

**National Children's Study
Federal Advisory Committee 31st Meeting
January 24, 2012
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

*Carol Henry, Ph.D., Chair, National Children's Study Federal Advisory Committee (NCSAC),
School of Public Health and Health Services, George Washington University*

Dr. Henry welcomed the meeting participants, who introduced themselves. Dr. Henry reviewed the highlights of the October 19, 2011, meeting:

- National Children's Study update
- NCS Research Day, August 24, 2011, presentations
 - Genetics: James M. Swanson, Ph.D., University of California, Irvine
 - Community Engagement: Nancy Dole, Ph.D., University of North Carolina, Chapel Hill
 - Informatics/Terminology: Michael G. Kahn, M.D., Ph.D., University of Colorado, Denver
 - Recruitment and Retention, Dean Baker, M.D., M.P.H., University of California, Irvine
 - Environmental Analysis: Howard Andrews, Ph.D., Columbia University
 - Behavioral and Social Science: Louise O'Donnell, Ph.D., University of Texas
- Meeting summary by NCSAC member: Alma Kuby, M.A., M.B.A.

Dr. Henry reviewed the agenda for the January 24, 2012, NCSAC meeting.

Welcome from the Director of NICHD

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

Dr. Guttmacher thanked the NCSAC members for their dedication and hard work in support of the Study, the six NCSAC members whose terms have ended, and Dr. Henry for serving as the NCSAC chair. He noted the following:

- The Study received about \$193 million in funding for fiscal year 2012—about a 4 percent increase from the previous fiscal year.
- The NIH and the NICHD are now actively discussing fiscal year 2013 funding with the Office of Management and Budget (OMB), the HHS, and other interested parties.
- Steven Hirschfeld, M.D., Ph.D., has been named the official director of the Study. He is no longer the acting director.

National Children's Study Update

Dr. Hirschfeld, Director, National Children's Study, NICHD, NIH, HHS

The Study is a congressionally mandated integrated system of activities to examine the effects of broadly defined environmental exposures and genetics on children's growth, development, and health. It is data driven, evidence based, and community and participant informed. The Study is required to:

- Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being
- Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures
- Consider health disparities among children, which may include the consideration of prenatal exposures.

The Study is a platform for constructing a resource and is not a study in the conventional sense. While there are and will continue to evolve domains of interest, the Study is not constructed to address a limited number of specific hypotheses, but rather to allow other scientists to use the data, samples, and specimens to test hypotheses and perform multiple analyses with an emphasis on exposure-response relationships and mechanisms. The Study will serve as a data acquisition platform that invites collaboration for both the Vanguard Study and the Main Study. The Study is designed to be interoperable because future opportunities cannot be anticipated with precision and some opportunities cannot be anticipated at all.

The Study anticipates differential attrition for various subpopulations. Item and visit completion rates will vary per participant and over time. Modeling that used three different methods indicated potential attrition over 21 years to yield a population of about 40 percent of initial enrolled population. The challenge is to respond to the model projections and improve retention. The Vanguard Study will systematically address retention globally and in specific subpopulations.

The proposed strategy to leverage data will harmonize with other studies and with domestic and international general and condition-specific birth cohorts regarding data collection and elements. The Study will share data and perform pooled analyses of uncommon conditions of interest. The strategy to leverage data requires ongoing discussions and cooperation with assurances for quality and consistency of data.

The major cost drivers are recruitment and data acquisition. Potential approaches to be cost-effective include consolidation of redundant operations (for example, informatics), use of data standards and nonproprietary instruments and methods, and modular operations to allow swapping out components.

NCSAC Questions and Answers/Discussion

- In response to a question from Ana V. Diez-Roux, M.D., Ph.D., M.P.H., about the status of the Study's sample size, Dr. Hirschfeld explained that increasing the sample size to 250,000

was an option considered to address retention and attrition concerns. Modeling of attrition indicated that 40 percent of the initial enrolled population will be retained over the Study's 21 years. This outcome is based on historic experience and reasonable assumptions of about 1 percent overall attrition rate per year. Given the estimated attrition, a larger sample size was proposed in order to have a sufficient number of informative events for conditions of interest. However, it was concluded that a sample size of 250,000 would not be feasible. Ways to leverage and harmonize with other studies are being explored to achieve sufficient numbers of events at the end of 21 years. The Study's target sample size remains 100,000.

- José F. Cordero, M.D., M.P.H., asked how the Study will ensure that participants who move will continue to be followed. Dr. Hirschfeld said one approach is to motivate participants to remain in the Study and maintain contact. By building trusting relationships, participants will have a sense of commitment and want to remain in the Study. Another approach is to create an infrastructure with the ability to continue engagement with Study participants.
- Dr. Cordero asked whether premature births are an area of interest. Dr. Hirschfeld emphasized that premature births are a critical component of the Study and the Study is committed to collecting data on prematurity. Because following women with premature births is not part of the Study's mandate, an organization or partner to study these women would be welcomed.
- Elena Fuentes-Afflick, M.D., M.P.H., asked whether the Study is collaborating with the National Cancer Institute (NCI) and other partners to study childhood cancers in the cohort. Dr. Hirschfeld said the Study is engaged operationally with the NCI on multiple levels. The Study is also the key partner in the International Childhood Cancer Consortium (I4C). He noted that the incidence of some types of childhood malignancies is increasing, and this increase is thought to be due to some environmental exposures. The Study is committed to studying childhood cancers. What is learned about cancer epidemiology in the Study will be leveraged and harmonized with the I4C, the NCI, and other partners such as the Children's Oncology Group.

Preliminary Recruitment Analysis from the Vanguard Study Alternate Recruitment Substudy

Dr. Hirschfeld

The Vanguard Study's current sampling frame randomly selected about 100 counties (primary sampling units) that were divided into segments (secondary sampling units) normalized to have about 250 live births per year. Recruitment was restricted to the secondary sampling units. Field activities began in 2009 using a household-based approach at 7 locations. In 2010, 30 additional locations were added, and three alternate recruitment strategies were implemented to determine whether the recruitment efficiency of the initial household approach could be improved. The three alternate recruitment strategies are enhanced household-based, provider-based, and direct to the public outreach (also referred to as Two Tier High-Intensity–Low-Intensity). Each strategy was assigned to a group of 10 locations (counties). The initial recruitment phase was completed in late calendar year 2011.

