



Final Transcript

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

October 4, 2007/10:30 a.m. EDT

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. John McGrath. Please go ahead, sir.

Dr. McGrath Thank you. This is John McGrath at the Communications Branch at the National Institute of Child's Health and Human Development. This morning we will hear three presentations from Dr. Duane Alexander, Dr.

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Yvonne Maddox, and Dr. Peter Scheidt with regard to the National Children's Study. This will be followed by questions from media on the phone and we will conclude at approximately 11:30.

With that as background, I turn this over to Dr. Alexander, Director of the National Institute of Child Health and Human Development.

Dr. Alexander

Good morning. Welcome. Thank you for participating in today's briefing. Today we announced the funding of 22 new Child Study Centers that will participate in the National Children's Study. These new study centers 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 Vanguard centers 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 its full operation.

Many of you are already familiar with the National Children's Study and others may be just starting to follow. For those new to the study, I will provide just a bit of background information. The National Children's Study is the largest and longest research study ever to look at the ways in which environment and genetics interact to influence child health and human development. It will look at how behavioral and social factors also interact with genetics in the physical environment.

Over the next quarter century, the 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 children that are of concern to all of us: 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 appears to be increasing. According to the Center for Disease Control and Prevention, its prevalence has risen from about 1 in 1,000 to 1 in 150 children. Asthma is also increasing. In 2005 about 9% of children ages 0 to 17 were recorded to currently have asthma and about 5% of children had one or more asthma attacks than in previous years. 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 material 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've also looked at the neighborhood structure, the family, the community, and the school to assess the social and behavioral environments in which children grow.

There are many reasons why we're conducting the National Children's Study now. Among them, there's 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 will one day enable scientists to target specific genes for more effective treatments. In addition to the genome, new tools for micro-assay of chemical exposures and new computer capability for storage and analysis of huge amounts of data are available for the first time.

Health disparities in many disease areas are on the rise among underserved populations. This study will help uncover these population specific differences in health, healthcare access, and disease rates. Special efforts will be made to enroll and retain minority populations in this study.

The 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 of not only their own children, but future generations of children as well.

The 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. The list of newly awarded centers is also listed in the press release.

The new centers are, in alphabetical order: Brown University, covering Providence County, Rhode Island; Children's Hospital of Philadelphia, covering Schuylkill County, Pennsylvania and Newcastle County, Delaware; Emory University covering Dekalb County, Georgia and Fayette County, Georgia; Johns Hopkins University covering Baltimore County, Maryland; Michigan State University, covering Wayne County, Michigan; The Mount Sinai School of Medicine, covering Nassau County, New York; Northwestern University covering Cook County, Illinois; St. Louis University, covering Macoupin County, Illinois and St. Louis, Missouri; The University of California, Davis will cover Sacramento, California; The University of California at Irvine will cover San Diego

County; The University of Hawaii at Manoa will cover Honolulu County, Hawaii; The University of Massachusetts will cover Worcester County in Massachusetts; The University of Minnesota is responsible for Ramsey County, Minnesota; The University of Mississippi will cover Hinds County, Mississippi.

The University of New Mexico has been chosen to cover Valencia County, New Mexico; The University of North Carolina at Chapel Hill will cover Rockingham County, North Carolina; The University of Pittsburgh will cover two communities, Marion County in West Virginia and Westmoreland County, Pennsylvania; The University of Texas Health Science Center in San Antonio is responsible for Bexar County, Texas; The University of Utah will cover Cache County, Utah; The University of California, Los Angeles will do Los Angeles County, California; The University of Washington will cover King County, Washington; and Yale University will cover New Haven County, Connecticut.

We selected these new study centers competitively, based on rigorous criteria, including their ability to collect data for the study, the ability to build extensive community networks for recruiting and retaining eligible

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 this 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 neural 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 the study.

Now I would like to introduce the Deputy Director of the National Institute of Child Health and Human Development, Dr. Yvonne Maddox, who is going to 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.

Dr. Maddox

Thank you, Dr. Alexander. I'm delighted that we have arrived at this point in the National Children's Study's evolution where we can announce today the participation of this large group of highly qualified study centers. As you all know, 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, in fact, in the early implementation.

