

**National Children's Study
Federal Advisory Committee 19th Meeting
August 7, 2008
WESTAT Conference Center
Rockville, MD**

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](#) (HHS), National Institutes of Health (including the [Eunice Kennedy Shriver National Institute of Child Health and Human Development \[NICHD\]](#) and the [National Institute of Environmental Health Sciences \[NIEHS\]](#)), the [Centers for Disease Control and Prevention \[CDC\]](#)), and the [U.S. Environmental Protection Agency \(EPA\)](#).

Welcome and Introductions

*Alan R. Fleischman, M.D., National Children's Study Advisory Committee (NCSAC) Chair;
Medical Director and Senior Vice President, March of Dimes*

Dr. Fleischman welcomed the NCSAC members, ex officio members, and other participants to the 19th meeting of the NCSAC. He reviewed the functions of federal advisory committees as defined in the Federal Advisory Committee Act and the NCSAC's roles and responsibilities. He briefly reviewed the current meeting's agenda. The meeting participants introduced themselves.

Welcome

Peter C. Scheidt, M.D., M.P.H., Director, National Children's Study

Dr. Scheidt welcomed the NCSAC and other participants and thanked them for participating in this important meeting to consider the scientific peer review of the Study's Research Plan. Since its inception, Study planners have recognized the critical importance of peer review of the Study. The National Academy of Sciences (NAS) was identified as the organization best suited for an independent review of the Research Plan. The review was conducted over a 1-year period from June 2007 to June 2008. Samuel H. Preston, Ph.D., Professor of Demography, Department of Sociology, University of Pennsylvania, chaired the panel.

National Academy of Sciences Report

*Constance F. Citro, Ph.D., M.A., Director, Committee on National Statistics, The National Academies
Samuel H. Preston, Ph.D., Chair, NAS Panel; Department of Sociology, University of Pennsylvania*

Drs. Citro and Preston presented a summary of the NAS report. NICHD requested the Committee on National Statistics of the National Research Council (NRC), in collaboration with the Board on Children, Youth, and Families of the NRC and the Institute of Medicine (IOM) and the IOM Board on Population Health and Public Health Practice, to conduct a review of the Study's Research Plan. To address this request, the NRC appointed the Panel to Review the National Children's Study Research Plan, a group of 12 people representing a range of expertise

related to the scope of the Study. The panel was charged with reviewing the Research Plan to assess the Study's scientific rigor and the extent to which it is being carried out with methods, measures, and collection of data and specimens to maximize the scientific yield of the Study. The panel addressed proposed outcomes and hypotheses; proposed measures of environmental exposure, genetic makeup, family and community environment, and personal characteristics; and proposed data collection and analysis methods. Other aspects of the plan were also addressed. The contents of the report included:

- Study goals, conceptual framework, and core hypotheses
- Priority outcome and exposure measures
- Study design, data collection, and analysis
- Ethical procedures and community engagement
- Conclusions and recommendations.

The panel concluded that the Study offers an excellent opportunity to examine the effects of environmental influences on child health and development, as well as explore the complex interactions between genes and environments. It offers an unparalleled opportunity to obtain critically important information for ensuring the health and development of the nation's children. If the Study is conducted as proposed, the database derived from it should be valuable for investigating hypotheses described in the Research Plan as well as additional hypotheses that will evolve. The panel stated that it fully supported the Study and was eager for it to succeed. The panel identified the Study's strengths and weaknesses and made recommendations. The panel emphasized that the weaknesses and shortcomings, if not remedied, could diminish the Study's expected value below what it might be. The panel's critique, suggestions, and recommendations were intended to improve the capabilities of the Study to respond to the Children's Health Act of 2000.

The panel identified five strengths of the Study:

- Responsive to Children's Health Act of 2000
- Large number of births to be included (25 percent preconception; 90 percent by end of first trimester)
- Longitudinal design stretching over the first 21 years of life
- Many variables to be generated on both outcomes and exposures
- Well-designed national probability sample.

The panel identified nine weaknesses. They may reflect the many areas the Study must examine and the lack of substantial funding until very recently. These weaknesses can and should be remedied. The weaknesses are as follows:

- Inadequate pilot phase
- Decentralization of data collection
- Inadequate plans to maximize response and retention rates
- Weakness of conceptual model
- Weakness of certain data instruments
- Insufficient attention to racial, ethnic, and other disparities
- Inadequate plan to integrate data from medical records
- Inadequate plan for disclosure of risk to participants
- Failure to plan for rapid dissemination of data.

The panel's report listed 10 major recommendations:

- The Study should delay enrollment at new sites to make effective use of initial findings from participant enrollment and data collection in the Vanguard Center sites to improve study procedures, as appropriate, and to refine key concepts, hypotheses, and measures of outcomes and exposures. Throughout the life of the Study, it should use the Vanguard Centers to pilot test and experiment with data collection methods and instrumentation. (The currently planned 1-year lag between Vanguard and other Study Centers is not enough.)
- The Study should consider ways in which the survey data collection could be consolidated into a smaller number of highly qualified survey organizations.
- The Study's Program Office should establish and monitor strict standards for enrollment, retention, and data collection at each of the Study sites and be prepared to take immediate corrective action if sites do not meet high-quality standards in data collection.
- The Study should begin planning for the rapid dissemination of the core study data, subject to respondent protection, to the general research community and for supporting the use of the data after dissemination.
- Study and non-Study investigators should be given equal access to the full Study data as soon as they are cleaned and documented. All analyses should be performed with the kind of strict safeguards used by the Census Bureau research data centers.
- The Study should give priority attention to seeking ways to bolster its ability to contribute to understanding of health disparities among children in different racial, ethnic, and other population groups, including the reestablishment of a working group to oversee this area and the encouragement of appropriate adjunct studies.
- The Study should define the criteria and the process for deciding what individual clinical and research information will be given to children and their families.
- The Study should seek resources and develop methods to obtain more frequent in-person measures and medical and other administrative records data on Study participants.
- The Study should add measures of access to and quality of services, including medical care, education, childcare, and social services, as potential mediators of health and development outcomes and to improve the assessment of information obtained through maternal reports.
- The Study should clearly define the key constructs of child health and development and more fully develop a conceptual framework for understanding child health and development over the course of infancy, childhood, and adolescence. (The research plan frequently defaults to a deficit model that focuses on disease and impairment and the risk factors that contribute to them, rather than on the factors that encourage healthy development.)

