Final Transcript

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT: National Children's Study

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SPEAKERS

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PRESENTATION

Moderator: Ladies and gentlemen, thank you for standing by and welcome to the National Children's Study conference call. At this time all participants are in a listen-only mode. Later we will conduct a question and answer session. Instructions will be given at that time. As a reminder, this conference is being recorded.

I would now like to turn the conference over to our host, Dr. Duane Alexander. Please go ahead.

Dr. Alexander Good afternoon. Welcome and thank you for participating in today's teleconference briefing. Today we announced the funding of 22 new study centers that will participate in the National Children's Study. These new study centers were awarded using fiscal year 2007 funding will operate in 26 communities around the country from which they will draw a diverse population of newborns and their families to participate in the study.

These new centers join seven initial or vanguard centers initially established in 2005. When fully implemented, we anticipate a total of approximately 35 to 40 centers in 105 locations being selected to carry out the study that will provide a representative sample of the diverse population of children in the United States.

Today's announcement represents a milestone for the National Children's Study. The Study's staff will now engage a broader cross-section of families and communities and take another step towards full operation of the study.

Many of you are already familiar with the National Children's Study and others may be just starting to follow it. For those new to the study, I will provide just a bit of background.

The National Children's Study is the largest and longest research study ever to look at the ways in which the environment and genetics interact to influence child health and human development. It will also look at how behavioral and social factors interact with genetics and the physical environment.

Over the next quarter century this study will involve more than 100,000 children from before they're born to age 21. Study researchers will search for environmental and genetic influences on the health conditions of concern to all of us, to parents, educators, healthcare providers and researchers.

These conditions include pregnancy related problems, such as birth defects and prematurity, autism, asthma, diabetes, heart disease, obesity, mental health problems and learning disorders among others. In large part the study will focus on diseases and conditions of increasing prevalence in the United States. For example, autism apparently is increasing in prevalence,

now estimated to affect 1 in 150 children. Asthma is also increasing; in 2005 about 9% of children ages 0 to 17 were reported to currently have asthma and about 5% had one or more asthma attacks in the previous year.

Environmental exposures are thought by many people to be responsible for these increases. Study researchers will examine not only what children are eating and drinking, but what's in the air they breathe, what's in the dust in their homes and their possible exposures to chemicals from materials used to construct or furnish their homes and schools.

The researchers also will analyze blood and other biological samples from study participants to test for exposure to environmental factors and whether these factors might influence their health. They will also look at the neighbor structure of the family, the community and the school to assess the social and behavioral environment in which children grow up.

There are many reasons why we are conducting the National Children's Study now. Among these there is mounting evidence that the health habits and exposures of early childhood, perhaps starting before birth, affect the health and well being of adults as well as children. The recent completion of the Human Genome Project provides scientists for the first time with an

extraordinary opportunity to analyze the interactions between genetic and environmental factors that affect health, research that one day will enable scientists to target specific genes for more effective treatments.

In addition to the genome, new tools for micro assay of chemical exposures are available as well as computer capacity for storage and analysis of huge amounts of data. Health disparities in many disease areas are on the rise among underserved populations. The study will uncover these population specific differences in healthcare, health access and disease risks.

Special efforts will be made to enroll and retain minority populations in this study. Study scientists will share what they find with children's families who in turn can share it with their children's physicians and other caregivers. Families and children who participate in the National Children's Study will directly contribute to the health and well being not only of their own children, but of future generations of children.

Study findings will benefit all Americans by providing researchers, healthcare providers and public health officials with information to revise

or develop new health and safety guidelines, disease prevention strategies and new treatments.

With that background, I'm pleased now to announce the names and locations of the 22 new study centers who have received a contract award from NICHD and the communities they will serve.

There are in alphabetical order: Brown University covering Providence County, Rhode Island; Children's Hospital of Philadelphia covering Schuylkill County, Pennsylvania and Newcastle County, Delaware; Emery University covering DeKalb County, Georgia and Fayette County, Georgia; Johns Hopkins University covering Baltimore County, Maryland; Michigan State University covering Wayne County, Michigan; Mount Sinai School of Medicine covering Nassau County, New York; Northwestern University covering Cook County, Illinois; St. Louis University with responsibility for Macoupin County, Illinois and St. Louis, Missouri; University of California Davis will oversee the work in Sacramento County, California; University of California Irvine will take care of San Diego County.

