

**National Children's Study
Media Telebriefing
October 3, 2008**

John McGrath: Thank you and good morning. Welcome to the National Institutes of Health and to this briefing on the National Children's Study. The first speaker today is Dr. Duane Alexander, the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, part of the National Institutes of Health. Dr. Alexander will present an overview of the National Children's Study and announce the names of the new Study Centers.

He will be followed by Dr. Peter Scheidt, Director of the National Children's Study. Dr. Scheidt will provide a brief chronology of the Study and details about the next steps in its implementation. And now, I would like to introduce Dr. Duane Alexander.

Duane Alexander: Good morning. Thank you for joining us. We're here today to announce 39 new locations and 27 Study Centers for the National Children's Study. Periodically we provide you with updates of the Study's progress. Many of you have been with us before for earlier announcements. I'm going to provide a crash course for those of you who are new and a review for those who have been with us before.

The Study will begin by recruiting women before they give birth and in many instances before they conceive their children. Study scientists will follow the children that these women give birth to until they're 21 years of age, monitoring their health and development closely from early infancy on through childhood and into young adulthood. Eventually 100,000 children will take part.

The National Children's Study will encompass a nationally representative sample, designed to be a composite of the U.S. population. It will include children throughout the United States from rural, urban, and suburban areas, from all income and educational levels, and from all racial groups.

The National Children's Study began with the Children's Health Act of 2000, which authorized the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and a consortium of federal agencies to conduct the National Children's Study.

Partnering with the NICHD to conduct the National Children's Study are the NIH's National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency. Since preparations for the Study began in 2000, researchers affiliated with it have been devising the methods needed to

conduct the Study. They've been deciding what kind of samples they'll need to collect, the means to analyze those samples, and how to develop ways to recruit a population of Study volunteers that is representative of the population of the United States in all its social, geographic, economic, and racial diversity.

In 2004, we identified 105 U.S. communities from which we would recruit and study participating families. Our first major announcement on the Study's progress was the awarding of contracts for Vanguard Centers in 2005. These seven were the initial Study Centers and will be the first Centers to recruit volunteers for the Study.

The Vanguard Centers will also test the research methods we need to conduct the larger Study. In 2007, we added an additional 17 new Study Centers. Each of the Study Centers will recruit volunteers from the Study locations that it manages. The researchers at the Centers will collect biological samples as well as samples from the women's and children's environment: air, water, and even house dust. They'll collect samples of the materials used to construct homes and schools to see whether these and other environmental factors influence children's health.

In its national scope in the number of children it will follow and its focus on development from infancy through adulthood, the National Children's Study is unique. There is no other American study quite like it. We look to it to provide new information that will help treat and perhaps even prevent any of a range of childhood and adult conditions that have roots in childhood: asthma, autism, attention deficit disorder, learning disabilities, mental health problems, obesity, diabetes, high blood pressure, and heart disease.

We anticipate that in the long term, what we learn from the Study will result in a significant savings in the nation's healthcare costs. According to one estimate, just six of the conditions that the National Children's Study will look at—obesity, injury, asthma, diabetes, schizophrenia, and autism—cost the United States \$758 billion per year. Estimating conservatively, even if what we learn from the National Children's Study results in only a 1 percent reduction in the cost of just these conditions, our nation will save about \$7.58 billion a year. That 1-year saving is more than double the entire \$3.2 billion the National Children's Study is expected to have cost when the children who participate reach 21 years of age.

In explaining the promises of the National Children's Study, we often talk about the Study's potential to provide information on conditions that manifest themselves in adult life. But we won't have to wait 21 years before we see results because the Study follows children from before birth

through adulthood. We expect it to yield information along each step of the developmental process, from infancy through early childhood, to preteen and teen years, and again in early adulthood.

Today we've reached a turning point. For 2008, a total of 27 Study Centers have been funded. Some of these have been funded in previous years. We've posted a listing of the 2008 Centers and their corresponding locations in our news release on the NICHD Web site at www.nichd.nih.gov.

Today's announcement brings the total number of new and previously funded Study Centers to 36, covering 72 of the eventual 105 locations. Contracts have been awarded to the Study Centers we're announcing today based on rigorous criteria. They have demonstrated a strong ability to collect information for the Study and the ability to inform their communities about the Study, to recruit eligible women, and to devise plans to retain the women and their children until the children reach 21 years of age.