The panel's additional recommendations included:

- Pregnancy outcomes: Consider replacing research on subclinical maternal hypothyroidism with a broader set of maternal physical and mental health conditions; investigate all pregnancy outcomes, including various types of pregnancy loss.
- Neurodevelopment and behavior and child health and development: Develop clearer rationale for selection of specific outcomes to be measured to obtain the best information possible within resource and burden constraints. (There are so many measures to choose from in these areas.)

- Asthma: The Study can make a major contribution to the knowledge of risk factors for the incidence of asthma (most studies focus on factors that exacerbate asthma); it should develop a clearer rationale for its hypotheses about risk factors.
- Obesity and growth: Consider adopting a broader approach that incorporates social and psychological factors as well as biogenetic ones.
- Injury: Consider replacing research on repeated mild traumatic brain injury with more nuanced research on environmental and treatment factors.
- Hormonally active agents and reproductive development: Develop refined and detailed protocols, particularly for outcomes measured at birth.
- Demographic and socioeconomic measures: Add questions on immigrant generation, languages spoken, and if possible, legal status of parents.
- Chemical exposures: Consider use of personal air sampling methods; measure paternal exposure to environmental chemicals and consider collecting other data to the same degree as on mothers.
- Physical exposure measures: Provide clearer rationale for housing and neighborhood conditions to measure and obtain measures at high-risk developmental stages.
- Psychosocial exposure measures: In choosing measures, prefer quality and analytic utility even if some measures must be dropped; dedicate funds to develop reliable and valid instruments of key psychosocial measures that reduce costs and burden.
- Biological exposure measures: Be sure to obtain measures, such as maternal glucose metabolism, at most appropriate times.
- Genetic measures: Develop clear mechanism for validation of genetic association studies before publication; revise candidate gene approach to take advantage of new genome-wide association methods; seriously consider consolidating genetic studies to reduce costs and coordinate best science (could store biological samples for later analysis with latest methods).
- Data linkage: Develop a plan for geocoding residential addresses from prebirth through adulthood of participating children to facilitate linkages of Study data with environmental exposures from other databases such as on government programs, pollution, crime, and neighborhood demographics.
- Sampling design technical issues: Modify the sampling design to allow for flexibility in increasing the number of Study participants in the event that the estimated number of screened households needed to reach 1,000 births per primary sampling unit (PSU) is incorrect; consider the proposed household enumeration approach to be experimental and conduct carefully designed field studies to clearly establish the statistical and practical implications of the proposed adjudicated listing approach; to ensure a diverse exposure profile in the sample, consider a careful assessment of variation in ambient exposure to chemical agents within each PSU.
- Data collection: Prepare a plan for monitoring progress in reaching sample size goals; set aside resources for an ongoing program of methods research and field experimentation.
- Informed consent: Engage communities in selected study implementation, data analysis, and data interpretation activities that go beyond recruitment; consider requiring every Study Center to formulate a more detailed plan to engage and collaborate with local communities.

NCSAC Questions and Comments

- Carol Henry, Ph.D., inquired about the issue of the conceptual framework. She asked Dr. Preston to describe the relative strengths and weaknesses of different conceptual framework models and what the Study might miss or gain by choosing one approach over another. Dr. Preston explained that the NAS panel discussed the conceptual framework issue at length. The panel members asked the same question that Dr. Henry just did. Ultimately, the panel recommended that the Study investigate whether there are different kinds of conceptual approaches that could inform what the Study is doing before implementation is too far along. The issue of healthy development was not thoroughly addressed in the Research Plan. The plan had a disease model, focusing on departures from health rather than on health itself. Increasingly, within disciplines such as psychology, there has been emphasis on resiliency, optimism, and variable attributes that are important outcomes in and of themselves, not simply departures from ideal health. There is a growing body of literature on this topic that was not adequately addressed in the Research Plan.
- Myron Genel, M.D., asked about the panel's criticism of maternal hypothyroidism. He noted that data support the relationship between maternal thyroid hormone levels and pregnancy outcomes. Dr. Preston said the evidence was not disputed, but the panel thought this was a relatively minor disease process and that some of the more major disease processes were not addressed. Dr. Genel noted hypothyroidism is easily measured and that some of the other disease processes are not easily measured quantitatively.
- Dr. Fleischman asked whether the panel realized that some of its recommendations might be viewed as competing or contradictory. In some cases, the panel recommended greater depth in an area to gather more specific information, particularly for social, behavioral, and developmental issues, whereas in another recommendation, the panel asked for broader information. Dr. Preston replied that the panel discussed psychosocial measures and deliberated whether they should be broader or narrower. The panel attempted to avoid conflict in that area. The panel recommended that the Study confer with subject matter experts to determine the most appropriate approach. Dr. Citro said that in the psychosocial area some of the gold standard measurements may be too burdensome. The NAS panel thought it was better to collect good measures in a few areas rather than average measures in many areas. The panel recommended that a working group examine the optimum balance between breadth and depth of measurements, given the Study's design and data collection methods.