The following data are current as of December 15, 2011. Overall recruitment status for the 37 Vanguard Study locations is:

- Women eligible for contact: 80,550
- Contacted for pregnancy screen: 74,350
- Completed screen: 65,730
- Pregnant or trying: 9,650
- Women enrolled: 6,750
- Babies enrolled: 2,200.

For the 2009 initial household cohort, 10 percent of the women who complete the screen were pregnant or trying to become pregnant and 64 percent of these women were enrolled. For the 2010 alternate recruitment cohort, 19 percent of the women who complete the screen were pregnant or trying to become pregnant and 73 percent of these women were enrolled.

Recruitment status for the alternate recruitment strategies is:

- Enhanced household
 - Women eligible for contact: 26,000
 - Contacted for pregnancy screen: 20,800
 - Completed screen: 19,450
 - Pregnant or trying: 2,500
 - Women enrolled: 1,500
 - Babies enrolled: 400
- Provider-based
 - Women eligible for contact: 3,350
 - Contacted for pregnancy screen: 3,000
 - Completed screen: 2,050
 - Pregnant or trying: 1,750
 - Women enrolled: 1,400
 - Babies enrolled: 500
- Direct outreach
 - Women eligible for contact: 16,250
 - Contacted for pregnancy screen: 16,200
 - Completed screen: 13,350
 - Pregnant or trying: 2,300
 - Women enrolled: 1,850
 - Babies enrolled: 250.

Pregnancy screen completion rates for women contacted by alternate recruitment strategy are:

- Enhanced household: 93 percent
- Provider-based: 69 percent
- Direct outreach: 82 percent.

Enrollment rates for women pregnant or trying to become pregnant by alternate recruitment strategy are:

- Enhanced household: 60 percent
- Provider-based: 81 percent

- Direct outreach: 81 percent.

The mean numbers of women screened per woman enrolled by alternate recruitment strategy are:

- Enhanced household: 13.7
- Provider-based: 2.1
- Direct outreach: 8.7.

The proportions of enrolled women who are pregnant or trying to become pregnant by alternate recruitment strategy are:

- Enhanced household: 52 percent pregnant, 48 percent trying to become pregnant
- Provider-based: 87 percent pregnant, 13 percent trying to become pregnant
- Direct outreach: 54 percent pregnant, 46 percent trying to become pregnant.

Each of the alternate recruitment strategies may have potential biases. The following are highlights of comparisons of enrollment data by alternate recruitment strategy and combined data from the 10 counties (primary sampling units) for each strategy. The baseline data for the primary sampling units (counties) are for age-eligible women only; there are no baseline data currently available for the secondary sampling units.

- The percentage distribution by race/ethnicity (Hispanic, non-Hispanic White, non-Hispanic Black, and non-Hispanic “other”) of women enrolled by each of the alternate recruitment strategies showed
 - Enhanced household: distribution of enrolled women compared with counties’ distribution about the same but with slightly smaller proportion of Hispanic enrollees and slightly larger proportion non-Hispanic White enrollees
 - Provider-based: distribution of enrolled women compared with counties’ distribution about the same
 - Direct outreach: a larger proportion of non-Hispanic White enrollees and a smaller proportion of non-Hispanic “others.”

The racial/ethnic demographics of the secondary sampling units for each recruitment strategy were about the same as the counties’ demographics. The average race/ethnicity distribution in the 10 counties for each strategy was based on 2009 American Community Survey data.

- The percentages of Study eligible and enrolled Asian women for each strategy were lower than the average percentages in the 10 counties, based on 2010 Census data.
- The percentage distribution of enrolled women by primary language (reference data was only English or non-English) according to recruitment strategy showed
 - Enhanced household: a larger proportion of non-English-speaking than counties’ average
 - Provider-based: a larger proportion of non-English-speaking than counties’ average
 - Direct outreach: a lower proportion of non-English-speaking than counties’ average
- The percentage distribution by age showed a larger proportion of enrolled women younger than 35 years old as well as a larger proportion of women 25–34 years old compared with counties’ average for each recruitment strategy. The counties’ distribution by age was among all women ages 18–49 years old, whereas for the enrollees were among pregnant women or women trying to become pregnant.
- The percentage distribution by marital status showed that a larger proportion of enrolled women were married compared with counties’ average for each recruitment strategy. For direct outreach, the proportion of married enrollees was about twice that of the counties’

average. Reference data were only married or unmarried. Compared with enhanced household and direct outreach, the provider-based strategy had the lowest proportion of married women.

- The percentage distribution of enrolled women by education (college degree or higher, some college, or high school or less) according to recruitment strategy showed
 - Enhanced household: a larger proportion of enrolled women with some college and a smaller proportion with college degree or higher compared with counties' average
 - Provider-based: a larger proportion of enrolled women with some college and a smaller proportion with college degree or higher compared with counties' average
 - Direct outreach: among enrolled women, a larger proportion with college degree and higher and a smaller proportion with high school or less compared with counties' average.
- The percentage distribution of enrolled women by family income according to recruitment strategy showed a greater proportion of enrolled women with family income less than \$30,000 per year and a smaller proportion with family incomes larger than \$100,000 compared with counties' average for each strategy. The provider-based strategy had the largest proportion of enrolled women with family income less than \$30,000 per year. The percentage distributions varied among the four income categories for each strategy.

In conclusion:

- The efficiency of enrollment differed among each recruitment strategy.
- Baseline demographics for each recruitment strategy location were generally similar.
- Demographics of women enrolled for each recruitment strategy differed by varying degrees from baseline and from each other.
- Recruitment method appears to influence recruitment efficiency and profiles of the enrolled population.

NCSAC Questions and Answers/Discussion

- In response to a question about incomplete information, Dr. Hirschfeld explained that much of the incomplete information is due to issues with data management and operations (for example, coding errors, data formatting, and data transmission). Data operations have been improving, and the amount of incomplete information is decreasing as nonproprietary information management systems (IMS) are improved and data management issues are resolved. Data have not been lost.
- Jonas H. Ellenberg, Ph.D., asked whether women must reside in a specific geographical location in order to be eligible for the provider-based recruitment approach. Dr. Hirschfeld said that all women must reside in a secondary sampling unit to be eligible. Each of the alternate recruiting strategies had the same eligibility criteria as the original household-based recruitment approach. With respect to potential bias, Dr. Ellenberg noted that alternate recruitment approaches are not equivalent to the initial randomization scheme.
- Benjamin S. Wilfond, M.D., asked why the boundaries of the secondary sampling units must be kept secret. There are no data to suggest a benefit from keeping the boundaries secret.