The University of Hawaii at Manoa will be responsible for Honolulu County; University of Massachusetts for Worcester County, Massachusetts; University of Minnesota will be responsible for Ramsey County of Minnesota and the University of Mississippi for Hines County, Mississippi; University of New Mexico will be responsible for Valencia County, New Mexico; University of North Carolina at Chapel Hill for Rockingham County, North Carolina; the University of Pittsburgh has two sites, Marion County, West Virginia and Westmoreland County, Pennsylvania; University of Texas Health Science Center at San Antonio will be responsible for Bexar County, Texas; University of Utah will be responsible for Cash County, Utah; University of California Los Angeles for Los Angeles County; University of Washington for King County, Washington and Yale University for New Haven County, Connecticut.

We selected these new study centers competitively based on rigorous criteria including ability to collect data for the study, the ability to build extensive community networks for recruiting and retaining knowledgeable women and newborns, and a demonstrated capability to protect the privacy of information collected on participants.

Finally, let me add that the National Children's Study represents an invaluable investment in the future of our children and the future of our nation. This investment will not only help prevent illness and save lives, but will result in significant cost savings as well. We anticipate that the health information we gain will significantly reduce the societal burden of illness and disability.

Currently the financial burden of just five of the Study's major health outcome theme areas – injury, obesity, diabetes, asthma and neuro-behavioral disorders – totals over $750 billion per year. A one percent reduction in just these five areas from knowledge gained from this study would save annually twice as much as the entire 25-year cost of this study.

Now, I would like to introduce the Deputy Director of the National Institute of Child Health and Human Development, Dr. Yvonne Maddox, who will describe in more detail the significant community engagement activities the new study centers will conduct to recruit and retain a diverse cohort of participants.

Dr. Maddox Thank you, Dr. Alexander. I am delighted that we have arrived at this point in the Study's evolution when we can announce today the

participation of this large group of highly qualified study centers. The study has been designed by many of the nation's top experts in child health and the environment. More than 2,400 scientists from academia, multiple federal agencies, national non-profit groups, and community health providers have contributed to the study's planning and its early implementation.

A major challenge of the NCS will be reaching out to the 105 communities to identify and engage the 100,000 participants. Each of the new study centers announced today, however, each has demonstrated success in reaching out to diverse populations. Indeed, the awarding of these new centers affirms the federal government's commitment to scientific research that will lead to the improvement of health for all of America's children.

The NCS is being led by the U.S. Department of Health and Human Services, including the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the NIH and the Centers for Disease Control and Prevention and the United States Environmental Protection Agency. But we also want to

mention that more than 40 other federal agencies and departments have also provided input.

The 105 study locations, which are counties across the United States, represent a cross section of America in terms of ethnic, racial, economic, religious, geographic and social groups. This is, indeed, a national sample of counties. A national sample of counties was selected and was necessary for the study to ensure representation of the entire nation.

The criteria for county selection included factors such as race, ethnicity, income, education level, number of births and number of babies born with low birth weight. So, how will recruitment take place? In these study centers and these study locations, study teams with the help of healthcare professionals and community leaders will recruit women who are pregnant or who are likely to become pregnant.

We also recognize that some women will join the study through their local physician's offices, clinics and hospitals. It was acknowledged early on that recruitment of such a diverse group of American women and their infants would be a complex undertaking, but we are not going to be dismayed because the groups that have already been selected, at least for

today's first wave, have demonstrated an ability to recruit diverse populations and they have built trust and trusting relationships with community leaders. This will be critical as maintaining trusting relationships with community leaders will be the course of the success of the study.

The study's success will require engagement of community based grass roots organizations to work with the campaigns to explain the benefits of the study, to build relationships with area healthcare providers and to reach out to parenting groups and other organizations who offer health information and support of families.

