

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
NATIONAL INSTITUTE ON CHILD HEALTH AND DEVELOPMENT**

**NATIONAL CHILDREN'S STUDY  
PRE-PROPOSAL CONFERENCE  
RFP NIH-NICHD-NCS-07-11**

**March 7, 2007**

**Doubletree Hotel Rockville  
Rockville, Maryland**

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## PROCEEDINGS

MS. OSINSKI: We are going to pull our webcast in first and then we wanted to talk a little bit about procedures.

### **Agenda Item: Welcome and Introductions**

MS. OSINSKI: My name is Elizabeth Osinski. Thank you very much for coming, and we would like to welcome you to the conference. We would also like to welcome our webcasters to the conference. I am going to go over some procedures and then introduce members of the panel, who will be answering the questions.

I am the contracting officer, one of the co-contracting officers on the project. I will be one of the main contact points, along with Fred Ettehadieh, the other co-contracting officer for contracts. We will be the primary contact points for this request for proposals (RFP) throughout the award process.

I'd like to introduce Dr. Peter Scheidt, the Program Director for the National Children's Study (Study). I'd like to introduce Dr. Ruth Brenner, the Project Officer for the Study sites. I'd like to introduce Dr. Alan Fleischman, the Ethics Advisor for the Study. I'd like to introduce Dave Songco, our Chief Information Officer for NICHD.

Now we will go over a few of the procedures for the conference. You may see some cards on your seats, for those of you who are in attendance. Those cards are for writing your questions down either now or during the conference. We want you to write one question per card and turn them in to Barbara at the registration desk in the front at the break. If you need additional cards, Barbara can provide you with additional cards. We will not be reading your names and your organization when we answer the questions, but we do ask that you put it on the card.

The other question is for the webcasters. Please continue to send your questions throughout the presentations to the webcast box on your screen. They will be printed and during the break we will look at those questions and will answer them later in the conference. Also, after questions have been asked during the conference, you can, if you have an additional question, hold up your hand and a card will be provided to you or you can give your additional question to Barbara. Thank you very much and that is the procedure for the conference.

This is our RFP number. This will be the summary of the slides that I will present. We can go on. These were the introductions and they are in your package.

I did want to bring up that we are in a competitive RFP and the exchanges between industry and the university community and any questions you have now on the RFP will be through Fred Ettehadieh and me, the contracting officers. So, we are going to ask that at this conference you do talk to any of our program staff or the other people about any questions on the RFP. We do want to say that all the presentations here as well as the questions, the answers, and the whole text will be, in the next few days, put out as an RFP amendment to the solicitation. So, the whole text of all these presentations will be available.

This is the Web site for the RFP and for all the questions. One thing that I do want to draw your attention to is that FedBizOpps is going to be the contact point for amendments and for any information that is happening on this request for proposal. So, I want to ask that you register at the site and then you will receive notifications. It could be at any time. We can't possibly notify all the people out there, so you are responsible for checking that site. This is the

official site for this RFP till the closing date. So, we do want to tell you that we will have an amendment out. There is already one amendment; it was a correction of a chart on the RFP. We will have another amendment out in the next 2 or 3 days on this conference and then we will probably have one more amendment out on other questions that we receive, in writing, about the RFP, so this is a very important site.

The purpose of the conference really is that we want you to be able to ask questions of us and to have a better understanding of our requirements. We are also trying to make sure that we clarify anything in an RFP amendment that you have a question about.

I have already received one question on it. I will be answering some of the questions we received yesterday in my presentation. One of them was on the Proposal Intent Response Sheet. This is actually attachment number two to the RFP. It is really a convenience for us and we realize there may be changes after March 21<sup>st</sup>, that you may have to make to this, but right now it assists the Division of Scientific Review in identifying peer reviewers and avoiding conflicts of interest for our outside peer review of proposals. So this is very, very important to us if you could send this in. If you don't know certain principal investigators (PIs), or if these are only the key people on your proposal, then you can amend this and send it to us, but we ask that you do send something in March 21<sup>st</sup> if you are going to respond to the RFP. It is not binding, but it does give us an idea of how to set up our review and we are on a very short time frame for this procurement.

The other thing I would like to say is that we would like you to Xerox this attachment and submit separate sheets if you have also proposed on the options and you have other investigators who are key on the options proposals. These sheets should go to Mr. Ettehadieh and this is all here.

This is actually very important and it is one of the things I want to spend a little bit of time on because we are on such a shortened acquisition schedule for this procurement. If you have other questions while you are preparing your proposals, we would have to answer them in an RFP amendment through the contracting officers and we are going to have a cutoff date for RFP written questions by March 29<sup>th</sup>, 2007, so that is an important date. The other important date is the receipt of proposals, which are due on April 17<sup>th</sup>.

This is our schedule because these contracts are going to be awarded by September 2007, so it is very tight. We will be notifying offerors in or out of the competitive range in June 2007; then we will have technical and business questions/negotiations in June and July 2007. Final proposal revisions will actually be due in July or early August 2007. So, this is very important because this schedule is very tight. Also, contract awards will be in September 2007 and there will be other contracting officers who will then be joining the award team. But, right now, Mr. Ettehadieh and I are the contact points for the RFP. .

This is just something I want to bring to your attention at this time so that you can think about it when preparing proposals. Any contract over \$550,000 is required by the small business laws to have a subcontracting plan, and we are asking that you think about this now. This is not due with your proposal. It will only be due at a later date if you are within the pool of successful offerors, but it is definitely something to be thinking about when you start preparing your proposals. Start thinking about these Department of Health and Human Services (DHHS) goals.

Okay, PIs. Dr. Brenner is actually going to be clarifying this a little more in her presentation, but we received a lot of questions about the PIs and if you have multiple sites and can you have co-PIs, can you have multiple PIs? Right now we must have, for these contracts, one PI at the prime contractor's site for oversight of the entire project. We may have co-PIs at

other locations and Dr. Brenner is going to go into this, but unlike a grant, the multiple PI model has not been implemented for contracts and therefore, can not be proposed on this project. So, we just wanted to make it clear that the multiple PI, as in a grant where you totally share the responsibility, cannot be proposed on this project.

Okay, type of contract. There have been a lot of questions on level of effort. Dr. Brenner is going to go in a little more detail on that, but one of our attachments, attachment 8 specifically, spoke to the estimate of effort for the project. This was for guidance only and you are not bound to this for proposal purposes. This was just our estimate of the effort required and it was in order to give you some type of guideline that you may want to go with or have as a starting point. There will be more in Dr. Brenner's presentation about this, but this is only an estimate. This is going to be a cost reimbursement completion-type contract, so the actual level of effort will be as you propose it. You will be required to stay within the bottom line of the contract, but you will be able to vary your cost categories, unlike a grant, other than certain restricted categories that required prior approval, the way you want to run your budget for the contract. So I do want to make that clarification and also that we plan to award these contracts as 5-year, incrementally-funded contracts with potential options for the locations.

The options and option location budgets. One of the things that will actually be in an amendment, your option budget will be an option. Okay, it will be part of your business proposal, but it should be tabbed separately. The option budget for the locations. We are giving you the estimate that they may start at the beginning of year 2 or at the beginning of year 3, but for proposal purposes right now, rather than proposing different starting points each year, we are asking that your option location budgets start with the date September 30, 2008, which would be a year from the award of this contract [see amendment # 2 to the RFP on FedBizOpps]. So, this is for proposal purposes and you may propose for as many option locations as long as you meet your mandatory criteria. We want your option budgets in your main business proposal, but as stand alone budgets, and that is why we would like them tabbed separately, apart from the Study center base proposal and the primary location that you select. That will be the base contract.

Again, these are Mr. Ettihadieh and my e-mail addresses for any additional questions that you may have after this conference when you go back and hopefully prepare proposals. After presentations by Dr. Brenner and Dr. Scheidt, we will be taking questions. I want to thank you very much.

### **Agenda Item: Development of the National Children's Study**

DR. SCHEIDT: Thank you, for all those clarifications and let me add my welcome to all of you who are here in the snow and to those who are attending by the webcast. Welcome to this pre-proposal conference. We are delighted to be at the point in this implementation of the Study to significantly expand the locations and the Centers and really get started with the Study.

