

**National Children's Study
Federal Advisory Committee 26th Meeting
October 14, 2010
Building 31, 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 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., Acting Chair, National Children's Study Federal Advisory Committee (NCSAC), School of Public Health and Health Services, George Washington University

Dr. Henry reviewed the highlights from the July 21, 2010, NCSAC meeting. Meeting topics included the following:

- Update on the Study
- Vanguard Study recruitment update
- Real-time specimen and sample analysis
- Return of individual research results: implications for real-time analysis
- Study environmental methodologies
- Drinking water quality: potential collaboration with U.S. Geological Survey
- Workshop on optimizing exposure metrics for the Study
- Study operations.

Vanguard Study Recruitment Update

Brian Haugen, Ph.D., Senior Scientist and Study Center Project Officer, National Children's Study, NICHD, NIH, HHS

Dr. Haugen provided an update on Vanguard Study recruitment and retention. Dr. Haugen also provided information on prepregnancy, prenatal, and birth data collection. As of the end of September 2010, recruitment status was as follows:

Recruitment Stage	Total	Response Rate*
Total listed households	83,851	
Household enumeration completed	67,177	86%
Age-eligible women identified	34,066	
Pregnancy screening completed	30,063	91%
Study eligible women identified	2,425	
Consented/enrolled women	1,396	68%
Pregnant at consent	968	
Not pregnant at consent	428	

*Participants found to be ineligible or in progress were excluded from these computations.

Dr. Haugen presented graphs and charts showing the following:

- **Consent rate by race and ethnicity.** Of the 1,396 women who have consented, African-American women had the highest consent rate (75 percent). White women had the next highest consent rate (68 percent). Asian women had a lowest consent rate (52 percent). Hispanic women had a consent rate of 72 percent. Of women who self-identified as “other,” 70 percent consented. However, only 66 Asian women have consented compared with 831 White women and 1,081 non-Hispanic women. The overall consent rate is 68 percent. Women found to be ineligible or in progress were excluded from these computations.
- **Consent rate by age range.** Of the women younger than age 26, 462 have consented. Of the women age 26–35, 760 have consented. Of the women age 36 and older, 131 have consented.
- **Consent rate by survey language.** Of the women who answered the survey in English, 1,213 have consented. Of the women who answered in “other,” 173 have consented.
- **Prenatal data collection.** The completion rate for the preconception mother visit was 84 percent. The completion rate for the first trimester first mother visit was 83 percent. For the third (T3) trimester prior mother visit, the completion rate was 90 percent. The completion rate for the T3 first mother visit was 77 percent.
- **Postnatal visits.** The completion rate for birth visits was 76 percent. The completion rate for the 3-month call for child was 74 percent. The completion rate for the 3-month call for mother was 66 percent. For the 6-month visit for child, the completion rate was 89 percent.
- **Cumulative number of enrolled women and births.** The original expectation for enrollment was 1,000 births per center over 4 years of recruitment, or 250 births per center, per year. The expected number of births in 1 year from the 7 original Vanguard Centers was 1,750. As of September 2010, with an average of 17 months of recruitment per Center, 1,397 have been enrolled; 798 women have completed one or more pregnancy Study visits. The total number of observed births was 594. Over the past 12 months, there have been 525 observed births, which is 30 percent of births expected in 1 year from the 7 original Vanguard Centers.

Dr. Haugen listed the following next steps:

- Legacy Vanguard data from the seven original Vanguard Centers
 - Analyze longitudinal completion of Study visits
 - Analyze Study visit measures for performance and longitudinal completion
- Vanguard data from 30 alternate recruitment substudies Vanguard Centers
 - Determine recruitment rates per substudy
 - Collect more information about income, education, race, and ethnicity at screening stage.

NCSAC Discussion and Recommendations

The group discussed the following topics and issues about Vanguard Study recruitment and enrollment:

- Jonas H. Ellenberg, Ph.D., asked for clarification on expected enrollment rates versus actual enrollment rates. Dr. Haugen said that there was an expectation of slightly higher household enumeration. There was an expectation that more women would be pregnant or “high triers” (that is, likely to become pregnant) at the time of pregnancy screening. The expected rate for

pregnant eligible women was about 18 percent, while the actual rate is about 5 percent. The rate for pregnant eligible women varies across the Study sites. The consent rate is about 5 percent lower than originally expected. Steven Hirschfeld, M.D., Ph.D., noted that the original expected consent rate was 75 percent, while the actual consent rate is about 68 percent. The number of women in the low-probability group was about three times greater than originally expected. The rate of pregnancy at the time of screening was about 0.05 percent, which is lower than the rate reported in the literature. An informal survey of participating birth hospitals reported that there was only a slight decrease in actual birth rates compared with historical rates.

- Dr. Ellenberg asked which of the three alternative recruitment approaches would modify the enrollment rates. Dr. Haugen said the two-tier high-intensity, low-intensity (H/Lo) approach would expand the recruitment area with the expectation of increasing enrollment rate by about two-and-half times, to about 100 percent of the original expected rate. The provider-based approach and enhanced household approach are also expected to increase enrollment rates.
- Ellen Silbergeld, Ph.D., said retention may be a bigger issue than actual enrollment. Enrollment and retention have to be linked. Enrollment has to be based on the goal of retention. Dr. Silbergeld asked for clarification on the differences in numbers of planned versus eligible women for prenatal data collection. Dr. Haugen explained that visits in the scheduling process were not included in the eligible numbers. Dr. Silbergeld asked whether the differences between numbers of planned and eligible women represent retention. Dr. Haugen said the differences in numbers are not related to retention. Dr. Hirschfeld said about 3 percent of eligible pregnant women have lost a pregnancy or dropped out of the Study.
- Maria Cancian, Ph.D., said it would be of interest to provide information on which women who have completed the preconception visit are at risk of not completing subsequent visits. Information on variations of effectiveness of the consent and retention processes across sites would be valuable. Dr. Hirschfeld said the shifts in data platforms and infrastructure of data sets will be able to provide this information in the future. Variations may be due to Study Center operations or Study location populations.
- Joan Y. Reede, M.D., M.P.H., M.B.A., asked, with regard to race and ethnic groups, how “other” was defined. Dr. Haugen said that of the 401 “other” women, 305 self-identified with multiple racial groups.
- Dr. Ellenberg proposed that a small group of NCSAC members (designated “champions”) be allowed adequate time to review the recruitment and retention data prior to the meetings. The small group would then provide comments at the meetings.
- Michael D. Lebowitz, Ph.D., said a spreadsheet showing data for each stage of recruitment and enrollment for the alternate recruitment substudies would be important. There should be separate data by Study location. Dr. Hirschfeld said the new data collection infrastructure will be able to provide such information. Legacy data and new data will be presented at the next meeting.

