involves hammering out the specific scientific, administrative, and operational efforts needed to develop and implement such a large, far-reaching study. Our staff is continuously giving presentations at meetings of various professional organizations, research advocacy organizations, and other government agencies. Many such organizations are excited about the opportunity to collaborate with us over the course of the Study. Our staff who manage the various Study Locations also perform site visits to their Locations in order to provide assistance as well as oversight of the ongoing activities.

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## The National Children's Study

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We are designing and refining such aspects of the Study as: which specific developmental evaluations to perform, which bio-specimens and environmental samples to collect, which analyses to do, what questions to ask in interviews and questionnaires, how much time can we utilize with participants in order to not produce excessive burden, how to obtain appropriate informed consent and get approval from the various Institutional Review Boards at the facilities around the country where the data is to be collected, and so many more interesting challenges.

So, what does the National Children's Study mean to you (the readers of *Exceptional Parent* magazine) and your family? We all want the best life possible, especially for our children, our grandchildren and their children. We all know people with health or developmental problems, be they physical, mental or behavioral. We continue to hear about unfortunate outcomes of pregnancy, such as birth

defects... and of conditions which appear to be increasing in frequency, such as asthma, obesity and type II diabetes, which used to be called "adult-onset diabetes," but is now frequently seen in teenagers. There are so many concerns about what is bad for one's health or what caused a bad outcome in a particular person. There is so much we don't fully understand... the environmental causes, the genetic factors, how the two interact, conditions which cause much suffering and financial burden to families and to society.

The readership of *Exceptional Parent* magazine has much to look forward to in the progress to be made by the National Children's Study. As stated in the July 2004 article, we expect this extraordinary Study to: "provide insight into such problems as: premature delivery and birth defects; autism and learning problems; schizophrenia, depression and other psychiatric issues; injury; asthma; obesity and physical development; and fetal influ-

ences on adult health — insight into the causes of many of the devastating conditions about which you share concern. Most importantly, we look forward to the Study providing insight into how we can prevent or minimize such risks to all our children, and grandchildren, and generations to come." We look forward to the National Children's Study sharing these insights so that healthcare providers can improve the healthcare we provide and so that health policy makers can make evidence-based decisions to most efficiently and effectively use our healthcare resources. •

To learn more about the National Children's Study, you may wish to visit the website at [www.NationalChildrensStudy.gov](http://www.NationalChildrensStudy.gov).

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