National Children's Study Response to the NAS Peer-Review Panel Report

Dr. Scheidt

Dr. Scheidt provided an overview of the Study's response to the NAS peer-review panel report. There are four components to the Study's plans and protocols. The Study Plan is a general plan for the Study and was used for Vanguard and Coordinating Centers' requests for proposals. The Research Plan provides the background, rationales, and specific approaches for peer and federal agency reviews. It was posted for public comment in June 2007. The Study Protocol describes the specific methods and instruments at 3-year intervals. It was used for Office of Management

and Budget (OMB) review and preparation of manuals from current enrollment to 24 months of age. The Study Manual lists the detailed procedures to implement protocols.

The scientific peer review of the Research Plan was important to ensure that the Study is scientifically rigorous and being carried out with the best available methods. The peer review was first called for by former Secretary of HHS Donna Shalala as part of the 2000 President's Task Force on Environmental Health Risks and Safety Risks to Children. The Interagency Coordinating Committee (ICC) and Program Office have consistently said there would be peer review. Peer review was expected by the scientific community, and it was required by the NICHD institutional review board (IRB). In addition, peer review was required to address congressional concerns about the Study.

There were several limitations of the Research Plan peer review. The review was not conducted to:

- Determine whether study of exposure–outcome relationships in children is meritorious
- Consider whether federal resources are better spent addressing different questions or using different approaches to supporting biomedical research
- Propose alternatives to the designated federal agency leadership and funding for the Study.

The peer-review panel was asked to answer several questions. Given the required size, finite resources, and limitations of participant burden, does the Research Plan:

- Respond adequately to the directives of the Children's Health Act of 2000 and the President's Task Force?
- Use the correct priority outcomes to meet the aims of the Study?
- Identify sufficient and appropriate hypotheses to adequately frame and guide the design of the Study?
- Use appropriate measurements of the outcomes, exposures, and confounders?
- Use state-of-the-science genetic and genomic measures and analyses to enable study of how environmental and genetic factors interact to result in the outcomes of children's health and development?
- Provide an appropriate and effective platform for future study and analyses of questions not yet proposed or currently recognized and are important to child health and development?

The peer-review panel concluded that the Study should be carried out and that its general approaches are appropriate. Some of the Study's strengths are that it is a large nationally representative sample, it will make observations from early pregnancy to adulthood, and its core exposures and outcomes are appropriate for study and responsive to the President's Task Force and the Children's Health Act. The panel identified weaknesses and shortcomings and made 33 specific recommendations.

The Study's general responses to the panel's recommendations are as follows:

- The panel took its charge seriously and worked very hard to complete the review.
- The report was thorough and thoughtful.
- For such a broad program, the NAS panel was limited in depth for any one topic.
- Evolution of the Study influences the significance and response to some recommendations.
- The majority of recommendations are helpful and beneficial to the Study.

- The Study appreciates the thorough, balanced, and helpful review.

The Study's responses to individual recommendations were put into one of four categories:

- Already implemented or in the process of being implemented
- Suitable but not possible with current resources
- Considered but alternative approaches chosen
- Require further work or future consideration.

The following recommendations are already implemented or in the process of being implemented:

- Use Vanguard Centers as pilots
- Examine a broader set of maternal health conditions
- Use detailed protocols on all pregnancy outcomes
- Focus on prenatal and early life risk factors for asthma
- Incorporate social and psychological factors in childhood obesity
- Refine protocols on reproductive development outcomes
- Consider personal air sampling in a subsample
- Reconsider measures of housing and neighborhood conditions
- Reconsider psychosocial measures in terms of high quality and analytic utility
- Ensure that the timing of biological sample measurement is appropriate
- Use a validated approach to genetic analyses
- Store biological samples until more cost-effective studies are possible
- Facilitate linkage to secondary data sources by geocoding residences
- Field test the proposed household listing approach
- Maintain strict standards for quality assurance of data collection
- Plan to monitor progress in reaching sample size
- Ensure rapid dissemination of data and provide analytic support
- Define the criteria for giving information to participants
- Engage communities in the Study.

The following recommendations were suitable but not possible with current resources:

- Use more frequent data collections from Study participants and more extensive data collections from other sources (for example, health care records)
- Increase data collection on fathers, including chemical exposure
- Add measures of access to and quality of health services
- Maintain an ongoing methods development program.

The following recommendations were considered but alternative resources were chosen:

- Add specific measures relating to immigrant legal status
- Dedicate funds and use the structure of the Study to support development of new instruments for key psychosocial measures
- Have reserve segment samples as an option to meet recruitment goals
- Consider use of exposure data in defining PSU-specific sampling strata
- Consolidate data collection into a small number of survey organizations.

The following recommendations require further work or future consideration:

- Give priority attention to health disparities
- Develop a clearer conceptual framework
- Develop a clearer rationale for studying neurodevelopment and behavior disorders
- Consider replacing the traumatic brain injury hypothesis to ensure adequate injury identification and to link with related factors and treatments
- Allow equal accessibility to data by Study and non-Study investigators.

The next steps are to post and distribute the Study's responses to the NAS panel review. The Study will proceed with appropriate actions such as establishing working teams, developing stronger conceptual models where needed, reexamining certain measures, and considering other detailed responses to the peer review. The Study will revise the Research Plan, taking into consideration the NAS review and evolving science.

Dr. Scheidt posed three questions to the NCSAC:

- How does the NCSAC view and interpret the NAS panel review?
- Is there a better or alternative framework for Study response and interpretation of the NAS panel recommendations?
- How can the Study best use the NAS panel review?