- Dr. Reede proposed that a small group review the new data to provide input on how the data are presented. Dr. Ellenberg, Dr. Silbergeld, Dr. Reede, Dr. Lebowitz, and Michelle A. Williams, Sc.D., S.M., M.S., volunteered to participate in this data review group. Dr. Hirschfeld said the Program Office will send to the group populated and unpopulated data tables by the end of December for the January meeting.

National Children's Study Update

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

- **Overview.** The Study will examine the effects of the environment, as broadly defined to include factors such as air, water, diet, sound, family dynamics, community and cultural influences, and genetics on the growth, development and health of children across the United States, following them from before birth until age 21 years. The goal of the Study is to improve the health and well-being of children and contribute to understanding the role various factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible.
- **Leadership.** The Study leadership includes the NIH (NIH Office of the Director [oversight and scientific direction], the NICHD [lead operational agency], and the NIEHS), the CDC, and EPA.
- **Structure.** The Study is being implemented in several phases. All components and phases together form the Study. Current major components are the Vanguard Study, Main Study, and substudies.
- **Vanguard Study goals.** The Vanguard Study is designed to evaluate feasibility (technical performance), acceptability (impact on participants, study personnel, and infrastructure), and cost (personnel, time, effort, and money) of Study recruitment, logistics and operations, and Study visits and study visit assessments.
- **Projected timeline.** Data collection of the pilot/feasibility study (the seven original Vanguard Centers) began in early 2009. The 30 Vanguard Centers implementing the alternate recruitment substudies began operations in October 2010. After analysis of the pilot data and plan and external scientific review, the Main Study is expected to begin operations in early 2012.
- **Alternate recruitment substudies status.** Kickoff meetings for the three alternate recruitment substudies were held in July and August. A meeting of the expanded Steering Committee that included all Vanguard Centers was held on August 10. Infrastructure and communications and outreach are being developed. Initial data collection efforts will focus on questionnaires. Specimen and sample collection will be phased in over the coming months. An analytics retreat was held on September 22, 2010.
- **Data collection instruments.** Twenty-six data collection instruments have been approved by the NICHD institutional review board (IRB) and the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA).
- **Informatics development.** Data fields, structure, relationships and data tables are being developed centrally to address specific operational questions. The focus is on operational data elements to study feasibility, acceptability and cost for the Vanguard Study. Data collection and transmission standards are conveyed to the Study Centers (primary contractors). The Study Centers are responsible for identifying, developing or adapting if

necessary, and deploying case management and data acquisition systems. All required data are transmitted per specifications to a central database at the NICHD.

- **Communications and outreach.** The Vanguard Study communications toolkit was launched on August 2010. A meeting with African American and Native American community organization representatives was held at the NIH. Satellite radio and television events were held with NICHD Director Alan Guttmacher, M.D., and NICHD Deputy Director Yvonne Maddox, M.D. The next phase of communications and outreach will shift emphasis from central to local design and implementation.
- **Formative research.** Formative research is an essential component of the data-driven, evidence-based strategy for the Vanguard Study. Formative research projects are focused, time-limited activities for Study contractors to address specific technical or methodological questions. Two rounds of formative research requests were initiated based on a gap analysis. Additional formative research opportunities are planned for the coming year. The Study has initiated several formative research projects that are limited in scope and duration and are intended to augment the Vanguard Study to address specific technical questions and provide information on the acceptability, feasibility, and cost of the research. These formative research projects will provide data to explore new and potentially cost-effective approaches in many areas—including genetic, cognitive, and environmental assessments—that have not been previously evaluated from an operational perspective. Based on the results of these formative research projects, the Study can evaluate the types of research questions that would be feasible for the Main Study. Formative research topic areas include:
 - Real-time analysis of Study samples, specimens, and measurements
 - Study logistical analyses and improvements
 - Biospecimen collection and processing
 - Environmental sample collection and processing
 - Physical measures
 - Questionnaire development and validation
 - Study infrastructure development.
- **Biobank.** A biobank planning conference was held in June 2010. The NIH, other federal agencies, and the UK BioBank were represented. The purpose of the meeting was to explore options to establish a long-term storage program for the Study that could archive environmental samples and human biospecimens.
- **Federated IRB launch.** The federated IRB model was approved for implementation in July 2010. Other NIH programs and studies have expressed interest in adapting the federated IRB model. A presentation to the Secretary’s Advisory Committee for Human Research Protections was scheduled for October 19.
- **Federated IRB participation.** As of October 8, the percentages of participation of the 36 Vanguard Centers by tiers of membership were as follows:
 - Tier 1—25 percent
 - Tier 2—3 percent
 - Tier 3—8 percent
 - Membership tier not selected—64 percent.
- **OMB interactions.** Successful and collegial discussions have been under way with the OMB and the OIRA within the OMB regarding the Vanguard Study protocol and the alternate recruitment substudies. The OMB has provided multiple helpful suggestions and is motivated

and supportive of the Study. Clearance for the alternate recruitment substudies was received in summer 2010. Clearance for formative research is pending.