They have also demonstrated a strong capacity to protect the privacy of the Study participants. All participants will remain anonymous. Progress of the National Children's Study is always contingent upon funding, which is approved by Congress on a yearly basis. With that in mind, we anticipate that the Study will start recruiting the first volunteers in early 2009.

Having introduced the Study to those who are not familiar with it and reviewed it for those who have attended our earlier briefings, I'll announce now the names of the 2008 Study Centers and their locations. After that, the Director of the National Children's Study, Dr. Peter Scheidt, will talk about the Study's immediate future and its projected launch in 2009.

The Study Centers funded in 2008 are:

- Arkansas Children's Hospital, covering Benton County, AR
- Baylor College of Medicine, covering Harris County, TX
- Brown University, covering Bristol County, MA
- Case Western Reserve University, covering Lorain County and Cuyahoga County, OH
- Children's Hospital of Philadelphia, covering Burlington County, NJ
- Emory University, covering Bradley County, TN, and Baldwin County, GA
- Johns Hopkins University, covering Montgomery County, MD
- Maine Medical Center, covering Cumberland County, ME
- Michigan State University, covering Grand Traverse County and Lenawee County, MI

- Mount Sinai School of Medicine, covering Monroe County, NY, New York City (Manhattan), and Passaic County, NJ
- Northwestern University, covering DuPage County, IL
- Saint Louis University, covering Jefferson County, MO, and Johnson County, Union County, and Williamson County, IL
- Tulane University, covering New Orleans, LA
- University of Arizona, covering Apache County and Pinal County, AZ
- University of California, Irvine, covering Kern County and San Bernardino County, CA
- University of California, Los Angeles, covering Ventura County, CA
- University of Colorado, covering Douglas County, CO
- University of Iowa, covering Polk County, IA
- University of Louisville, covering Jefferson County, KY
- University of Miami, covering Baker County, Orange County, and Hillsborough County, FL
- University of North Carolina at Chapel Hill, covering Cumberland County, Durham County, and Burke County, NC
- University of Texas Health Science Center San Antonio, covering Hidalgo County, TX
- University of Texas Southwestern Medical Center at Dallas, covering Lamar County, TX
- University of Utah School of Medicine, covering Bear Lake County, ID, and Lincoln County and Uinta County, WY
- University of Washington, covering Grant County, WA
- Vanderbilt University Medical Center, covering Davidson County, TN
- Yale University, covering Litchfield County, CT.

You can see from this listing that this is an extremely diverse group of counties covering a population that will look like America. I'm now pleased to turn the microphone over to Dr. Peter Scheidt, the Study Director.

Peter Scheidt:

Thank you, Dr. Alexander. And thank all of you on the call for joining us. We now see the light at the end of the tunnel of the preparation for actual data collection in the National Children's Study. We are on schedule for the National Children's Study's Vanguard Centers to begin recruiting for the pilot phase of the Study in January 2009.

The Vanguard Center at the University of North Carolina at Chapel Hill will begin recruiting in Duplin County, North Carolina, and the Vanguard Center at Mount Sinai School of Medicine will begin recruiting in Queens, New York. I'd like to emphasize that this will be for the pilot phase of the Study. That is the very early phase of the Study in which we will test the sampling methods, recruitment methods, and the full core protocol that we've developed to see how they work out and how they might be

improved—and if they work as well as we think they will work and with the opportunity to improve them before launching the full Study.

Of course, as always, and as Dr. Alexander pointed out, our funding is allocated by Congress each year, and all the projections we're making today are contingent on yearly funding renewals for the Study.

We plan that in April 2009, the other five Vanguard Centers will continue the recruitment for pilot testing at the locations in California, Pennsylvania, a group of rural counties in North Dakota and Minnesota, in Utah, and in Wisconsin. I won't name all of the remaining Centers and locations here, but they're available on the Study's Web site. That is at www.NationalChildrensStudy.gov with National Children's Study all one word, and there's no apostrophe before the "s" in Children's.