NCSAC Questions, Comments, and Discussion

- Janet Currie, Ph.D., asked Dr. Citro to elaborate on the panel's recommendation that Study and non-Study investigators have equal access to data. Dr. Citro replied that the panel's view was that Study and non-Study investigators should have equal access to the full Study data as soon as they are cleaned and documented. The NAS panel emphasized that all analyses should be performed with the kind of strict safeguards used by the Census Bureau research data centers.
- The Study Centers were chosen in areas designated by the National Center for Health Statistics as the PSUs. Therefore, equally qualified and interested investigators that were not in one of the PSUs would not be allowed to participate as Study Centers because of the selection process. The panel interpreted the Study Centers' role as primarily community outreach and engagement and managing the data collection. For research purposes, the entire research community should be seen as the consumers of Study data. Dr. Scheidt said that this is one comment in the report where the panel was wrong. The Study Centers will engage communities and collect data, but they will also provide needed scientific input. The Study Center investigators are required to contribute to protocol development and the evolving science of the Study. Therefore, these investigators have a vested interest in the use of the data. However, it is not appropriate to reserve the data exclusively to those investigators. As soon as possible, the data will be made available to non-Study investigators through the various levels of public access.
- James N. Jarvis, M.D., said that the framework for the Study's response and interpretation of the panel's recommendations is correct (that is, the responses being placed in one of four

categories). Whether the responses have been placed in the right categories remains to be seen.

- Helen M. DuPlessis, M.D., M.P.H., said that the framework is a good one. It would be beneficial if Drs. Citro and Preston identified the panel's main recommendations, and it would be useful to know the rationale behind the main recommendations. That the main recommendations seem to be equally distributed among the four categories should be further examined.
- Robert E. Chapin, Ph.D., agreed that the four categories are a reasonable way to group the responses. He applauded the quality and thoughtfulness of the Program Office's responses.
- Dr. Genel asked that a list of the major recommendations be made available to the NCSAC.
- Dr. Henry asked whether the major recommendations were prioritized. Dr. Preston said they were not, only "major" and "other."

Dr. Fleischman noted two conclusions: The NCSAC thoroughly applauds the NAS panel's thoughtful and extremely helpful review of the Research Plan. Dr. Fleischman said he was impressed with the depth, thoroughness, and thoughtfulness of the panel's review. The NCSAC thanks the panel for its thoughtful, positive, and constructively critical report. In general, the framework of responses seems reasonable, and it is important to address the major recommendations in the report.

Dr. Fleischman asked the NCSAC to comment on the issue of the adequacy of funding for the Study because addressing many of the criticisms would require additional resources.

- Dr. Jarvis noted that several years ago there was discussion that the Study would diminish resources from other institutes, centers, and research projects. The Study has been funded by Congress with additional special monies added to the NIH budget and has not diminished funding to the Institutes. He said that the Study should not ask for additional funding until it can demonstrate success.
- Dr. Genel proposed that the Study estimate the costs that would be required to implement the NAS panel's recommendations, particularly the 2-year in-person visit.
- Dr. Chapin said there is a limited time to generate early exposure data from which health outcome associations can be assessed. It is important to collect data early. He proposed that the Study seriously consider the panel's recommendations and seek additional funding to collect as much early data as possible to fulfill the early visions for the Study. He agreed with Dr. Genel about estimating costs.
- Maria Cancian, Ph.D., said, assuming the budget is fixed, the Study has a responsibility to think about reallocating resources within the plan. To the extent the NAS report has highlighted things that need to be done, it is not sufficient to say it is not in the budget. The

Study needs to continue to reassess its priorities. She emphasized the need for the Study to support development of new instruments and methodological testing.

- Dr. Henry commented that the idea of adjunct studies is considered a panacea. She noted that EPA was not approved by OMB to conduct the pilot study in North Carolina. She suggested that the NCSAC consider sending a strong message to OMB to involve other federal agencies in the Study.
- Michael D. Lebowitz, Ph.D., said it is important to pursue, through the ICC, funding from lead federal agencies for the NAS panel's highest priority recommendations.
- Dr. DuPlessis said the Study should rely on the NAS report to advocate for funding and other resources.

Dr. Fleischman summarized the NCSAC's recommendations as follows:

- The Study should recognize that it is working with finite resources.
- Staff, however, should estimate costs to implement the NAS recommendations.
- Funding sources inside and outside of the federal government should be sought, and in order to do that, other sources of funding (such as foundations) must be made aware of the Study and the potential to use it as a platform for research.
- There may be some potential to reassess priorities and reallocate resources to address some of the NAS criticisms.

Session 1—Operational and Logistical Issues

Kenneth Schoendorf, M.D., M.P.H., Director, Protocol Development, National Children's Study

Dr. Schoendorf addressed four topics from the NAS report:

- Use of Vanguard Centers to pilot the Study
- Consolidation of data collection
- Increased data collection (more frequent in-person contact and medical and other administrative record abstraction)
- Data access and availability.

For each topic, Dr. Schoendorf reviewed the issue, the panel's recommendation, and the Study's response.

The NAS panel recognized the importance of a pilot phase for such a large, complex study and identified the absence of an adequate pilot phase as an "important shortcoming" of the Study. The panel recommended using the Vanguard Centers to full advantage, now and throughout the course of the Study, and specifically delaying wave 1 at least 6–12 months. In response, the Study fully agrees with the panel's recommendation. Wave 1 implementation has already been pushed back 6 months. The evaluative areas in the pilot phase were specified in the OMB submission. The start of wave 1 is contingent on adequate evaluation and response to Vanguard results. Although an adequate pilot phase is important, so is maintaining momentum. Contracts have been awarded to Study Centers for about 30 wave 1 locations. These Study Center personnel and Study Location communities are ready and eager for the Study to begin.