- **Program Office reorganization.** Six new Project Managers were hired to handle all contract oversight. All Project Managers are Contracting Officer's Technical Representative certified and will be Project Management Professional certified. Program Office activities are aligned in four areas: planning, operations, analysis, and communications. The adoption of data standards with interoperability is a priority. The Program Office will manage initial development of all Study instruments, data architecture, and specifications in order to maintain consistency and quality and gain flexibility and efficiency.
- **A learning community.** Except for the focus of the Study remaining on the health of children, all other aspects of the Study are potentially subject to reevaluation and change. The concurrent deployment of three different recruitment strategies plus a formative research program provides an exceptional opportunity for launching a learning community with structured and systematic training, feedback, process maps, process improvement, modeling, and simulations. The Study has adapted these approaches both centrally and in the field, particularly in the Hi/Lo recruitment substudy, to build an effective learning community.
- **Next steps.** The next steps are as follows:
 - Alternate recruitment substudies enrollment and data analysis
 - Continued analysis of legacy data including biospecimens and environmental samples
 - Gap analysis for formative research opportunities
 - New models for visit schedule
 - New models for visit assessments.

NCSAC Discussion and Recommendations

- Everett Rhoades, M.D., asked whether the Study would have a central IRB for its federated IRB. Dr. Hirschfeld said currently there is no central IRB although in the federated IRB, the NICHD Intramural IRB will function as a lead IRB for the Study. The Program Office has been working with the Office for Human Research Protections in developing the federated IRB model. The Program Office is building a framework for collaboration and trust among the Study's many IRBs. The current federated IRB model allows different levels of participation, but all IRBs must agree to share their decisions with the other IRBs. This way, each IRB will learn what the others are doing.

Comments from the Director's Office, NICHD

Alan Guttmacher, M.D., Director, NICHD, NIH, HHS

Dr. Guttmacher thanked the NCSAC for their participation in the meeting and their input in the discussion sessions. The NICHD leadership remains firmly committed to the Study. The Study aligns with the NICHD's mission and provides a unique opportunity to produce a level and type of knowledge that no other means would allow. The NICHD leadership wants the Study to go forward in as highly effective a way as possible, working in partnership with the CDC, EPA, and the NIEHS. The NCSAC plays a particularly important advisory role in the Study. The Program Office and NICHD leadership have regular communications and meetings with NIH Director Francis Collins, M.D., and others in the Office of the Director. Dr. Collins is personally

committed to the Study because the Study provides an opportunity to advance the NIH's mission. Dr. Collins also wants the Study to go forward in a highly effective manner. One of the challenges for the Study is gathering input in an open process from many sources and voices.

Dr. Guttmacher explained that the NICHD is embarking on a year-long scientific visioning process. This process is not a typical NIH strategic plan. It is an effort to involve the external community, including other NIH Institutes and Centers, other federal agencies, and the public to identify future scientific research opportunities for the NICHD's broad mission over the next decade. Nine workshops with about 60 participants each will be held in January, February, and March 2011. Dr. Guttmacher said NCSAC members may be invited to participate in the workshops. Each workshop will produce a white paper, which will be posted on the NICHD Web site for public comment. After the workshops, a large meeting with several hundred participants will be held. The goal of the meeting is to clarify the NICHD's scientific future.

Dr. Guttmacher briefly addressed the issue of the Study's future funding. Congress has been informed that the Study's budget requirements for fiscal year 2011 are not currently known but that budget estimates will be data driven. It is expected that the Study will operate within its current budget.

Comments from the NIEHS Director's Office

Linda S. Birnbaum, Ph.D., DABT, ATS, Director, NIEHS, and National Toxicology Program (NTP), NIH, HHS

Dr. Birnbaum said she has been a strong supporter of the Study since its inception. She remains a strong and ongoing Study supporter. The Study is a valuable tool for understanding how the environment affects health and developmental outcomes. The NIEHS's commitment to the Study is reflected in the service of several NIEHS staff: Allen Dearry, Ph.D., Kimberly Gray, Ph.D., and Sheila Newton, Ph.D. Dr. Newton is the new chair of the Study's Interagency Coordinating Committee (ICC). NIEHS scientist Walter J. Rogan, M.D., will be serving on the Independent Study Monitoring and Oversight Committee (iSMOC).

NIEHS and NTP research programs have been generating information about the critically important processes that occur early in development and shape health and well-being throughout life. The Study is a vital resource for understanding the windows of susceptibility to environmental exposures. In addition to chemicals such as lead, the concept of critical windows also applies to hormonally active agents that disrupt the endocrine system. This is a key area of NIEHS and NTP research. For example, the NIEHS is funding studies of bisphenol A and the effects of developmental exposures on health outcomes such as behavior, obesity, diabetes, reproductive disorders, cancer, and asthma.

Environmental exposures are being implicated in the obesity epidemic. There is a growing body of evidence for the developmental origins of obesity and the theory that environmental exposures during development play an important role in the current epidemics of obesity, type 2 diabetes, and metabolic syndrome.

Dr. Birnbaum noted that the NIEHS is sponsoring a workshop organized by the National Academy of Sciences on the use of *in utero* and postnatal indicators to predict health outcomes later in life. The workshop is focusing on advances in development of short-term animal studies and human biomarkers of effects that could be used to investigate associations between *in utero* exposures and diseases later in life. The results of these types of studies will be useful in interpreting the results of human studies such as the Study. The results will help to make decisions about critical analytes for measurement.

The Study is an important complement to the NIEHS's overall research efforts in children's environmental health. The centerpiece of these research efforts is the joint EPA–NIEHS program of the Children's Environmental Health Research Centers. NIEHS scientists are exploring possible collaborations with the Study, the Pediatric Environmental Health Specialty Units, and national birth defects surveillance programs. The NIEHS breast cancer and environment research program is investigating whether there are periods of susceptibility in the development of the mammary gland when environmental exposure may impact the breast and endocrine system that can increase the risk of breast cancer in adulthood.

