National Children's Study
Federal Consortium Meeting
July 25, 2007
Hyatt Regency Crystal City/Reagan National Airport
Arlington, VA

This meeting was held in conjunction with the National Children's Study, which is led by a consortium of federal agency partners: the U.S. Department of Health and Human Services (DHHS) (including the National Institute of Child Health and Human Development [NICHD] and the National Institute of Environmental Health Sciences [NIEHS], two parts of the National Institutes of Health, and the Centers for Disease Control and Prevention [CDC]) and the U.S. Environmental Protection Agency (EPA).

Welcome and Introductions

Duane F. Alexander, M.D., director of NICHD, welcomed the participants to the fifth meeting of the Federal Consortium of the National Children's Study (the Study).

The National Children's Study: Responding to the Challenge of Enhancing the Health of America's Children

Anand K. Parekh, M.D., M.P.H., senior medical advisor, Office of the Assistant Secretary for Health, DHHS, discussed the potential for the Study to provide valuable information about environmental, genetic, behavioral, and familial risk factors that affect chronic diseases in children. He described the significant interagency collaboration and public collaboration that is involved in the Study.

Overview and Update of the National Children's Study

Peter C. Scheidt, M.D., M.P.H., director of the National Children's Study, described how the Study began with the recognition of the need for new knowledge about environmental contributions to high-burden conditions in children.

He described the history of the Study, which was first recommended by a Presidential Task Force. In 2000, Congress passed the Children's Health Act, which authorized NICHD to conduct the Study by establishing a consortium of representatives from appropriate federal agencies, including CDC and EPA. The Interagency Coordinating Committee (ICC), consisting of senior scientists and staff from agencies involved in the Task Force, guided the planning process for the first 3 years and continues to guide the development of the Study. The National Children's Study Federal Advisory Committee (NCSAC), overseeing 22 working groups of scientists from within and outside of the federal government, was also involved in the planning process. The working groups contributed many workshops, pilot studies, scientific reviews, and white papers to planning the Study.

The Study was designed to

- Be hypothesis driven
- Measure exposures as early as possible (during pregnancy)
- Include a large sample size to examine high-priority exposures that are infrequent

- Examine the interaction of environmental and genetic factors
- Involve a consortium of federal agencies
- Include public-private partnerships
- Provide a national resource for future research.

Dr. Scheidt explained the development and review process for the Study's Research Plan and described the data sets the Study would produce. In July 2007, the Research Plan was posted on the Web and sent to the National Academy of Sciences for scientific review. In 2008, pending funding, Vanguard Centers will begin enrollment; and laboratories, repositories, and additional centers and locations will be established.

Dr. Scheidt asked the participants to consider the design and measures of the Study, how the agency can provide feedback on the Study, how the Study can help meet agency needs, whether additional studies can be conducted, and how federal scientists and programs can access and use the Study data and resources.

Presentation of the Research Plan

Ruth A. Brenner, M.D., M.P.H., director of protocol development, National Children's Study, provided a high-level overview of the Research Plan and encouraged participants to review the plan. She described the parts of the two-volume Research Plan, focusing on the Study design, which includes sampling design, recruitment and enrollment procedures, the schedule of visits, and an overview of measures. She explained how researchers chose Study locations and how they would identify participants and collect data. She described the schedule of follow-up visits for households selected for the Study. Visits are more frequent early in the Study, and data will be collected by mail and telephone interviews between visits.

Dr. Brenner presented the detailed schedule of contacts and data collection during pregnancy and infancy/early childhood. She described the data and samples that will be collected during the early phase of the Study, including physical assessments and biological specimens from the mother, father, and child; environmental samples; questionnaires and interviews; neurodevelopmental assessments; samples from the community and specific settings outside the home such as daycare centers and schools; and medical record extraction.

She explained that analytes will be collected and stored and most of the analysis will be deferred. A very limited set of analytes will require immediate processing. She provided some examples of the types of analytes taken by the Study.

