

**National Children's Study
Federal Advisory Committee 32nd Meeting
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Natcher Conference Center, National Institutes of Health
Bethesda, MD**

The National Children's Study (the Study) is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners. Study partners include the National Institute of Environmental Health Sciences (NIEHS) of the NIH, the Centers for Disease Control and Prevention (CDC), and the Environmental Protection Agency (EPA).

Welcome and Introductions

Patricia O'Campo, Ph.D., Chair, National Children's Study Federal Advisory Committee (NCSAC), Centre for Research on Inner City Health, St. Michael's Hospital, University of Toronto

Dr. O'Campo introduced herself as the new NCSAC chair and welcomed the meeting participants, who introduced themselves.

Opening Remarks from the Director of NICHD

Alan E. Guttmacher, M.D., Director, NICHD, NIH, Department of Health and Human Services (HHS)

Dr. Guttmacher described the current status of the Study's sampling frame and its future direction. Based on the experience of and data from the seven original Vanguard Study locations, the Study's sampling frame has shifted from a door-to-door, household-based strategy to a provider-based model for recruitment. The most appropriate sampling strategy or strategies to further develop for the Main Study have not been determined. Seven potential sampling strategies have been proposed:

- Geographic-based probability sample of prenatal care providers
- Geographic-based probability sample of prenatal care providers supplemented by a second probability sample from an administrative list frame
- Convenience sample of prenatal care providers
- Convenience sample of prenatal care providers supplemented by a second convenience sample
- Convenience sample of prenatal care providers with a supplemental geographic-based probability sample
- Probability-based prenatal care provider sample supplemented by a convenience sample
- Prenatal care provider convenience sample with a nested geographic-based probability sample, which could be supplemented by another convenience sample.

Although the provider-based strategy may be considered an appropriate primary recruitment strategy, relying on this single strategy may not be able to address health disparities, as mandated by the Children's Health Act of 2000. The provider-based strategy would not be able to recruit women who do not have health care providers. The subpopulation of women and children

without health care are most likely to suffer health disparities. Supplemental sampling strategies will be needed to recruit this subpopulation.

The purpose of this meeting is to discuss and identify the characteristics, factors, assets, and liabilities of potential sampling strategies for the Study's sampling frame. Additional meetings will be held with the Study's contractors, federal statisticians, and the Study's federal partners. The final decision for the Study's sampling frame will be made by the Steven Hirschfeld, M.D., Ph.D., Director, National Children's Study; Dr. Guttmacher; and Frances Collins, M.D., Ph.D., Director, NIH. Based on input from the advisory groups and analysis by the Study's Program Office, a sampling strategy that will be incorporated into the protocol and future Requests for Proposals (RFPs) will be drafted and submitted to the Office of Management and Budget (OMB). Once the design concept is approved by OMB, the RFPs will be developed and publicly posted.

Opening Remarks from the Director of the National Children's Study

Steven Hirschfeld, M.D., Ph.D., Director, National Children's Study, NICHD, NIH, HHS

Dr. Hirschfeld introduced and thanked NCSAC members, NCSAC ad hoc participants, and guest experts. He stated the meeting's expected outcome is not selection of the Study's sampling frame but exploration of the characteristics—advantages and disadvantages—of a range of options for the Study's sampling frame or frames, which may use different recruitment strategies. Guidance is being sought on the most important characteristics that must be included in the Study's final sampling frame. For example, a characteristic that allows generalizability of certain findings may be important and desirable. Design characteristics of geographically based studies such as the Avon Longitudinal Study of Parents and Children, the Project Viva study, and the CANDLER Study may be able to inform the advantages and disadvantages of Study sampling frame options. The Study's sampling frame may want to include characteristics that are not in these other studies. Design characteristics that allow inclusion of certain subpopulations should be considered. There may be characteristics that should not be minimized or avoided because they would not allow the Study to reach its sampling goals. Another meeting outcome is to identify a set of reasons and some type of weighting or hierarchy of reasons as to what would make an acceptable Study design.

Advantages and Disadvantages of Proposed Sampling Models for the Main Study

Discussant: Edward J. Sondik, Ph.D., NCSAC Ex Officio Member, Director, National Center for Health Statistics, CDC

Dr. Sondik explained that a meeting of federal epidemiologist and statisticians was held on March 22 to discuss the Study's potential sampling frame. The meeting participants agreed that details on the sample are needed to address the issues. The Study's goal is to conduct a longitudinal data collection effort monitoring children's health to understand the environmental factors—physical, chemical, biological, and psychosocial—that may influence health. The key to this effort is understanding the nature of the sample. The current sample is considered to be representative of demographic and environmental factors. It is assumed that the environmental factors of a probability-based sample will be included. However, environmental factors may be clustered across the country. The sample was not chosen with respect to specific environmental

exposures. these clusters. In evaluating changes to the sampling frame, the sample from the provider-based strategy needs to be compared with the sample from the household-based strategy. There may be biases in the provider-based strategy that exclude certain children or certain environmental factors.

Dr. Sondik expressed his opinion that a convenience sample will not fulfill the Study's goal and will not inform the sampling biases. He noted that large-scale clinical trials are not "the usual science" because they are not repeated. Similar to a clinical trial, the Study is not going to be repeated, at least on the same scope. A question remains: How good is the sample? Another question was raised at the March 22 meeting: What is the population that is being studied? A third question relates to the percentage of preconception women who the Study wants to recruit. It is possible that the desired percentage recruited may not be met through the provider-based strategy and that some of the Study's hypotheses may not be addressed. It may not be possible to analyze certain factors to answer specific questions. It is not known at this time whether a provider-based sample would be close to a representative sample. Given the range of providers, it is also not known what a representative set of providers would be and how they would be chosen. Differences between a provider-based sample and a representative sample may include prevalence of health conditions, attrition rates, and environmental exposures. Potential differences need to be considered in designing the sampling frame.