Evidence has shown that this type of relationship really does enhance and maintain retention. Retention of participants is going to be crucial in the study and this will be a challenge and if we maintain these relationships between study staff and between the children and their families, it is likely that we will have great success.

This will be done by engaging local community groups and advocates. It will also mean that study participants will need to be kept regularly informed and up-to-date. This will be done through newsletters,

interactive Web sites for the children, periodic get togethers and public presentations.

To summarize, everything possible will be done to enroll and maintain a diverse population of participants to ensure representation of our nation. Now it gives me great pleasure to introduce Dr. Peter Scheidt, Director of the National Children's Study.

Dr. Scheidt Thank you, Dr. Maddox. As you and Dr. Alexander have conveyed we are especially enthusiastic about today's announcement because it means that the 22 new study centers will begin preparations to recruit participants in the communities that they will serve. On behalf of the Program Office that has worked so hard to come to this day it is incredibly exciting to hear him read this list of new Study centers and locations as the Study lurches forward.

Allow me to briefly present some chronology of the study up to this point and to offer a quick look into the next phases of its development and implementation. The National Children's Study officially began in the year 2000 when Congress directed NICHD and other federal agencies to lead a national, long-term study of children's health and development.

This directive from Congress was issued through the Children's Health Act of 2000. In 2004 we identified 105 U.S. communities from which we would recruit and study participating families. We selected the 105 locations using a scientific probability based method to ensure that the children and their families from diverse ethnic, racial, economic, religious, geographic and social groups are all fairly included in a way that will be representative of the U.S. population and to ensure that we include the critical exposures that all of our children experience.

Then in 2005 the study officially got underway when we announced the selection of the first seven study centers. These centers, called vanguard centers, will be the first to recruit participants and will pilot test the study's different components for incorporation into the full study.

We also awarded the contract for a large coordinating center that will manage information from the study centers, support other parts of the study and integrate all of these parts into a smooth operating large enterprise. All vanguard centers are actively engaged in pre-recruitment activities today and recruitment in the vanguards for the pilot locations will begin in 2008.

Funding for these new study centers and the study's initial phase comes from the $69 million appropriated from Congress in fiscal year 2007. This funding allowed NICHD to issue the requests for proposals, or RFP, for new study centers earlier this year and to make these contract awards that we announced today.

With the large group of study centers funded we are now well underway and can now finally prepare for recruitment in earnest. The centers will begin hiring and training staff, meeting with local community groups and healthcare professionals to inform them about the study and forming community advisory boards to provide ongoing guidance on a range of study related issues.

When enrollment begins for the pilot next year and the full study the following year, the centers will recruit women who are already pregnant or are likely to have a child in the near future and we will also recruit their families to participate. During the four years of recruitment phase all Study centers will aim to enroll at least 250 women each year. These are women who are either pregnant or likely to have a child and it will be 250 women in each location.

Initially researchers will collect information on women's pregnancies, including their diets, environments, chemical exposures, emotional stress and many other factors in their environment. When the children are born and periodically thereafter, researchers will collect biologic samples and environmental samples like air, water, and dust from children's environments.

The researchers will meet with the families, both in their homes and in clinical settings and data will also be collected remotely by telephone, computers, mail-in questionnaires and other technologies as they evolve over the life of the study.

The newly awarded study centers announced today will begin study start-up activities in 26 locations this year. We anticipate in the coming years, in the next two years, competition for the future waves of both next year and the year after, providing that funding is available in order to complete the full sample of 100,000 participants throughout 105 locations.

And with that we can move on to the next comments.

Dr. Alexander Thank you, Dr. Scheidt. We have several people who we have identified to make some brief comments representing various components of the support groups and participants in this Study. The first to speak is Dr. Nigel Paneth from Michigan State University who is one of the new investigators of one of the sites funded. Nigel, are you there?

Dr. Paneth I am here. Can you hear me?

Dr. Alexander We can. Please go ahead.

Dr. Paneth Very good. Let me say that I'm very happy to be here today as the Principal Investigator for the Michigan Alliance for the National Children's Study, which is the name of collaboration among several institutions in Michigan who will together conduct the National Children's Study in Wayne County, which includes the city of Detroit.