Qualification and Validation of Environmental Assessments

Considerations for Analyte Selection

Mary Ellen Mortensen, M.D., M.S., Senior Medical Toxicologist, National Center for Environmental Health, CDC, HHS

Dr. Mortensen has been working with the Program Office to review the current biospecimen collection protocol. She was asked to make recommendations on the protocol. She summarized the biospecimens for exposure assessment and their target analytes from the Study's Research Plan as follows:

Types of Samples	Target chemical/agent/analytes (measures)
Blood (maternal, paternal, and cord blood)	Polychlorinated biphenyls (PCBs), persistent and nonpersistent pesticides, PBED, perfluorinated compounds, perchlorate, lead, mercury, cadmium, bisphenol A, cytokines and chemokines, immunoglobulins, Hgb A1c, fasting glucose and insulin, lipids, adipokines thyroid studies, corticosteroid studies, estrogens, progesterone, dietary antioxidants, folate, complete blood count, lymphocyte subsets, DNA, RNA
Urine (maternal and 6-month infant)	Alkyl phenols, mercury (inorganic), arsenic (speciated) perchlorate, halogenated phenols (phencyclidine), phthalates, atrazine, organophosphates, carbamates, pyrethroids, ethylenethiourea, ethylenebisdithiocarbamates, cadmium, cotinine, infection (polymerase chain reaction)
Breast milk	Dioxins/furans, organochlorine pesticides, PCBs, cytokines and chemokines, immunoglobulins, macro and micro nutritional components

Meconium	Cotinine, organophosphate metabolites
Nails (infant)	Mercury (organic and inorganic)
Hair (infant)	Cadmium, cotinine, mercury, nicotine
Saliva	Cortisol
Vaginal swab (prenatal)	Gram stain, cytokines and chemokines, metalloproteinases
Placenta, umbilical cord	Histology, cytokines and chemokines, immunoglobulins, DNA

The Study's original plan was to serve as a biobank. All samples were to be stored for future analysis. The biobank approach has both advantages and disadvantages. One advantage is that stored samples can be analyzed for analytes that may not currently be identified or recognized as important. A disadvantage is the analytes must be stable for future analysis and contaminant-free.

One approach to determine what samples to collect is to target analytes of primary interest. With this approach, the required amount of the sample can be determined, the use of the sample is known in advance, and the analyte stability and sample storage conditions are known. Analyses of the analytes can be conducted before the outcome of interest is known. Currently available laboratory methods can be used. However, some quantity of sample must be preserved for future analyses when new analytes of interest become identified. Targeting analytes may be cost-effective, feasible, and acceptable.

Targeting analytes would help develop groupings or panels of analytes that may be related to outcomes of interest, such as diabetes, asthma, development, and reproduction. The panels of analytes would already be known to be associated with the outcomes from peer-reviewed research in animals or humans. Additional consideration may include the likelihood of detecting the analyte, based on biomonitoring data in similar populations, if available. As an example, Dr. Mortensen listed environmental and nonenvironmental analytes that may be grouped to study thyroid function.

NCSAC Discussion and Recommendations

The group discussed the following topics and issues about the Study analytes:

- Dr. Birnbaum commented on the importance of collecting biospecimens as early in a child's life as possible. She noted that the effects of several current chemicals of concern were not known 10 years ago. Long-term storage of biospecimens is critical to studies of future chemicals of concern. Managing contaminants in stored biospecimens is an important area of concern.
- Dr. Silbergeld commented on the linkages of analytes and outcomes. One approach would be to start with outcomes of interest and work backward to risk factors. This approach would focus on as many biomarkers as possible for the outcome. It is important to look at early indicators, not clinical status assessment. The Study should be exposure-driven instead of

endpoint-driven. Dr. Hirschfeld commented that the Study is not going to preselect outcomes. The Study is an evidence-gathering platform that is interested in certain domains of health outcomes. The Study's data should be able to link with other data sets.

- Dr. Guttmacher noted that the Study is not designed to answer a set of specific hypotheses. It is a data-gathering platform, and it will be a scientific resource for future analyses. The samples that are collected are those that are most likely to be of use to the research community to answer questions about child health and development over a long period of time.
- Dr. Silbergeld said there should be some prioritization of the samples to be collected and associated health outcomes. She noted that it is challenging to design a study without informing hypotheses. The Study should collect as many samples as possible to address the hypotheses. The Study should be hypothesis-driven.
- Dr. Birnbaum said the value of the Study is to develop a framework upon which hypotheses can be driven. The Study will be a data platform for many future studies whose hypotheses have not yet been determined.
- Dr. Lebowitz said some of the samples that are being collected are related to the hypotheses that were previously identified in the planning phases of the Study. However, there are scientific issues regarding what is not known about exposures and outcomes. It is important to collect and store samples in a manner that can address these unknown exposure–outcome associations so that as science advances, these associations can be analyzed. Samples that degrade with time will have to be analyzed in a timely manner. Samples that are stored for long-term stability can be analyzed in the future to address future hypotheses.

Developing the Third Edition of the American Academy of Pediatric's (AAP) *Pediatric Environmental Health (Green Book)*

Helen J. Binns, M.D., M.P.H., Chair, AAP, Council on Environmental Health; Director, Lead Evaluation Clinic and the Nutrition Evaluation Clinic; and Professor of Pediatrics and Preventive Medicine, Feinberg School of Medicine, Northwestern University

Dr. Binns reviewed the process for developing the third edition of the Green Book, which is considered AAP policy. The revisions began in 2007. The AAP Committee on Environmental Health (COEH) identified gaps in the second edition. The gaps were reviewed with the editors. Forty-two chapters were retained or merged from the second edition. Nineteen new chapters were added to the third edition. The COEH and editors identified experts to lead the revisions and write for each chapter. After a series of reviews by the COEH, editors, and writers, a list of the chapters was sent to all AAP committees and sections. After another series of reviews by the COEH, editors, and writers, the chapters were approved by the COEH and editors and sent to the AAP board for final approval.

NCSAC Discussion and Recommendations

- Dr. Henry asked whether the AAP would consider a chapter on the Study in the Green Book's resource section. The chapter would alert pediatricians that the Study will be a resource for the pediatric community for decades to come. Dr. Binns said the AAP would probably be hesitant to include a chapter on any particular study.

Overview of Proposed NIEHS GuLF Study: Long-term Follow-up of Oil Spill Clean-up Workers and Volunteers

Aubrey K. Miller, M.D., M.P.H., Senior Medical Advisor, NIEHS, NIH, HHS

The Deepwater Horizon explosion occurred on April 20, 2010. As a result, there are several areas of exposure concerns for the Gulf Oil Spill (GOS): crude oil, dispersants, and chemicals from burning. Other concerns include heat stress and physical hazards. The proposed NIEHS GuLF Study will focus on the following health areas: respiratory, cardiovascular, liver, immunologic, hematologic, renal, mental health, dermatologic, cancer, reproductive, and neurologic.