At this time, it not known whether the use of electronic medical records (EMRs) would be an advantage or disadvantage. Providers' roles may be limited to identifying eligible women or could be expanded to actively conduct exams and collect data. The role of providers needs to be considered in designing the sampling frame. If providers collect data, the quality of EMR data may be an issue. The use of EMRs may be an advantage but would require enrolling and training providers, which may be a burden on them.

Although the provider-based strategy would be an efficient way to identify eligible women, birth certificate data have shown differences in the percentage of women who first receive prenatal care in the first trimester, those who first receive care in the second trimester, and those who receive no prenatal care. These percentages vary by age and race/ethnicity.

Dr. Sondik expressed concern about the generalizability of a convenience sample and whether the scientific community would accept a convenience sample for the Study. He recommended constructing a simulation model to examine the range of environmental exposures and determine the probability that a given sampling design would be able to detect an exposure–outcome relationship for a given hypothesis with sufficient power.

Discussion Championed by NCSAC Member

Alma Kuby, M.B.A., M.A., Survey Methodologist

The role of an NCSAC member discussion champion is to ensure that all NSCAC members have an opportunity to provide input. The champion will summarize the discussion and convey any NCSAC recommendations. Dr. Kuby reviewed the seven proposed sampling strategies listed above. Two of the strategies are probability designs, two are convenience designs, and three are hybrid designs. Advantages and disadvantages for each potential strategy were listed. Dr. Kuby

asked the discussants to focus on the advantages and disadvantages, given the context of each strategy.

- Joseph Andrew Konstan, Ph.D., expressed several concerns. First, critical exposures and environmental factors over the next 20–25 years are unknown. The geographic distribution of the Study’s currently proposed 105 locations may not be able capture the full range of exposures and factors compared with a much broader, true nationally representative sample. Dr. Konstan said the unknowns are not known. The second concern is the correlations between exposures of interest and the success of provider-based recruitment. He asked whether consent rates of young women who lived with their parents were different from those of women who did not in the household-based strategy. The provider-based strategy may affect—either positively or negatively—the ability to recruit young women who live with their parents. A third concern is the correlation between consent via provider and the type of care being provided. For example, midwives may be less cooperative in helping to recruit compared with physicians who have training in medical research. Differences among providers’ willingness to cooperate may bias the type of women who are enrolled. Dr. Konstan asked whether other ways to validate the quality convenience sample were explored (for example, the use of early pregnancy tests at medical labs and inserts in over-the-counter pregnancy tests).
- Dr. Hirschfeld noted that Study data show that the provider-based strategy tends to enroll women who are younger compared with other strategies. There are no data on the effects on recruitment of whether a woman lives with her parents.
- Robert L. Brent, M.D., Ph.D., D.Sc., commented that costs are a key issue in the Study’s ability to implement certain sampling strategies and collect all of the data it would like. He emphasized the importance of collecting and storing as many samples as possible, particularly cord blood, for retrospective analysis. Dr. Brent questioned the use of resources and utility of collecting data from women before they are pregnant. He noted that if blood is not collected before the 20th week of pregnancy, the Study will not be able to collect data on miscarriages that occur before the 20th week and environmental factors related to birth defects. The most sensitive time for pregnancy is the first 14 days after conception. He asked what blood tests the Study is currently doing and what blood tests will be done later.
- Dr. Hirschfeld explained that there were technical issues with the storage of cord blood, which have since been addressed. Blood and other samples cannot be collected until the woman is enrolled and allows sample collection, for example, at the 20th week of pregnancy. The Study plans to “front load” data collection, that is, collecting as much data and as many samples as possible during pregnancy and early childhood. The rationale for the preconception cohort is to enroll women who may become pregnant in order to evaluate them early in pregnancy. It is estimated that about 15 percent of the women enrolled in a preconception cohort will become pregnant over a 2-year period.
- Narayan Sastry, Ph.D., said one of the factors that will affect the sample is migration/population movement and its effect on the ability to understand geographic and environmental exposures. A simulation study may provide valuable information on the range

of distributions across different geographic and environmental areas. The Study should be committed to following women and children who move out of Study areas.

- Warren Strauss, Sc.M., commented that an issue with a convenience sample is selection bias versus response bias. Provider-based sampling will be able to enroll people with access to Medicaid and the Women, Infants, and Children (WIC) program and those with health care coverage through their employer. Using provider-based sampling, the Study is at risk of missing the working poor, that is, those without health care benefits. An issue with a nationally representative probability-based sample is the distinction between gathering data on the prevalence of disease and environmental exposures and determining the relationship between disease prevalence and exposures, that is, how exposures lead to disease. If the Study is gathering data on prevalence of disease and exposures, it is imperative to use a probability-based sample with appropriate weighting. Dr. Strauss expressed his preference for a probability-based sample because of his belief that exposure is the intersection between human behavior and the environment. A representative sample would be able to capture the range of behaviors in a population. He noted studies such as the Framingham Study have shown the value of a nonrepresentative sample. He asked for clarification on what the Study is trying to sample (that is, pregnancy, women, or children). Dr. Strauss said simulation studies have shown that clustered sampling does allow inferences to be made about the relationship between exposure and disease.
- Sharon Wyatt, Ph.D., described the Framingham Study as the “grandfather” of epidemiologic cohort studies. The study represented a small area of the U.S. population and did not include minorities and ethnic subpopulations. Subsequent studies were designed to include these other subpopulations. These other studies include the Honolulu Heart Program, the Strong Heart Study, and the Jackson Heart Study. However, none of these studies has a full probability sample. These studies, as well as the Bogalusa Heart Study, can help inform the Study’s sampling design.
- Bruce D. Gelb, M.D., asked for clarification on the type of EMR data that will be collected and the role of providers in collecting data on children.
- Dr. Hirschfeld explained that one approach is to identify mother and child through referral networks or within the same care system. The Agency for Healthcare Research and Quality and the NIH have successfully engaged different types of providers, particularly those in clinics or family practices, and gained access to EMRs across a spectrum of populations. However, because care providers use different EMR systems and there are no national standards, EMRs need to be abstracted. The Study could use providers as a means of entry into the Study and then engage a team for primary data collection. EMR data collected through health care providers could be analyzed for consistency, calibration, and quality control to better understand the EMR data that are being collected. Using EMR data would allow resources to be redirected to collect additional primary data and therefore extend the scope of the Study. Providers would not collect primary data but would collect data in routine health care delivery that would be of interest to the Study.