Our Alliance includes the University of Michigan, Wayne State University, the Henry Ford Health System and the Health Departments of the State of Michigan, Wayne County and the city of Detroit. Michigan State University, where I serve as Professor of Epidemiology, Pediatrics

and Human Development in the College of Human Medicine, will coordinate the overall effort.

I'm also here to represent my colleagues in this study who are principal investigators at the other 21 Study centers whose names are being announced today. All of my colleagues at the new centers share my sense of anticipation as we move forward in this landmark effort to chart the health of 100,000 American children from pre-natal development to age 21.

As a pediatrician and epidemiologist I am convinced that this study will develop a rich body of evidence that will enable us to better understand the causes of childhood disease and the pathways to healthy child development. We as a nation can then use that understanding to improve child health.

At Michigan State Department of Epidemiology we've worked with several study partners and supporters on investigations related to the National Children's Study. We were privileged to be one of six sites in the nation supported by the March of Dimes Foundation to conduct studies on the cause of premature birth. We serve as the Data Coordinating

Center for CDC's study of the epidemiology of autism and NIH supports among several projects in maternal and child health a research training program in perinatal epidemiology. So, improving the health of children through focused research has long been a part of our mission as it has been for each of our study center colleagues.

Like all study centers we'll work closely with healthcare professionals and community leaders in the Study counties to recruit women who are pregnant or planning a pregnancy. We'll collect information first on women before they're pregnant, then on their pregnancies and births and then on their children's health and development.

We will meet the families at home and in the clinic and we'll learn from other by telephone, computer and mail. We will also collect biological samples and samples of the air our children breathe and the water they drink. Each of the 22 Study centers was chosen because it has shown the capacity to perform these complex research activities.

So, on behalf of my Study center colleagues across the nation I want to say thank you for this opportunity to be part of the National Children's Study.

Dr. Alexander Nigel, thank you very much. We appreciate your being part of this and representing the new principal investigators for the new sites just added.

During the course of our earlier remarks we mentioned that NICHD is not alone in the group of federal agencies in the lead part of planning this study. In addition to the National Institute of Environmental Health Sciences here at the NIH, we've also had major leadership participation from the Center for Disease Control and Prevention and the U.S. Environmental Protection Agency.

I'd like now to introduce from the CDC, Dr. Bob Spangler to make some comments. Bob.

Dr. Spangler Yes, thank you, Dr. Alexander. The Center for Disease Control and Prevention is pleased and privileged to be collaborating with the U.S. Environmental Protection Agency and the National Institute of Health on the National Children's Study.

CDC has been involved for the past six years and it is committed to this unprecedented inter-agency effort. Our involvements have included collaboration in planning efforts over the past few years, development of

methods for assessing environmental and parental occupational exposures, a focus on the fetal origins of health and disease including birth defects, developmental disabilities, obesity and diabetes.

We have provided leadership in the oversight of the collection, storage, laboratory processing and analysis of bio markers of exposure. We've been providing leadership in the incorporation of genetics and the gene environment considerations in the Study plan as well as developing the probability sampling frame that will allow for the enrollment of the representative sample of women and children in the U.S. population.

The study's implementation represents a major and exciting accomplishment for all those involved. The study also embodies the hope that many of the gaps in our knowledge and understanding of pediatric environmental health will finally be addressed.

Of interest to CDC are several knowledge gaps the study will address including defining the nature and extent of the problems facing infants, children and adolescents throughout their life stages; the impact of environmental and genetic factors on child health and development; and

exposure outcome relationships for conditions that are of concern to the pediatric community, public health and families nationwide.

The study will address also two of CDC's new health protection goals, healthy people in every life stage of health, which aims to ensure that all people and especially those at greater risk of health disparities achieve their optimal life span with the best possible quality of life at every life stage. And second healthy people in healthy places, which aims to ensure that the places where people live, work, learn and play will protect and promote their health and safety.