The primary objectives of the GuLF Study are to assess short- and long-term health effects associated with oil spill clean-up and create a resource for future collaborative research, with focused hypotheses and specific subgroups. The scientific hypotheses are as follows:

- Controlling for other factors, exposure to oil-spill related chemicals is associated with adverse health effects.
 - There is a dose-response relationship between exposures and health effects (using qualitative and semi-quantitative measures).
 - Biomarkers of potentially adverse effects are associated with chemical exposures.
- Workers from the Gulf Region will be at greater risk for mental health outcomes than workers and controls from other regions.

The study population will be adults older than age 18 and will include workers (oil companies, vessels, shoreline crews), volunteers, and federal and state personnel (for example, Coast Guard, fish and wildlife, and others). Communication will be in English, Vietnamese, Spanish, and other languages to be determined. The study population will include exposed and unexposed people. The expected cohort size is 55,000. The study will recruit a subcohort of 27,000 people for follow-up in a long-term clinical study, with a follow-up of 10 or more years.

Home visit data will be collected with detailed questionnaires, environmental samples, physiologic and anthropometric measures, and biospecimens, including blood, urine, toenail clippings and/or hair, and possibly saliva for DNA.

A biomedical surveillance subcohort study of about 5,000 people will be conducted in collaboration with other researchers in the Gulf Region, using a common protocol with some variation. This study will have an extensive clinical assessment at 1 and 3 years.

The GuLF Study will have a comprehensive, transparent data-sharing plan modeled on recent studies, following NIH guidelines. Oversight will include peer-review of the protocol by NIEHS scientists, IRBs, the OMB, federal agencies, committees, and the public. The study advisory

board will be a subcommittee of the NIEHS Board of Scientific Counselors. There will be ongoing oversight by the Institute of Medicine and federal panels.

NCSAC Discussion and Recommendations

The group discussed the following topics and issues about the GuLF Study:

- Dr. Birnbaum noted that the GuLF Study was funded about 4 months ago and will be in the field in the next month. The study's toxicology effort is focusing on analytical chemistry issues. The analytical focus is on the mixture of crude oil, dispersants, and weathered materials. In the near future, the NIEHS will lead an NIH-wide effort to form consortia of research institutes in the Gulf Region. The consortia will determine the focus of GOS studies. Funding should be awarded for at least three consortia in June.
- Dr. Henry asked whether any studies are monitoring children's exposures. Dr. Miller said there is no specific monitoring of children, but there is monitoring of exposures of the general community in the region.
- Dr. Lebowitz said it would be interesting to study children born to workers with preconception DNA or RNA damage. Dr. Birnbaum said this area of investigation may be proposed by the newly formed research consortia. Environmental samples and biospecimens collected and stored by the GuLF Study will provide a platform for future GOS studies.

General Discussion

The group discussed the following general issues and topics:

- Dr. Ellenberg said the National Collaborative Perinatal Project (NCCP) was funded and conducted by NIH's National Institute of Neurological Diseases and Stroke. The NICHD became involved in the project by storing the project's frozen samples. The hypothesis that originally drove the NCCP was very broad and ultimately nonexistent. But the NCCP has been highly successful. He said that the Study would be valuable by simply being an observational study not driven by hypotheses. The Study should determine those measures that are most likely to be useful for studying the broadest range of outcomes.
- Michael F. Greene, M.D., expressed his concern with informing Congress that the Study will simply collect data and not state what questions about exposures and outcomes it plans to address. The Study's costs depend on the number of samples to be collected and the number of analyses to be conducted. Dr. Green's concern is that people who support the Study will consider the data-collecting approach too vague and will not understand how the data will be used to address public health issues. Dr. Hirschfeld said the Study's approach is credible. The Study's mandate is to investigate environmental and genetic influences—both positive and negative—on child health and development. One of the challenges for investigating these influences is to define "healthy" and identify the dimensions of health. The Study will be able to contribute to understanding the spectrum of health. Defining health may be able to lead to goals of health outcomes. Another important part of the Study is to focus on

operational components and develop platforms and infrastructure for conducting large, multi-institutional longitudinal studies. By collecting minimal data at this point in the Vanguard Study, the Study will be able to better determine the costs of infrastructure. Dr. Hirschfeld explained that the Study cannot afford to “do everything” concerning data collection. The Study needs to determine what samples and specimens are most valuable to collect—for both current needs and potentially future needs. The Study’s current emphasis is on cost, feasibility, and acceptability.

- Dr. Silbergeld commented that one of the Study’s urgent criteria is to have a representative sample. Dr. Hirschfeld explained that there is a long history of the Study’s sample. Because there are issues with the definition of “representative,” the Study is using a probability sample based on geographic areas. This approach allows a framework to judge the inclusiveness, deficiencies, or biases of Study enrollees. Based on data so far, the enrollees appear to reflect the descriptions of the populations in the Study location geographical areas. By focusing on the operational approaches (for example, through the three alternate recruitment substudies), the Study can make adjustments in its outreach and recruitment efforts and strategies.
- Dr. Silbergeld asked whether one of the criteria for the alternate recruitment substudies’ “success” is confirming that the substudies have recruited a representative sample from their geographical areas. Dr. Hirschfeld said this type of data will be captured. The Study will be working with the U.S. Census Bureau to ensure that Study data are compatible with Census data in order to compare enrollees with the general population.

Study Informatics

*Steven Hirschfeld, M.D., Ph.D., Acting Director, National Children’s Study, NICHD, NIH, HHS
Dave Songco, M.E.A., Chief Information Officer, Office of Administration Management, NICHD, NIH, HHS*

Dr. Hirschfeld provided the following informatics update:

- **Informatics goal.** The goal of the Study’s informatics is to develop modular scalable systems based on open-source standards that are interoperable and semantically and service aware. The informatics system will require and should support periodic technology refresh. The system will operate on a facilitated decentralization model to balance consistency with flexibility and innovation.
- **Anticipated contributions.** The Study will collect prospectively rich data from a broad scope of measures beginning prior to or during pregnancy through 21 years of age on a large, representative sample. It will form the basis of child health guidance, interventions, and policy for generations. The Study is in dialogue with multiple international partners, including the World Health Organization, the International Childhood Cancer Cohort Consortium, and several national studies in Europe and Japan regarding collaboration.
- **Data sharing.** Data from the Study are intended to be shared broadly with other researchers. Data will not be reserved for use by participating Study investigators. There is a Data Access Committee with specific policies. As appropriate, data from supplemental methodological studies (integrated with the Vanguard Study) and adjunct studies (integrated with the Main Study) will also be shared.