The NAS panel considered decentralized data collection as “unusual” for a national probability sample. The panel cited two issues: Study Centers and Locations should be “invisible” in terms of data collection, and managing and ensuring uniform data collection among 30–40 different Study Centers will be challenging. The panel recommended that the Study consolidate data collection into a small number of survey organizations. The Study appreciates the panel’s concerns, but the center-based approach has already been chosen. The Study is not a typical household-based federal survey. It is a longitudinal, long-term, fairly high-burden, observational study that requires active and willing participation of local health providers, hospitals, schools, and childcare facilities. Community knowledge and engagement are crucial to the Study’s success. Involvement of center-based scientists is critical to success and addresses other concerns in the NAS report. A central coordinating center will oversee training of personnel across Study Centers and will provide quality assurance and quality control. In addition, national survey organizations are involved with data collection at many Study Centers.

The NAS panel noted that the timing and frequency of in-person contacts are not optimal for some important relationships (for example, maternal glucose metabolism and early childhood development). The panel also noted an underuse of medical (and other) records as part of data collection. The panel recommended that the Study “seek resources” to obtain more frequent in-person and medical record data measures. Data collection requires an ongoing balancing act within the Study. An optimal balance of cost, participant burden, and data collection is elusive. Establishment of Study infrastructure and essential measures is a priority. Targeted adjunct and substudies will provide additional depth in many areas. Development of low-burden data collections (for example, remote or self-collected specimens) will enhance core measurements. Advancement of electronic health records is necessary, and the Study will use these records as the science evolves.

The NAS panel reported that the data use plan outlined in the Research Plan is cumbersome and unlikely to foster optimal use of Study data. The panel recommended rapid “dissemination” of documented and supported data files for broad use and equal access for Study and non-Study investigators, all within the context of ensuring participant confidentiality (for example, development of research data centers). The Study acknowledges the need to optimize the balance between confidentiality and data use. Data will be made available as rapidly as feasible while maintaining confidentiality and data quality. The Study recognizes that different levels of data contain varying amounts of personally identifiable information or different amounts of data perturbation and that different levels of data require different access criteria. All researchers, regardless of Study affiliation, will be subject to the same confidentiality and data access rules. A Data Access and Confidentiality Committee has been constituted and is actively developing specific approaches to data access and availability.

NCSAC Questions, Comments, and Discussion

- Dr. DuPlessis asked, with the 6-month delay of wave 1, whether the lag time between the pilot phase and wave 1 was now 18 months. Dr. Schoendorf explained that some Vanguard Centers have begun field work that does not require OMB approval. Field work for wave 1

Study Centers is scheduled to begin in January 2010. Regardless of the lag time, the intent is to ensure adequate evaluation of and response to the Vanguard experiences.

- Dr. Genel asked Dr. Schoendorf to elaborate on his explanation. Dr. Schoendorf said there are a number of specific studies or evaluative criteria for assessing things such as enrollment and community engagement, both within and across Study Centers. Different approaches will be evaluated to determine what works, what does not work, and what would be considered best practices. Dr. Schoendorf cited the electronic consent form experiment.
- Dr. Genel asked whether it is realistic to think there will be enough time between the start of the pilot phase and the start of wave 1 to gather enough information that would inform wave 1 implementation. Dr. Schoendorf said the Study expects to begin the initial phase of field work in early 2009. The start dates will depend on OMB and IRB approvals. The timeline will shift if necessary. Dr. Genel suggested that it might be beneficial to further delay the start of wave 1 by another 6 months to allow an adequate pilot phase.
- John L. Butenhoff, Ph.D., commented on the importance of community involvement for the success of the Study. The NAS panel's recommendations to increase the frequency of certain types of data collection and to consolidate data collection appear to be opposing. He said that the Study cannot be expected to increase data collection while consolidating it.
- Dr. Cancian encouraged the use of a broad set of administrative record abstractions. This approach would minimize burden and reduce cost. The informed consent should be designed to allow the merging of administrative records data from different sources.
- Ana V. Diez-Roux, M.D., Ph.D., M.P.H., agreed with the NAS panel's recommendation that Study data be made available to non-Study investigators, probably through confidential data analysis centers. However, there should be a mechanism that would allow Study investigators exclusive data access for a short period, such as 1 year. This approach is used in many multisite studies. A publications committee generally manages this process.
- Dr. Schoendorf said the Study will have a publications committee to address some of these issues. The committee will deal with Study investigators to ensure that the core hypotheses are addressed and that they are addressed in a reasonable fashion.
- Dr. Lebowitz said the decentralization of data collection is critical for community engagement. He asked Dr. Schoendorf to explain why the Study's infrastructure is a priority. The Study needs to address the issues of the timing and frequency of collecting some types of data.
- Dr. Henry said the lag time between evaluating pilot phase results and their incorporation into wave 1 protocol should be further examined. It is important that the lessons learned in the pilot phase adequately inform the main protocol.