Conducting high quality research through efforts such as the National Children's Study is critical to help the scientific community, parents and policy makers gain sufficient knowledge in understanding of environmental influences on child health and development.

We look forward to the next phases of the study and in continuing our collaborations with EPA, NIH and other partners on the National Children's Study. Thank you very much.

Dr. Alexander Bob, thank you. And we certainly thank the CDC for its lead role in joining us with the planning and development in oversight of this Study.

Also one of our colleagues in the leadership and design for this study has been the Environmental Protection Agency and the Director of their Office for Children's Health Protection is Dr. Bill Sanders. Bill, we welcome your comments.

Dr. Sanders Well, thank you very much and good afternoon to all and thank you, Dr. Alexander. I should tell you all, though, that as of Monday of this week I'm now the Director of the National Center for Environmental Research still here at EPA and still focusing on Children.

So, I guess I should start by saying how tremendously excited I am to be part of this event today announcing the next step in our nation's most far-reaching study on children's health and the environment. It is quite appropriate that we take this momentous announcement during this Children's Health Month, the purpose of which is to focus our national attention on children's health.

The mission of my Agency, the Environmental Protection Agency is to protect human health and, of course, the environment. It is no surprise then that EPA has been deeply involved with the planning and implementation of the National Children's Study from the very beginning.

We have conducted and supported much of the science which laid the foundation for this ambitious study. For instance, EPA's scientists have conducted methods development and pilot projects, which tested the feasibility, the cost and effectiveness of many of the Study's environmental measures and sampling designs.

EPA scientists are developing information on the environmental measures that will be included in the study to identify factors that are helpful, harmful or harmless to children's health and, of course, we hope for the latter.

We've also been identifying exposure outcome links and gene environment interactions to be studied that can be useful in improving risk assessment. EPA scientists have applied their considerable expertise to this effort for one reason – compared to adults, children may be at

increased risk from environmental influences because of vulnerable developing systems and enhanced exposure to many agents.

Those environmental influences include air quality, lead levels and exposure to chemicals and mode, factors that are within society's power to control. The National Children's Study will look at these in the context of the other environments in which children live and grow, including their culture and their communities.

Only a long-term, multi-dimensional study such as this involving children and their parents from across the nation can validate the importance of environmental factors to children's health and development.

As most of you, I'm sure all of you will recall the study's roots reach back ten years to a presidential order that directed each federal agency to identify and to evaluate environmental health and safety risks to children's health. This study, and the multi-agency collaboration, unprecedented I might add, that has guided the development of the study is a direct outcome of that Executive order.

The National Children's Study is truly an unprecedented collaboration among government agencies, private industry and foundations, community leaders, university-based scientists and 105 Study locations around the nation plus, of course, 100,000 children and their parents.

This study will produce important information that will enable my agency to make decisions that will protect children's health. EPA is proud to have the opportunity to be part of this collaboration, which will help improve the health of America's children for generations to come. And thank you on behalf of myself, my office and behalf of all of my colleagues at EPA.

Dr. Alexander Bill, thank you very much for being with us today. We've enjoyed very much the collaboration from EPA and we look forward to that partnership continuing.

Many of the Institutes at the NIH have participated with us in the planning of this study, but the lead partner among them has been the National Institute of Environmental Health Sciences. They are represented today by their Interim Associate Director of the National Toxicology Program, Dr. Alan Deery. Alan, would make some comments, please?

Dr. Derry Thank you, Dr. Alexander. I'm pleased to join my colleagues from NIH, CDC and EPA, with whom we at NIEHS have been working on planning and implementing the National Children's Study for the past decade on this very momentous occasion.

And NIEHS we believe this study will give us a far greater understanding of the role that a wide spectrum of physical, chemical, biological and social environments play in the development of many chronic illnesses, both in childhood and those that appear later in life.

For example, as Dr. Alexander mentioned, asthma is the most prevalent chronic disease affecting American children and it leads to 15 million missed days of school per year. One in six youths age six to nineteen is now overweight and that represents a 45% increase in the past ten years alone.