Adjunct Studies and the Potential Role of Federal Agencies

Marion J. Balsam, M.D., Research Partnerships Program director, National Children's Study, discussed opportunities for participants and their government agencies to conduct adjunct studies, noting that the Study's Research Plan, the potential links between exposure and outcome measures, and ongoing research findings will spark ideas for future research that can leverage on the core Study Protocol.

Adjunct studies involve a subset of the Study cohort at one or more centers, use the Study infrastructure, and may be initiated by government scientists, Study Centers, research advocates, independent investigators, and industry. Adjunct studies may focus on a unique research interest or a specific public or community concern. These studies should be of mutual benefit to the proposing entity and the Study. Outside funding, rather than core Study funding, will be needed to support adjunct studies.

Dr. Balsam described the criteria considered when adjunct studies are reviewed. To facilitate the review and approval process, applicants first complete a brief electronic preliminary application. If reviewers believe the adjunct study could be approved, they will request a full application. Adjunct studies can begin after July 2009. Dr. Balsam emphasized that participants should begin thinking about adjunct studies on preconception, pregnancy, delivery, and early infancy that could be conducted during the early phase of the Study. Applications for adjunct study proposals will be available on the Study Web site in August 2007.

Data Access and the Potential Role of Federal Scientists

Adolfo Correa, M.D., M.P.H., Ph.D., medical epidemiologist, National Center on Birth Defects and Developmental Disabilities, CDC, DHHS, and member of the ICC, discussed data access and the possible roles of federal government scientists in the Study. He described the role of the Publications Subcommittee of the Study Steering Committee in developing policies and procedures for data access and publications.

Two types of data sets will be made available once they have undergone disclosure control procedures to ensure confidentiality:

- De-identified data sets for the scientific and research community
- Data sets for public use.

There will be two types of data access requests for federal government scientists:

- Requests for data analysis for scientific publications, submitted to the Study Publications Subcommittee through the ICC
- Requests for data in pursuit of the mission of an agency, submitted to the Study Program Office or the ICC.

Possible roles in the Study for federal government scientists include supporting the Study research management (contributing expertise and serving on review committees) and using Study data in pursuit of an agency mission. Federal government scientists may use Study data to conduct research using a life stage approach.

Questions and Discussion

The following items were discussed during the question-and-answer session:

- Adjunct studies may be proposed by any investigator—from a Study Center, from industry, from academia, or anywhere. If an adjunct study of a subsample at one or more Study Centers is proposed, the adjunct study would require the approval and collaboration of investigators at those Study Centers, but the lead investigator and staff of the adjunct study could be entirely outside the Study community.

- Data from the Study will be released in successive phases, as the cohort ages.
- When gathering information from fathers in the study households, paternity testing was not planned because of the ethical issues involved.
- The Study will participate in the International Childhood Cancer Cohort Consortium (I4C) to examine rare diseases such as childhood cancers.
- The Study will not enroll mothers who are unable to give informed consent and will not enroll women under the age of 18 at the time of the initial visit. No conditions would exclude the child from the Study.
- All 100,000 children are expected to be enrolled in the Study within 6 years.
- If the Study uncovers information that requires medical attention, the investigators are charged with ensuring that proper referrals are made and that referrals are followed up. The Study will collect information about medical experiences participants have between visits by using a personal health record kept by the mother or caretaker.

Interagency Collaboration to Enhance the Health of America's Children

Rear Admiral Kenneth Moritsugu, M.D., M.P.H., acting surgeon general, Office of the Surgeon General, DHHS, discussed the Office of the Surgeon General's committment to the Study. He described the Office's efforts to promote child health through the Year of the Healthy Child in 2005 and beyond. He described the Office's collaborations with other agencies to raise awareness of public health issues such as secondhand smoke, radon, asthma exposures, underage drinking, and preterm birth. He emphasized the value of interagency collaboration on these issues.