- Dr. Hirschfeld commented that there is a difference between provider-based recruitment as just evaluated in the Study and provider-based sampling which is the next planned Vanguard activity. For provider-based recruitment, the participant must reside in the secondary sampling unit. For provider-based sampling, the provider and potential enrollees only need to be in the primary sampling unit;. Implementation of the provider-based sampling approach is still under review by the OMB.
- Dr. Cordero asked whether providers in the proposed provider-based sampling strategy who work outside a primary sampling unit would be eligible to recruit women for the Study. Dr. Hirschfeld said that these providers cannot recruit women who live outside the primary sampling unit. Dr. Cordero commented that there may be differences between rural and urban areas in where women receive care (that is, women in rural areas may be more likely to receive care outside the sampling unit).
- Joan Y. Reede, M.D., M.P.H., M.B.A., asked whether what the Study has considered the impact of health care manpower shortage areas—both inner city and rural—on the provider-based recruitment. Dr. Hirschfeld said these areas have been considered. Supplemental recruitment in these areas may be a future option. The Study will leverage its existing infrastructure and recruitment strategies to address recruitment “gap” issues.
- Dr. Ellenberg commented that the random sample of providers for recruitment cannot be used in all Study locations.
- In response to a question from Edward J. Sondik, Ph.D., M.S.Hyg., Dr. Hirschfeld explained that the enhanced household approach improved logistics and community outreach to better promote the Study and raise awareness. These enhancements had only a modest effect on recruitment. Dr. Hirschfeld noted that, compared with the other approaches, the direct outreach approach was operationally less resource intensive.
- In response to a question from Dr. Reede, Dr. Hirschfeld said that Asian enrollees have not been disaggregated to determine enrollment differences among subgroups.
- Dr. Diez-Roux commented that the demographic comparisons should be between the distributions of enrolled women who are pregnant or trying to become pregnant and the counties’ distributions.
- Jeffrey Krischer, Ph.D., said the Study must consider the racial/ethnic subgroups that are being missed in recruitment and the potential interaction with outcomes of interest, with regard to bias. There will be differential retention rates by race/ethnicity, and data analyses will have to be adjusted.
- Dr. Hirschfeld noted that while all of the outreach materials for the alternate recruitment strategies were in English, a subset of the materials were in Spanish and other languages.

- Dr. Ellenberg said only standard and measured characteristics for each alternate recruitment strategy are being analyzed. Unknown and unmeasured factors can influence bias. Without having a random sample, measures of potential bias may not be particularly valuable.
- In response to a question from Dr. Sondik, Dr. Hirschfeld said the upper age limit for enrollment is 49 years.
- Dr. Sondik said the demographic comparisons should be between babies born in the secondary sampling units and babies born in the counties. Dr. Hirschfeld agreed, but noted that acquiring demographic data on babies born in the secondary sampling units is challenging. He clarified that the demographic comparisons were intended to determine whether there were differences among the three alternate recruitment strategies.
- Dr. Krischer commented that it is not known how good the alternate recruitment strategies are, but how well they reflect the demographics of the counties can be determined. An alternate strategy is to screen and rescreen to estimate the underlying prevalence of a characteristic. The comparison then becomes a comparison of enrollments. This approach could reveal whether the recruitment strategies yield enrolled populations with different characteristics.

Discussion Championed by NCSAC Member

Patricia O'Campo, Ph.D., Centre for Research on Inner City Health, St. Michael's Hospital, Professor, University of Toronto

Before the meeting, the NCSAC was provided the following questions to guide its discussion:

- Study overview
 1. Do you have any comments or questions about the Study's goals?
 2. Do you have any suggestions on communicating the Study's scope, complexity, and goals to the public?
 3. Do you have any comments or suggestions on the Study's strategy to conform to data standards as much as feasible and harmonize data collection practices and formats with other studies?
- Vanguard Study recruitment update
 4. Do you have any comments or questions on the overall Vanguard Study enrollment?
 5. Do you have any comments or questions on the analysis of efficiency comparing the three recruitment strategies?
 6. Do you have any comments or questions on the racial and ethnic enrollment comparing the three recruitment strategies?
 7. Do you have any comments or questions on any of the other demographic parameters comparing the three recruitment strategies?
 8. Please comment on any perceived biases in any or all of the three recruitment strategies.
 9. Do you have any suggestions on how to minimize bias during recruitment?
 10. Do you have any suggestions on how to handle any observed bias in designing data analyses?

- Dr. O'Campo asked whether the alternate recruitment strategies will be retained, and if so, whether the Study is interested in improving them. Dr. Hirschfeld said the data will provide information on the potential biases of the strategies, and based on the data, the strategies may be modified or a strategy may not be used.
- Dr. Reede commented that the questions are too narrowly focused on recruitment. They are not framed in a way that will inform about potential biases in the Main Study.
- Dr. O'Campo asked the NCSAC to identify new questions or request specific analyses to better address bias issues.
- Dr. Reede asked whether immigration status has been considered in the analyses. Dr. Hirschfeld replied that immigration status has not been part of the analyses so far. The Study has not yet developed what it considers appropriate screening questions to address critical issues of immigration status.
- Dr. Wilfond said an area of interest is whether the different recruitment strategies will have different retention rates.
- Dr. Ellenberg explained that the data from the three alternate recruitment strategies and the yet-to-be implemented provider-based sampling strategy will be useful if all strategies are equivalent with regard to bias and baseline characteristics. If the strategies are equivalent, the issues then become cost and efficiency, and the goal of randomization may be compromised in an effort to lower costs. The Study may move away from a true randomized sample. What is not known are the effects of the different recruitment strategies on outcomes.
- Ms. Kuby asked whether the lag in analysis of missing data from the enhanced household strategy will affect the analysis of cost and efficiencies. Dr. Hirschfeld said the Study is continuing to follow through with data collection and the data sets for the enhanced household strategy are becoming more complete.
- Dr. Diez-Roux noted that the women enrolled by the provider-based and enhanced household strategies are generally comparable to the overall demographics of the counties. The differences, however, are consistent with the expected demographics of women who are pregnant or trying to become pregnant. The demographics of the women enrolled by the direct outreach strategy are much different than the reference population and should be reconsidered, given the Study's need for a diverse and representative sample. The Study needs to ensure that the sample has enough variability for exposures of interest and that variables on which the sample is overrepresented do not modify the relationship between exposures and outcomes (that is, introduce bias).
- Dr. Cordero commented that the relative costs of the number of women contacted versus the number enrolled among the alternate recruitment strategies should be considered.
- Dr. Fuentes-Afflick said the issues of recruiting Asian women are important in terms of barriers and strategies that can be used. She also said the Study should analyze the sample's