- Dr. Gelb expressed that using health care providers may introduce some unintended selection bias. He also noted that the use of pre-existing medical records could lead to highly variable data quality and gaps.
- Dr. Konstan asked whether the Study has explored the possibility of working with insurance companies, which might allow more efficient data access.
- Jeffrey Krischer, Ph.D., said an alternate sampling design would be to consider all births as a prospective cohort, sampling from hospitals, not providers directly. Birth is the key access point, but certain types of prenatal data could be collected. A woman would enroll at the time of birth. The Study would then follow her and collect prenatal data for a subsequent pregnancy. This design could be conceptualized as two different studies. He noted that the Vanguard Study established the feasibility of the alternate recruitment strategies but also showed some biases. Dr. Krischer asked that the data on the alternate recruitment strategies be made available to the NCSAC. He commented on the condition prevalence data tables regarding the effects of the number of events and prevalence of exposure on power calculations.
- Dr. Sondik commented that some type of data analysis of the 3,000 children in the Vanguard Center could possibly provide information on prevalence of outcomes and environmental factors.
- Dr. Hirschfeld explained that the only outcome analyzed for the Vanguard Study so far is the incidence of preterm birth. The incidence in this cohort was somewhat lower than the national average but within the same range. Comparisons of the alternate recruitment strategies included conventional demographic data such as race/ethnicity, marital status, age, education, and household income. A key issue for the comparisons was whether the mode of recruitment influences the characteristics of the women who enroll (that is, whether there is a bias). The reference population frames were the U.S. Census Bureau's American Community Survey and various natality records. Some differences among the recruitment strategies were found. Provider-based recruitment yielded women who tended to be younger, less likely to be married, and less educated than women recruited through the other strategies. Women recruited through direct outreach tended to be married, somewhat older, and somewhat higher educated, factors that do not necessarily translate to higher income.
- Dr. Krischer said the recruitment data can be presented descriptively or analytically. If there are biases or differences in distribution, the weights can be applied to make the recruited population more reflective of the general population. He encouraged the Study to move from a descriptive stage to an analytic stage. Comparisons could be made to quantify the rates of under- or oversampling. He noted that birth certificate data could be used to calibrate any systematic bias.
- Dr. Hirschfeld said the Study has been targeting conditions with a prevalence of 0.5 percent or greater. Rare diseases are those with a prevalence of about 0.06 percent. The prevalence of childhood cancer is about 320 per 100,000. For the Study, the conditions of interest have a prevalence of 0.5 percent to 5 percent in the general population. The conditions in this range

of prevalence have important public health impacts. In addition, the Study is trying to define and measure health using objective quantitative measures.

- Dr. Wyatt noted that factors affecting alternate recruitment strategy data were the length of time the Study Centers were in the field and their ability to operationalize the sampling frames. For example, the provider-based recruitment data for the Hinds County (Mississippi) Vanguard Location do not reflect the location's 10 segments because birth certificate data were used to prioritize which providers were accessed first. Providers that were first identified and prioritized were federally qualified health centers, WIC programs, and health departments. More data were collected from these providers because of their longer participation. Private providers were not fully engaged. As a result, a higher percentage of African-American and low-income women were enrolled.
- Dr. Sondik recommended that independent group review and report on the data. An independent review could provide input in terms of costs and efficiencies of the sampling designs.
- In response to a question from Dr. Strauss, Dr. Hirschfeld explained that issues of provider-based bias in recruiting underrepresented populations can be addressed with supplemental sampling designs, which may not be provider-based.
- In response to a question from Dr. Brent about the preconception cohort, Dr. Hirschfeld said the blood samples are being collected from the cohort but not uniformly. Some resources are invested in collecting samples and data from questionnaires.
- Dr. O'Campo commented that she is part of a study that is focusing on the period between two pregnancies, with the goal of trying to understand exposures before the second pregnancy. This study is part of an NICHD-funded network. The enrolled women were screened for their intent to have second child. It was anticipated that about 30 percent of the women would have a second pregnancy within 3–4 years after the first pregnancy. However, the actual percentage of women who became pregnant was much lower. Dr. O'Campo asked whether the Study would follow Dr. Sondik's recommendation to use simulation models and have an independent review of existing data.
- Dr. Hirschfeld noted that simulation models have been underutilized in designing trials. He said that Study sampling scenarios were previously modeled. A formative research project is currently modeling sampling scenarios. Sandia National Laboratories may provide input on environmental and exposure modeling. A new sampling design model could be developed in about 90–120 days. The Study already has an independent Study Monitoring and Oversight Committee that reviews the data.
- Yolanda Padilla, Ph.D., M.S.S.W., asked whether a nationally representative hospital-based birth cohort such as the Fragile Family and Child Wellbeing Study—which engages children at birth—could supplement the Study. Dr. Hirschfeld said such a birth cohort could be used to supplement the Study.