I will start this section with the presentation of the development of the Study because many of the aspects of the development of the Study and how we got here add meaning and understanding to the shape of the Study and the kinds of proposals that you will need to submit. Following that, Dr. Brenner will focus on the specifics of this RFP and then during the questions and answers we will also introduce, in addition to the panel that has already been introduced, members of the Program Office staff who will be available to assist us in answering questions. Let me quickly introduce them.

Marion Balsam, who is the director of the adjunct studies and partnership development of the Program Office. Marsha Hasson, who is in the Coordinating Center as director of the IMS part of that center. Ken Schoendorf, from the Centers for Disease Control and Prevention (CDC), who works with us in the Program Office on the protocol. And Sarah Knox, who is directing the behavior and psychosocial aspects of the Program Office.

I cannot talk about the Study and the development of it without at least a brief mention of why and how the Study was proposed, which could be an entire afternoon of scientific presentation. It began in the preceding decade with a convergence of a number of factors that led to this proposal.

There was clearly emerging—the realization that children experience a significantly increased vulnerability to a number of environmental exposures in comparison to adults and concerns raised about that. There were a number of examples of that vulnerability that heightened our awareness, such as the experience with lead and Fetal Alcohol Syndrome and so on. There were a number of environmental exposures that the scientific community became aware of, for which there was increasing concern about possible effects, such as the reports of plasticizers or phthalate exposures, about pesticides and even down to the possible effects of witnessing violence and other behavioral and psychosocial exposures. At the same time, there were a number of conditions and health problems that our children experience that either were refractory to attempts to reduce them or increasing in frequency such as autism, birth defects, learning disabilities, and so on.

It was the convergence of these factors that led to an appointment of the President's task force on Environment and Health Risks and Safety to Children in 1998. This task force, chaired by Secretary Shalala of DHHS and Carol Browner, the administrator of the Environmental Protection Agency (EPA) and seven other cabinet officers, was charged with developing national strategies to control the risk of environmental exposures to our children. This task force very quickly came to the realization that in order to meet that charge, a program of research that defined and clarified what those risks actually were was absolutely essential; and that this program should consist of a large longitudinal study that should be boldly planned with additional funds then were currently available in existing federal budgets.

I always go into a little detail about the task force because I think it is important for all of us engaged in the Study, or even interested in it, to realize that this was not an idea of a couple of scientists sitting up in a lab or a room somewhere at CDC, EPA or the National Institutes of Health (NIH), but conceived with very careful deliberations at the highest levels of government with a clear mission. This task force proposal then was followed by the Children's Health Act of 2000 that authorized NICHD, with a consortium of federal agencies, to undertake the planning and implementation of this large longitudinal study that would include physical, chemical, biological, and psychosocial measures of exposure and important outcomes of children's health and development.

From that very beginning until today, the concepts of this Study have been and are that the Study be capable of identifying potential environmental effects that may be harmful and equally important, maybe helpful, or at least not harmful. Regarding those many conditions for which we are concerned about our children's health and development, the environmental contributions to those conditions, must be identified so that implementation of interventions could be possible. Finally, with the understanding that this Study would provide an enormously valuable national resource of rich data and specimens, it should be planned in a way to optimize this potential for future research over the upcoming decades.

Also, since the very beginning, it has been our understanding that the planning of this Study should be hypothesis driven in order to provide the framework, guidance and boundaries for planning a Study of this size and in order to assure that the Study can meet its goals: that the concerns about exposure begin as early as possible in pregnancy, that it be large enough to identify relationships of exposure to conditions of infrequent prevalence and incidence, that it include the measure of extensive genetic factors, and as I have mentioned, be a resource for future studies.

The planning process for the Study has been long and complex. It began with an interagency consortium, that I mentioned previously, that convened to form what has been known and is still known as the Interagency Coordinating Committee (ICC). These are senior staff and scientists from the lead agencies that have been engaged in both planning and providing financial support for this Study, including staff from the NICHD, the National Institute of Environmental Health Science (NIEHS), the CDC, and the EPA. I will say a few more words about the ICC in a minute.

The planning process also has included the establishment of a federally-chartered advisory committee. This committee was undertaken with its expert working groups because we realized very early in the process that even though multi-disciplined, the federal scientists on the ICC needed a much broader scientific expertise and broad support and engagement from the scientific community all over the country. In the federal government, there were only a couple of ways you can get scientific input and consultation and we reasoned that we needed this consultation on an ongoing basis. The most appropriate way to do this was the establishment of a federally-chartered advisory committee, which operates under the Federal Advisory Committee Act and has certain guidelines, which most importantly, mean that that process is a public process. In addition to these, there were 22 working groups formed in specific discipline areas that provided input and guidance on the hypotheses used to frame the Study, the associated measurements and the study design.

In addition to these planning processes, a number of specific *ad hoc* workshops were conducted, actually 30 of them. A number of literature reviews, white papers, detailed analyses, and specific pilot studies were conducted, some of which were funded by the other agencies and the majority of which were funded through the joint operating funds for the planning of the Study.

These reports from the workshops and pilot studies and white papers, for the most part, have been posted on the Study webpage and are available to you. There is far more information there than you would ever want to or be able to read, but to the extent that they can be helpful in developing proposals, by all means, they are available to you.

About 3 years ago, we began to actually staff a Program Office at NICHD with scientific staff that I have introduced to you already to do the day-to-day work and operations in scientific development of the Study. A year and a half ago we established the initial (Vanguard) centers of the Study and the scientific staff of those initial centers have also been contributing to the continued planning and implementation of the Study.

I mentioned the importance of hypotheses in planning the Study and I will just very briefly clarify that. Hypotheses are not the be all and end all for the Study by any means, but we felt they were necessary in order to provide assurance that the big issue questions are in fact, answerable with this Study and the approaches taken. We also established, for the planning process, that if we are going to expend valuable national resources in carrying out this Study, that there should be an important hypothesis or compelling hypothesis underlying the expenditure of

those resources. The hypotheses should assure that a study of this size and complexity is necessary and capable of answering the question. We understand that the hypotheses that have been posted are neither complete nor totally sufficient and that the science evolves over time. Some may be outdated, and there are certainly missing hypotheses. We anticipate continued revision and updating of those hypotheses and, in fact, are currently engaged in that process. Those 30 hypotheses are also available on the Web site, though, let me add, they are in the process of being updated.

All of these questions and hypotheses have been organized into a group of key, or what we call priority exposures and priority outcomes, for the purposes of organizing and clarifying them. The priority exposures embraced by the Study include the physical environment; the chemical exposures; and the biologic, genetic, and psychosocial environment. I will not list the examples given, but these are just some selected examples in order to understand their impact on priority health outcomes, including outcomes of pregnancy, neurodevelopment and behavior, injury, asthma, obesity, and physical growth.

That ends the very quick overview of what the Study is about and why. The first major decision that we faced in planning the Study was to determine who would participate and what would be the sample? To summarize in one very brief, short paragraph, an exhaustive and extensive process on which we spent 2 years and a great deal of attention, study and deliberation, led to the conclusion that the most appropriate sample for the Study is a national probability sample. This was important for several reasons, not in order to estimate prevalence of exposure or outcome, because this is a study of exposure-outcome relationships, but, those relationships, we felt, needed to apply to all of our children and all of the major subgroups of our children. In order to assure that, the probability based representative sample of our children provided the best assurance that that would be the case.

A second, and I think, major reason for a representative or probability sample is that the exposures of concern in this Study are varied and many and the distribution of those exposures varies greatly from one to another across the country. For many of the exposures, the distribution is unknown and the best assurance for not missing key, important exposures is to use a sample that represents the experience of all of our children.

We also felt that it was important that the sample be fairly highly clustered in order to increase efficiency in carrying out the Study and to be able to measure the characteristics of communities, both physical and other characteristics. In order to have enough data points in any given community a certain degree of clustering was required. However, in spite of the decision and commitment to use a representative sample, we also, at the same time, felt that we needed the broad expertise and capabilities of centers of excellence around the country. The most effective approach to carrying out the Study would be with the use of centers of excellence in order to gain that broad scientific input and the capabilities to carry out the kinds of measures that the Study requires.