- **Trends.** Some of the informatics trends are modular architecture, terminology with curation, scalability, data transmission standards, robust security, open-source platforms, integration of processes, and interoperability.
- **Terminology.** There is a general absence of consistent child health-oriented terminology. The NICHD in collaboration with the National Cancer Institute began an initiative in 2008 to link concepts through developmental stages. A model developed in the Unified Modeling Language (UML) was used to associate concepts of interest and generate metadata.
- **Business development model.** The development business model is “facilitated decentralization,” with (1) central architecture, specifications, and archive and (2) local case management, data acquisition, and temporary data storage. Selection of local systems is flexible, but data transmission must conform to specifications and schedule.
- **Data and information management.** Efforts to manage the Study’s information and data can be categorized into three primary approaches: centralized informatics, facilitated decentralization, and a main information management system (for the Main Study).
- **Data collection.** Data collection will be implemented in several phases. Four types of data and information has or will be collected during the course of the Study: questionnaires, physical measures, environmental specimens, and biological specimens.
- **Types of data and information.** Four types of data and information has been or will be collected: questionnaires, physical measures, environmental specimens, and biological specimens.
- **Advancement of information technology.** The Study will contribute to the advancement of information technology that supports the broader science community. Vanguard Study recruitment approaches serve as a test-base for applying technology in new ways to support research in the Main Study. Many of the modular systems and approaches developed to support the Vanguard Study can be tailored to meet the needs of other research efforts, including automated data collection tools, content authoring and management data collection, and data quality control (QC).
- **Challenges.** The Study’s informatics has several challenges. The schedules for both the alternate recruitment substudies and the Main Study are extremely aggressive. There will be an evolving system of requirements and protocols. External approvals will be required from the OMB and various IRBs.
- **Summary.** A study of such complexity, scientific potential, and duration requires solutions that:
 - Provide exceptional architectural flexibility to incorporate new technologies
 - Accommodate evolving scientific inquiries with functional extensibility
 - Are scalable to a capacity exceeding any comparable study
 - Ensure the highest quality data and lowest burden of data capture from children
 - Guarantee participant privacy and security while respecting cultural boundaries
 - Facilitate data releases to the scientific community
 - Ensure no data are lost and archives are secure for future generations
 - Are reusable, either in full or in part, for other studies.

NCSAC Discussion and Recommendations

The group discussed the following issues and topics regarding informatics:

- Thomas Ten Have, Ph.D., M.P.H., asked for a definition of decentralized data entry. Mr. Songco explained that in the initial information management system, the Study supplied all hardware and software for the seven original Vanguard Centers. There was a central system for visit scheduling and data collection. In a decentralized approach, each Study Center will use its own hardware and software and manage its own scheduling and data collection. However, all data will be transmitted in standard formats to a central system. There will be some data quality, security, and data transmissions issues. The central system will manage QC and quality assurance (QA) of the data.
- Patricia O'Campo, Ph.D., asked whether all processes will have the same quality and quality checks. Mr. Songco said these issues will be analyzed over the coming months as the Vanguard Centers shift their informatics platforms. The Study is already testing the quality of data being transmitted. The data files transmitted by the 30 new Vanguard Centers implementing the three alternate recruitment substudies will be analyzed for quality and compliance to standards. The different informatics platforms from the Vanguard Centers will be evaluated.

Tools and Solutions for Data Capture

Pacific Northwest Center for the National Children's Study (PNWNCS): Informatics

Elaine Faustman, Ph.D., DABT, Principal Investigator, PNWNCS, University of Washington

The goals of the PNWNCS informatics system are to (1) create a paperless, open-source, tablet-based system with geographic linkages; (2) develop an easy-to-use but scalable and flexible, robust informatics platform; and (3) use a modular approach if possible. The PNWNCS informatics system was designed by the Collaborative Health Studies Coordinating Center, which is part of the Department of Biostatistics at the University of Washington.

The informatics system uses iPads to collect data in the field. A secure Web site is used for case management and scheduling. The call center has been integrated into the informatics system. Geolocation capabilities have been leveraged. The geolocation capabilities allow the integration of census data and other existing data sets with geocoding. They also allow a paperless interface for the listing process.

The iPad secure client is password protected. Data stored on the iPad are encrypted with OpenSSL (the key is not stored on the device; it is derived from the password, so it is protected even if the iPad is stolen and jailbroken). The iPad secure client has remote data wipe capabilities and an encrypted data transmission to a central server (via Secure Socket Layer). The central server is in a secure FISMA-compliant facility at the University of Washington. The global positioning system (GPS) in the iPad automatically records latitude and longitude where an instrument was completed.

The informatics system's current capabilities include the following:

- Prototype instruments have been implemented on the iPad.
- The thin and light tablet has high-resolution display and long battery life.
- Thick client collects data even if a Wi-Fi or 3G cellular network connection is not available.
- Skip logic shows only relevant questions based on previous answers.
- Automatic time stamps gather metrics data.
- Built-in GPS records location where an instrument was completed.
- The system has auto-validation.
- The system has calculated fields.
- The system can upload data via encrypted Wi-Fi or 3G cellular network to the secure server at the University of Washington.
- The software system allows for quick development and modification of forms, which is essential for rapid entry into the field.
- The system is scalable to a large number of sites and interviewers.
- Field validation is underway.

NCS-Arkansas: Open-Source Informatics Solution

Umit Topaloglu, Ph.D., Medical Faculty/Staff, University of Arkansas for Medical Sciences

The Study's informatics faces many challenges, including numerous and diverse types of data and Study Centers. System interoperability is a key requirement. No single software application will be sufficient. Standards will be essential. There needs to be data uniformity, quality, and transparency. The informatics platform needs to be compliant with the Federal Information Security Management Act (FISMA).