A major challenge, as we all know, of the NCS will be reaching out to the 105 communities to identify and to engage 100,000 participants. But in fact, each of the new centers that we will be launching today have already identified and have already demonstrated success in reaching out to diverse populations. The awarding of these new centers really affirms the federal government's commitment to scientific research, to scientific research that will lead to the improvement of the health and well being of all of America's children.

The NCS is 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 U.S.

Environmental Protection Agency. In fact, more than 40 other federal agencies and departments have also provided input.

The 105 study locations, which are counted across the United States, represent a cross section of America, a cross-section of America in terms of ethnic, racial, economic, religious, geographic, and social groups. This is required if the study is to be a national sample of the country and a national sample of counties were selected for the study because this will 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 weights.

How would this recruitment take place with all of these challenges before us? In these study locations teams with the help of healthcare professionals, help from community leaders will begin to 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, local clinics, and hospitals.

The study planners early on acknowledged that recruitment of such a diverse group of American women and their infants would indeed be a complex undertaking. But we all realize that we can build on the trusting relationships that have already been established. Particularly with these new centers that we are launching today, these investigators have already shown that they can recruit and they can retain individuals from various racial and ethnic groups. Working with community leaders this will again be a critical aspect of the study to ensure that recruitment takes place and that retention is maintained. This will require working with grass roots organizations, working to develop campaigns to explain the benefits of the study, to build relationships with the various area healthcare providers, and to reach out to parenting groups and to other organizations that offer health and information to families throughout the world. Evidence shows that many Americans have misconceptions about health and the research process, but we realize that we can build on our already trusting relationships to ensure that these misconceptions are clarified.

Retention of participants in this study will be a challenge. We all know this, but these strong relationships that our study participants will be able to put in place with each other and with the staff of the NCS I think, and we believe, will ensure continuity and retention. This will be done by

engaging local community groups and advocates. It will be done by getting participants much more engaged with the community. This will be done through newsletters, interactive Web sites for children, and periodic get-togethers in order to maintain this continued relationship between the staff of the NCS and the participants.

There will be public presentations going on throughout the study.

Everything that we can do and that the leadership of this study can do to maintain, to enroll, and maintain this diverse population will be done to ensure that this study is a representation of our nation.

Now I'd like to turn the session over to Dr. Peter Scheidt. It's my great pleasure to introduce him as the Director of the National Children's Study.

Dr. Scheidt

Thank you, Dr. Maddox. 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. It is incredibly exciting to hear Dr. Alexander read the list of these new partners in moving this landmark research forward this morning. Allow me to briefly present a chronology of the study up to this point and to offer a 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 after four years of extensive planning and input from the many scientists across the country, we identified 105 U.S. communities from which we would recruit and study participating families. We selected the 105 locations, using a probability based method to ensure that children and families from diverse ethnic, racial, economic, religious, geographic, and social groups are fairly included in a way that will be representative of the children in the United States and the experiences that they have, and to assure that we include in those experiences the critical exposures all of our children experience.

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 awarded the contract also for a large coordinating center that will manage information from the study centers and support the other aspects of the

study and integrate all of the diverse components of this study into a coordinated enterprise. All Vanguard centers are actively engaged in the pre-recruitment activities today and recruitment in the Vanguards for the pilot 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 '07; that's this past fiscal year. This funding allowed NICHD to issue the request for proposals in the RFP that is, for new study centers earlier this year, and to make these contract awards today.

With this large group of study centers funded, we are now well underway and will 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, women who are pregnant or are likely to have a child in the near future and their families during the four-year recruitment will be

recruited. All study centers will aim to enroll at least 250 women every year who are either pregnant or likely to have a child from each location.

Initially researchers will collect information on women's pregnancies, including their diets, environments, chemical exposures, emotional stress, and many other widely varied exposures. When the children are born and periodically thereafter, researchers will collect biologic samples and environmental samples, like air, water, and dust from the children's environments. Researchers will meet with families, both in their homes and in clinical settings and the data will be collected remotely by telephone, computer, mail-in questionnaires and other technologies, as they become available over the life of the study.

These newly awarded study centers announced today will begin study start up activities in the 26 locations this year. We anticipate additional competitions next year and the year after for the 16 waves, wave one and wave two, in order to complete the full sample of the 105 locations.