- Randall J. Olsen, Ph.D., commented on the intracluster correlations of a provider-based sampling design. Providers are associated with transfer programs, state-based support care, or employment arrangements. Study participants will be linked to providers based on their socioeconomic status. Because of this, an intracluster correlation can be presumed. The Study may have to compensate for these provider-based design effects. A sample size of 100,000 may not be necessary. The Study should focus on conducting the best science possible and not be committed to a sample size of 100,000. The Study can, however, use both the population-based representative sample and the tightly clustered convenience sample.
- Dr. Strauss responded to Dr. Padilla's comments about engaging children at birth. The Study's intent to capture exposures before and during pregnancy makes it unique. In response to Dr. Olsen's comments, Dr. Strauss said the Study focus is on exposure-outcome relationships, not disease prevalence. The clustered nature of a provider-based sample has an impact on prevalence estimates, in terms of sample size, but has little impact on the associations of exposure and disease.
- Dr. Sastry recommended that the Study use a nationally representative probability-based sample and not a convenience sample. He said that power calculations are needed for disease prevalence to determine whether a sample size of 100,000 is needed. If cost containment is an issue, a convenience sample size of 50,000 may be adequate, depending on the power calculations. However, there are a variety of strategies to contain costs, other than using a smaller convenience sample size.
- Robert Kaplan, Ph.D., noted that the Study offers an unusual opportunity and ultimately will provide valuable information about children's health. He explained that there are three issues regarding inferences made from studies. First, inferences are made about the distribution and prevalence of disease in populations, which requires random sampling. The unit of variability of interest is people. Second, the units are replicates, and therefore, there is less interest in the variability between people than the effects of exposures. Third, there will be the unique combinations of people and exposures and interactions among exposures, behaviors, and outcomes. Benefits of the Study to be optimized are based on budget and inferences about the Study population. Alternatives to probability and convenience samples include multilevel designs and oversampling certain subpopulations. Regardless of design, the use of EMRs needs to evolve.
- Adda Grimberg, M.D., listed two areas of concern: (1) mobility/migration and its implications for long-term retention and (2) the use of practice-based sampling as a surrogate of patient characteristics. There may not be strict correlations among provider location, practice characteristics, and patient characteristics. Children may not stay in the same provider network that the mother was part of during pregnancy. Without standardization across providers, the quality of the health measurements will be an issue, particularly with EMRs. Data collection at 2-year intervals beginning when a child is 5 years old may be problematic in capturing developmental information during the onset of puberty. Information may be missed with such a longitudinal approach.

- Dr. Hirschfeld explained that the Study is concerned about missing events if data are collected every 2 years. A flexible approach where some of number of visits will occur within some timeframe has been considered. For example, subgroups could be staggered 6 months apart. One subgroup would begin the 2-year collection interval at 5 years of age, another at 5½ years of age, and another at 6 years of age.
- Martha Linet, M.D., M.P.H., said the challenges of a national probability-based sample include identifying and enrolling participants, achieving high participation rates, and capturing comprehensive data. Key issues are maintaining participation and retention and variability in participation and retention in subpopulations. Generalizing results will be challenging if certain subpopulations have lower retention rates. In the United States, participation rates of healthy children and their families in epidemiologic research have been dramatically declining for years. As a result, study populations tend to be better educated with higher socioeconomic status. For the Study, maintaining high participation rates and retention of all subpopulations are critical.
- Dr. Konstan said the Study is attempting to include four dimensions: inexpensive, representative, large, and deep. All four cannot be included. It is assumed that the Study's budget will not be increased. Therefore, tradeoffs among the other three dimensions will be necessary. Other data sets, such as U.S. Census survey data, could provide broad data to augment Study data, but they do not provide depth. The Study should consider trading off sample size to achieve more depth. Sample size is not as critical as detail, depth, and representativeness.
- Dr. Sastry commented that comparative data sets—particularly from longitudinal studies—to supplement the Study do not exist.
- Dr. Brent asked about the Study's mandate to follow children to 21 years of age and the expected attrition rate from 15 years to 21 years and whether the loss of these participants would undermine the value of the Study. The Study might benefit from spending more resources earlier in childhood. He said that sample size is important, depending on what the Study is looking for.
- Dr. Olsen commented on the National Longitudinal Survey of Youth (NLSY), which has been following mothers and perinatal experiences since 1979. In 1986, the NLSY began assessing its study's children. This study showed attrition rate when the children turned 18 was low. Because there are risks in following a cohort of 100,000, compromises may be necessary. It may be better to follow a smaller cohort, focusing more on tracking and retention, to achieve greater detail and depth.
- Dr. Hirschfeld explained that the Study is not committed to a sample size of 100,000; this sample size is a target but is not yet fixed. He clarified that the Children's Health Act mandates that children be followed from birth to 21 years. The Food and Drug Administration Amendments Act of 2000 defines a child, for research purposes, as 0–21 years of age. The Study follows this definition.

General Comments and Discussion

- Michael Bracken, Ph.D., M.P.H., commented that, in randomized clinical trials (RTC), it is important to control for unknown confounders, not nonconfounders. Probability-based sampling does control for unknown confounders. For an effective therapy in an RCT, the number needed to treat depends on the risk of the population. The number needed to treat for an effect in a high-risk population is low. For a low-risk population, the number needed to treat to get an effect is high. The same holds true for the National Children's Study. In a probability-based sample, the effect of an environmental exposure on an outcome can be determined by removing that exposure from the population. However, in a convenience or bias sample, the effect of removing the exposure from the population will be biased and will not give accurate estimates. Conclusions drawn from a national sample must be valid. The study of interactions also depends on an unbiased sample. Dr. Bracken explained that there has been a great investment in the Study so far; before creating a new sampling frame, this investment should be utilized. Providers are convenient, but they can be developed into a national probability sample. The providers must be studied in great detail, which requires local knowledge of the Study locations. There is no evidence that population-based samples are more expensive for recruitment and retention than a convenience sample. Provider-based sampling and household-based sampling have a similar bias: Women who are hard to reach through providers are also hard to reach through households. The use of administrative data from providers is not adequate. Hypotheses cannot be addressed without high-quality data. Specific disease phenotypes are needed, not phenotypes that may be broadly grouped by providers. The Study needs to be able to estimate prevalence and exposure-outcome associations. The Study must be a prenatal study; another birth study is not needed. Preconception women should be a different cohort, and sampling frames should be developed for both preconception and pregnant women. Using meta-analyses depends on the quality of data. In some cases, there may be only a few high-quality meta-analyses that are suitable to address specific hypotheses. With regard to the Study's sample size, a sample size of less than 100,000 would constrain the types of questions that could be answered.
- Carol J. Hogue, Ph.D., M.P.H., explained that she was involved with the alternate recruitment strategy as the principal investigator (PI) of Emory Battelle Morehouse Chattanooga Study Center. She endorsed Dr. Sondik's recommendation to evaluate the alternate recruitment strategies with sufficient depth to better understand the differences among the strategies with respect to household-based recruitment and costs. The data suggest that the number of pregnant women enrolled is about the same, irrespective of the recruitment strategies. Cost savings of provider-based recruitment were only in the number of women contacted per number enrolled, which was expected. But to give up a probability sample based only on the amount of time to enroll the same number of women requires more detailed examination. In-depth information on the conduct of the alternate recruitment substudies from all 37 Study location needs to be collated, compared, and presented to the NCSAC so it has enough information to provide advice to the Study.
- Christine A. Bachrach, Ph.D., said she is representing the Population Association of America (PAA) and the Association of Population Centers (APC). These affiliated associations consist of more than 3,000 members and 40 U.S. research centers. The PAA and APC have