The goal of the University of Arkansas for Medical Sciences (UAMS) Study Center is to create an open and interoperable clinical research infrastructure that addresses the needs of the Study, with limited funding or personnel. The options for such a system were to buy, build in-house, or collaborate and reuse standards and open-source initiatives. The UAMS Study Center chose open-source initiatives. No vendors will be involved.

The informatics suite at the UAMS Study Center is based on cancer Biomedical Informatics Grid (caBIG) components. The system has a portal that allows easy access to the applications and is integrated with a single sign-on. There is an emphasis on standards (common data elements and terminologies). The components include a central clinical participant registry and tracking tool (C3PR), a patient study calendar (PSC), an open-source LimeSurvey tool, caTissue for tracking biological specimens, and OpenClinica for data capture.

Currently, the UAMS Study Center is building instruments in LimeSurvey, finalizing the Study in C3PR, beginning to analyze requirements for data transmission to the Program Office, and working on address lookup.

OpenClinica: An Alternative for the Study

J. Michael Dean, M.D., M.B.A., Chief, Division of Pediatric Critical Care Medicine, University of Utah School of Medicine

OpenClinica is open-source software. There are several main advantages to open-source software: access to source code and the ability to read it and understand it; ability to enhance functionality; and ability to fix problems more quickly. There are three main disadvantages: perception of amateur quality, perception that the cost should be free (it is not free), and potential lack of support. Access to source code enables the user to read the actual code, potentially alter the code, and perhaps identify ways to improve the whole system. For the Study, direct access to the underlying data model is critical and perhaps more important because relevant data will need to be mapped to the central Study data that will be held at the NIH.

There is a perception that open-source software, because it is free, must be of lower quality. An alternative view is that open-source software is often superior to most commercial software because of potential peer review. Support of open-source software is often superior. OpenClinica can use an entirely open-source software stack, all components of which are highly reliable and established. OpenClinica will completely support several open-source systems (for example, Redhat, Linux, and Tomcat) and will support several proprietary systems (for example, Windows and Oracle). The company will not provide paid support for unsupported platforms. OpenClinica provides a menu of support services ranging from training through full validation and hosting services.

Skip patterns are a complex problem in Web-based applications. OpenClinica does not currently have skip patterns, though this feature is in the current alpha software. Skip patterns have significant technical disadvantages from a database standpoint. Although skip patterns sound like a great feature, they are not simple.

Because open-source software offers significant advantages, OpenClinica has the potential to be useful to the Study as informatics requirements change. OpenClinica is a good open-source system for developing Web-based data collection systems. Its rapid event and form definition process will permit Study Centers to be flexible to changes that will inevitably occur over the course of the Study. Open-source software will prevent vendor lock and enhance the Study's ability to keep up with novel input methods based on future hardware technology.

Research Electronic Data Capture (REDCap)

Paul Harris, Ph.D., Research Associate Professor, Biomedical Informatics and Biomedical Engineering, Vanderbilt University School of Engineering

In 2004, Vanderbilt University conducted a needs assessment for researchers who needed help managing data for small- to medium-sized nontrial research projects. At that time, there were many projects and few resources. The hypothesis was that researchers will “do the right thing” (for example, FISMA compliance, security, and audit trails) if provided an easy way to get needed tools. The solution was a metadata-driven application (that is, no per-project programming).

In 2006, the REDCap Consortium was launched to share with other universities and foster collaboration for future development. In 2008, the university received a Clinical and Translational Science Award for an informatics pilot project to increase capacity and streamline processes for collecting and managing data in diverse scientific areas of study. The REDCap Consortium model was designed to provide software and support at no cost to partners who host their own data. Currently, there are 9,430 end-users, 3,020 projects, and 136 full institutional partners.

REDCap has an iterative workflow for creating projects that includes all research team members, helping to solidify the data management before enrolling the first patient. It has a proven track record in supporting diverse studies, including basic research, clinical research, community research, global health, and research operations. REDCap is currently supporting many underserved locations worldwide.

REDCap is cost-effective, and the setup infrastructure is minimal. Most sites using REDCap leverage one or two staff members to support studies for the entire research enterprise. REDCap may be quickly configured to support a variety of single-site and multisite study needs. The setup can be completed in hours if the data collection plan is in order. REDCap provides data deidentification services, participant scheduling support, data transfer services and application programming interface (API), graphical data review, double data entry, multisite data collection, and full audit trails and logging.

The Vanderbilt University Study Center currently has REDCap projects to support Study operations for screening and enrollment and for the Hi-Lo alternate recruitment visit database. The Study Center has submitted its final FISMA security plan. A new data server room has been completed. Hardware and software for the data server room have been installed. The Study Center is waiting for authority to operate. The expected technical “go-live” date is November 3. The case report forms have been shared with other Study Centers that are using REDCap. The FISMA security plan has not been shared because it has not yet been officially approved.

NCSAC Discussion and Recommendations: Tools and Solutions for Data Capture

The group discussed the following issues and topics regarding tools and solutions for data capture:

- Dr. Hirschfeld asked whether the four systems described in the presentation would be able to “talk” to one another (that is, appropriately linked and interoperable). Dr. Harris said that the systems could not. One of the goals of open-source and modular software is to achieve system interoperability.
- Dr. Dean commented on the utility of open architecture to ensure that data can be transmitted. Open architecture does not necessarily require open-source software.
- Dr. Faustman commented that the PNWNCS informatics modular approach was to expedite the implementation of field operations. The PNWNCS is still working on FISMA compliance

and connectivity. Dr. Faustman noted that the informatics platform has multiple levels of QC. She said there is a need for QA/QC procedures and reviews among the Study Centers.