After we complete the pilot phase, we will begin the 4-year recruitment for the full Study in three successive waves, beginning in July of 2010 with wave one and then July 2011 and finally in July of 2012. A maximum of 250 births are expected in each of the Study locations for each of the 4 years. Currently, the established Centers that are doing the work in their respective locations are hiring and training staff, meeting with the local community groups and healthcare professionals to inform them about this study, and establishing community advisory boards to provide ongoing guidance on the range of study relations issues that occur in the locations.

Now, in the past we've talked about the Study following the children through their 21st birthday, but right now I'd like to focus on the Study's early outcomes and benefits. With more than 100,000 participants, we believe that the National Children's Study will be the largest study of pregnant women ever conducted—certainly the largest study conducted in the United States. We expect the Study to yield information on a variety of pregnancy- and birth-associated conditions. Let me just exemplify one important anticipated outcome as an example of what we hope to gain from the Study.

Paramount among the conditions, we need to learn more about preterm birth. According to the findings from the Surgeon General's conference on preterm birth last summer, every year nearly 500,000 American babies are born prematurely. That is more than 12 percent of U.S. births that are preterm. This rate has actually been rising in recent years because of advances in research and health care. Many preterm babies survive and do well; however, a sizeable number of them experience serious complications, some of which are life-long.

Preterm infants are at risk for early death from the direct complications of prematurity. They're also at increased risk of sudden infant death syndrome, which is a sudden and unexplained death in the first year of life. Furthermore, they're at increased risk for cerebral palsy, for mental retardation, for learning disabilities, visual difficulties, hearing problems, and so on.

Low birth weight infants who reach adulthood are at increased risk for obesity, high blood pressure, heart disease, diabetes—all conditions that reduce the quality of life, contribute to healthcare costs, and rob productive years of life. The costs associated with prematurity are substantial—as estimated from the Surgeon General's conference, the costs are \$26 billion per year.

We look to the National Children's Study to provide information that will be helpful in reducing the proportion of preterm births and their considerable economic costs. With the 100,000 pregnancies in the Study, the Study will include genetic samples from women and their infants, information on their diets, possible exposures to chemicals and other environmental factors, and measures of maternal stress.

So, in addition to the many long-term benefits of the Study, we can expect early and important benefits as well. We expect that what we learn from the National Children's Study will provide new information that we can use to begin to solve the problem of preterm birth, and we anticipate that we will have this information in just a few years.

With that example, thank you very much and let me turn it back to John McGrath.

John McGrath: Thank you very much, Dr. Scheidt. We now welcome questions from any of our participants about the National Children's Study. I'll ask the facilitator to please introduce the caller, and we'll be happy to answer questions.

Operator Thank you. Ladies and gentlemen, if you'd like to ask a question, please press the 1 key on your touchtone telephone. If you feel your question has been answered or you wish to remove yourself from the queue, please press the pound key. Once again, ladies and gentlemen, if you have a question please press the 1 key at this time.

Our first question comes from Will Dunham of Reuters. Please go ahead.

Will Dunham: Yes, it's Will Dunham with the Reuters News Agency in Washington. My question: How much money has already been provided for the Study and how much do you think will be provided over its entire course?

Duane Alexander: Excluding the funds that were expended during the planning phases of the Study between 2000 and 2007, which is approximately \$50 million by the agencies that were engaged in the planning, the Congress provided \$69 million during fiscal year 2007 and \$111 million in fiscal year 2008 that ended on Tuesday of this last week. The need for fiscal 2009 is about \$192 million. The cost projected for the life of the Study is approximately \$3.2 billion.

Will Dunham: I'm sorry, \$3.2 "b" billion?

Duane Alexander: "B" billion.

Will Dunham: Okay, and I'm sorry, you gave me a bunch of numbers there. So how much money to date has been spent on it?

Duane Alexander: Okay, it's about \$50 million in the planning phase, \$69 million the first year of funding from the Congress, and another \$111 million. That's about \$220 million so far.

Will Dunham: Okay, sounds good. Thank you.

Operator: Thank you. Our next question comes from Heidi Raleigh of the *Tucson Citizen*.

Heidi Raleigh: Hi, what was the total number of Study Centers again?