This combination of a clustered, representative sample predetermined across the country combined with a center-based strategy is a unique combination that poses very significant challenges to centers engaged in carrying out this research. It means that the centers do not have the choice of exactly where and what population to use or to be able to choose that population which is most convenient and most readily available. The sample is determined on a scientific basis and not on a convenience basis, and this requires considerable flexibility and adaptation of the centers to the design of the Study. It also requires considerable support, guidance, and coordination from the Program Office and especially the Coordinating Center.

The sample for the Study is a multi-stage, clustered probability sample based on the distribution of live births in the United States. Starting with all births in the country, approximately 4 million, that occur in the 3,141 PSUs of the country—3,141 counties, they are not exactly the same as sampling units, but starting with those counties, we identified 105 locations with a stratified sampling process, guided by the National Center for Health Statistics, to identify 105 as the primary sampling locations of the Study.

Within each of those primary sampling locations, segments will be determined collaboratively by the Coordinating Center and the centers, to identify the sections or the segments of each PSU, or largely counties, which will be included in the Study. Then, within the segments for the most part all eligible households will be included and invited to participate in the Study and then those households will be screened for eligible women and all eligible women identified will be included.

By definition, a national probability sample stipulates that every individual and every geographic location in this country has a known chance of having been or being included in the Study. There are 105 locations, roughly corresponding to counties or clusters of adjoining counties, 79 metropolitan areas and 26 rural areas. Thirteen of the samples are called self-representing or certainty locations because with a sample of this size, those 13 will always be included because they are so large that they will always be included.

It is important to emphasize the distinction between locations and Centers. The locations or sites are those locations or counties from which participants are recruited. They are selected by the stratified probability sampling process that I just described. There are 105 of those and those are on the map in the next slide. Centers, on the other hand, are the entities or institutions that will carry out the locations. They are selected by a competitive process in which many of you are participating or contemplating participating now. Each will cover, on average, more than one site and we anticipate 30–50 Centers to carry out the work in those 105 locations. This is the current map of the primary locations, largely counties, of the Study with those seven initial Vanguard locations listed on the map and with the red dots.

Now, as you are aware, just as we are now issuing an RFP for the first wave of the additional centers for the Study, we also conducted a solicitation with an RFP for the original first seven locations a year and a half ago. Being cognizant of the challenges that we placed on Centers, we were concerned about what kinds of proposals we would get and whether they would be able to meet the demands of carrying out the Study with this sampling approach. For that reason, let me share with you a little more detail about those seven Centers because it can be instructive in subsequent proposals.

The Vanguard Centers that were selected from that procurement to begin the study include for Orange County, California, the University of California at Irvine teamed with the Children's Hospital of Orange County. For the PSU at Queens, the borough of Queens in New York City, the Vanguard Center is Mount Sinai School of Medicine teamed with Columbia Mailman School of Public Health, the University of Medicine and Dentistry of New Jersey, the Department of Health and Mental Hygiene of New York City, and the Mailman School of Public Health and Columbia University. For the Duplin County site, one of the rural sites in eastern North Carolina, the Center is the University of North Carolina teamed with the Battelle Memorial Institute and Duke University. For the Montgomery County, Pennsylvania location, which is a county suburban to Philadelphia, the Center is Children's Hospital of Pennsylvania teamed with the University of Pennsylvania and Drexel University School of Public Health. For the location of Salt Lake County, Utah, the Center is the University of Utah. For the location of

Waukesha County, Wisconsin, the Center is the University of Wisconsin teamed with the Medical College of Wisconsin and the National Opinion Research Center at the University of Chicago. Finally, for the other rural location of a combination of four counties in order to have an adequate numbers of births, in Brookings County, South Dakota, and three counties in southwestern Minnesota, is the South Dakota State University teamed with the University of Cincinnati. So, that gives you a flavor of some of the composition and some of the relationships of the Centers for this initial procurement.

The next slide gets to, why did we use a contract mechanism for establishing the Centers in the Study? We considered a number of options and if one looks at the options available on a continuum of the degree of control and independence on the part of the Center, one can depict this on a Likert scale from the maximum control of the government using a contract mechanism to the maximum independence of the Center with a grant mechanism. In between is a mechanism called a cooperative agreement, which is basically use of a grants where the Centers partner with the funding agency and together they evolve a protocol that is then carried out.

After considerable deliberation and consultation with a number of other studies, especially the Women's Health Initiative and several other large studies, we decided to use the contract mechanism for two main reasons. This research project had a long history of a clear mission and directive from those federal agencies that had been engaged in the planning to meet certain important goals, to understand the relationship of environmental exposures in children. To assure that those goals are addressed by the Study, we felt the contract mechanism was important. Secondly, with so many large Centers, it is essential that a core protocol be carried out according to a rigorous protocol and to assure that that is done, we felt the contract mechanism was most appropriate.

On the other hand, as I mentioned previously, we felt that in the planning of this process we needed the input, ownership, and expertise of scientific expertise scattered throughout Centers in the country. For that reason it is our plan to manage this contract-research program as closely as possible to how a cooperative agreement is managed. There is a strong steering committee, and a great deal of guidance and decision making about the science of the Study currently will be carried out by the investigators from the Centers collaboratively with the scientists of the agencies that are carrying out the Study. When necessary, that red line might have to move toward the contract or control end, but for the most part, the planning of this Study is carried out much more like a cooperative agreement than a strict contract.

What are the key entities that are currently envisioned and in place for the Study? I have mentioned the ICC, consisting of senior staff of those supporting federal agencies, that provides federal oversight for the Study. A federal consortium has been convened with representatives from all of those agencies, including the NIH institutes, EPA offices, CDC Centers, as well as all of the cabinet-level agencies concerned with health and environment of children, for their strategic input. In fact, we have had a handful of large meetings with all of those agencies and are in the process of now, with funding, planning another meeting to bring the federal agencies with the concern about children's health and environment back together with us.

There is a federally-chartered National Children's Study Advisory Committee (NCSAC), and I have neglected to mention that Alan Fleischman is the chair of that committee, which provides review and advice to the director of NICHD and the Study director. The Program Office at NICHD provides the day-to-day scientific and operational management of the Study. The Steering Committee, composed of Center PIs and representatives of the Program Office and the ICC, is the place where the primary scientific deliberations and decision making will go on, and I

will give a little more information on that in a minute. There is a Coordinating Center that provides the data management and clinical coordination that Ruth will talk about in more detail and a Data Safety and Monitoring Committee, not yet constituted, but must be, that will monitor data and advise on interventions based on findings as they emerge.

What about the steering committee? The steering committee is composed of the PI from each of the Centers, and that will continue to be the case when the Centers expand, as well as representatives from the ICC and the Program Office. Specific defined responsibilities of the steering committee are that it will identify problems and best practices that arise in the conduct of the Study. It will provide scientific input and expertise in support of the decision making. It will be engaged in making recommendation regarding scientific content of Study components. It will provide review and approval of adjunct studies and add-on studies, but it will not be the only approval, but it is one of the essential reviews. It will provide decision making about non-direction changing and budget-neutral issues related to protocol and the manual of operations, and it will propose whatever changes are needed to the protocol based on both expertise and experience.

Reviewing key components of this Study by when they are available, we have in place extensive scientific support and planning, which I have described already. An information technology development contract is in place with the contractor Booz Allen Hamilton teamed with the Coordinating Center are well along in developing the information management system. The Clinical and Data Coordinating Center is in place and of course, the initial Study Centers or the Vanguard Centers.

This year, and the purpose of this meeting and this RFP is to establish wave I Study locations and the Study Centers. We anticipate approximately 30 locations and 15–20 Centers. Following this procurement will be additional procurements for a specimen repository and for laboratory services. Let me mention that our partner lead agencies are involved in this process as well. Marion Balsam from the Program Office, is currently working on developing those RFPs and acquisitions. In addition we have a memorandum of understanding with the National Center for Environmental Health at the CDC, which is a very large laboratory, probably the largest and most developed laboratory for biologic specimens of environmental exposure, to do some laboratory work. They are working with us in providing laboratory work for those types of assays. The EPA labs also may be used in certain aspects, for providing some of the environmental assays, and a number of contracts are anticipated.