With that, I think we can begin to move on to questions.

- Dr. Alexander Thank you. We will now take questions from the media. We are ready for the first question.
- Moderator Our first question comes from Mini Kolluri with *Cox Newspaper*.
- M. Kolluri The question I have is that I couldn't hear the last part. I just want to know if there are going to be more centers next year and the year after that. Is there going to be an announcement about new centers?
- Dr. Scheidt The study plans call for two additional waves of centers to join the first wave that we have announced and funded today. That is dependent on the funding being provided for the continuation of the study. Once the budgetary questions are resolved and if funding is provided, then we will announce the competition again in 2008 like we held in 2007 to add the next one-third of the sites to participate in this study. Again, if funding is provided, in 2009 there will be a solicitation for the third wave, the final one-third of the sites in 2009.
- M. Kolluri Thank you.

- Moderator Thank you. Our next question comes from David Templeton with *Pittsburgh Press*.
- D. Templeton How long before you begin to get any results? It's obviously a long-term study, but will you be presenting results along the way or will you wait to the very end?
- Dr. Scheidt It is important to understand that we will not need to wait 21 years in order to see results from this study. We will be able to look at final results of the outcomes of pregnancy within five years of the beginning of enrollment and we will be able to look at preliminary results within two to three years of beginning enrollment. So we can anticipate beginning to learn important scientific information from this study as early as 2011 and 2012.
- D. Templeton And a follow-up question, the seven Vanguard universities, have they not begun anything yet? Are they going to start? It sounds to me like they haven't really gotten anything going, maybe some preliminaries, but they haven't started the study yet.

Dr. Scheidt It is correct that the seven Vanguard Centers that are now currently operating have not yet begun to enroll participants. The past year and a half has been spent in preparation, planning, finalizing the research plan and protocol moving forward with the required reviews from institutional review boards, those are the ethics committees in each community, and various other planning and preparation activities. Enrollment in the Vanguard Centers is scheduled to begin approximately nine to ten months from now.

D. Templeton Where would we get the names of the seven Vanguard Centers?

Dr. Scheidt I won't pause to go over all of them at the moment, but they're available on our Web site. They're available in almost all of the materials that have been distributed from the study and very easily available on the Web site. That is <http://nationalchildrensstudy.gov>. That has a great deal of information about the study in addition to the Vanguard Centers and locations.

D. Templeton Thank you.

- Moderator Thank you. Our next question comes from Chris Emery with *Baltimore Sun*.
- C. Emery I just was wondering if there's an overall estimate for the total cost of the study and for the centers announced today, if there's an estimate of how much each center will receive in funding.
- Dr. Alexander The amount the centers funded as announced today will receive varies, depending on the size of the center and the scope of the activities that they'll engage in over the first year. They range from about \$700,000 up to about \$1.2 million. The total cost of the study projected over 25 years is about \$3.2 billion.
- C. Emery Thank you.
- Moderator Thank you. Our next question comes from Oliver Uyttebrouck with *The Albuquerque*.
- O. Uyttebrouck The county here in New Mexico is Valencia County. It's a suburban county, but it's also very Hispanic and has a lot of rural elements to it. I

was wondering why did you happen to pick Valencia County and when is recruitment going to start there?

Dr. Alexander Valencia County, like all of the counties in the study, was picked as part of the scientific representative sampling process. The characteristics of Valencia County added with the characteristics of all of the counties in the study make up a true representation of the experience of all of the children that will be born in the country over the four years of enrollment. The sampling process is what picked Valencia County, but once picked, its characteristics are critically important to contribute to the entire picture of the study.

Does that answer your question?

O. Uyttebrouck Yes. When is recruitment going to start there?

Dr. Scheidt Recruitment should start, again, as Dr. Alexander mentioned, depending on available funding to meet the projected needs of the study.

Recruitment is planned to begin in the summer of 2009.

O. Uyttebrouck Summer of 2009?

Dr. Scheidt

Correct.

O. Uyttebrouck

It depends, so the funding is not immediately available at this point.