Duane Alexander: The total number of Study Centers funded to date is 36.

Heidi Raleigh: Okay. That was my question.

Duane Alexander: That covers 72 of the eventual 105 locations where the Study will be conducted.

Heidi Raleigh: Okay, thank you.

Duane Alexander: Now, that means that wave three, which is to be competed for and added next year—next fiscal year—would bring in another 33 locations that would be covered by the existing 36 Centers plus probably a few more—maybe four or five more—bringing the total number of Centers to somewhere around 40.

Heidi Raleigh: Okay, that makes sense. Thank you.

Duane Alexander: Sure.

Operator: Thank you. Our next question comes from Claudia Kalb of *Newsweek*.

Claudia Kalb: Hi, thanks so much for your time. I'm hoping I can ask three quick questions. One is, I'm interested in the age of the mothers you're recruiting and how you'll deal with variable ages. I'm also interested in whether you have target dates for when you will release the first data from this study. And finally, I'd love to get a few details on the environmental factors that you're planning to look at.

Peter Scheidt: This is Dr. Scheidt. The age of the mothers is not restricted in any way. So, we will include mothers of all childbearing ages, which will include both teenage mothers, as they become pregnant, and mothers throughout the childbearing age range.

Regarding the target dates for data release, we anticipate release of data for each successive phase of the Study. So, as the pregnancy and infant period completes, data will be released both to the investigators to analyze for testing the hypotheses of the Study and for investigators outside the Study in public use data sets.

In addition, we anticipate preliminary analyses for those questions that don't require the full data set as early as 2012 and 2013. This would be for just the early phase of the Study outcomes of pregnancy.

And the—I'm sorry, the third question?

Claudia Kalb: I was interested in some examples of the environmental factors you're going to be looking at.

Peter Scheidt: Yes, environmental exposures are defined quite broadly in this study: chemical, physical, biologic, and social and behavioral. So, the environmental factors for chemical exposures will be those chemicals in the children's environment to which they're exposed that can be measured by the environmental specimens of air, water, dust that will be collected and would include such things as you've heard—the common pesticides and plasticizers in the news over the past number of months. We would be certainly looking at phthalate chemicals as well as metals and other possible chemicals.

A number of chemicals can be analyzed that we don't currently plan because the specimens will be available over the length of the Study as questions may arise in the future. The biologic variables include infection, nutrition, and diet factors, and certainly behavioral exposure such as stress and parenting experiences are other examples of the kinds of environment. Again, I invite you to visit our Web site for more specific information at NationalChildrensStudy.gov.

Does that provide your answer?

Claudia Kalb: Yes, thank you.

Peter Scheidt: You're very welcome.

Operator: Thank you. Our next question comes from Katie Getz of KUNZ.

Katie Getz: Thank you very much. I'm curious to get a detailed—maybe not a completely detailed portrait—but a portrait nonetheless of the Study and how it works on a micro level. So, for instance I'm calling from Colorado. CU has been named one of the new sites. I'm curious how they'll get connected up with pregnant women, how many times they'll go out to her house to see her during the course of her pregnancy, when the child's finally born. What—is that CU research[er going to] go to the child's school, and as that child ages, to his or her workplace or where that person attends college? I mean, what does that relationship look like from start to finish?

Duane Alexander: I would love to spend the rest of the day providing those details to you, but I can only give you the slightest sketch. And again, on the Web site you can learn a great deal more.

The hookup for participants in the Study is driven by the importance of this being a sample that represents the experience of all of our children. And in order to have a truly representative sample, we needed to sample women across the country in the areas where they live. And so, each of the locations in the Study will define the segments or the neighborhoods, again in a scientific way, where the Study will be conducted, and households [will be] identified, and then investigators will visit the households and identify women of childbearing age and invite them to participate in the Study. That will form the initial relationship.

Those women then identified who are either pregnant anytime during the 4-year enrollment period or actively trying to become pregnant will then be enrolled and extensive data [will be] collected through interviews and visits in the home to collect the kinds of exposure samples that I described previously. And then [there will be] visits in clinical settings at the Centers conducting the Study and again in the home three times during pregnancy, examination and samples collected at birth in the birth hospital or at home if home delivery or birthing center where the baby's born, and then at subsequent visits as the child ages through infancy and then school age and adolescence.