What about access to data and publications, a question that many investigators and prospective Centers will have. Let me say that a guiding, an overriding principle in all our thinking about access to data in publication is that we intend and our goal is for the maximum use and publication of the data provided by the Study. Regarding primary hypotheses and analyses and also secondary hypotheses, data access and analyses will be primarily through Center PIs and designated investigators at participating Centers, and that includes federal agency scientists as well. The data access will follow the publication policies that are currently under development with various drafts, but not final. The development of those drafts is occurring in the Data Publication Subcommittee of the Steering Committee that is engaged in drafting the policies. That subcommittee will also be engaged in providing oversight for the whole process of publication under the Program Office and the ICC.

We do anticipate and are committed to providing public-use datasets, to be available with each stage of the Study and as required by NIH guidelines. We would hope that they would be available even sooner than the maximum amount of time that is required by the NIH guidelines

and at the various levels necessary, depending on the requirements for confidentiality in use of the datasets. However, one must always add that there are federal statutes and contractual agreements that will prevail and override any of the policies or other decisions that are made and we are constrained to whatever the federal statutes and contractual agreements are.

Finally, a comment about adjunct studies. We envision that in addition to the full core national protocol, that there will be an opportunity for many adjunct studies. Such studies would involve a portion of the full sample, using some Study infrastructure and data to address additional in-depth questions. In fact, the Women's Health Initiative, comparable in size has now over 250 what they call ancillary studies, as part of that large longitudinal adult women study and we anticipate a similar experience. The funding for such adjunct studies could be from a variety of mechanisms. We anticipate they may be funded by the traditional NIH grants, ROIs, other kinds of grants, public/private partnerships, foundations, industry, and when specifically needed, the Study itself.

A carefully developed process for review and approval of adjunct studies has been established in the Program Office and is ready for handling adjunct studies. Examples of such adjunct studies may be, for instance, a genomic analysis of subgroup specimens for targeted gene-environment interactions that might not otherwise have been planned or available or in-depth functional neuroimaging at a certain Center or a small cluster of Centers of an exposed subgroup for mechanisms of effects of environmental exposures on child development. However, in contrast to the request for proposals for the Vanguard Centers, for this proposal, adjunct Study proposals are not a requirement for this solicitation. We are not anticipating or asking that additional proposed adjunct projects be included.

The timeline for major events of the Study - we are now at the 2005–2006 startup phase for the Vanguard Centers. We are within weeks from the completion of the first phase of the Study protocol and by first phase we mean from enrollment to 18 months of age for the child. We are anticipating a number of important reviews over the next year, which will continue beyond, but these include a review and approval by the Office of Management and Budget, scientific peer review, and the requisite institutional review boards (IRBs) starting with the NIH/NICHD IRB and then the other necessary Center IRBs, which will continue through the duration of the Study.

The RFP for the wave 1 Study Centers is out and that is why you are here. Ms. Osinski has already laid out the timetable for that RFP. We anticipate enrolling participants at the Vanguard Centers in 2008 and in some fashion, for at least some pilot tests, even as early as the end of 2007 and then for the wave 1 Study Centers beginning full enrollment in 2009 and so on.

Finally, comments about funding. Through 2006 approximately \$50 million has been spent from the existing budgets of the lead agencies to establish the infrastructure and this extensive planning process, including all of the workshops and pilot studies that I have mentioned, as well as establishing the Clinical Coordinating Center and the seven Vanguard Centers. In fiscal 2007, \$69 million was appropriated for the Study just 3 weeks ago, and I am pleased and proud to be able to be participating in a conference presenting an RFP for this Study within 3 weeks of the Senate vote and the President's signature for the funding of the Study.

We are preparing for recruitment enrollment at Vanguard Centers and establishing the initial Centers for the expanded locations. In fiscal year 2008, as we experienced last year, there are no funds in the President's proposed budget for 2008 funding of the Study. However, I can say that yesterday in the House appropriation hearings for the 2008 budget the Chair of the House

Appropriations Committee commented to the Director of NIH, Dr. Zerhouni, that it is his intent to fund the Study in 2008, as well as 2007. That is hopeful, although it is not certain. There are many steps between that and a budget.

To conduct the full Study for the entire 26 years, we are estimating approximately \$120 million a year throughout the length of the Study with a large early bubble of funds for the more expensive recruitment in the early years of the Study and then leveling out at around or just below \$100 million a year. That ends my presentation. Thank you very much, and Dr. Brenner will now go into more details about the RFP itself.

### **Agenda Item: Technical Requirements**

DR. BRENNER: Welcome. I will go right into the presentation. Hopefully in the next half hour, I will present first a review of some central components of the Study design, really as a grounding for the rest of the presentation, I will talk a little bit about the purpose of the solicitation and will focus on the mandatory requirements, then we will turn to some specific answers to questions that were submitted in advance of the meeting. I also might mention that throughout the presentation I tried to incorporate answers to many of the questions that were submitted, so I will try to draw your attention to that as I move forward.

The next several slides focus on the Study design. We plan to enroll and follow approximately 100,000 children from before birth through 21 years of age. Children will be enrolled primarily through their mothers. This is to allow us to assess those very important exposures early in development, particularly in the first trimester and early in pregnancy. For that reason we will be enrolling women during pregnancy and for a subgroup even prior to pregnancy.

Again, children in the Study will be representative of all U.S. children and as Dr. Scheidt described in his presentation, we will use a multi-staged probability sampling approach. In the first stage of sampling, 105 locations were selected as the geographic areas from which participants will be recruited. The primary method of recruitment is through household screening. Data collection will follow a standard protocol. We did receive a question about that and there will be a common protocol that all the Study Centers will be expected to follow for collection of data within the location.

The data collections include, but certainly are not limited to, interviews, physical examinations, observational assessments, collection of environmental samples, and biologic specimens. The primary participants are mothers, fathers, and their children. At this point, this was all I was going to say about the Study design, but there is an attachment that I want to bring to your attention, which is the Overview of Study Design and Methods, that is attachment 4. I also want to mention there was a table that was to be included with that attachment. When the RFP was initially posted that was not there. It is there now and it is posted at Fed Biz Opps as addendum 1 to the RFP. It includes an overview of the data collections that will occur in the Study. We did get a question about this and I was not sure if the person who submitted the question had seen the table yet, but the question was 'are we going to specify the data collections as part of this RFP' and this is the level that we think is needed to be able to respond to the procurement, so I will point you to this table in answer to that question.

Now, turning to the procurement, the purpose is to award up to 20 new contracts to organizations that will be responsible for data collections in up to 30 locations. I just wanted to point out, and I'll touch on this again later, that in that purpose is embedded that it is anticipated

that some of the organizations will oversee data collections in more than one Study location, even in this initial wave. I'll talk about that a little bit later when I talk about base and option proposals.

No more than one Center will be awarded a contract for data collection in a given location. I want to clarify that for just a minute. What I mean is that we are not planning to award two separate contracts to collect data in a single Study location. That does not mean that a contractor cannot have subcontractors working with it, but we will not be awarding two separate contracts for data collections in a single location, so we are not going to have two different contractors trying to enroll the same participants and that will also come up again later.

It is anticipated that there will be subsequent phases of implementation such that data collections are ultimately occurring in all 105 locations and we anticipate that these additional locations, within the 105, will be added in two ways. One, by exercising the options that are awarded in this procurement, and we anticipate there will also be a need for additional solicitations.

Again, just to mention, the first wave, which is the one that this procurement is for, will have approximately 37 locations, seven of which are the Vanguard locations. Contracts have already been awarded for the Vanguard Locations, but we are hoping to add about 30 new locations with the current procurement. In wave 2, about 35 locations will be added and in wave 3, the final set of locations will be added.

So, you have heard this term a couple times from me, what is a Study location? In the full Study, the Study locations are the 105 geographic areas. They are counties, or in sparsely populated areas, they are groups of contiguous counties that were selected as a part of the first stage of sampling.

Attachment 9 is the map that you have seen already once today and you will see again here. This is followed in the procurement document by a list of the counties so that there is a reference for the dots on this map. Again, these are the areas from which Study participants will be recruited. Contracts have already been awarded for data collections in seven of the locations, the Vanguard locations. For this solicitation, offerors must submit a proposal for data collections in one of the remaining 98 locations.