Of those children newly diagnosed with diabetes, the percentage with Type II diabetes, which is directly related to obesity, has risen from less than 5% to nearly 50% in a ten-year period. Neuro-developmental disorders affect one in six American children today with autism and attention deficit hyperactivity disorder reported at all-time high rates. And

one in eight babies is born prematurely, an increase of nearly 30% since 1981.

Environmental factors influence and contribute to all of these conditions, whether it's allergens or ozone, proximity to parks and safe neighborhoods, exposures to pesticides or metals, or access and availability of good nutrition. The scope and length of the National Children's Study will allow us to develop a comprehensive body of data about environmental risk factors for these and other diseases from autism to breast cancer and Parkinson's.

By reviewing data throughout the course of this study, we will be better prepared to prevent adverse health outcomes associated with hazardous environmental exposures that many of our citizens and their children deal with everyday. And we at NIEHS continue to look forward to working with our partners at NIH, CDC and EPA to further implement the National Children's Study in the coming years. Thank you.

Dr. Alexander Alan, thank you very much. There's really been a triumvirate of organizations that have worked to get this study this far. First have been the four federal agencies with leadership in developing the study. The

second has been the outside scientific community represented in planning of this study and now as principal investigators for the sites. The third component has been the advocacy community and leadership of that coalition of advocacy organizations has been provided by the March of Dimes and the American Academy of Pediatrics.

I'd like now to introduce Dr. Jennifer Howse, the President of March of Dimes, thanking you, Jennifer, for this leadership your organization has provided and welcoming you with the opportunity to make some comments.

Dr. Howse Thank you very much, Duane, and on behalf of our board of trustees and our three million volunteers nationwide, I'm really pleased to be part of this special announcement as we mark the next critical step in the development of this National Children's Study. At March of Dimes, of course, our mission is to improve the health of babies by preventing birth defects and premature birth and infant mortality. We believe that the National Children's Study will make a vital contribution to our mission in a number of important ways, especially as one of the targeted areas of the study is, as you pointed out, pregnancy-related outcomes.

And even though our nation has made great progress in maternal and infant health over the last century, it's still true that the United States lags behind more than two dozen industrialized countries in infant morality rates. There are also, of course, within our nation significant disparities in maternal and infant health outcomes amongst different ethnic groups.
And here again, the National Children's Study, which will have substantial ethnic, economic and racial diversity will help illuminate the reasons for these health disparities, and we believe will help point us towards ways to achieve more equitable outcomes.

And, of course, beyond that, the study will provide invaluable data on the causes of birth defects and premature birth, including the role that diabetes and pre-diabetic conditions might play in birth defects and the impact that infection and inflammation may have on causing pre-term birth, which affects one in eight births in our country.
So by following these 100,000 children from diverse backgrounds through gestation, infancy, childhood, adolescence and young adulthood, the National Children's Study can provide researchers a much needed, detailed health portrait of our nation. We believe that portrait will prove invaluable in making future generations of Americans healthier by improving pregnancy-related outcomes.

So the future of this very important study depends on all of our support, all the stakeholders on this call and beyond. So I would just urge each of you and all of us to join the advocacy community, the March of Dimes, the American Academy of Pediatrics and numerous other groups to continue working with the Congress and the present and future administrations to educate them as to the importance of the study, the meaning of the study and to continue full funding. So thanks very much for the opportunity to comment.

Dr. Alexander Jennifer, thank you for your comments and for your continued strong support of the study. The other lead organization among the advocacy coalition has been the American Academy of Pediatrics. They're represented today by Dr. David Schonfeld, Chair of the Committee on Pediatric Research from the American Academy of Pediatrics. David, welcome.

Dr. Schonfeld Welcome. It's my pleasure to join the call today representing the American Academy of Pediatrics, an organization that represents 60,000 pediatricians nationwide, to add my congratulations to the new study

centers and to reiterate our ongoing strong support for the National Children's Study.

The AAP is an organization committed to the attainment of optimal physical, mental and social health and well-being for all infants, children, adolescents and young adults. So it should stand as no surprise that we were a strong supporter of the National Children's Study since the passage of the Children's Health Act in 2000 that initiated the project. Even back then we realized that this landmark study will provide important findings that will influence healthcare decisions for children for decades to come.