[There will be] a total of 13 planned visits over the course of the Study with about half at home and half at Centers, with extensive contact being maintained by phone, by mail-in questionnaires, etc., with the Study Centers according to the core protocol. A great deal of effort, which may vary by the Center, will be undertaken to maintain a contact and encouragement of participants to participate as the cohort ages. I think I'd better stop with that and [ask] if you have any other specific questions.

Katie Getz: I think that's sufficient. Thank you.

Duane Alexander: Good.

Operator: Thank you. Our next question comes from Bob LaMendola of the *Sun Sentinel*.

Bob LaMendola: Thanks for taking the question. I have two. The first is: Do you have an estimate for how many of the people you recruit will kind of drop off as time goes along—you'll lose track of? And secondly, how would you adjust for the fact that people move and may move from Miami to Philadelphia. How do you account for that in your data?

Duane Alexander: Yes, once establishing the cohort, the participants in the cohort are extremely valuable, and we will work very hard using the experience of many cohort studies prior to this to retain participation in the Study. But experience from other similar cohorts with all of the efforts that we're putting in to retain the participation, we anticipate that at least 80 percent of the sample will continue to participate and hopefully higher than that. But some will drop off and we will certainly adjust for that both in the analyses and in conduct of the Study.

And as you point out, some will move. About 5 percent of the population will move each year, so we have to anticipate that. That's one advantage of a national study. Given the example that you gave, if a mother moves from Florida to Philadelphia, it so happens we have Centers in Florida and in Philadelphia. And that mother will be transferred from one Center to the other as long as she consents to do that and wishes to continue in the Study.

Where participants move anywhere within reach of a Center, that Center will continue to follow [them]. If [participants move] to a new Center, a new Center will follow [them], and if they move to a location out of reach, then the Coordinating Center will have the capability to follow them in those locations. I'll stop with that.

Bob LaMendola: Thank you.

Operator: Thank you. Our next question comes from Yurina Rico of *La Opinion*.

Yurina Rico: Yes, hi. I have two questions. First, why do Americans need this type of study? How will it help them?

Duane Alexander: Let me start with that. One of the great mysteries in health—published health [literature]—is the causes of a wide variety of diseases and conditions that affect children and adults. And questions have been raised about the role of environmental exposures either to the physical and chemical environment or the social, cultural, educational environment in terms of their relationship to causation of disease, disorders, or conditions.

The only way you can answer questions like this is to do a prospective longitudinal cohort study of very large size so that you can look at exposures that are not very common, but looking at a large population gives you enough people to study those particular exposures. Also, studies that have been done so far tend to look just at one exposure in isolation and often look at it just at one period of time in life. What happens in nature is not that. We're exposed to many different things at different periods of life and some of those exposures may not have an effect immediately, but they may have a longer term effect.

What this study gives us the ability to do is look at a wide variety of exposures to a very large population occurring over different periods of time and different periods during a life course and look at them in combination, so that we cannot look just at exposures to a particular chemical, but to groups of chemicals at a time, and [we can] look at them in relationship to other things that may be going on in the child's environment as well and follow that child not just for a year or two after the exposure, but for many years. This should give us the answers that we need about the relationship between these exposures and interrelationships as well. Also, because of the advances of the Human Genome Project, we now will have the capability of looking much more directly at these exposures in relationship to the person's genetic inheritance and genome. So we will be able to correlate exposures and outcomes with a person's genetic constitution.

Many people believe that development of diseases, conditions, and disorders is [due to] a combination of environmental exposures in relationship to the genetic constitution that an individual has and that some people with certain genetic constitutions are more susceptible than others to these consequences from environmental exposures. So, this study will have genetic data on every participant, every child as well as the mother and siblings and fathers in most instances, so that we can look at the relationship between environmental exposures and genetic constitution.

So, that's why a study like this is so important and why you can only get this kind of information from this kind of a study.

Yurina Rico: One more question. What's the hypothesis of the Study?

Duane Alexander: Well, there are many, many hypotheses of this study. Pete, you want to give some examples?