This brings us to the first mandatory criterion that was listed in the RFP and this is in Section M—offerors shall prepare proposals to serve as a Center to conduct data collections at one or more than one of the remaining 98 pre-specified Study locations. Again, most correspond to a single county; six of the 98 locations include groups of contiguous counties. We actually received a number of questions about whether we would accept proposals for collection of data in a county that is not included in the list of Study locations. And the answer to that is no. The first criterion specifies that the proposal has to address data collections in one of the pre-specified counties or locations.

Will proposals for collection of data in one of the seven Vanguard locations be considered? The answer is no. We already have contractors for that work. And we did get a question asking whether existing Vanguard Centers can submit a proposal. And the answer to that is yes; they can submit a proposal for one of the 98 locations in the same way that others would submit one.

There is more to the first mandatory qualification criteria so I just wanted to continue with that. In addition to submitting a proposal for one of the 98 pre-specified areas, the Study location must be either in the same state as the Study Center—I think that is pretty clear and self-

explanatory—or in a state that is contiguous with the state of the proposing Center. Again, we did not receive any questions on that so I think that was clear.

The next one is the third criteria that could qualify an offeror to become a Study Center is that they be in a state that is not contiguous, but separated from the border of the proposing Study Center by no more than 100 miles. I wanted to give just one example. Somebody in Kansas could propose for a location in Texas because this little piece of land of Oklahoma is less than 100 miles. There are other examples that could be cited and if there are specific questions on that you should submit them after the conference in writing to the contract office and we can clarify whether or not your Center would meet that criterion.

Participants will be identified through screening of households in selected neighborhoods and again I would refer you to attachment 4, which is an overview of the Study design. In general, the goal is to enroll a sufficient number of women such that there are 1000 live births enrolled over a 4-year period, an average of 250 per year, in each Study location. But, there are a few exceptions and those are Cook County, Harris County, and Los Angeles County, which would bring us to the second mandatory evaluation criterion. Offerors submitting a base proposal for data collection in Cook, Harris, or Los Angeles County must also submit an option proposal, or option proposals in the case of Los Angeles County, that describes the Centers' capacity and plan for enrollment of additional births in subsequent waves.

I will go into more detail about this qualification criterion, but before doing that, since this is the first time that I have specifically talked about the base and option proposals, I want to pause and talk about those two requirements. The base and option requirements are actually described in several places in the RFP. I think that the place that goes into the most detail about it is in attachment 6, which is the Additional Technical Proposal Instructions. Basically, the technical proposals must address the base requirement. The offeror is to describe how they will conduct the tasks in the Statement of Work in one of the 98 locations. The offeror, importantly, can choose any of the locations, for which they are eligible, for inclusion in the base proposal.

We did receive a question about whether or not Vanguard Centers have to propose in the same manner and the answer to that is yes; they would have to pick a location and propose how they would serve as the Study Center and how they would do the data collections in that location, the same way as other offerors, so the same applies to everybody.

In terms of the option requirement, offerors may submit proposals to perform the option requirement. So, you do not have to include the option, you can submit just the base proposal. You are not required to submit the option proposal. The option proposals are for data collections, in what we are referring to as secondary locations. These are locations in addition to the location included in the base proposal. I will say that offerors, who are eligible to do so, are encouraged to submit option locations. As I said in the beginning, our hope is to award up to 20 contracts to do the data collections in 30 locations. So, we are going to have to have some contracts that are conducting data collections in more than one location, even within this first wave of Centers. There is no limit to the number of option proposals that may be submitted as long as the mandatory criteria are met. We did get some questions about that and there is no limit to the number.

Just a couple things about the evaluation and award of contracts relative to the base and option proposals—only those offers selected for award of a contract based on the base proposal, that is, the Study Center in the primary location, will be eligible for award of one or more of the options. Evaluation of option proposals is independent of evaluation of the base proposal and if you go to the evaluation criteria, you will see there is separate scoring of the base proposal and

the option proposals. Specifically, and again this is in answer to a question, if a Center scores low on an option proposal that would not affect the score on the base proposal; they are scored independently.

The first bullet on this slide was not included in the RFP and will probably be included as an addendum in FedBizOpps. If a Center is awarded a contract for the base proposal and an option. (that is offerors who are awarded a contract for data collections in more than one location) the order and timing of implementation of data collection in the multiple locations will be discussed as part of the negotiations, with the expectation that at least one location would be implemented in wave 1. We are hoping that some offerors will be able to start data collections in Wave 1 in more than one location to allow us to have no more than 20 contracts for data collections in 30 locations. But, in addition to that, this provides some flexibility in our ability to look at the locations for which we have successful offerors and maintain the representative sample with each wave of implementation. This addresses the concept of maintaining the representative sample with each wave of implementation as described in the RFP.

Now that I have talked about the base and option requirements, I wanted to get back to the mandatory evaluation criteria and Cook, Harris, and Los Angeles Counties. To maintain the representative, self-weighting nature of the sample, areas with large number of births, such as the three counties that we are talking about, need to enroll a greater number of children. They need to contribute a greater number of births to the total sample of 100,000. For every other location that number is 1,000. For these three locations, the number of births that needs to be contributed is 4,000 for Los Angeles and 2,000 each for Cook and Harris Counties.

The method that will be utilized to do that is to add additional neighborhoods, (segments and neighborhoods are being used synonymously here), within the counties in the subsequent waves. Because, there will be no more than one contractor per location, those who are proposing to do data collections in Los Angeles, Harris, or Cook Counties must demonstrate their ability to expand in subsequent waves.

I tried to make this clearer in this slide. So, in the first wave we might identify—this is hypothetical—maybe we will identify 10 neighborhoods from within a county that will be enrolling participants over a 4-year period with 1,000 enrolled during that time period. In wave 2, we might identify an additional 10 neighborhoods or segments within that location and begin enrollment a year later within those neighborhoods.

So, to summarize, for the first wave of implementation, the enrollment goals are the same as for other Study locations. Therefore, the base requirement is really the same. In subsequent waves, additional segments or neighborhoods will be added, and because we are planning to award only one contractor for data collections in a given location, the offerors must demonstrate their ability to expand. The way they would do that would be through the submission of options that would address those subsequent waves.

Now I would like to turn to some of the questions that came in for clarification. This also gives me an opportunity to walk through some of the materials that were provided in the RFP. We did have some questions about the evaluation criteria. I have already touched on those and I am not going to be talking more about them in this presentation. The Statement of Work was provided in attachment 3 and an Overview of Study Design and Methods, which I have referred to many times, was in attachment 4.

I would like to call your attention to Reporting Requirements and Deliverables, which is attachment 5. We did have a number of questions on attachment 6, Additional Technical Proposal Instructions. I will spend a couple minutes answering those questions.

Attachment 7 was the Additional Business Proposal Instructions and Ms. Osinski will be answering some of those questions later. We provided an Estimate of Effort by Annual Contract Year and we did receive a number of questions about that so I will talk about that as well.

There is a Study map and list of locations. There was an error in attachment 10, Timeline of Activities, and I want to point that out. We will be revising that. Attachment 11 was the Pre-proposal Conference Information. There was a table of Study visits per year in attachment 12 and there was also a printing error in that. We will be providing a new attachment 12 as an addendum, but I will point out what the problem was there. There were definitions in attachment 13.

So, turning to the additional technical proposal instructions, the first section of that talks about the base and option requirements and we have already gone through that. We did state that proposals for the options shall be submitted with the base proposal. We received a question asking whether these could be submitted as a single volume and the answer to that is yes. They can be submitted in a single volume as long as the options are clearly delineated in separate sections and Ms. Osinski has addressed that also for the business proposals. In the option proposals, we had a question about whether the offeror could refer to the base proposal and the answer to that is yes you can, and from that perspective it is very useful to have them in the same volume. So, there is no need to repeat or attach the same information in the option if it is already covered in the base.

There was a page limit that was provided in the additional technical proposal instructions. It was 25 pages for the main part of the technical proposal and then attachments could be up to 75 additional pages. The options had a page limit of 15 and the attachments were 35. We are actually not changing those, although I know some would like us to.

However, a concern was raised about the resume or the CV for the key personnel. There are only two key personnel specified in the RFP—the Principal Investigator and the Study Coordinator/operational manager of the Study. Those can be submitted as a modified resume, not the full resume. The modified resume should include educational background, recent experience, and listing of relevant publications. For others a biosketch is acceptable. So, that should take care of the problem that some people had that the CVs would take up all of the pages that they had in the attachments.