data to ensure that their demographic characteristics are similar to those of women in the general population. In addition, the direct outreach strategy could be modified to address specific populations (for example, immigrants).

- Michelle A. Williams, Sc.D., S.M., M.S., said birth records could be used to compare the distribution of demographic characteristics of the babies in the alternate recruitment strategies with those of the babies in the primary sampling units. Dr. Hirschfeld said this is a key analysis but collecting data from birth records in a timely way has been challenging. In some cases, there is a 2-year lag between births and acquiring the birth records. There are also inconsistencies in the types of birth record data across the 37 Vanguard Study locations. Dr. Williams commented that the birth record data among the alternate recruitment strategies could be compared.
- Dr. Sondik commented that analyses of birth record data could be used to determine biases in recruitment and exposure-outcome relationships. Analyses of potential biases should be continuous. With regard to the alternate recruitment strategies, they may not yield a representative sample. The direct outreach strategy is most problematic. However, adjustments to the other strategies could be made to balance the sample if the direct outreach is used.
- Dr. Hirschfeld explained that the initial household strategy was considered a reference standard when it was first implemented. The Study recognized that this approach was resource intensive. The initial household and enhanced household strategies have yielded similar results. The provider-based and direct outreach strategies were implemented to determine the differences between these potentially more cost-effective strategies and the household strategies in terms of recruitment efficiency and sample characteristics.
- Dr. O'Campo summarized the discussion as follows:
 - The issue of whether household recruitment is the gold standard for achieving a random sample needs to be resolved.
 - The recruitment data and demographic analyses of the alternate recruitment strategies may not be able to resolve this issue. Additional analyses and strategies may need to be considered.
 - There are concerns that the direct outreach strategy is not a random sample and perhaps should not be pursued.
 - Comparing the demographic characteristics of the women recruited by the alternate recruitment strategies with those of the women in the counties is an informative first step. Analyses of the demographic characteristics should continue.
 - Comparing the demographic characteristics of the babies enrolled by the alternate recruitment strategies with those of the babies in the counties would be an informative second step.
 - A third step would be to compare the demographic characteristics of the women across the three alternate recruitment strategies.
 - Retention rates of the three alternate recruitment strategies should be compared.
 - The relationships between the demographic variables should be analyzed for bias.

Presentation of the NCSAC Working Group: Providing Input to the National Children's Study

Dr. Henry

At their October 19, 2011, meeting the NCSAC agreed to form a working group to develop optimal approaches to ensure that the NCSAC is providing needed advice and input to the Study's Program Office. Members of the working group are Bruce Gelb, M.D. (Chair), Dr. Ellenberg, Dr. Henry, Ms. Kuby, and Ellen Silbergeld, Ph.D.

The NCSAC charter states the committee will advise, assist, consult with, and make recommendations to the Director NIH, the Director NICHD, and the Study Director on present and future issues in the planning and implementation of the Study. The NCSAC is one of many entities providing advice to the Study.

During its conference call on December 22, 2011, the working group identified the following issues:

- Advice requested seems somewhat ad hoc and not strategic in nature.
- Too little time is devoted to dialogue during the NCSAC meetings.
- There are too many presentations where NCSAC members are “observers”; learning about the issues during the presentations.
- Meeting materials, especially non-Program Office information, are not sent in a timely way for advance review.
- There is ambiguity on understanding the level of advice provided by the NCSAC.

The working group identified the following goals for NCSAC meetings:

- Slide decks and all other briefing materials should be sent at least 1 week, preferably 2 weeks, in advance.
- No slides should be used during the meeting, except for reference during discussions.
- There should be a limited number of issues for each meeting; issues to be resolved should be identified 3–6 months before discussion.
- All critical technical information should be presented so the issues can be understood, requests for more information are not needed, and timely, strategic advice can be rendered.
- More formal meetings.
- The issues should be framed by the Program Office.
- New thinking or new issues should be discussed early so that questions can be revamped during the process.
- For the NCSAC's final review, questions should be specified and time should be allowed for the NCSAC to debate and make formal recommendations.
- The Study may choose to modify or ignore the NCSAC's recommendation.

As an example of the NCSAC providing advice to the Program Office, the working group proposed the following process for addressing the issue of the Study leveraging with other studies:

- A briefing paper would be prepared for the March or July 2012 NCSAC meeting.
- The paper would identify and describe candidate studies for leveraging.

- An analysis of the similarities and differences of the candidate studies, barriers to leveraging, and timelines for leveraging would be described in the paper.
- The paper would specify the goals for collaboration or harmonization (for example, information sharing or attaining sufficient sample numbers for analysis).
- The paper would have a proposal for how to “harmonize” with other studies.
- The NCSAC would review the completeness of the analysis and make recommendations on the proposal.

The working group listed the following questions that the NCSAC could address in order to provide advice to the Study:

- How will the Vanguard Study inform the Main Study?
- What are the barriers for implementing the Main Study?
- What data will the Main Study collect?
- Who or what organizations will conduct hypothesis-driven research?

Ms. Kuby commented on the working group’s deliberations:

- The working group expressed the NCSAC’s frustration with the process of providing input to the Study and the extent of its role in providing input.
- The working group discussed some questions that could be raised to improve the process and the ways in which the NCSAC can be more helpful.
- The working group recognized that the NCSAC wants to receive presentation materials from speakers well in advance before its meetings in order to be more informed about the issues to be discussed and ask the right questions about the Study.