Peter Scheidt: Yes. Again, they're on the Web site and there are 30, and of course there are potentially many, many more hypotheses than we have defined. But examples that we've used in planning and framing the Study are, for example: Do certain chemical exposures to the fetus during pregnancy result in later long-term cognitive deficits? That's one hypothesis.

Does exposure—this will be of interest to you—does exposure to media during the early years of life, during the first 1 to 2 years of life—and we've learned that many children spend many hours exposed to the media—does that affect their language acquisition and their social and emotional development during later years of life?

A third one—I'll stop at that—based on empirical suggestive data: Does exposure to certain infections and mediators of infection during the fetal life result in the development and severity of schizophrenia in late adolescence and early adulthood? That is a hypothesis that's based on some suggestive data. The only way to answer it is with a large study like this that collects the necessary genetic information, the necessary intrauterine exposures, and the necessary long-term diagnoses to answer this question that, if resolved, could benefit and reduce an enormous burden to this country. Thank you.

Operator: Thank you. Our next question comes from Richard Prudenti of Morning News. Mr. Prudenti, your line is open. Do you have your phone on mute?

Thank you. Our next question is from Eric Whitney of Colorado Public Radio.

Eric Whitney: Hi. I have a couple of questions about the size of the Study, and I'd like to start with: Do you know how many researchers total will be involved over the life of this study?

Peter Scheidt: Again this is Dr. Scheidt. The short answer is a great many researchers will be involved in the life of the Study. During the planning phase, at one point we actually sat down and counted—this was in 2004. We counted all of the researchers that had worked with us in various ways just to that point before establishing any of the many Centers we had, and I think the count was 2,245, something like that.

Now there will be a great many more researchers because each of the approximately 40 Centers have a good handful if not more of researchers and investigators that are working with us in both carrying out the Study and carrying forward the necessary planning as the Study moves through various phases. Many of those researchers are listed on our Web site and as acknowledgements, and I refer you to the Web site for more specifics about that as well.

In addition, if I could just add something, in addition to the investigators and scientists who are at the Centers, we will be making available at various intervals during the Study public use data sets to investigators who wish to pursue other hypotheses and other questions using the data from the Study that we make available to them through applications for grants to the NIH or to other organizations. So, it's really impossible to estimate the size of the number of investigators who will be using this data set to do analyses and studies that we haven't even thought of yet. So, the number total then has to include that large number of the investigators and scientific pool who will be using the Study data in that way.

Eric Whitney: Could I follow up with a question just about—help me put in context this large longitudinal cohort study. Can you just give me some context of other studies NIH or other organizations might be doing that are of this size and magnitude? And maybe talk about the—you said this is the largest study of pregnant women in the United States. Can you give me some idea of an order of magnitude larger than any previous studies trying to look at the same kind of exposures and outcome?

Duane Alexander: Let me start with that and Dr. Scheidt can add to it. The first study that was done at the NIH that has some relationship to this dates back to the 1950s and the 1960s. It was called the Collaborative Perinatal Project. It was supported by the Neurology Institute, and it was looking at the causative factors of cerebral palsy and whether hypoxia or during labor in particular was the cause. That study followed almost 60,000 children born in 9 different hospitals around the country from gathering information at birth and then followed them at 3 years of age and again at 7 years of age. That data set is still being used today. Basically it showed that many of these children with cerebral palsy had the condition previously—prior to birth—and the hypoxia during birth and labor was not a major cause of cerebral palsy.

Other studies that have been done by the NIH include the Women's Health Study, which involved in various components of it more than 100,000 women. That was done just about 8 or 10 years ago. Other studies have been done by other countries. The Avon Longitudinal Study in the United

Kingdom follows about 15,000 children in a birth cohort, and it has followed these children now up to about 12, 14 years of age.

Other countries are very interested in this study and in duplicating it on a smaller scale in their countries and asking some of the very similar questions. And some of them have worked with us in designing their studies to make the protocol as similar as possible so that the data in some instances can be combined. In fact, in the area of cancer, we're not going to have enough participants in our study, even at 100,000, to answer some environmental exposure questions in relationship to the development of childhood cancer. So, we are combining our efforts with cancer studies in England and Australia and other places around the world so that we will have the 500,000 or more that we need to answer questions about that.