As pediatricians our days are filled with questions from parents, other family members and other healthcare providers about what we and they can and should do to ensure the health of children and to optimize their development and well-being. We, therefore, look forward to the results that will emanate from the National Children's Study that will help us answer these critical questions.

Just as this study will involve mothers and children from every region of the nation and from every socioeconomic and ethnic group, so do the Academy's members serve the full diversity of American children from

the inner cities to rural counties to suburban communities. Our members look forward to working with the staffs at these study centers, as well as others yet to be named, to do our part to ensure the success of the study. And again, I'd like to add my congratulations to the new study center.

Dr. Alexander David, thank you very much for that perspective that's so important on the value of this study and for the ongoing support from the Academy. We now begin the question and answer portion of the tele-briefing. Please state the name and the organization you are calling from before you begin. Thank you.

Moderator And our first question comes from the line of Joanne Dotson from Department of Public Health. Please go ahead.

J. Dotson This is Joanne Dotson in Montana. We were interested in more information about the sampling design. We're located out in one of the several states with no study sites.

Dr. Scheidt This is Dr. Scheidt and yes, you're correct. You are located in one of the states with no study site. As I mentioned previously, as both Dr. Alexander and I mentioned previously, this was a sampling design that it was a scientifically derived probability sample. And all states and all

counties in all states had an equal probability of being able to be included in the study, based on the distribution of their population and the characteristics of their locations.

As with every probability-type sample that is derived, one invariably gets voids and clusters. And indeed with this sample, that did happen. And it was unfortunate that some locations, some areas, some states, did not get included and other locations appear to be included fairly extensively. It is a true probability sample and that has been tested by comparing the characteristics of all of these locations with the entire U.S. population and indeed matches very well.

We have a good explanation why Montana's not represented in the sample and we're sorry that Montana is not represented in the sample. But nonetheless, it is a sample that does indeed represent the true experience of all of our children and Montana can well benefit from this study.

Moderator Next we'll go to the line of Carrie Mulford from National Institute of Justice. Please go ahead.

C. Mulford Hello. You said that there was going to be 250 women recruited who are either pregnant or planning to get pregnant. What happens to the sample of women who are not able to conceive? How long do they have to conceive or do you follow them for, is there a plan for analysis of fertility or what's the plan there?

Dr. Scheidt Women who are in the eligible areas are eligible to have their children participate as long as the pregnancy results during the four-year enrollment period. Once the four-year enrollment period is over and the full sample is obtained, then if they didn't get pregnant and had hoped to be pregnant during that time, then there would not be a child to follow.

C. Mulford Okay, thank you.

Dr. Alexander But the sample will include women who have gotten involved with assisted reproductive technology in order to get pregnant. We estimate that the sample will include maybe 1.5% to 2% of all the pregnancies will be conceived by assisted technology means and they will be included.

C. Mulford Good, thank you.

Moderator Next we'll go to the line of Irva Hertz-Tickasiddel from University of California Davis. Please go ahead.

I. Tickasiddel Yes, this is Irva Tickasiddel. One of my students has a question.

A. Ibrahim Yes, hello, my name is Ahmed Ibrahim. I'm an MPH student here at UC Davis. With regards to including women who are likely to be pregnant, are you including couples, new couples? Are you also including high school students, adolescents? And is that standard overall for each site or is it specific to one study site or the other? Thank you.

Dr. Scheidt For inclusion in the sample, any woman in the eligible area will be included in the sample as long as they are not cognitively impaired to impair their ability to give informed consent. We will not offer the possibility of participating in the study prior to pregnancy, that's prior to conception, for women under 18 years of age. Once a woman is pregnant of any age, and this includes adolescent pregnancies, they're eligible and encouraged to participate with the consent of their parents, depending on the local jurisdiction requirements for consent. Does that provide the answer?

A. Ibrahim Yes, it does, thank you.

Moderator Next we'll go to the line of Dr. William Rodriguez from FDA. Please go ahead.