Dr. Ellenberg made the following comments:

- The working group concluded that details on Study operations and strategic planning that do not require advice do not need to be presented at NCSAC meetings. This would allow more time to focus on a limited number of important issues that do require advice.
- The role of the NCSAC is to make recommendations, which has not occurred at the meetings. The Study may choose to modify or ignore the recommendations.
- During its meetings, the NCSAC members express their opinions, but the committee as a whole does not come to conclusions and does not give advice.
- Instead of the Study providing a long list of questions to the NCSAC, as it did for this meeting, specific proposals and assignments for advice should be presented.

NCSAC Questions and Answers/Discussion

- Dr. Cordero noted that federal advisory committees have the legal ability to come to consensus and provide formal advice to the federal government. Dr. Cordero cited the Advisory Committee on Immunization Practices as a model of a successful advisory committee. Issues for the NCSAC advisory process are the types of materials and questions that should be provided so advice can be given in a meaningful way.
- Dr. Fuentes-Afflick asked for clarification on the NCSAC’s meeting being more formal. Dr. Henry said formal meetings would give the NCSAC the ability to review background information, discuss issues, and come to consensus.

- Dr. Henry explained that, instead of four 1-day meetings per year, the NCSAC could have two 2-day meetings per year. Two-day meetings would provide the opportunity for more social interaction and exchanging of ideas among NCSAC members.
- Dr. Reede commented that more meeting time would allow the NCSAC to discuss and explore individual member's ideas and opinions, gain clarity on the issues, and come to consensus.
- Dr. Diez-Roux agreed that the meetings should have a smaller set of topics, issues, and questions that need the NCSAC's advice and recommendations, and the NCSAC should be making recommendations during its meetings.
- Dr. O'Campo said the NCSAC should recommend that the meetings have more time for discussion. She also agreed that meetings be 2 days and all materials be provided well in advance. The NCSAC could discuss issues via e-mail before the meetings.
- Dr. Sondik said the NCSAC could review agendas during conference calls before meetings. Such conference calls would not violate Federal Advisory Committee Act (FACA) rules. If the meetings are 2 days, and materials are provided before meetings, the NCSAC could discuss the materials and issues during the first day and make recommendations on the second day. He noted that NCSAC members have a responsibility to review materials before meetings and be prepared for discussions.
- Dr. Guttmacher said the Study and NCSAC's role in it are unique. He noted that advice comes from numerous sources, including the HHS, the OMB, members of Congress, various NIH Institutes and Agencies, Study investigators, and many others who are invested in the Study. The NCSAC has a particular legal and scientific role that these other entities do not. He agreed that changes are needed in the way the NCSAC provides advice and recommendations to allow more meaningful input. Because of the dynamic nature of the Study, some topics cannot be discussed in public meetings, which limits some of the scientific input.
- Dr. Hirschfeld commented on the frequency of NCSAC meetings, noting that they are the only way to make Study information public. The Program Office has tried various mechanisms to enhance the quality of meetings, better inform the NCSAC, and improve the process. The Program Office provided materials and questions on average 2 weeks before meetings, but invited speakers have been less compliant. The number of topics per meeting has generally been two. The discussions at each meeting for the past year and a half have been led by a champion for each topic, who is a member of the NCSAC, and the champion has had responsibility for ensuring that all members have input, summarizing the discussion, and conveying any recommendations. In addition, a rapporteur for the entire meeting, also a NCSAC member, is responsible for summarizing the entire meeting at the conclusion. The Program Office also organized a joint meeting with the Independent Study Monitoring and Oversight Committee and the Interagency Coordinating Committee (ICC) with the NCSAC to clarify roles and responsibilities. All these changes have been documented in prior meeting

summaries. Lastly, the NCSAC had been meeting twice a year for 2 days, but in response to feedback that the frequency was insufficient and the meetings were too long, the present schedule of 1-day meetings four times a year was instituted. Dr. Hirschfeld said the Program Office wants to be responsive, but the context of the Study is unique. The Program Office will continue to evaluate the NCSAC's role and experience.

- Kate Winseck, M.S.W., said she is willing to help put into place any changes the NCSAC comes to consensus on. She explained that FACA rules require all discussions of the NCSAC must be public. Working groups and subcommittees can meet and privately discuss issues, but they must report their findings to the NCSAC in its public meetings.

The attending NCSAC members voted on the following:

- NCSAC meetings should be more than 1 day, and meetings should be held three or four times per year.
- All slide decks and other briefing materials should be sent at least 1 week, preferably 2 weeks, in advance.
- In general, only concise summary slides should be used during the meetings for clarification and to focus discussions.
- Planning of the meeting agenda, discussion questions, and perhaps briefing materials should be an iterative process involving the NCSAC chair and committee members.
- There should be a limited number of issues for each meeting; issues to be resolved should be identified 3–6 months before discussion.
- All critical technical information should be presented in advance so the issues can be understood, requests for more information are not needed, and timely, strategic advice can be rendered.
- The meetings should be more formal.
- The issues should be framed by the Program Office.
- Discussion questions and meeting agenda should be formulated in a way that reflects the decisions that have to be made and advice being sought.
- New thinking or new issues should be discussed early so that questions can be revamped during the process.
- For the NCSAC's final review, questions should be specified and time should be allowed for the NCSAC to debate and make formal recommendations.
- The Study may choose to modify or ignore the NCSAC's recommendation.

Presentations to Outgoing NCSAC Members

Dr. Hirschfeld presented certificates of appreciation and formally thanked the following individuals whose terms have ended:

- Ms. Brakefield-Caldwell
- Dr. Cancian
- Dr. Cordero
- Dr. Diez-Roux
- Dr. Henry
- Dr. Wilfond.

Considerations for Definitions of Children’s Health: National Children’s Study Health Measurement Network

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The context for measuring child health includes:

- Historic changes in the U.S. health care system
- Concerns about the adequacy of the Study’s conceptual and measurement framework
- Previous work by the National Academy of Science to conceptualize, define, and measure children’s health
- Challenges and opportunities in measuring child health
- New developments in measurement capacity such as the NIH-funded Patient Reported Outcome Measurement Information System (PROMIS) and the NIH Toolbox for neurologic function.