- Dr. Currie agreed that Study investigators should have exclusive data access for a short period before the data are made publicly available. There should be a consistent policy across Study Centers on how the data will be made available. Specifics on this process are needed.
- Dr. Schoendorf responded to Dr. Lebowitz's question about the Study's infrastructure. He said that the adjunct or substudies that would add depth to the Study have not been formulated. Adjunct studies cannot be implemented until after the pilot phase. This infrastructure includes the Study Centers, which will ensure that the data are collected; the Study population, which needs to be recruited, enrolled, and retained; and a basic structure of visits, which includes a reasonable schedule of visits. With regard to the period between the pilot phase and wave 1, there are specific plans to evaluate targets and criteria for enrollment, percentages of nonresponse, and so on. There will be daily or weekly assessments of data. There will be evaluations to determine whether one Study Center is doing better than another, and if so, why. The lessons learned and best practices will be incorporated into the wave 1 protocol. The Study will be flexible and will adjust the timeline as necessary. Dr. Scheidt said there is a tension between completing an adequate pilot phase and implementing the full Study. Each congressional funding wave has been linked to the requirement that additional centers be established and begin work. There is considerable pressure to begin the full Study. The Study is, however, fully committed to the pilot study recommended by the NAS panel. Because meetings with Vanguard Center investigators and wave 1 Study Center investigators are infrequent, there is already ongoing communication and the exchange of information about pilot phase activities and the lessons learned so far.
- Dr. DuPlessis said there needs to be a well-designed, structured, performance improvement/quality improvement process for the Study. Continuous quality improvement needs to be incorporated into the Study.
- Dr. Cancian commented that there are different norms within different fields of research. For example, in the social science community, data access is equal. The data are made available as soon as they are ready.
- Edwin Trevathan, M.D., M.P.H., said Study investigators should have priority data access.
- Dr. Scheidt said the protocol is continuously reassessed through established working teams that represent fairly broad scientific domains. The teams are chaired by a Program Office scientist and composed of Study Center investigators. There are narrowly defined subgroups.
- Dr. Genel reiterated the need to determine incremental costs to implement the NAS panel's recommendations.

Dr. Fleischman summarized the NCSAC's discussion:

- The NCSAC agrees with the NAS panel's recommendations on the need to optimize the pilot nature of the Vanguard Centers' activities.
- The NCSAC rejects the recommendation of consolidated data collection but acknowledges the needs for aggressive quality data collection management.

- The NCSAC recommends that the timing and frequency of data collection be determined by the need to address the necessary exposure and outcome measures for the core hypotheses. However, reassessment of the timing and frequency of data collection should be an ongoing process.
- The NCSAC agrees with the Program Office’s commitment to maximize data access as rapidly as possible and make data available to the broader community of non-Study investigators. The NCSAC does not recommend equal access and timing of data availability to Study and non-Study investigators. It is critical that the PO maximize data access as quickly as possible but ensure high data quality before the data are made publicly available. Study investigators should have priority access for data analysis and publication of results.

Session 2—Conceptual Models

Gitanjali Taneja, Ph.D., Project Officer, National Children’s Study

The NAS report states that conceptual models were not well articulated in the Research Plan. There was an overemphasis on disease and impairment relative to health and functionality and an overemphasis on risk factors relative to protective health-promoting factors. There was a conflict between “healthy development” and the “deficit model” of disease. The NAS panel recommended that the Study clearly define the key constructs of child health and development and more fully develop a conceptual framework for understanding child health and development over the course of infancy, childhood, and adolescence.

In *Children’s Health, The Nation’s Wealth*, the Committee on Evaluation of Children’s Health (NRC and IOM, 2004) describes three domains of health:

- Health conditions
 - Disease, impairment, injury, and symptoms
 - Important to measure incidence and prevalence
 - Clustering of health conditions
- Functionality
 - Physical, cognitive, emotional, and social functioning
 - Functional status measures
- Health potential
 - Competency
 - Resilience.

With regard to health conditions, the Study’s Research Plan focuses on health outcomes delineated in the Children’s Health Act of 2000, including obesity, asthma, autism, and injury. The Study will gather data on comorbidities and clustering of diseases, as well as data on behavioral and emotional disorders. The Study acknowledges that an emphasis on accumulation of risk is needed.

With regard to functionality, other studies have generally focused on limitations related to performance in school or ability to play. The Study recognizes the importance of assessing physical, cognitive, emotional, and social functionality. Mental health should also be assessed. The Study is looking at incorporating functional status measures into the protocol (for example,

adapting Stein and Jessop's Functional Status II and adding measures that can capture the full range of functioning).

With regard to health potential, it is challenging to succinctly define and to operationalize. Two aspects of health potential are competency and resilience. Competency in some domains will be captured through assessments, including social competence and problem-solving abilities. Resilience includes recovery from physical illness and the ability to deflect adversity and thrive in the face of adversity.

To more clearly define the key constructs of child health and development and more fully develop its conceptual framework, the Program Office will continue to discuss the Study's conceptual framework, review the protocol for measures of health potential and resilience, and identify gaps. The Program Office—in collaboration with the Study Center investigators, federal scientists, and outside experts—could convene working teams on child development. These teams could focus on (1) neurodevelopment and cognition and (2) adult psychosocial, child socioemotional, and behavioral assessments. Dr. Taneja asked the NCSAC for their advice on operationalizing and measuring health potential.

NCSAC Discussion and Recommendations/General Discussion

- Dr. Fleischman asked whether the Study's Research Plan places too much emphasis on the health deficit model and not enough on a health promotional model. Dr. Scheidt replied that there is not so much an overemphasis on disease but an underemphasis on conceptual models of positive development because acceptable hypotheses could not be developed. The Study was started because of concerns about environmental exposures that lead to diseases such as autism, diabetes, and cerebral palsy. The Study is interested in what makes children normal, healthy, and prosperous, but the challenge is conceptualizing positive, healthy development.
- Dr. Lebowitz commented that the response to the NAS panel is appropriate. He agreed that the Study needs to develop a clearer conceptual framework.
- Dr. Jarvis noted that one determinant of a functional outcome is the child's parents. He cited the example of a parent's perception of the severity of juvenile rheumatoid arthritis symptoms in a child. Disease-oriented models have limits.
- Dr. DuPlessis said it is challenging to operationalize health potential and define optimal health and development. There are other conceptual models to consider, for example, ecological models (that is, neuromaturational versus transactional models of development). Dr. DuPlessis commented on the three levels of stress (routine, moderate, and toxic) and the impact they have on both affirmative development and deficits. Measuring levels of stress could be incorporated into the Study's data collection.
- Dr. Fleischman said the Study must balance between gathering in-depth information on the etiology of diseases such as juvenile rheumatoid arthritis, obesity, and autism while concurrently assessing complex outcome measures that allow for optimization of functionality. There are both data collection and analytic challenges for these approaches.