Dr. Rodriguez Hello. I'm excited as hell, excuse the expression, about the progress of this initiative, this evaluation. I have a couple of questions. They have to do with, one is with the feedback to participants. In other words as the study goes on, you were talking about keeping them informed. And if you find something significant, in other words, what mechanisms are there for that? More importantly, if any of the studies finds any critical area, for example exposure, let's say in the Mississippi Valley or something like that, would that information be, which could conceivably affect public health, would that lead to a pronouncement at that time regardless of whether the study has been finished or not?

Dr. Scheidt Thanks, Bill, it's good to hear from you. Regarding feedback to participants, we do plan to provide, reveal to participants any information that we learn through the data and specimens that will be collected that can be useful and actionable for their benefit. If we gather information for which it is unknown whether or not it's beneficial or not, we do not plan to

provide that. Nor do we plan to provide genetic information unless specifically requested by the participants.

On what we may learn about exposures as they're distributed in specific areas, if we uncover that there is an emerging risk in a particular area, we will be working closely with the communities involved. We'll be working closely with all the communities involved in the study throughout the study.

But with regard to how we handle that kind of information, we will especially engage the communities with us in how best to use it for the benefit of those communities. Communities will not be able to dictate just what we do with it, but we'll certainly work with them. It's our intent that, where possible, that they be able to benefit from this kind of information.

Dr. Rodriguez Thank you.

Moderator Next we'll go to the line of MaryAnn Felice from University of Massachusetts Medical. Please go ahead.

Dr. Felice This is Dr. Felice and one of my colleagues has a question.

T. McLaughlin This is Tom McLaughlin at UMass. I was wondering if you could give us an update on where the budget is, the federal budget and specifically the NCS line item in the Congress for fiscal year 2008. And I guess a second part of that question is what, if any, are the contingency plans in case this does not get written into the budget or it is not approved?

Dr. Alexander All the funding that we are talking about today, all the funding that was provided to start this first wave of centers and sites was provided by the Congress in the appropriation process in fiscal year 2007. All these awards were made during the last week in September to get them into fiscal year ’07. No funds have been appropriated yet to the Department of Health and Human Services for fiscal year 2008.

The next wave of sites to be recruited, the second wave, the ongoing work in the sites that are funded today, in the Vanguard sites and the other activities for the center will depend on receiving funding in 2008. All of these activities are funded a year at a time in the federal appropriations process just like NASA space missions are or education activities in programs are. It’s all a year at a time.

Like the 2007 president's budget request, the 2008 request did not include funds for the continuation of the National Children's Study. In the appropriations process, both the House and the Senate Appropriations Committee added specifically $110 million to the NIH Office of the Director appropriation, specifically earmarked for purposes of conducting the National Children's Study. That provision has cleared the House, which has acted on the appropriations bill for Labor and HHS for fiscal year 2008. No floor action yet has taken place in the Senate.

So we remain waiting to see what will happen with the funding for 2008. We are prepared to do whatever results from that appropriations process. If that process does not provide funding for 2008 for the Children's Study, we are prepared to close it down, to end the contracts when the funding expires and not continue any further action. If the Congress provides the $110 million in funding, we are prepared to proceed to go ahead to complete the next wave of centers and make awards for another 30-or-so sites in 2008. So it all depends on the outcome of the budget process and I've let you know exactly where that stands.

T. McLaughlin Thank you.

Moderator And now I'll turn the conference back over to you, Dr. Alexander.

Dr. Alexander Okay. That concludes our presentation for today. We thank all of you for joining us. We thank you for your participation in various roles in the course of the National Children's Study to date. We look forward to continuing to interact and work with you as we try to bring this study further along the road to full implementation.

A rebroadcast of this conference will be available for one week after this briefing. If you wish to hear the rebroadcast, please dial 1-800-475-6701 and refer to reservation number 886812. For more information about the study please visit the study's Web site at www.nationalchildrensstudy.gov. Thank you very much. This concludes our call.

Moderator That does conclude our conference for the day. Thank you for your participation and for using AT&T Executive Teleconference. You may now disconnect.