Although there are challenges in measuring health potential, the Study has an opportunity to develop evolving conceptual frameworks for children’s health. Because of the urgency in developing measures of potential health, the Study needs a measurement schema that will provide strong functional scaffolding for data collection. A measurement development learning system will help the Study’s concepts and measures to continuously evolve in response to changing science, evidence, constructs, and the need to be strategic and responsive. A measurement development learning system will capitalize on the enormous capacity within and across Study Centers. The Study’s Health Measurement Network (HMN) was created to address the needs for conceptual frameworks and measurement schema for children’s health.

In year 1 (October 2011–September 2012), the HMN has the following aims:

- Develop an organizational architecture for the HMN that supports a community of scholars interested in advancing the science of health measurement
 - Vision: The HMN will use the Study as a platform to advance the conceptualization and measurement of health so that researchers and practitioners can identify and address those factors that optimize health across the life course.
 - Mission: The HMN will harness the collective intelligence of Study-affiliated scientists to review, develop, validate, and continuously improve theoretically derived, multi-modal and efficiently administrable measures of children’s life-course health development from preconception to the transition to adulthood.
 - Goals: (1) The HMN will develop a network design and organizational structure, (2) conduct network in-reach (between the Study and the NIH) and outreach, (3) recruit members into the HMN, (4) formalize HMN communication infrastructure based on principles of open science, and (5) develop a long-term funding strategy for the HMN.
- Norm and field test NIH Toolbox and PROMIS instruments among women and children

- Develop a working theoretical model of health that drives innovation, a working typology of health domains mapped to current Study instruments, and a consensus-derived prioritization of child and maternal health domains; develop a Study instrument library
- Provide informatics support to enable portability of final health profile measures across Study IMS platforms
- Select theoretically driven maternal and child health measures for high-priority domains.

Aims for future work are as follows:

- Develop, evaluate, and validate a final list of prioritized and innovative health profile measures
- Field test the health profiles, assess their construct validity, and develop integrated summary scores and profile-type taxonomy.

The HMN will conduct a multicultural review to evaluate the extent to which potential Study measures are culturally sensitive and conceptually adequate across different cultural groups. The reviewers will make specific recommendations to the HMN scientific team that highlight strengths, limitations, and strategies for remediation for existing and newly developed instruments.

The HMN will conduct a translatability review. All instruments will be evaluated to ensure that they are suitable for culturally diverse populations; include wording appropriate for translation into multiple languages; and have similar scores for comparable trait levels, regardless of the instrument translation.

The HMN will also conduct an accessibility review to ensure that measures support the inclusion of children with disabilities (that is, children who have functional impairments in vision, hearing, motor skills, cognition, and reading). Measures should be designed to be natively accessible without modification, or an approved alternative measure should be available to measure a construct.

Future HMN activities include harmonizing Study measures with other national child health data collection activities such as the National Survey of Children's Health, the National Survey of Children with Special Health Care Needs, the National Health Interview Survey (NHIS), and the Early Childhood Longitudinal Study. The HMN is considering cross-validation and testing strategies. The HMN is developing a framework and typology for classifying and developing different exposures and influences on health outcomes. The HMN is also considering ways of improving collection and measurement of exposures, contexts, and other influences on health.

The following are year-1 deliverables:

- Theoretical model of life course health
- Conceptual typology of life course health
- NIH Toolbox measures and their applicability to the Study
- Maternal self-reported measures from PROMIS and the NIH Toolbox
- Study instrument library content analysis
- Health domain prioritization
- Version 0.5 of the maternal and child health measure profile.

NCSAC Questions and Answers/Discussion

- Dr. Ellenberg noted that the HMN is developing concepts from defining disease entities to a model of causality. He asked whether the typology will drive the Study's selection of the data collected or vice versa. Dr. Halfon said the HMN is attempting to ensure it can provide a comprehensive and integrated typology that has the capacity to support a range of causal explanations and frameworks that the Study may choose. The Study will be a dynamic process that is learning as it moves forward. Hypotheses will emerge and be tested, the frameworks will be tested, and issues of critical and sensitive periods of development will be tested.
- Dr. Hirschfeld explained that the one of the Study's mandates is to measure health. Among existing assessment tools for measuring health across ages and stages of children, there is a lack of continuity, there are domains that do not have assessment tools, and there is no framework. Measuring health in a positive, quantitative, objective manner requires appropriate tools. The tools will vary according to context and will involve multiple modalities. Most existing tools measure disabilities, with health defined as the absence of disease or disability. There need to be positive measurements on optimizing health and concepts for health potential. The Study outcome measures of health will evolve by developing conceptual frameworks and leveraging existing NIH resources. The Study will move forward without a comprehensive toolkit of all potential dimensions of health at all ages.
- Dr. Ellenberg asked whether limited funding will affect decisions on what data will be collected. Dr. Hirschfeld said data collection has to be practically oriented. The Study needs deliverables that can be moved into the field. The Study will leverage other efforts to determine what data can be feasibly collected and validated.
- Dr. Sondik noted that the Study will be limited on the data it can collect. Because not all measures can be performed on the entire cohort, state-of-the-art measures could be performed on a subcohort. Dr. Halfon replied that the core measures might be broad or narrow. But different measure may be added to certain subcohorts to focus on particular relevant aspects of these subcohorts. Study measures can be harmonized with measures from other data sets (such as the NHIS), cohorts, and population-based systems. Dr. Hirschfeld said leveraging opportunities include 60 NICHD-supported networks.
- Dr. Wilfond asked whether health will be measured to simply capture the absence of disease or whether health will be measured in the presence of disease. Dr. Forrest said health will be measured in the presence of disease. He noted that the HMN will measure profiles of health. Additional assets and models are needed to develop these profiles.
- Dr. Sondik asked whether measures of health potential include risk factors for adult functioning and disease. Dr. Forrest explained that "potential" has two connotations: the presence or absence of reserve (for example, bone strength). Potential refers to a desirable

positive attribute that confers a positive outcome. Dr. Sondik said defining and measuring positive health will be challenging.