supported the Study since its inception because of its potential for interdisciplinary research. Her statement focused on general design issues that are critical to the two associations. The Study's value to the PAA and APC depends on two essential elements: the use of probability sampling methods and development of a sampling frame or frames that will capture the population of U.S. births with full representation, including immigrant families and other vulnerable populations such as the uninsured. Geographically based sampling will reach the goal of full representation. If a provider-based sampling frame is adopted, the PAA and APC recommend that the Study devote substantial resources to designing it so it can demonstrably capture all U.S. births. If the provider-based sampling frame cannot meet such standards, the PAA and APC urge the Study to consider a dual-frame approach that would select a portion of the sample through a geographic area probability frame. Tradeoffs in sample size would be supported.

- Neil Halfon, M.D., M.P.H., described the history of his involvement with the Study. He is a PI with the Los Angeles–Ventura Study Center. He posed two questions: How does the Study become a national resource? Why is the Study needed? He explained that the United States invests less in its children than do other advanced industrialized countries. The United States has some of the worst child health outcomes compared with these other countries. There are larger health inequalities in U.S. children, which projects into adulthood. The United States is facing runaway health care costs, increases in chronic disease, and an enormous need to shift both health and cost curves. The period with the greatest leverage to shift the health curve is during childhood. Significant changes can be made by focusing on childhood. The Study must be a resource not only for epidemiologists and demographers but also for policy makers and children and families. The Study must use a probability design to become a national resource and to shift the child health curve. The Study needs to look at both population-attributable risk and relative risk and carefully characterize children's environments. Using a provider-based sampling frame may mean that the Study could potentially lose the ability to sample children's environments in sufficient depth.
- Dr. Brent asked about the Study's plans for storing and testing blood samples. He said there is controversy about the impact chemicals on human biology. He explained that the Ames test can be used to predict whether an agent is mutagenic using a *Salmonella* culture with reverse mutation. According to Bruce N. Ames, Ph.D., there may be more mutagens in foods than chemical mutagens in the environment. Dr. Brent asked whether the Study has a protocol to analyze Study participants' diets. In the *Toxicology in the 21st Century: A Vision and a Strategy* report, the U.S. Food and Drug Administration (FDA) noted that there are 850 additives in U.S. food products. The FDA does not require toxicity testing of food additives if their concentration is less than 5 parts per billion. Dr. Brent asked whether food additives would be tested in Study blood samples. Dr. Brent commented that there are existing tests for chemical exposures such as a patch test for alcohol consumption that do not require blood samples. The Study could incorporate these tests into its protocol.
- Dr. Hirschfeld replied that the Study is interested in diets and chemical exposures. Consideration has been given to the types of biological samples that could be analyzed immediately and those that could be stored for future analyses. Analyses of diets and food

additives can be discussed in future meetings. However, the Study's current focus is on the sampling frame.

- In response to a question from Meredith Wadman of *Nature News* as to whether the Main Study sampling frame will include all of the currently proposed 105 sites, Dr. Hirschfeld said the decision to include any of the Study's 105 locations will be guided by the science. The final determinant should not be finances. However, the Study will operate within the budget approved by OMB and authorized by Congress. At this time, it is not known which locations will be in the final sampling frame. However, the 40 locations of the Vanguard Study have been established. The populations in these locations will be followed for another two decades or so.
- Jennifer Culhane, Ph.D., PI from the Children's Hospital of Philadelphia Study Center, said the seven original Vanguard Centers are in the process of discontinuing their Study activities and the infrastructure that was developed will be shut down. Once the activities have stopped, it will be challenging to re-engage communities, community-based organizations, prenatal providers, and delivery hospitals and reinstitute the Study at the seven original Vanguard locations.
- Dr. Konstan noted two intertwined issues: how the Study is selecting participants and how the data are collected from the participants. Once the sampling frame is determined, the issue of whether providers will collect data needs to be addressed. If the role of providers is to simply identify participants, Study researchers should collect data.
- Dr. Hirschfeld said provider engagement would be a vehicle to identify participants. Although the providers could be passive partners, the formal research data would be collected by Study contractors. There will be specifications and standard operating procedures for data collection. The use of EMRs from prenatal and childcare providers is a technical issue regarding the credibility of the data. Dr. Hirschfeld acknowledged the challenges for measuring child growth and development. He commented on the three options for contacting potential Study participants (the household approach, direct outreach, and provider-based approach) and described some of the issues for each option.
- Dr. Konstan asked how much is paid annually to a Study Center that is responsible for two or three Study locations.
- Dr. Hirschfeld responded that although the amounts spent to date are known, the best way to conduct the Study has not been established. Many of the Study Centers have conducted other types of studies and work with universities that have existing resources. Of the 36 Study Centers under contract, 28 are members of the NIH-sponsored Clinical and Translational Science Awards consortium, which has developed expertise and infrastructure. The Study Centers under contract were encouraged to explore procedures and methodologies for implementing a large complex study such as the National Children's Study. About 60 percent of the Study Centers engaged contract research organizations to help develop and implement operations. The heterogeneous approaches used by the Study Centers for operation, informatics, and recruitment allowed a broader investigation of potential ways to conduct the