Japan is considering a study and visited with us to again try to keep the study protocols as compatible as possible. They're about to launch a study of about 60,000 births. China has a study of about 100,000 and may enlarge it beyond that. And so there are many other countries that, having seen what we're about to do here, are interested in doing a very similar thing in their country.

Peter Scheidt: I think that pretty well covers it. The Norwegians and the Danish each have 100,000 cohorts, as large as the National Children's Study—not as in-depth data collections, but very useful to merge with the U.S. Study.

Eric Whitney: Maybe one last question on the cost and the \$3.2 billion price tag for this study. How does that compare to other major studies at NIH? Is it in the top 5, top 10, something like that?

Duane Alexander: The close comparator would be the Human Genome Project. That study was conducted over about a 10-year period and its cost was about \$3 billion. Our study's about \$3.2 billion over 25 years. The Women's Health Study was around \$1 billion over a period of about 5 years.

Eric Whitney: Thank you.

Operator: Thank you. Once again ladies and gentlemen, if you have a question, please press the 1 key at this time. Our next question comes from Amanda O'Toole of the *Arkansas Democrat Gazette*.

Amanda O'Toole: Good morning. I have a couple of quick questions for you. We're speaking of when children are moved from place to place. I was under the impression that unless they moved to the specific county that those Study Centers were located in, they would be lost to research. Is that not accurate?

Peter Scheidt: This is Dr. Scheidt. That is not accurate. Once they deliver an infant into the Study, we will make every effort to follow them through in the country, wherever they move. So, they do not have to move to another location that is part of the Study.

Amanda O'Toole: And then will you also be recruiting more than the 100,000 women in case there are some factors that people drop off, et cetera?

Peter Scheidt: As of the moment, our aim is 100,000 live births, and if you do the numbers, you realize with 105 locations, that actually is an enrollment of 105,000 pregnant women, but we are not planning to increase the sample above 100,000 to compensate for the inevitable drop-off of some degree. But the Study is adequately powered with that anticipated drop-off to answer the questions that are being asked.

Amanda O'Toole: Sure. One other quick question. You had said that there were six things led to \$785 billion in healthcare costs. Can you list those six again, please?

Duane Alexander: Yes, the six that we included in that group were obesity, injury, asthma, diabetes, schizophrenia, and autism, which have a net cost to the United States of \$758 billion per year.

Amanda O'Toole: Sure. Is there a condition that you are most hopeful to figure out personally?

Duane Alexander: Well, we're interested in all of them. I think there's a lot of national interest at the present time in autism and factors that may be causative of autism. Much focus in terms of ideology is on environmental triggers of autism—environmental factors during pregnancy or very early in infancy that may interact with the genetic constitution of some children to result in autism.

Only a study like this with this size and this nature as a longitudinal prospective study can give you the capability of answering questions about these kinds of exposures and genetic constitution in relationship to autism. We will have, we project, somewhere between 600 and 800 children with autism in this sample of 100,000 and an awful lot of controls so that we hope that we'll be able to get some very valuable information about causative factors in autism.

Amanda O'Toole: Thank you.

Operator: Thank you. Our next question comes from Coshandra Dillard of the *Tyler Morning Telegraph*.

Coshandra Dillard: Hello. In selecting the participants, is there a universal formula that the Centers will follow, or will each Center be responsible for developing that model in regard to diversity and economic backgrounds of the participants?

Duane Alexander: In selecting the participants, each Center will follow the same protocol and methods to enroll the participants, and it's by doing that that we assure the broad diversity and the true representativeness of the sample.

Coshandra Dillard: Okay, thank you.

Operator: Thank you. I'm showing no further questions at this time.

John McGrath: Well, thank you very much and thank everybody for participating in this briefing. For those who are on, if you would like to have follow-up questions with Dr. Alexander or Dr. Scheidt, please call our media relations office. Here's the number: It is 301-496-5133. We'll be happy to arrange these and set you up with interviews. In the meanwhile, thank everybody for participating, and this concludes the briefing on the National Children's Study.

Operator: Thank you. Ladies and gentlemen, this does conclude our conference. Thank you for your participation and have a wonderful day. You may all disconnect.