Discussion Championed by NCSAC Member

Dr. Williams, Stephen B. Kay Family Professor of Public Health and Chair Department of Epidemiology, Harvard School of Public Health

- Dr. Williams asked Dr. Hirschfeld to put the HMN presentation in context of the Vanguard Study data collection and the Main Study’s objective for outcome measures. Dr. Hirschfeld explained that the questionnaires used in the Vanguard Study addressed some aspects of disease and exposures and their adverse consequences but did not address health per se and potentially positive consequences of exposures. Vanguard Study data collection efforts have focused on operational and logistical issues. The Vanguard Study has used “placeholder” questions borrowed from other instruments and questions that are being probed to evaluate how informative they might be at different ages and stages. At this time, the Study does not have a way to grasp the concept of health to determine whether certain exposures enhance health.
- Before the meeting, the NCSAC was provided the following questions to guide its discussion of the HMN:
 11. Do you have any comments or questions regarding the use of a multidimensional definition of health?
 12. Do you have any comments or questions related to incorporating into the Study’s assessments positive, objective, and quantitative measures of health?
 13. Do you have any comments or questions related to assessing health across all ages and stages of childhood?
 14. Do you have any suggestions for specific domains, modalities, or items for assessing health at any age or stage?
 15. Do you have any suggestions or comments on organizing a systematic effort to validate and, if need be, develop items and assessments of health measurement?
- Dr. Henry noted that the Study’s sample size was designed to have enough power to detect adverse outcomes. She asked what sample size would be needed to have enough power to detect positive health outcomes. Dr. Gershon explained that the primary NIH measurement development efforts have focused on equi-discriminant measurements (that is, disability and health status are measured equally). The Study’s sample size was predicated on having a limited number of people who develop disability. Without a definition of health, it is not known whether the Study’s sample size is sufficiently powered to detect meaningful differences in health because meaningful differences in health have not yet been defined. However, because the Study is powered to detect uncommon negative events, it may be well powered to detect gradations of positive health.
- Dr. Cordero said the Study is not just “a study” but a platform for infrastructure development. It is significant that this infrastructure will help determine ways to measure health and functional status, regardless whether a child has a disability or not. The HMN will be a key aspect in harmonizing the study of children’s health.

- Dr. Halfon commented that children’s health can fluctuate from year to year, with different trajectories and velocities. The Study will provide insight into the nature of health development.
- Dr. O’Campo asked how the theoretical constructs will be applied in order to understand how exposures relate to measures of positive or negative outcomes. Dr. Forrest explained that there are two threads: measure development and theory. Theory is conceptualized in two dimensions: the need to have a theoretically based set of health constructs (that is, establishing the boundaries) and modeling the pathways to health assets (that is, the mechanisms) and what they enable. The health measures have not yet been put into a theoretical model.
- Dr. Firestone said the EPA has been moving toward a life-stage approach of risk assessment that considers how exposure changes over time. In terms of toxicology, the EPA is looking at windows of susceptibility for environmental stressors. The EPA has developed a standard set of age groups in order to define children and exposure factor information about children. He asked how the Study will determine the frequency of measuring health status and the frequency of collecting environmental samples. Dr. Halfon said the frequency of measuring will be variable depending on the traits and exposures of interest. Dr. Gershon explained that frequency of measuring will be partly theoretically driven.
- Dr. Ellenberg commented that the Study’s approach for defining statistical power for assessing negatives outcomes may not be applicable for assessing healthy outcomes. For example, when defining health in terms of the absence of disease, disease may be a rare event. When defining health in terms of cognitive deficits, cognitive deficits are probably not such rare events.
- Dr. Diez-Roux commented that global measures, versus component measures, may not be able to address etiological questions. Dr. Halfon said the Study is developing six-point scale for global measures of positive health at different ages. The goal is to have profiles and continuums of health.
- Dr. Wilfond asked whether the Study is attempting to measure a continuum of health states for a wide range of people. Dr. Forrest replied that whether positive states and negative states are on the same continuum and whether positive assets are separate have not yet been determined.
- Dr. Halfon explained that the Study Centers were contracted to implement the Study, not design or redesign it. Because the Study Center teams are not measurement developers, they have brought in colleagues and scientists who are experts in developing measures. PIs from many Study Centers are engaged in the HMN and measure development. Dr. Hirschfeld noted that there are other contractors and several mechanisms to involve experts outside the Study.

- Dr. Sondik said it is important to have a small number of core measures for each domain. If these measures are applied to the entire cohort, they can be tracked over the length of the Study and provide a sense of dynamics of and influences on outcomes.
- Dr. Henry said, based on the presentation, she believes that measure development will drive the Study's data collection.
- Dr. Halfon explained that until now, the Study has been governed by a loose conceptual framework stating that a number of influences affect a number of outcomes. Measures of these influences do not have a good typology. The HMN is developing a typology of what the health outcomes might be. Once the typology is in place, existing measures can be matched with the typology. A gap analysis can then be performed to identify which domains have no measures, which have no good measures, and which have adequate measures. The next step is a "gap filling" exercise. Moving forward, the measurement set will become more robust. The potential for what can be measured will influence the types of questions that can be asked. Through such an iterative process, the Study creates a learning system.
- Dr. Ellenberg cautioned against the construct of flexibility and constant renewal of measures over time. At some point, measures should be selected that are used for the entire Study. If new areas of interest are identified, new measures would be needed. Hopefully, measures will not be continually changing. Dr. Halfon said there will be a core set of measures for each age group but that new measures may be added for different age groups. The process will be interactive. Measures in one age group (for example, 3-year-olds) may inform the measures of other age groups (for example, 5-year-olds).
- Dr. Williams described the discussion as rich and innovative. The NCSAC embraces bringing rigor and creativity to Study measurements. Being innovative and building on existing measures, improving and validating them, and having nimble measures with the ability to be used broadly and applicably across Study populations are all positive. However, there are issues and questions about ranking priorities in order to make decisions on which measures will be used. She summarized the discussion topics and issues as follows:
 - The direction of the HMN's activities in knowledge creation and development and assessment of measures versus determining priorities
 - Concerns about the practicality of activities, for example, distinguishing between health and health status and using short assessments for all domains
 - Concerns about remote measurements, which may be feasible for measures of cognitive function but not measures of physiologic function
 - Benefits of infrastructure building
 - Linking theory to etiologic or development pathways
 - Establishing priorities of intensity, frequency, and sequencing of measures that are informed by the types of questions
 - The use and value of global measures in the context of etiologic questions and what can be learned from them
 - The HMN's intersection with Study PIs who might be focusing on other health outcomes
 - The importance of having a set of core measures for the domains of interest

- Embracing measures that appropriately quantify the outcomes of interest (for example, health, health status, disease status, function) and link theory to practice.