Dr. Scheidt

It is available to establish the centers and to begin the work to move forward, but the forward funding does not extend beyond the \$69 million that was appropriated in 2007. This program, like every other program in the federal government, is funded on a year-to-year basis with annual appropriations provided from the Congress. Whether it's NASA and the space program or a defense program or an education program or the National Children's Study, it depends on annual appropriation from the Congress. So we have the plans for what we would do were funding provided for the course of the study, but it depends for its funding and its implementation on that annual appropriation process.

Dr. Maddox

Also, realizing the diversity that is necessary to make a study like this sound, realizing that Valencia will give us that, we are hopeful that the leadership of this center will begin early on with the money that they receive this year to begin working on their infrastructure for developing brochures and engaging the community early on, so that we can get the recruitment that's necessary for a site, such as Valencia.

- Dr. Scheidt Valencia is a very diverse community with not only Hispanic, but small groups of Native American communities and others.
- Moderator Our next question comes from Tina Saey with *St. Louis Post Dispatch*.
- T. Saey My question is about the actual collection of samples and how and where those will be analyzed.
- Dr. Alexander I'm sorry. We cannot hear the question. I wonder if you could speak a little louder.
- T. Saey Can you hear me now?
- Dr. Alexander Yes. Thank you.
- T. Saey I'm wondering about what types of samples you are going to collect and exactly where and how those will be analyzed.
- Dr. Alexander The samples that will be collected will be at first, biologic specimens, blood samples, cord blood from delivery, bits of the placenta, hair, nails from the children participating for biochemical type of analyses.

Environmental specimens will include water from the home or the water system that families use, air samples from the home, samples of soil from the play areas of the children, and also from the food and diet that the participants use.

There will be some samples analyzed initially, but most of the samples and specimens will not be analyzed until later when the children experience the kinds of conditions and diseases of concern for the study: asthma, learning problems, autism, diabetes. The samples, both environmental and biological samples, can then be analyzed for those children who experience these various conditions in comparison to the many children who do not experience those conditions. That is called embedded case control studies is how the majority of analyses and research analysis will be conducted to inform us about the causes and factors that contribute to these conditions.

T. Saey

And are those going to be stored at each center, or will there be some sort of central repository for it?

Dr. Alexander

There will be a large, central repository that will maintain these samples available for the researchers involved in the study and for the use of

researchers outside of the study from across the country, who are experienced and capable of taking advantage of this extremely valuable national resource.

T. Saey I also had a question about recruitment. You said that the Vanguard Centers will be starting to recruit next year. How long do you anticipate it will take to have your recruitment of all of the study participants?

Dr. Alexander We anticipate the recruitment for each location is over a period of four years. They're expected to recruit 250 participants per year for a 4-year period to recruit 1,000 participants for each location. Given that all centers are not starting at the same time, but they're starting in three waves, the entire recruitment period will require six years from the beginning of 2009.

T. Saey Thank you.

Moderator Our next question comes from the line of Katie Drake with *The Salt Lake Tribune*.

K. Drake My question was, we understood here in Salt Lake that you were going to be adding Utah State University to cover Cache County. When you announced the universities, you said the University of Utah, which we had understood was a Vanguard site. I just wondered if you could clarify that.

Dr. Alexander Yes, we can clarify that. These centers are very often partnerships of different institutions and organizations and entities that come together as partnerships to be the most capable to carry out the study in those locations. Utah State is participating as a partner with the University of Utah, so the University of Utah is named as the study center, but it's in partnership with Utah State.

K. Drake All right. Thank you.

Moderator Our next question comes from the line of Charles Geraci with *The Herald Journal*.

C. Geraci I have a two-part question. First I'm wondering how are you guys going to balance the privacy concerns and not be too invasive at the same time getting the research you need.

Secondly, are you going to provide any incentives to the families that participate?

Dr. Alexander

The privacy issue is extremely important and one that we are very concerned about and have paid a great deal of attention to. The data and all of the information will be managed in a way that an individual's identity and privacy cannot be revealed in any way, so that they will not be known when the data are published or presented in any forum.

The study does require a fairly significant level of participation. There are planned to be three face-to-face visits during pregnancy, data information, and specimens collected at delivery and same face-to-face visits at 6 months and 12 months of age and then approximately every 3 years after. This is a not insignificant burden, but it is not so much that women will not be willing to participate and to undergo these visits and to provide this information.