Study. Operational data elements were introduced into the Vanguard Study protocol to standardize data collection of specific operational elements. Last year, based on discussions with the NCSAC, the Study instituted a new approach to provider-based sampling in which certain constrictions were removed, such as geographic secondary sampling units and requirement of participants to remain at the same address within the same segments. Three Study locations have implemented a new approach in which the primary sampling is still geographically based but the secondary sampling unit is the health care provider. The efficiencies, performance, kinetics, and costs will be evaluated for this new approach. Recruitment data from this provider-based approach will be used to make cost and operational models. Based on the data and projections, new RFPs and specifications will be developed, which will then be used to estimate future costs.

- Dr. Konstan asked how much is at stake for the Study Centers that have a vested interest in potential outcome of a new sampling frame.
- Dr. Hirschfeld explained that new contracts will be awarded, and any organization or institute can compete, but those organizations and institutes that are most qualified are highly encouraged to compete. All current contractors are eligible. The awards will be in the millions of dollars per year per contractor. There will be an open contracting process.

Advantages and Disadvantages of Proposed Sampling Models for the NCS Main Study (continued)

Discussion Championed by NCSAC Member

Dr. Gelb, Gogel Family Professor of Child Health and Development, Professor of Pediatrics, Professor of Genetics and Genomic Sciences, Director, Child Health and Development Institute, Mount Sinai School of Medicine

- Dr. Sastry asked whether parameters other than the potential sampling design—such as the number of Study locations and which organizations will be Vanguard Study contractors—should be considered at this time. The current discussion could provide input on the principles of the sampling frames as well as suggestions and ideas for sample size and efficient ways to generate a sample.
- Dr. Hirschfeld said the current discussion should focus on the depth of potential sampling designs. The Study needs to focus on developing the principles for making a decision on the sampling design. Discussions of strengths and weaknesses, and advantages and disadvantages, of potential sampling designs would provide valuable input for the Study.
- John Bancroft, M.D., PI of the Maine Study Center, said the Study needs to be able to address questions about health disparities. He also said that a provider-based convenience sample will make it more challenging to address health disparity issues. He noted that convenience sampling in rural settings may also be challenging.
- Dr. Strauss commented that, 8–10 years ago, there were two groups advocating different Study designs: medical epidemiologists and survey methodologists. The medical

epidemiologists believed there was a risk that the Study would not be deep enough if a large national probability-based sample was used. There was a greater opportunity to implement the Study in medical centers of excellence throughout the United States, recruit participants from areas around the medical centers, and capitalize on existing infrastructure. The survey methodologists believed that the Study had to be a national probability-based sample. At the time, the survey methodologists wanted a 400-cluster sample. Ultimately, the Study's initial design was a compromise between the two groups. The medical epidemiologists were concerned that the rates of recruitment and retention would be inadequate because of implementation outside medical centers' sphere of influence. Dr. Strauss noted that many of the Study locations are near medical centers with existing infrastructure. He asked whether there is a cost-inefficiency in developing infrastructure and implementing the Study in locations that are not near existing medical infrastructure. Dr. Strauss said it makes sense to use a probability-based sample for selecting large geographic areas such as entire counties. To preserve the Study's representativeness, the issue then becomes the need to determine approaches to best access births within the selected locations. Current sampling theories do not support a sample that is not representative of locations across the United States.

- Dr. Wyatt stated that she was invited to represent the Study's PIs. She reported on a document titled A Cost-Effective and Feasible Design for the National Children's Study: Recommendations from the Field, which was prepared and submitted on behalf of 28 of the 40 Study Centers engaged in the conduct of the Study. Dr. Wyatt noted that she also represents Mississippi, which has some of the greatest health disparities in the United States. The PIs emphasize the open and transparent communication and discussion of the sampling design options in order to balance scientific and economic consequences in a way that will elevate both the quality and relevance of the Study. The primary interest of the Study PIs is to create a Main Study design that is scientifically sound and will address the key charges of the Children's Health Act of 2000. The Study is a once-in-a-generation opportunity that should not be squandered. The Study provides an opportunity to build a structure that will answer critical question for generations to come. The key element of the PIs' proposal is that the best science possible must be employed. The PIs' proposal did not address contracting issues because the assumption is one about science, not about who carries out the science. Based on field experience and what has been learned over the last several years, the PIs can make contributions to help the NCSAC and other entities in crafting the best scientific study. The PIs understand the need to craft a rational balance between cost and science. The current goal is to address the pros and cons of potential sampling designs and attain a compromise that will ultimately not meet the goals of all the Study's major constituencies. The PIs' proposal has three elements that can be accomplished within budgetary constraints. First, the Study must maintain a geographic probability sample. There is a large scientific gap between a probability sample and a convenience sample. A convenience sample would threaten both the external and internal validity of a cohort study. Abandoning a national probability sample would seriously flaw and impoverish the science that can come forward, particularly the ability to link biological relationship and pathways with psychosocial, environmental, and socioeconomic parameters. The PIs strongly support the continuation of the original 105 Study locations to the degree possible or some legitimate subset of those locations, which will serve to continue to leverage some of the important infrastructure and resources already developed. The PIs agree that provider locations within the existing geographic sample are a

legitimate secondary sampling frame. Supplemental sampling of women who do not receive prenatal care could occur from birthing centers at the time they present for delivery, although some home births might be missed. Recruitment can be done at provider locations proportionate to the relative volume of deliveries based on birth certificate records or provider data. Successful recruitment through partnership with providers has been demonstrated, provided sufficient time is allowed and attention given to defining provider sampling frames, building transparent relationships with providers, and recognizing and honoring the significant logistical issues that operate with practices while recruiting. At most provider-based recruitment sites, birth certificates provided the birth attendant data that allowed investigators to then prioritize practices to be engaged. Abandoning the address look-up process would make provider-based recruitment more efficient. Data collection on environmental exposures can be maintained by keeping the geographic probability sample. The national probability sample can be assembled within the existing cost constraints and can address health disparity issues. If needed, the national probability sample can be supplemented with other sampling frames.