- Dr. Ellenberg asked whether the just-discussed methods were designed to achieve certain functionalities, which are not necessarily new. He also asked if there is a risk from using multiple users with multiple approaches that open-source code could be accessed and potentially denigrate the Study's uniform specifications. Dr. Faustman said that there is a potential for corruption, but there are a variety of approaches to QA/QC of the data systems.
- Dr. Ten Have said there should be some standardization of data entry, data management, and case management systems across the different systems at the different Study Centers.
- Dr. Ellenberg asked about the design of assessing the different data systems. Dr. Hirschfeld said the Program Office has designed some data elements to evaluate operational characteristics and costs. There will be users groups to get informal, ongoing feedback. The Program Office will be conducting site visits. Through remote monitoring, interviews, and site visits, the Program Office will have a good idea of the strengths and weaknesses of the different approaches. The data will inform the Program Office as to what the next steps should be for Study informatics.
- Dr. Henry asked how the use of open-source system versus proprietary systems will be evaluated. Mr. Songco said the Study, for a variety of reasons, decided to move away from proprietary systems and a centralized approach. Mr. Songco described the process for evaluating the Study Centers' informatics platforms, making decisions about what platforms will work, and designing the final informatics platform for the Main Study. The Study will evaluate and make decisions based on the Vanguard Centers' experience and available data.
- Dr. O'Campo summarized the discussion of data acquisition and management as follows:
 - The NCSAC has concerns about the quality of data and the need to ensure that whatever system or systems the Study adopts for the Main Study is able to be checked in terms of its ability to generate high quality data.
 - There was clarification that the Study is not necessarily looking for open-source software but for nonproprietary vendor software and open architecture.
 - The NCSAC would like to see some transparency about the criteria that will be used to choose the Main Study's informatics platform.
 - The NCSAC would also like to see some transparency in how some of the QA/QC activities are undertaken in order to determine the system or systems that are adopted for the Main Study.

NCSAC Discussion and Recommendations: Environmental Assessments

The group discussed the following issues and topics regarding environmental assessments:

- Dr. Silbergeld said there are two approaches to collecting environmental samples and biospecimens: (1) collecting a variety of samples and specimens that would be stored for future analyses and (2) developing hypotheses and selecting samples and specimens to

address the hypotheses. The Study does not necessarily have to choose one approach or the other. The approach could be a combination of the two.

- Dr. Silbergeld asked for clarification on real-time analyses. Dr. Hirschfeld said real-time analyses involve analyzing samples and specimens as soon as possible after they are collected to lessen the concerns with shipping and storage, essentially not archiving the samples and specimens. Dr. Silbergeld said the samples could be split so that there could be immediate and intermediate analyses, with other portions of the samples archived for future analyses. Most of the challenges with stability of long-term storage have been met. With regard to missing scientific opportunities, the design of the Study could be adjusted. With regard to delaying deliverables, shorter time or intermediate analyses are likely to be incomplete in terms of representing the population that is being sampled. The Study should be careful about what deliverables would be delivered. Full data sets often provide different information than intermediate analyses do. Doing intermediate analyses and future analyses of stored samples increases the work load. The option of using a hierarchy of environmental substances, with a subset of a larger class as index analytes, may have limitations.
- Dr. Hirschfeld said that in its previous meeting, the NCSAC discussed the inconsistencies in the different types of environmental assessments. The Study is exploring an initiative to align different concepts and operations across different fields. So far, terminology has been aligned. Dr. Silbergeld agreed that the methodologies for environmental analyses should be standardized across the different Study labs to ensure that comparable data can be combined.
- Steven K. Galson, M.D., M.P.H., asked whether decisions have been made about the best methodologies for measuring environmental exposures such as lead (for example, in blood, deciduous teeth, or bone). Dr. Silbergeld said the methodology would depend on the type of information that is desired. There are ethical issues with using certain methodologies in children. Given the uncertainties of the Study's design and purposes, it is challenging to decide at this time what methodologies are most appropriate.
- Dr. Lebowitz commented on biomarkers. Studies have found that certain biomarkers are unstable, and their value was decreased within months. For the Study's proposed samples, some are stable and some are unstable. With regard to deliverables, one of the goals is to provide information to participants and/or their physicians about levels of concern. Panels of analytes and/or pollutants can provide information on cumulative and additive exposures and effects. Biomarkers can provide information beyond information gathered through environmental questionnaires.
- Melissa Tassinari, Ph.D., noted that NIEHS studies may be collecting that same types of samples that the Study is. The Study should be proactive in leveraging its efforts. Other studies may have already answered questions that the Study is attempting to answer, or the Study could take steps forward based on the findings of other studies. Dr. Hirschfeld said the Study has been communicating with studies around the world in an effort to leverage data collection activities. The leveraging will be driven by informatics. The Study will continue to communicate with similar longitudinal studies.

- Dr. Lebowitz asked if the ICC has addressed questions about environmental assessments and data acquisition and management. Dr. Henry said the NCSAC has requested reports from the ICC and the iSMOC.

Rapporteur's Summary

Dr. Green summarized the meeting as follows:

- There is a consensus among the NCSAC members that the quantity and method of presentation of the data regarding recruitment and retention of Study subjects was inadequate for the NCSAC to understand how well recruitment and retention were proceeding. The NCSAC may be vulnerable to criticism for inadequate oversight, feedback, or advice to the Study without more detailed data for review by the NCSAC.

The NCSAC still has some concerns about the Study design because it is specifically not driven by a plan to test specific hypotheses. The NCSAC recognizes that there may be questions or issues that may come up in the future that cannot be anticipated at this time.

- There is some tension between collecting and storing a wide range of samples in the hope that the Study will have the type of demographic data and/or biospecimens collected in the appropriate containers with the appropriate preservatives at the appropriate time to answer the questions that are later formulated.

There is some tension between immediate measurements and recording of analytes that can be reasonably anticipated to be of interest versus long-term storage of biospecimens for future analyses as specific research questions are formulated. As samples are collected, they should be stored with a maximum granularity, which would permit categorization into groups later rather than categorizing the samples at the time of collection.

There remains some concern that the new recruitment substudies may not preserve the planned representativeness of the sample. Many NCSAC members are not convinced that the representativeness of the sample will be preserved just because the new recruitment substudies are being implemented in the originally planned geographical areas and Study sites.

There remains some concern that the lag time between the Vanguard Study activities and the planned launch of the Main Study may not allow enough time to inform best practices for recruitment and retention for the Main Study cohort.

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



January 18, 2011

Date

Carol J. Henry, Ph.D.
Chair
National Children's Study Federal Advisory Committee