One other thing about the previous slide, we did get a question of what could go in these attachments and the only restriction is the page limits. It is up to the authors of the proposals to determine what they would like to include within those page limits, in addition to the required elements that are specified in the RFP.

We had a lot of very specific questions about the estimate of annual effort by contract year. So, I am going to give some general guidance. We are probably are not going to provide additional information about the specific questions that came in. These estimates were provided as guidance. Offerors can, and certainly are encouraged to calculate their own staffing needs based on the requirements that are laid out in the Study. You are also encouraged to explain the assumptions underlying the staffing needs. The estimates of effort provided in the RFP are provided as a starting point, but they are certainly not binding and offerors are actually expected to propose the staffing that they think will be required to conduct the Study.

The next slide does have a couple of specific questions that I will address as I think it might help to clarify things. In our estimates, there was a small amount of effort provided for Study Center infrastructure, primarily investigative and administrative time and then a per location estimate of staffing for each location. Again, these are estimates and in the submissions

that come in this can be structured the way that best meets the needs of your offer, but that is the way that we structured it as a starting point.

There have been questions about the role of multiple PIs. In the staffing estimates, we identified a PI at the Study Center level and also what we referred to as a PI at the location level. The reason that we did it that way is that we believe that there is a need for scientific oversight at both the Study Center and at the Study location level, particularly when you get into Study Centers that are overseeing data collections at more than one location. This could be the same person. It is up to you to decide if you want a lead person at the location that is different from the PI at the Study Center. From a contracting standpoint, there is only one Principal Investigator for the proposal and for the contract as Ms. Osinski described. We apologize if this was confusing; we do think there is a need for scientific oversight at the locations, but it is up to you to decide how to structure that.

There were a couple of specific questions about the level of effort staffing estimates, that came in from more than one offeror, which we thought would be useful to review, although I am not going to go through all of these questions. You are not bound by the level of effort estimates that were provided. You need to propose what works best for your location and your offer. The level of effort estimates assumed multiple staff members doing the household listing and screening, but working independently, so they were not going out in teams. That was a question that came in a couple of times, but again, you are free to propose otherwise if you think something would work better in your location.

Staffing time for the phone calls that are the responsibility of the local Centers was included in the estimates. We had a number of questions about the level of training required for the data collectors and again this is up to the offerors to propose the staffing that they think would be needed to fulfill the requirements of the Statement of Work. The only one that we did specify—and this is in the Statement of Work—is that the ultrasounds must be performed by an American College of Radiology-certified ultrasound technician. That was the only specific guidance that we gave and it is in the Statement of Work.

We received a couple questions on whether or not our staffing estimates assumed the need for an industrial hygienist for the collection of environmental samples and that was not assumed in our estimates.

This is a correction to attachment 10, which is the Timeline of Activities. The period for “Listing and Household Enumeration” should have a start date of July 1, 2009, and then an end date of December 31, 2009. This is consistent with the 6-month period allotted for this activity in the Overview of Study Design and Methods, and we will be posting a correction to that.

A footnote was truncated in the estimated number of Study visits per year, which was attachment 12. We will be reposting a new table as an amendment to the RFP on Fed Biz Opps, just as all the things I am mentioning will be posted on Fed Biz Opps. There were some abbreviations for which there were no descriptions and those will be corrected in the amended version of this table.

Attachment 12 actually included two tables, so this is the bottom of the two. The abbreviations at the top of this Table, are T1, T2, and T3. The T1 is the first trimester, T2 is the second trimester, and T3 is the third. In the RFP, the Table also had something called TI Prior on it and that referred to the first trimester visit for a woman who had had a previous visit through enrollment in the preconception cohort. It distinguished between that first trimester visit and a person who is enrolling in the Study in the first trimester. To simplify this a bit, the one that is going to be reposted combines those into a single visit. The other thing I wanted to point out, we

did have a question of why the total number of births shown in this table did not equal 1000, but this table only goes through the contract period so we will not have finished enrolling births. I just wanted to clarify that because it applies to all the data collections....all the visits that are included here. Visits will continue beyond the time period shown in the table, so the numbers do not add up to the total for the whole Study; they add up to the total for that 5-year contract period.

Again, this is just a reminder that I can not answer questions that come to me. If they do come to me, they will be forwarded to our Contracts Office. So, all the questions that you have need to go through the Contracts Office and this is the contact information. Thank you.

MS. OSINSKI: Thank you, Dr. Brenner. We are going to take a short break and then we will take questions and we will come back and answer your questions from the webcast and from the cards. If you have not taken your cards out to the main desk, please leave them there. Thank you.

### **Agenda Item: Government Response to Prospective Offerors' Questions**

MR. ETTEHADIEH: First question: **Is it possible to get an Excel file of Table 1 from Modification 1**, which is very difficult to read? The response to that is yes. We have realized what you are trying to identify in this question and we have to look into this matter and if it is going to be done, that we are going to go ahead and do it as part of the amendment to the RFP that is going to be posted on FedBizOpps.

The next question: **Addendum table off the FTE, does this entire table apply both to the base and to each options?** To answer that question I would like to refer to RFP attachment 8, which is entitled Estimate of Effort by Annual Contract Year. Again, as was discussed in the presentations before the break, these are just estimates, these are not binding. It does apply to what the question is asking. The first part, does Study Center professional staff applies to, could be assumed that they apply to the base.

MS. OSINSKI: The Study Center.

MR. ETTEHADIEH: And the other categories, starting from Study location professional staff down, it could be used for submission using those estimates for submission of option locations.

MS. OSINSKI: And the primary location that you choose. When preparing the options budgets is the order in which we present them significant? No, because our program staff will evaluate them separately and our program staff will actually decide on the implementation of the option, when we would want to negotiate, and which ones we would want to negotiate with you.

**Another question, the RFP states that renovations can be charged to the project.** No, it does not. Renovations can not be charged to the contract. These are unallowable costs on government contracts, so we can not pay for any renovations of facilities for this.

**If a location proposes a base and an option, will the program office decide to start an option instead of the proposed base?** It could be in order to determine the representativeness of the sample. The timing of either the option or the primary location is up to the Project Officer based on our needs of the representativeness.

**Can general purpose office supplies be included in the budget?** Yes, if your accounting system charges them directly to your project, and not in your indirect cost rate.

**MR. ETTEHADIEH: There is an inconsistency between the requirements for past performance listed on pages 40 and 64 in the RFP asking for two separate pieces of information. Can you clarify the content of past performance that is wanted.** Response to that question: An amendment to the RFP is going to clarify this exact point, so we are going to have an amendment, and thank you very much for pointing it out to us [see amendment # 3 to the RFP on the FedBizOpps].

**MS. OSINSKI: If we use the start date of September 2008 for the options, but the actual start date is later, for example June 2009, can the options budget be adjusted or renegotiated to accommodate inflation or changes in cost?** Yes, it will be. At the time of negotiations, yes, the answer is yes [see amendment # 2 to the RFP on the FedBizOpps].

**DR. BRENNER: Okay, I think I am going to handle the ones that I can answer quickly and then we will go to the more complicated ones.**

**Can an existing Vanguard Center serve as the base for additional locations?** So, yes it can, a Vanguard Center can propose to pick up a location.

**If a Vanguard Center is located in our state, how do we know which locations in that state need to be covered by a new Center?** On the map and the list of locations, the Vanguard locations are specified, so that is in an attachment to the RFP. The rest of the locations are available for offerors to bid on.

**Is there a maximum number of counties that one Center can serve?** The answer to that is no, there is not a maximum number as long as you meet the mandatory evaluation criteria.

**If a Center is serving more than one county, what is the expectation for the percent efforts for the professional staff?** Again, this is really up to the offerors to propose that. We have given some guidance, but that is just guidance and you did need to propose the percent effort for all the positions that you think is sufficient to fulfill the needs of the Study.

**Can the PI at the primary location be different from the PI of the Study Center/the whole project?** The answer is yes, but as Ms. Osinski has explained, you can only have one PI on a contract award. The others can be co-PIs or location investigators; they can have a different title; but there can only be one PI on the proposal from a contracting perspective.