- Dr. Konstan asked what steps would be needed to coordinate local adaption of secondary and tertiary sampling units so that it did not introduce bias across different locations.
- Dr. Wyatt said the experiences of certain locations could be standardized and transferred to other locations. However, for any sampling frame, it is potentially dangerous to say there is no local adaptation. There will always need to be allowances for local adaptation, which needs to be vetted through centralized decision making.
- Dr. Bracken commented that the secondary sampling units should be selected by local researchers who know the locations best.
- Dr. Olsen asked about the confidence that Study Centers have that, given reasonable local flexibility, the original cost parameters could be met. Dr. Wyatt replied that the cost parameters could be met on a fixed price contract if all parameters are clearly stated.
- Roderick Little, Ph.D., said that sampling 1,000 births from each Study location differs from an equal probability design. He asked whether there were discussions on how variable the weights would be and the considerations were.
- Dr. Strauss explained that it was determined that the original design with the 105 locations would yield a self-weighting sample; 1,000 births per location were deemed an appropriate number across the majority of locations.
- Dr. Halfon said that although he has not signed onto the PIs proposal, he believes the scientific aspects of the proposal are sound. He had some concerns about contracting mechanisms and administrative issues, but in terms of moving the process forward—retaining the 105 Study locations and getting the Study back in the field—the proposal offers the best possible compromise.

- Dr. Culhane said, although not all PIs have signed on to the proposal, none have expressed any opposition to it.
- Pat McGovern, Ph.D., M.P.H., PI of the University of Minnesota Study Center, said she supports the science of the proposal. She did not sign on because of issues about the financing mechanisms. She expressed concerns about conducting the Study on a fixed-price contract.
- Dr. Sondik asked about the importance of the size of the preconception cohort. He also asked how the bias of using the provider-based approach in the geographic regions could be minimized, compared with a household-based sample.
- Dr. Bracken replied that the provider-based approach would have the same bias as the household-based approach because women who are reluctant to seek prenatal care are also very hard to find through household surveys.
- Dr. Sondik said it is important to understand the demographic characteristics of patients in a practice. He asked whether patient characteristics in certain practices would introduce bias in terms of health disparities.
- Dr. Bracken explained that provider information is linked on birth certificates, which can provide patient profiles for any particular practice. Understanding patient profiles would allow for stratification or sample overweighting. Dr. Bracken said the Study should be open to all women, no matter when they seek prenatal care. Women who do not receive prenatal care should be enrolled at the time of birth in a birthing center. Dr. Bracken commented that the prenatal cohort sampling design should be separate from provider-based design.
- Dr. Wyatt said provider-based recruitment goal was to have 20 percent of the women enroll before pregnancy. At the Hinds County Vanguard Location, this goal was met through prenatal care providers. However, it is not known whether the preconception sample is an unbiased sample.
- James Robbins, Ph.D., an investigator from the Arkansas Study Center, commented that the women with health insurance coverage who seek care from private prenatal care providers will not be the only sample that is needed. In Benton County, AR, about 15 percent of the women were recruited from the federally qualified health center. The demographics of women who were recruited through the provider-based approach, including those from the federally qualified health center, matched the demographics of the entire county, as determined through birth records. Without the women from the health center, the sample was biased.
- Dr. McGovern noted that, for the provider-based recruitment strategy, about 15 percent of the sample was preconception. For the enhanced household and direct outreach approaches, about 50 percent of the sample was preconception. However, with regard to race, age, and marital status, the enhanced household approach best match overall county data. For a preconception cohort, the Study should focus on the approach with the highest yield and then

determine how to implement the approach to ensure that health disparity issues can be addressed.

- Dr. Sondik asked about the relationships of interest in the preconception cohort and the rationale that for a certain percentage of preconception women in the Study sample.
- Aubrey K. Miller, M.D., M.P.H., commented that, assuming the 105 Study locations are representative of environmental exposures across the country, the sampling design should consider stratification to capture exposures of interest with populations and subpopulations, including the preconception cohort.
- Dr. Sastry said there may be different recruitment approaches that are better suited for the preconception cohort versus the postconception cohort. The cost and benefits of the approaches should be considered. With regard to collecting data on siblings, it may be cost-effective to have information already collected on one child. There is a scientific rationale for collecting sibling data. Although some environmental factors affecting children cannot be measured, it can be assumed that siblings will share some of them. There may be innovative ways to collect data on preconception women, for example, from other national surveys.
- Charles R. Pierret, Ph.D., of the Bureau of Labor Statistics noted three areas of potential trade-offs: the sample size, how far back data are collected, and the probability sample versus the convenience sample. What needs to be considered is the expense of trade-offs. Given the low yield of preconception women who enroll versus the number who must be screened, including a preconception cohort may be cost prohibitive. An issue may be the value of the preconception data compared with the costs of collecting the data. This may be the first area to trade off.
- Dr. Brent asked whether the purpose of enrolling a preconception cohort is to ensure data collection as early as possible in pregnancy. The Study should not wait until the 20th week of pregnancy to begin collecting data.
- Dr. Hirschfeld said there is some level of consensus about the value of the capacity to measure exposures and events very early in pregnancy. There is also value in knowing exposures and events before pregnancy. However, once a preconception woman is enrolled, she would not be followed for more than 2 years if she did not conceive during that period. Dr. Hirschfeld explained that the Study has a core visit, which includes some blood samples, for some of women who are enrolled before conception. The data from the core visit establishes a baseline for subsequent data. The costs associated with the preconception cohort have not been a major cost-driver to date. The major cost-driver has been cost associated with recruitment. Although attempts to enhance and enrich data from preconception have not been successful, there is still value in collecting data as early as possible in order to understand exposures and outcomes.
- Dr. Gelb summarized some of the discussion topics and issues regarding the principles regarding the probability sampling: internal and external validity, health disparities, and effects of prevalence estimates on public policy. He asked whether there were NCSAC

members willing to present topics and issues regarding a convenience sample that should be further discussed.