They will be offered compensation in the way of incentives. There are many. First is the importance of participating in such landmark research for the benefit of all of our children and the country. There will be some inconvenience and the individuals will be compensated in an appropriate

level for that inconvenience guided by the institutional review boards at the local communities and the ethics boards for the study, so that it is appropriate and expresses appreciation, but is not coercive.

In addition, they will be recognized for participating from the centers and provided with thank you's and small gifts of appreciation. But for the most part, we think that the most important value in participating will be what the mothers and the families can learn about their children, their children's health and the children's environment as a result of participating in this study. Other large studies have informed us that, in fact, that aspect is what participants most value about this kind of research.

C. Geraci Is there any truth to the notion that participants could receive contributions to an educational account?

Dr. Alexander There is no plan at the moment for use of study resources to contribute to educational accounts for the children, who will end up being participants in the study.

C. Geraci But if I have it right, they will receive some financial compensation possibly.

Dr. Alexander Yes, at an appropriate level.

C. Geraci Thank you.

Moderator Thank you for your question. Our next question will come from the line of Adam Sarvana with *Inside EPA*.

A. Sarvana I have kind of a more technical question. I'm wondering how much this study and the results, I know it will take a couple of years to get anything in. But how much will this enable EPA and other public environmental and health agencies to rely less on animal data when they're setting health standards and clean-up standards? Obviously human data is sort of the gold standard. I'm just kind of curious to know how we'll move that forward.

Dr. Alexander Well, EPA is one of the primary participants in planning and organization and oversight of the study, so they have a very high stake in its outcome. Our belief is that one of the reasons that they value this so much is that it will provide them with top quality human data on extent of exposures and possible consequences of exposures. Whether that will enable them to replace animal data, I really can't say. I think that will probably vary from

one point in case to another. But it will certainly be extremely valuable to them in any decisions that they make to the extent that data can contribute to decision making about exposure limits, for example.

A. Sarvana

I do have one kind of small follow-up. I had written a story earlier this year that since there are no FY'08 funds in place, and you sort of addressed this already, but the prospect had been raised that there might only be one or two people working at some of these centers throughout this next year because they're still stringing along FY'07 money. Can you just kind of address that a little further?

Dr. Alexander

Yes. The funding is available to these new sites. The funding is provided to them at the outset from fiscal year '07 dollars. They are approved for funding for years beyond that, but it always is contingent on the availability of funds. That's a clause in the contracts. They have funding for more than one or two people to be working. There's extensive funding available for start-up activities in these sites. There will be a demand, a need, a requirement for considerable effort outreach in the community, planning, putting staff in place, working with other sites in decision making. It's going to require more than a couple of individuals.

The funding for contracts like this is also provided a year at a time. They have negotiated a budget for funding for the first year. That first year funding is provided. Funding for future years will be determined by the availability of funds, which depends on appropriations.

A. Sarvana But for this next year, you don't envision that there will be quite such a skeleton crew. Can you give us some description of how many people will be working there and what they'll be doing?

Dr. Alexander I wouldn't describe the activity at the Vanguard Centers and with the future centers as a skeleton crew. That picture could have applied to the circumstances prior to the FY '07 appropriation of \$69 million. The \$69 million is what the planners of the study projected was the need to move the study forward full-scale. That is now happening and so the teams are, with that appropriation, being built, put in place, and the Vanguard Center and now the new study centers, are going forward towards full implementation of the study. With anticipated funding for '08 has currently been discussed in Congress, that will continue full scale in 2009.

A. Sarvana Thank you.

- Moderator Thank you. The next question comes from Dorsey Griffith with *The Sacramento Bee*.
- D. Griffith I am interested in understanding sort of, who will actually be analyzing the data and doing the study? How open will this process be to the private sector researchers?
- Dr. Alexander There are two groups that will be responsible for the data analysis. The study has a large number of hypotheses that it is testing. And these are hypothesis that the data will be used to assess by the federal investigator team working in collaboration with the principal investigators at each of the sites. They will determine the analyses to be done, the timing of those analyses, and just how that will be worked. They will use the initial data runs that are made available from the study at the various times. These first cohort that will be analyzed will be the newborn data. Then it will be the one-year evaluation data and then the three-year evaluation data. These will come in waves.
- In addition to the federal effort, our plan is to make the data sets available to investigators in the field, so that they will be able to propose their own studies to test their own hypothesis that go beyond the hypothesis central

to the study that are part of the federal effort and that are being funded by the federal government's funds.