Protocol/Instrument Development for the Vanguard Study

Ruth Brenner, M.D., M.P.H., National Children's Study Program Office, NICHD, NIH, DHHS

Base data collections will be conducted in person (five visits) and by telephone (four calls) from pregnancy through 24 months. There is a great interest in preconception data collection. Health care logs of medical system encounters will be kept during pregnancy and infancy. Base data collections began in November 2010. Expanded data collections, which began in November 2011, include the base data collections, two maternal blood and urine collections at the first two visits (at the preconception and first pregnancy visits or at the first and second pregnancy visits), cord blood, dust and water collection at the first pregnancy visit, and a father interview. As of December 31, 2011, 15 Study Centers had sent in biologic specimens or environmental samples. Data collection instruments currently under development are the core interview, the 30-month interview, a noninterview respondent questionnaire, biospecimens at 6 and 12 months, physical assessments at 6 and 12 months, and modifications to a subset of existing instruments (father and 24-month interviews).

The process for development of data collections is as follows:

- Development of domains and subdomains by the Study Visit Content Team (SVCT)
 - Review by the Study Director, Study Centers, and ICC
 - Revisions to domains/subdomains
- Development of data collection instruments by the SVCT
 - Review by the Study Director, Study Centers, and the ICC
 - Revisions to data collection instruments
- Regulatory reviews
 - Review by the public (included as part of the OMB review)
 - Postapproval processing (for example, design of forms, programming of instruments).

The guidelines for proposal of items for inclusion in a questionnaire require:

- Validated instruments or questions (with known scientific properties)
- Wide use in standard surveys
- Low burden or the least possible
- Analytic utility in relation to other concurrent and longitudinal data collections in the Study
- Harmonization with other studies, as appropriate.

For the core and 30-month questionnaires, the domains and subdomains have been defined by the Program Office and reviewed by the Study Director and Study Centers. Changes to the domains and subdomain have been incorporated. The questionnaires have been drafted and posted to the Study portal for review by Study Centers and the ICC. The questionnaires were posted in both a wiki format and as stand-alone documents. After a 45-day comment period, additional changes will be incorporated. There will be a public posting around the time of the 30-day *Federal Register* notice, as part of the OMB review.

NCSAC Questions and Answers/Discussion

- Dr. Henry asked how long the review process is. Dr. Brenner said the review process is somewhat tailored to the length of the OMB review. For this review, there is an initial 60-day notice, which is followed by a 30-day notice. All new instruments need to go through this 90-day process. The entire instrument development process takes about 6 months.
- Dr. Henry asked whether an OMB-approved instrument requires another round of approval if the Study decides to use it. Dr. Brenner said it does, but if the construct of the instrument is basically the same and only a few questions are being changed, there is some flexibility in the 60-day review window. However, once a finalized instrument is posted at the 30-day review, any changes would need to go through a new approval process.
- Dr. Sondik commented that instruments developed through the HMN would also have to go through the OMB-approval process. A strong research base needs to go into the measures that are added.
- Dr. Henry asked whether the OMB has vetted NIH Toolbox and PROMIS instruments. Dr. Hirschfeld said that the instruments have not necessarily been vetted. He noted the OMB review policies have changed the Toolbox initiative was exempted. The Study does not have this option.
- In response to a question from Dr. Fuentes-Afflick, Dr. Brenner explained that interviews and biologic specimen and environmental sample collections at the initial seven Vanguard Study locations were limited to 3 hours. Since then, abbreviated instruments have been used in order to focus on Study operations, not exposure-outcome relationships.
- Dr. Fuentes-Afflick asked whether data collection should be at developmental transitions (for example, when a child starts preschool or kindergarten) and not just at certain ages. Dr. Brenner said that a modular approach, which would augment core measures, could be used to collect transition data. Dr. Hirschfeld explained that there will be some flexibility in schedules. For example, in a child's first 2 years, there might be four, six, or eight visits that occur during certain windows of time. Because the interval between visits might not be the same for all children, the data will be distributed across the 2-year period. There will also be event-triggered visits.
- Dr. Williams asked whether the Study has considered the PhenX Toolkit for other possible measure instruments. Dr. Hirschfeld said there have been discussions with PhenX Toolkit representatives. The Study is also investigating international measure instruments.
- Dr. Sondik asked whether physician or hospital records are being used to collect data. Dr. Brenner said the alternate recruitment substudy is not abstracting physician records, but hospital records were abstracted in the initial Vanguard Study. Dr. Hirschfeld said collecting this health record data has been a logistical challenge. Birth record data are not part of the Study's central database, but some Study Centers are collecting birth record data locally. Dr.

Sondik said birth record data could be appropriately protected by involving local registrars. He noted that birth record data are tightly guarded by states.

Meeting Summary by the NCSAC Chair

Dr. Henry did not summarize the meeting, deferring to the summaries by Drs. O'Campo and Reede and the written summary of the meeting.

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- *Sally P. Darney, Ph.D., ORD, EPA
- **Michael Firestone, Ph.D., Office of Children's Health Protection, EPA
- *Kimberly Gray, Ph.D., NIEHS, NIH, HHS
- Steven Hirschfeld, M.D., Ph.D., NICHD, NIH, HHS
- *Danelle Lobdell, Ph.D., ORD, EPA
- *Mary E. Mortensen, M.D., M.S., National Center for Environmental Health, CDC, HHS
- *Sheila A. Newton, Ph.D., NIEHS, NIH, HHS
- *James J. Quackenboss, M.S. (chair), ORD, EPA
- *Marshalyn Yeargin-Allsopp, M.D., National Center on Birth Defects and Developmental Disabilities, CDC, HHS
- *Did not participate*
- **Also represented EPA Ex Officio Member*

Program Office Members

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



February 21, 2012

Date

Carol J. Henry, Ph.D.

Chair

National Children's Study Federal Advisory Committee