- Dr. Olsen said that the depth of information collected is critical to the Study. He said that data from siblings can add to the depth of information, and it would be valuable to incorporate them into the Study. He cited the National Longitudinal Survey of Youth as an example of study that included sibling data.
- Dr. Gelb commented that the Study will enroll participants in a relatively short period (about 3 years) in order to maintain the validity of exposures. The probability of women who enroll in the Study and have a second child within the 3-year period may be low.
- Dr. Robbins said an inexpensive, albeit biased, approach to enrolling the preconception cohort is to recruit women who are seeking preconception counseling from the same providers that are recruiting pregnant women.
- Dr. Sastry commented that the siblings can be recruited in a scientific, probability-based approach in an unbiased way that is not a convenience sample.
- Dr. Krischer explained that many, if not most, large studies are based on convenience samples. Many federally funded prospective cohort studies are based around the catchment areas of the institutions that are grant holders and the institutions' outreach networks. Most clinical trials are convenience samples. Participants are recruited by a network of physicians with existing institutional affiliations. The participants recruited by physicians may not necessarily be representative of individuals with a given disease. Patients that are seen in major medical institutions may be dissimilar to patients with a given diagnosis who might be followed by community practitioners. Probabilistic sampling is a rarity and, for the most part, not affordable. However, there are advantages of convenience sampling. One of the issues of a convenience sampling is generalizability. The relationships between exposure and outcome hold regardless of whether a participant is a member of a class defined by economics, education, social status, or race. If the relationships are independent of such classes, the analytical results can be reweighted to be representative of any standardized population, without probabilistic sampling. Epidemiological studies often standardize one population to another. Direct or indirect standardization techniques can be used. Another issue is the challenge of ensuring the implementation of a probabilistic sample—defining the population from which the sample is drawn and enumerating and constructing the sample (for example, whether a sample will be drawn from all women of childbearing age). A study with a convenience sample can be just as good as a study with a probabilistic sample.
- Dr. Sastry said convenience studies are not the standard in the field of social sciences. A convenience sample would not have scientific weight. Although probabilistic samples may be the standard, there seems to be acceptability of convenience sample for clinical and prospective cohort studies. But there is not a strong enough case for using convenience samples as an initial plan.

- Dr. Little cautioned about weighting samples to make them representative. Weights can be assigned to observed variables but not to unobserved variables, and therefore, there are limitations to weighting. He noted that epidemiologists that were previous members of the NCSAC were in favor of probability sampling. He commented that using a convenience sample versus a probability sample is not an “either/or” proposition because a “real” probability sample cannot be achieved due to issues such as nonresponse. But a real probability sample is ideal. Issues include how close the Study’s probability sample can be to a real probability sample, maintain full representativeness, and make the sample practically feasible. The medical center model would have to be supplemented for it to be probability sample. The goal for the Study is to have as good, as solid, a sample as possible.
- Dr. Bracken commented that assumptions about the unknown variables can hinder extrapolations. He said one of the early Study outcomes could be the identification of biomarkers that could be used for screening disorders such as autism.
- Dr. Sondik said the Health Interview Survey and the National Health and Nutrition Examination Survey (NHANES) track mortality and are therefore rudimentary longitudinal studies. NHANES has provided solid data on the relationship on obesity and mortality risk.
- Dr. Strauss explained that previous work on the Study’s sampling frame did consider hybrid options. National probability samples are often designed with respect to statistical efficiency of the parameter estimates, which lead to the Study’s 105 locations with stratum with the same number of Study participants. A nationally representative sample could be designed but with prioritized logistical implementation and cost-efficiency. The locations with the most capacity to yield information to the Study by capitalizing on their medical infrastructure could be selected. Each of these locations could have a minimum sample size (for example, 500) and the rest of the sample could be allocated to locations that have the best capacity to enroll participants. This hybrid approach would capitalize on operational feasibility and depth of measurement. There is opportunity for creativity for implementing a national probability-based sample. There is also an opportunity for multiple sampling frames in the same location.
- Dr. Olsen noted that the provider is not determined at birth. A woman’s provider is a function her socioeconomic status, age, and other factors. However, there is an underlying logical model of assigning respondents to providers. This model is important in terms of understanding what the characteristics of sampling from providers would be.
- Graham Kalton, Ph.D., explained that both segments and providers have interclass correlations, which will inflate the variances. He commented on the differences between provider-based sampling and provider-based recruitment. He listed several critical issues: getting a good frame of providers to cover as many women as possible, getting a measure of provider size to sample in proportion to size, and carefully stratifying the providers. The problems with provider-based approaches are the lack of preconception women and not enrolling women in early pregnancy. Other issues are whether providers will sign on to Study, whether the providers will help recruit, and whether women will cooperate with the Study.

- John Bancroft, M.D., said that unlike neighborhood geographic stratification that generally will not change much within a 2-year recruitment period, in some marketplaces, the patient population of a particular group of providers can change quickly, for example, due to changes in insurance coverage and whether a woman is participating in a network.
- Dr. Gelb noted that the discussion was robust and favored the establishment of a national probability sample. He inquired if there were additional topics to discuss that the Program Office would like input on and Dr. Hirschfeld noted that the Program Office was grateful for the input, and thanked him, the NCSAC and guests for an informative and lively discussion.

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



July 16, 2012

Patricia O'Campo, PhD
Chair
National Children's Study Federal Advisory Committee