He noted that the Study will provide greater understanding of how children's genes and environments interact to affect their health and development. The Study will further one of the top priorities of DHHS: prevention of illness and injury. There are six key steps to prevention: good nutrition, physical activity, maintenance of a healthy weight, regular health screenings, vaccinations, and preventing exposure to tobacco and to secondhand smoke. He noted that health care spending—focused on treating, rather than preventing, disease—in the United States was doubling with each generation, and the increasing costs are unsustainable. Dr. Moritsugu described partnerships among federal agencies and between agencies and the private sector and public to promote prevention. He praised the Study as a model of collaboration that will improve the health and futures of the nation's children.

National Children's Study Interagency Coordinating Committee Introduction of ICC and Lead Agency Role in the Study

Elizabeth H. Blackburn, B.S.N., coordinator, Community Affairs and Outreach, Office of Children's Health Protection, EPA, and member of the ICC, gave an overview of the history of the Study and the ICC.

She noted that the ICC's role is changing to take a broader view of the Study, ensuring that it meets the needs of various agencies. The Program Office manages the Study and its contractors—the Coordinating Center, the Vanguard Centers, and the Study Centers—on a day-to-day basis. The Steering Committee makes non-direction-changing decisions about the Study. The Program Office, the Steering Committee, and the ICC provide checks and balances to ensure

that the Study remains true to the Children's Health Act. The Federal Consortium provides input to ensure the Study addresses the most important public health issues today.

Lead Agency Remarks

CDC and the Study.
Robert F. Spengler, Sc.D., director, Office of Public Health Research, Office of the Director, CDC, DHHS, discussed strengthening existing partnerships, the value of the Study for CDC, and what CDC can bring to the Study. He said that over the past 4 years, CDC has refocused its priorities, organization, and efforts around protecting the public health through health promotion, disease prevention, and preparedness for emerging threats. Dr. Spengler noted there is a strong alignment between the Study and CDC initiatives.

He outlined CDC's commitments to the Study, including scientific and laboratory expertise, a public health perspective and approach, contributions to health protection goal priority areas, partnership in interagency collaborations, and adjunct studies as appropriate. The Study, in turn, can help CDC meet its health protection goals by assessing problems and health disparities facing children, examining the impact of environmental and genetic factors on children's health, evaluating exposure-outcome relationships through a life stage approach, providing opportunities for CDC scientists to address critical and emerging public health issues, and allowing CDC to participate collaboratively across disciplines and agencies in this complex research project.

The Study and NIEHS.
Allen Dearry, Ph.D., interim associate director, National Toxicology Program, NIEHS, NIH, DHHS, spoke about what NIEHS has contributed to the Study and what it hopes to contribute in the future. NIEHS supports a broad array of research that is complementary to the Study, including health effect studies, exposure assessments, and intervention studies.

Dr. Dearry noted that for the last decade, NIEHS and EPA have had 12 centers for children's environmental health and disease prevention research. These centers provided relevant information for the implementation of the Study. He explained that the NIEHS has been involved in the new Genes and Environment Initiative, which combines an exposure biology program and a genetics program to examine the interplay between these two areas and understand the causes, prevention, and treatment of chronic disease. The results will be useful to the field of environmental health and to the Study.

EPA's Partnership with the Study.
Kevin Y. Teichman, Ph.D., acting deputy assistant administrator for science, Office of Research and Development, EPA, discussed how the Study would inform EPA's policy development. The Study will provide EPA with information that will help minimize the costs and maximize the benefits of regulations. The Study will directly link exposures to health status, increase understanding of environmental influences on children's health, provide up-to-date information about children's health, and offer EPA the opportunity to participate in targeted adjunct studies.

Closing Comments and Future Directions

Dr. Alexander said he hoped participants would leave with a better sense of the Study and the opportunities for agencies to increase their involvement through adjunct studies, particularly those dealing with pregnancy-related, neonatal, and infant issues. Such proposals must be submitted soon so that the studies can be carried out during the early phase of the Study.

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