**MS. OSINSKI: And he or she must be employed by the prime contractor that is proposing.**

**DR. BRENNER: What percentage of response rate did the Vanguard Centers achieve with enrollment?** They have not begun enrollment yet, so we do not have an answer for that yet.

**Is there such a position as a location co-PI?** Again, it is up to you to propose the specific titles of the positions, so you could have a location co-PI.

**DR. SCHEIDT: I'll do a couple. There were several questions about the expertise required and the type of individual designated as a PI. Did we expect a researcher, a clinician, a pediatrician, etc.?** The answer is that we are not prescribing what expertise or discipline would be designated as a PI. If you look at the Vanguard Centers you will see significant variation in types of disciplines. So, we anticipate, also, variations in types of disciplines in the proposals for the Centers.

**Here is another question, although not required for the RFP, may a proposal include proposals for adjunct studies in the Study proposal?** We are not prescribing what is included. It would not be ruled non-responsive, but there is a page limit and there is no request for adjunct studies. We are not prescribing that you may not do it or to do so would not render it non-responsive, but it would use up some space.

**There was another question: can offerors with offices in multiple states propose Study Centers in these multiple states, even if these states do not meet other mandatory requirements?** We are stipulating that any single offer must designate a home base or a central office and that will define the location of a Center for the purposes of the mandatory requirement.

**MR. ETTEHADIEH: Will the PowerPoint and the audio of this conference be available for reviewers after this meeting?** The answer to that is no. The information will be available only on FedBizOpps in the form of amendments [See amendment # 3 to the RFP on the FedBizOpps].

**Another question, is there a budget range you are suggesting for new Centers?** The answer is no, other than what is already presented in the RFP in the form of estimate of efforts and that is again just a guidance.

**DR. FLEISCHMAN: I have a question, at what point will the women be consented?** It is our intention to have a prepregnancy consent process and then a pregnancy consent process and at each interaction between the Study and the women, subsequent to their overall consent for the Study, there will be an oral consent for that activity. We will provide that to the IRBs in our explanation to them. We also intend to have a consent process for the fathers and ultimately, assent for the children and even more ultimately, consent for the adolescents as they reach adulthood.

**Does an individual Center need a data safety monitoring board?** No.

**Can PIs at Centers release screening data to the individuals from whom the data came?** The Study will have a very specific policy concerning revealing findings to Study participants that will be for all parts of the Study and all kinds of data.

**Are you anticipating inducement to families to enroll and if so what are they and how do they fit into the budgeting?** Attachment 4, page 16, section 8.5, the Overview of Study Design and Methods describes incentives and compensation, which basically tells you that it is estimated that \$50 per face-to-face visit or interaction will be the incentive paid, as well as some compensation for expenses incurred in travel to and from research Centers, parking, etc. You must put that into your budget estimates.

**DR. SCHEIDT:** Let me answer a few more questions, but before that I think those in attendance, both online and physically present, might be interested in knowing that there are 125 separate lines joining us today by the webcast, as well as those approximately 30 to 40 who are here physically in attendance. I just thought you would be interested in knowing that.

I'll answer a question. **Are clinic visits to be at a subject's prenatal care provider's office or at centralized site determined by the Study Center?** That is not prescribed and this Study is being conducted in so many widely varied areas that one venue may be best for one Center and a different venue best for another Center. So, it not prescribed and could be either way.

**There were a number of questions about access to data.** Describe in more detail the access that Study Centers will have to data from their location before the public use dataset is released. May we store the data collected at our Study location at our Study Center, in addition to submitting the same data to the Study? Will access to data by students, fellows, the investigative community of Centers be allowed? These issues, first of all, will be determined by statutes and contractual arrangements and will be part of the negotiation process, and there is an extensive history of access and use of data that is determined by legal precedents. Our data access policy is currently under review by the General Counsel and we have not yet received the results of that

review, so we cannot tell you the specifics of what we will be informed by the General Counsel review. In addition, the Data Use and Publications Committee is drafting policies for how the community of investigators, composed of the Center investigators and the federal scientists that I described to you, will use those data. That is currently in process and will continue to be in process as an ongoing policy as the Study evolves. Participants and investigators from the Centers will be part of that process and the investigators on the Steering Committee are as equally interested in access and use of data for the same reason that these questions suggest as you are. So, participating investigators will all share in establishing this policy for the collective benefit of all the investigators involved and that is as specific as I can be about that question, which is almost a non-answer, but suffice it to say that you, as investigators in the Centers, will be part of that process.

**DR. SCHOENDORF: This is a specific question about the prenatal ultrasounds, if they are done by certified obstetricians/gynecologists (OB/GYNs), is there an issue about technician certification because the RFP specified American College of Radiology certification?** And no, that is not an issue or a problem because the OBGYNs are kind of considered *de facto* certified.

**DR. FLEISCHMAN: I have two additional questions about compensation. Are there guidelines for setting the amounts of incentives for self-administered data collection activities?** Yes, the \$50 per interaction will be the amount that will be used. **Should we include these incentives in our budget proposals?** Yes.

**MS. OSINSKI: I have a couple more about the options.** [See amendment # 2 to the RFP on the FedBizOpps]. The options in the RFP, the way it now reads, did call for what this question is asking, separate option proposals, with budgets starting at different times. We are changing that and simplifying it to say start your option location proposals at the beginning of year 2, which is September 30, 2008. We will negotiate with you if we are going to exercise an option at contract inception and not award your primary location until a little later, so just for proposal purposes at this point assume the start date for the options of September 30, 2008, all option locations. This will not be the case because there will probably be an increase factor if they are exercised later or maybe a little decrease factor of 2 or 3 percent if they are exercised at contract inception, in place of your primary location.

**There is another question about the budget preparation because there is phasing in our Statement of Work.** However, our business proposal instructions do require you to prepare annual contract budget years. In other words, starting on September 27, 2007, we need a year budget and then we another year budget. You would have to work your phasing into that. Therefore, it will not be as simple as just saying 3 percent a year for this whole project, but we do need the budget by annual contract year because that is how we would negotiate this. Thank you.

**MR. ETTEHADIEH: If a site needs to lease space, can build out costs be part of that lease?** I believe that question was answered in another form, but the answer to that question is these costs are unallowable costs. If they are proposed during negotiation, they are going to be requested to be removed, so, the answer is no.

**Another question, which was submitted through the Internet, says cost-pricing information is listed as "just in time" documentation during the competitive process; however, section L2C2B lists the detail at which we must submit cost-pricing information.** This appears to be asking for information in written form plus vendor invoices or quotes for materials. Please clarify the level at which cost-pricing information is required with the proposal

submission versus “just in time”? I would like to answer that question by referring to the RFP, section L, and if you have the RFP, your page would be 31. There are about five categories which talk about “just in time.” The response to this question is those are the categories that are affected by the “just in time” requirement for this RFP.

**MR. SONGCO: I have a couple of questions having to do with configuration and security. People have asked what computing hardware will be provided. Will laptop and systems be equipped with encryption software?** Yes, all laptops will be included with encryption software. As far as configuration, that is still under development but for now you can just assume that it will be a minimum footprint, a server, and all laptops and desktops will be provided. There was also a question about whether we would provide a scanner. Yes, we will provide a scanner.

Now, connectivity is something that we will work out and you will need to provide Internet connectivity. The extent of that Internet connectivity will vary depending on how many physical sites there are and what your local connectivity is. We will need to know what you propose in terms of the number of sites and that connectivity.

**The other question asks if the information security requirements described in this section relate only to the use of Study-supplied information management systems.** I will read this answer. The information security requirements apply to all systems used to support the Study as described in Federal Information Management Security Act (FISMA) and interpreted in various guidance such as SP800-26, Security Self-Assessment Guide for Information Technology Systems. The good news is the NCSIMS technical staff will assist the Study Centers in planning for security appropriate to your plans.

We have a general idea of what the information technology situation is going to be and by the time of the awards we will know a lot more. For now, just assume that we are going to provide you wonderful equipment, actually, and that we will provide the support.

**DR. BRENNER:** I am going to do several and then ask that Randy Curtin come up and do one that he has about sampling. You have one on sampling?