- Dr. Henry noted that the two conceptual frameworks (the deficit model and the health promotion model) are not mutually exclusive. One can be used to inform the other. Both models have a role. Dr. Fleischman commented that there are good measures for health deficits but fewer and less validated measures of health promotion.
- Allen Dearry, Ph.D., said that the NIEHS primarily looks at environmental factors and how they lead to diseases. Potentially health-promoting factors and how they lead to healthier outcomes are generally not examined. NIEHS has a biomedical orientation in its research activities. NIEHS has begun to assess communities' assets to determine the strengths, resources, and measures of resilience.
- Dr. DuPlessis said there is an increasing body of literature showing that physicians influence only about 15 percent of overall health status. Therefore, the Study should not overly focus on the medical sector.
- David J. Schonfeld, M.D., said there are other conceptual models, such as the biopsychosocial model, that suggest biological, psychological, and social variables all play a role in health status.
- Liliana J. Lengua, Ph.D., said there is extensive literature in the psychosocial research area that describes various models of resiliency and protection. Many of them can be used by the Study to assess risk factors and factors that contribute to resiliency and protection.

Dr. Fleischman summarized the NCSAC's discussion:

- The NCSAC agrees with NAS panel's recommendation to consider a broader conceptual framework.
- The NCSAC encourages the Study's direction as presented by Dr. Taneja as well as integrating the health deficit and health promotion models in a meaningful way. The Study should better articulate this issue in future protocol development.

Session 3—Ethical Issues

Dr. Fleischman, M.D.

The NAS panel made three recommendations regarding ethical issues:

- The Study should define the criteria and processes for deciding what individual clinical and research information, such as environmental assessments, test results, and survey scales, will be given to children and their families.
- The Study and non-Study investigators should be given equal access to the full Study data as soon as they are cleaned and documented. To protect respondent confidentiality, all analyses should be performed with the kind of strict safeguards used by the Census Bureau research data centers.
- The Study should engage communities in selected study implementation, data analysis, and data interpretation activities that go beyond recruitment. The Study should consider requiring every Study Center to formulate a more detailed plan to engage and collaborate with local communities.

In response to the first recommendation, the NCSAC and Program Office recognize that there is a diversity of opinion in the literature on the issue of revealing findings to individual participants. The Study will routinely return data of clinical interest and relevance, including, for example, anthropometric measures and blood pressure. There will be a process for “red flag” or emergency revealing of findings in a timely manner when there are findings of immediate clinical importance. Many measures will have unknown clinical relevance and no known “actionable” levels of exposure. For many environmental measures, the Study will not know the clinical relevance and what levels of exposure require action. The Study has created two mechanisms for addressing issues of revealing findings. The Sample Oversight Committee will review requests for delayed analyses of samples, and the Data and Safety Monitoring Committee will review reporting decisions.

In response to the second recommendation regarding protection of confidentiality, there are issues about the de-identification of participants. Although there are many variables for an individual, the possibility of reidentification may exist. Therefore, the Study should be at the cutting edge of understanding what is possible and should be committed to protecting confidentiality; however, the Study may not be able to protect against illegal activities. A Data Access and Confidentiality Committee has been convened to address these issues. The Study will balance the maximizing of scientific analysis with the full protection of participant confidentiality. This balance will always be challenging, and the Study should always use current best practices.

In response to the recommendation on community engagement, the Research Plan did not adequately reflect all of the work that has been done by the Program Office, the NCSAC, and the Community Engagement and Outreach Subcommittee. Much of this work has occurred in the last 2 years. In addition, the Research Plan did not adequately reflect the Study’s commitment to community engagement and the extensive involvement of communities in the Study. All Study Centers do or will have community advisory boards and are engaging their communities in meaningful ways. The Study has developed community representation on the Steering Committee, the Executive Steering Committee, and the NCSAC. The Program Office will identify a senior staff member to deal extensively with community outreach and engagement and provide technical assistance to Centers.

NCSAC Questions, Comments, and Discussion

- Dr. Genel said there is a tension between determining which findings are clinically relevant and what useful information should be provided to participants. The answers are currently not known but will emerge. There needs to be ongoing oversight, not a preset policy. Questions remain about to whom the Study will release information (for example, to the primary care provider or directly to the participant). Findings could be revealed simultaneously to both, provided there is written permission to do so.
- Benjamin S. Wilfond, M.D., said the Sample Oversight Committee and the Data and Safety Monitoring Committee are exactly what are needed to respond to the NAS panel’s recommendation regarding the revealing of findings.