They will be able to have the datasets available to them, the same datasets that the federal investigators will use. They will also have the opportunity to request access to the stored biological samples from the center to test their hypotheses. They can make application to the NIH, to other federal agencies, or to private sector for funding to test their hypotheses and use the dataset and the biological samples from the study to do that.

So there is the combination of the federal data analysis effort that will involve federal scientists and the principal investigators at each of the sites working to do those central analyses, testing the core hypotheses, and the availability of the data set to investigators with all identifiers removed, so that they can test their own hypotheses and expand the value of the study far beyond just the data analysis capacity of the federal effort.

D. Griffith

Thank you.

Moderator

Our next question comes from Don Finley with *San Antonio Express*.

D. Finley

I understand you're also going to be looking at psycho-social factors, as well as biological and environmental samples, like television viewing. If that's the case, can you elaborate on what you're going to be looking at and what sorts of questions you're going to be asking with it?

Dr. Alexander

We will be looking at a large number of factors that are psycho-social factors, of which television is only one. We'll be looking at how families function and interact, how the approaches to discipline and behavior control families use and the amount, the volume of exposure to media, especially television and other media forms. Most of this information will be by report from the parents. There have been proposals to go into more detail about these kinds of variables, but a great deal of depth about media exposure and the content of media exposure will require more in depth, more focused studies that we term adjunct or ancillary studies. There have been some suggestions and proposals about doing those kinds of studies with regard to media.

I'll take advantage of this to comment about the value of this National Children's Study as a platform for other kinds of more in-depth studies that we anticipate being able to do throughout the study on portions of the

entire sample and the in-depth examination of media exposure is one of those categories.

Does that answer your question?

D. Finley Yes. Thank you.

Dr. Scheidt Let me just add one thing to that. That is that this capability and inclusion of assessment of the social behavioral environment the child grows and develops in is a very unique and unusual feature of this particular study. When most people talk about environmental influences, they sort of stop with chemical or pesticide exposures or the physical environment that a child lives in.

This study goes well beyond that and we'll have extensive evaluations, measures ... and the quantification that will allow of the kinds of social and behavioral environment the child grows up in: the neighborhood, the community, the school, the church, any other exposures that the child has of this kind of a nature. So that we will have not just physical and chemical environments to look at, but the social and behavioral and neighborhood features as well.

Moderator Our next question comes from Russell Dinnage with Greenwire.

R. Dinnage Just touching on a question that was asked a little earlier, what's the regulatory end gain for the use of this data? Aside from the 100,000 people that are going to benefit from being able to take any adverse information that's discovered through the course of the study on their children to their doctors, how will the rest of the American public benefit in the future from the vast amount of epidemiological data that's going to be gathered here? Is there like a toxicological end point to all of this at all? Is there any way this is going to be analyzed from a toxicological standpoint to eventually provide for real, clinical health consultations or regulatory provisions?

Dr. Alexander One of the hopes for major uses of this study data will be to guide policy making in a variety of arenas, part of which could be from a regulatory standpoint of exposure limits for a variety of chemicals and other agents. Whatever amount of data will be sufficient in and of themselves to allow for that, we don't know yet. In some instances, we hope they will. In others, they may not. But certainly, they are going to be helpful to people in a variety of policy making roles in terms of whether a product should be

licensed for use or not in a broader extent than it is already, whether more stringent limits might be set for exposures, or maybe less stringent limits on exposures. There are lots of reasons to believe that for a number of agents in the environment where questions have been raised about them that the data from this study may, in fact, show that there is not the harm associated with them that some smaller studies limited in terms of numbers of patients, times of exposures, times of follow-up have raised questions about.

We anticipate that the data from this study will be used extensively in terms of policy making. That extends not just to chemical exposures, but guidance for, as one of the questions related to earlier, media exposures and types of social and behavioral experiences that children may benefit from or may be harmful.

So we anticipate that there will be lots of that kind of use of the data.