- Dr. Jarvis asked, given the high number of samples that will be collected and the many categories of tests and analyses, whether it will be possible to reveal findings in a timely manner. The samples may be stored and the analyses delayed. It may not be possible to review findings in real time.
- Dr. Genel noted that because the Study is a long-term observational study, it may not be possible to “mine” the data in real time and provide clinically relevant and actionable findings back to participants. Many of the findings will be incidental.
- Dr. Wilfond said that unless the Study investigators are looking for a particular outcome, there will be a lag time between data collection and determination of clinically relevant findings. There is the issue of the obligation to look for things versus obligations to report what is known.
- Dr. Henry commented that one of the challenges for the Sample Oversight Committee and the Data and Safety Monitoring Committee involves the biomonitoring of chemicals. For many chemicals, neither clinical significance nor actionable levels are known. There is the issue of revealing findings when nothing can be done about the findings. Participants may be concerned about revealing information that an insurance company might use.
- Dr. Scheidt said all Study Centers are required by contract to deliver a community engagement plan. All current Vanguard Centers and wave 1 Study Centers have developed such plans. A comparative analysis of the plans has been completed, and the results will be reported to the Steering Committee.

Session 4—Health Disparities

Christina H. Park, Ph.D., Project Officer, National Children’s Study

The NAS report cited insufficient attention to racial, ethnic, and other disparities. According to the report, the research design was not informed by a concern with understanding the basis of disparities,; there were no hypotheses on racial and ethnic disparities,; and no attention was paid to generating data on factors that are important in studying health disparities, such as interaction with health systems and psychosocial experiences. The NAS panel recommended that the Study seek ways to bolster its ability to contribute to the understanding of health disparities by reestablishing a working group on health disparities and encouraging appropriate adjunct studies.

The Study recognizes that health disparities are a major concern, as directed by the Children’s Health Act of 2000. The Study’s large, representative sample and longitudinal collection of environmental and genetic data provide a unique opportunity to study health disparities in a comprehensive way. The Study’s past developmental work included the Health Disparities Working Group and the Health Services Working Group.

The Study understands that there are multiple pathways to health disparities through differential exposures and mediators by different population subgroups. Risk factors are at both the individual level and the community level. In the Research Plan, health disparities are considered

to be an overarching concern applicable to all hypotheses. Race, ethnicity, socioeconomic status, and geographic variables (for example, rural versus urban environments) are recognized as important confounders or effect modifiers in many exposure–outcome relationships. Many important factors needed for health disparities research are embedded in the data collection plan.

Although many determinants of health disparities are currently included in the Study, further work is needed to include measures that are missing or lacking (for example, health care access and quality measures, psychosocial measures), determine the adequacy of level and specificity of measures (for example, parental measures, age-appropriate child measures), and develop or adopt analytic models to study mechanisms involved in health disparities.

To address health disparities issues in the Study, a Health Disparities, Access, and Utilization Working Team with Program Office, Coordinating Center, and rotating Steering Committee members is currently being formed. The working team will draft a longitudinal plan of measures that should be collected through the life of the Study and identify important subdomains for each age period. Smaller subdomain expert working teams from a pool of Steering Committee experts will be convened as necessary to develop protocol measure recommendations specific to each age period.

Dr. Park offered the following topics for discussion:

- Research questions on health disparities that can be addressed by the Study
- Conceptual model on health disparities appropriate for the Study
- Biomarkers for stress or psychosocial exposure
- Guidance on the working team’s approach
- Ideas for adjunct studies.

NCSAC Questions, Comments, and Discussion

- Dr. Jarvis said much information on biomarkers of stress will come from animal studies. Biomarkers might include histone acetylation, gene methylation, and micro RNA expression. Research will reveal that there is a large biological component in how people react to stress. There is an ongoing retrospective study called the Adverse Childhood Event Study sponsored by California Kaiser Permanente. Findings from this study should be able to inform what the Study does prospectively.
- Dr. Fleischman said the Study has an opportunity to observe a changing health system. The Study should be able to collect data on how system changes affect health disparities. Dr. Fleischman mentioned an IOM report on the physician communities’ role in medical racism. The Study may want to consider collecting data on participant perceptions of physicians’ attitudes and practices in terms of health disparities.
- Dr. DuPlessis noted that geographical location is an important determinant of health disparities.
- Dr. Currie explained that studies of health disparities are enhanced through geocoding. Data from different sources can be merged. For example, information on a mother’s residential

address can be combined with information on surrounding environments and environmental exposures. Study data could be merged with outside data, but only if there is geocoding.

- Dr. Diez-Roux said it is important to define health disparities. She encouraged the Study to think broadly about health disparities. Not only should racial and ethnic differences be considered but also social inequality and economic disparities. The working team should begin thinking about all of the potential domains that may contribute to health disparities, the key elements of the domains, and reasonable measures for the key elements.
- Dr. Fleischman commented on recent findings from animal studies on the biology of prematurity and potential genetic reasons for disparate outcomes. There are multiple factors that create disparate outcomes. The Study will need to think prospectively in developing the analytic plan for considering health inequities before determining measures of health disparities.
- Dr. Henry said access to health care is a key element in health disparities. She asked whether there is a mechanism within the Study to compare locations that have different access to and availability of health care and to compare access/availability of care with utilization of services. Dr. Scheidt answered that the Study will be collecting maternal self-report data on health care access, availability, and use. In addition, administrative databases could be merged with self-report data.
- Dr. Lebowitz noted that there is substantial literature on differential exposures and differential health care related to race, ethnicity, and socioeconomic status. Recent studies have shown that even with the same insurance, disadvantaged groups do not have the same access to and utilization of health care for a variety of reasons. A number of subhypotheses could be developed on health disparities.

Dr. Fleischman summarized the NCSAC's discussion:

- The NCSAC is pleased that the NAS panel reminded the Study of the critical nature of the problem of health disparities.
- The NCSAC is pleased with Dr. Park's input and the reestablishment of mechanisms to further examine health disparities issues.

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I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

09-15-08

Date



Alan R. Fleischman, M.D.

Chair

National Children's Study Federal Advisory Committee