Whether the data will be sufficient from just this study to provide definitive answers or whether they will point to things that need more intensive study, we just have to wait and see.

R. Dinnage Okay. Just to be clear, no study participants have been enrolled at this point, but enrollment is set to begin within nine to ten months' time.

Dr. Alexander Correct.

R. Dinnage Thank you.

Moderator Our next question is a follow-up question from Tina Saey with *St. Louis Post Dispatch*.

T. Saey I was wondering how much information gathered in the study will be actually disclosed to the study participants. For instance, will you give them data about all chemical exposures that you find, or only ones, say, lead exposure that might be of concern and have proven medical consequences?

Dr. Alexander The question about how much data to provide back to or reveal to the participants, as I described previously, much of the chemical analyses will be delayed until it can be used to inform us about the experiences of children that actually develop certain conditions. So much of those analyses will not be done initially when the samples are collected. Given

that we will not be in a position to provide the information back to those participants, let me give you just a quick example to illustrate why that's the case.

If we're going to test about what kinds of exposures might have occurred to the 600 children who develop autism in the study, when that happens, after they're three to four years of age, we will only need to do the analyses for the necessary chemicals for that 600 and maybe another 1,200 controls or 1,800 analyses, rather than the entire 100,000. We cannot afford to do many, many chemical analyses on the full 100,000. For that reason, most of those types of test results will not be available for all of the participants. Where there are results available from the tests that will be done routinely and where those results are clearly of benefit or what we call actionable and of some importance to the participants, we do plan to share those results with the participants.

Does that answer the question?

T. Saey

Yes.

- Moderator Thank you. Our next question comes from Meredith Wadman with Nature.
- M. Wadman I had a question on the funding aspect. President Bush did not ask for any money for the Children's Study in his '08 budget request. I noticed that the report language and the House have \$110 million for FY '08, but the Senate does not explicitly state that, I don't believe. Do you expect Congress to continue providing along the lines of what the House has written into its bill this year? Why or why not, in particular, against the backdrop of basically flat or even decreasing in real terms overall NIH funding and stress on junior investigators and so on?
- Dr. Alexander This is a difficult point in time to be launching any kind of a large, new, major initiative. The fact that the Congress in 2007 to start this project that was all new funds not taken out of anything else from the NIH indicate that Congress felt in a very broad, supportive way that this study was important to do. They, in fact, said that, "We ask that this study be done," and, "We believe it's important and it should go ahead." This, like every other project, depends on annual appropriations for its continuation, whether it's the space shuttle missions or other appropriations for education or whatever. We depend on that annual appropriations process.

You are correct in saying that the budget request sent to Congress in 2008 did not request funds for this study. The House Appropriations Committee provides \$110 million, which is the target number needed in study projections to continue funding in 2008. That figure passed the entire House.

The Senate Appropriations Committee also provided \$110 million, but no Senate action has yet been taken on the appropriation by the full Senate. We are waiting to see what happens. If the appropriation of the \$110 million for the study passes and the bill is signed by the president, we will proceed with solicitation for the next wave of the study centers and expanded activities on the part of those already funded. If the appropriation is not provided, as was stated in the appropriations request sent to Congress, we will shut down the study and close the contracts, release the staff, and the study would come to an end.

So it depends on the appropriations process. Congress has to make a choice on this, as does the president when he receives a bill in terms of whether this is a go or no go. That will be true for 2008 and that will be true for the ensuing 25 years of the study.

M. Wadman Was that Dr. Alexander or Dr. Scheidt? I'm sorry.

Dr. Alexander That was Alexander.

M. Wadman Thank you.

Moderator There are no further questions. Please continue.

Dr. Alexander Thank you very much. This concludes our telebriefing of the National Children's Study center announcements. A rebroadcast of this telebriefing will be available for one week. It can be heard at the following telephone number: 1-800-475-6701. The reservation number to hear this is 885753.

As Dr. Scheidt mentioned earlier, to get more information about the National Children's Study, please visit the Web site at www.nationalchildrensstudy.gov.

Thank you for participating. We appreciate your interest. This concludes the telebriefing.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Host: John McGrath

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Moderator

Ladies and gentlemen, that concludes our conference for today. Thank you for your participation and for using AT&T Executive Teleconference. You may now disconnect.