**DR. CURTIN:** Yes.

**DR. BRENNER:** The first one is not about sampling. **Will all of the Centers be awarded with locations to be added to these Centers later or will there be another RFP for additional Centers later?** The answer to that is that the current solicitation is for the locations that will be implemented in wave 1. In addition, options can be awarded now but they are only exercised depending on funding. So the two ways for additional locations to come in is being a successful offeror in this solicitation for an option for a later period or as I mentioned during the presentation, it is anticipated that not all 105 of the locations are going to be covered with this current solicitation. We are fairly certain that there will be an additional solicitation but that would be for the locations that are not covered with the current solicitation. Of course, all of that is dependent on funding.

This is a specific question that may apply to other areas as well as this one. **If institutions in Indiana, Kentucky, and Tennessee want to submit a joint bid for four sites, one or more in each of the three states, is it the case that the only arrangement acceptable to the government is for the bid to come from the institution in Kentucky, with the institutions in the other two states to be proposed as subcontractors for involvement only in option proposals?** The primary location of the contract has to meet the mandatory evaluation criteria. That applies for data collections in options as well as data collections in the base requirement. There has to be single [principal] investigator named. The only way I can think of to have

multiple lead institutes for different locations is to have different proposals coming in rather than including them all within a single proposal with options.

MS. OSINSKI: I would say, yes.

DR. BRENNER: Do you want to clarify that?

DR. SCHEIDT: No.

DR. BRENNER: This is the same question basically. **Does the restriction that a Center proposal target a Study location in same state, contiguous state, or non-contiguous state within a 100 miles, apply equally to the base and option proposals?** The answer to that is yes.

**The follow-on, if the base proposal meets the geographic restrictions may the options be located in a non-contiguous state that is more than a hundred miles?** The answer to that is no.

**Has the NCS defined the PSUs for Los Angeles or is that to be part of our proposal? Is there guidance for specifying the clusters in determining the stratification within those clusters for Los Angeles?** The answer to that is the number of PSUs has been determined, but neither the PSUs nor the segments have been determined. The expectation is that this—there is another question about segments as well—the expectation for both multi-PSU counties and for the segments is that the selection for those areas is actually the responsibility of the coordinating Center and the government with the National Center for Health Statistics. We are not expecting selection of PSUs or segments in proposals. I don't know if you want to add?

MR. CURTIN: What we are looking for is that the offerors state how they would be involved in the design at the household segment level. That sort of brings us up to a highly technical question here so if you are not really interested in probability sampling you may want to take a quick break.

**This particular question states that in section 3.2, notice that the sample segment is defined a Census block. The next paragraph states that 10 to 15 segments will be sampled per household and an attachment states that approximately 9000 households will needed to be screened per location. This seems to be a contradiction since the average Census block contains about 50 households. They then asked for clarification.**

This actually requires three separate clarifications. The actual term in section 3.2 is that segments will be defined in terms of Census blocks. It does not imply that it should be a single block. So the clarification is that segments will be formed by combining groups of Census blocks or Census geographic areas, typically defined in the lowest unit of Census block.

The other assumption here is that we are sort of stating that approximately 9,000 households will be screened per location. We are looking for the offerors to help us because the number of households to be screened per location is a function of the characteristics of the local area. It depends upon a number of factors. I do not think I should tell you what those factors are because we want you to tell us what those factors are, but the number of households to be screened will be a function of the expertise of the local area in what you expect to get in terms of recruitment and retention, as well.

Furthermore, the 10 to 15 segments needs local input in terms of what you, for your local area, feel is an adequate number to provide local coverage. It might be 10, it might be 15; this also depends upon the locality. However, given those numbers of 9,000 households and 10 segments, yes, a segment should come up with an average of 900 households per segment—which is going to be more than one Census block. Is that clear? So, segments will be put together to form an average number of households but the total number of households to be screened is

really location specific and depends upon also the ability of the offeror to get to those sample sizes.

DR. BRENNER: This is a similar question which easier to answer. **Do you anticipate single or multiple clusters per location?** I think that means segments. Yes, we do anticipate multiple segments per location. That is described in the overview of the Study design and methods.

DR. SCHEIDT: I will slip in a question or two. **Would adjunct studies using an arm mechanism—NIH grant mechanism—be funded from the NCS budget or regular extramural institutes budget?** For the most part, the adjunct studies will not be funded by out of the regular Study budget. That might be possible, and we have contemplated such a study to look particularly at assistive reproductive technology. It is not currently planned but that has been discussed. For the most part they will be funded by other budget sources.

I want to add a clarification to the previous question about access to data. **I meant to include the question about the use of data by the community of investigators for analyses in publication prior to public use data sets;** yes, we do anticipate access and publication of data prior to public use data sets. I would add however, we do not expect to wait around for publications before proceeding as quickly as possible to establish public use data sets.

**Third question, what is the definition of a non-Study hospital, as mentioned in appendix 5 on page 37?** That would be a hospital in the area of a location where participants might go and from whom data might be collected that is not the hospital of the mega-medical Center designated as the Study Center. There will be many community hospitals from which we will collect data that are not designated as Study Centers.

MR. ETTEHADIEH: **Although the contract technically starts on September 30<sup>th</sup>, can we budget effectively for months such as October to December?** The offeror has to propose the budget from September 27, 2007.

MS. OSENSKI: The first year would be September 27, 2007 to September 27, 2008.

MR. ETTEHADIEH: **We have received about three questions on this subject.** For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of their availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include the specific items or the expertise they will provide, availability to the project, the amount of time anticipated, willingness to act as a consultant, and how rights to publications and patents will be handled. **Do the above requirements apply to consultants only or all other personnel to be hired (field technicians, field supervisors)? Due to the lack of time prior to starting certain activities such as the household enumeration, offerors have considerable time to hire select team members. Can the government clarify which personnel must be named?**

The answer to that question is the government is requesting for the offerors to propose named individuals as much as they can. Specifically, the government is requesting that the named individuals—the most important point that I would like to identify here is discussing the RFP in section G, Contract Administration Data, and that article G.2, Key Personnel—two titled individuals must be named in the offeror's proposal. The first one is principal investigator and the second one is Study coordinator operational manager. Also I would like to add that the consultants and other individuals proposed should have a letter of commitment submitted with the proposal.

DR. BRENNER: These are two questions that are again on the same thing. **If one county is chosen as the base and another as an option, but the review team Study office finds that**

**an option county is preferred for sampling reasons, can a submitted option county become the base?**

Another question about the flexibility of the base and the options. **Does it mean that during negotiations we could agree to move the primary location to wave 2 or 3 and have one of the option locations moved to wave 1?** The answer to this is if an offeror is awarded both a base and option, we are maintaining the flexibility to rearrange the implementation, the start date for the data collections within those different locations. This is one of the ways that we have of assuring that we can get a representative sample in each of the waves by maintaining that flexibility.

MS. OSINSKI: **This question is can you be listed as a subcontractor on another Center's base or option, and at the same time apply to this RFP as its own Center?** Nothing that we have written in this RFP would preclude this, so you can.

DR. BRENNER: Okay, so here is a series of questions and they are all related and I will just read them all together and then do the best I can to answer them. **If NICHD receives high quality proposals for significantly more than 30 locations in response to the current RFP, will award decisions also be made for locations that would initiate implementation in wave 2 and 3 as described in the RFP?** The answer to this one, but I will give a broader answer after I read all of them, as it says in the RFP, you have to be awarded the base. You have to be in the competitive range and acceptable for the base award for the options to be considered. I just want to make sure that is clear, but I will read the rest of these.

**On what basis is the number of Centers in each wave determined—quality proposal, geographic variation, or other criteria? How will two base locations be chosen for those Centers that will initiate two locations in the first wave of the Study? The RFP indicates that geographical balance will be a consideration. Please explain the relative importance of this criterion and compare with the quality of the Study location. And, it is unclear whether to select the base location with a Center based on the best Study location and collaborators or based on being different from an existing center, such as a Vanguard location.**

So, the answer to that is the factors that are going to be considered in selection of contracts are outlined in the RFP. They will be evaluated on their technical merit. There will be an acceptable and an unacceptable range determined. We are expecting that not every location will have an offeror that will be successful. So, we are not expecting, based on experience with other large studies like this, that in the first round of solicitation, we will have successful offers for all 98 locations.

What we will do is put together the successful offers for both the base and the option locations and take into consideration the technical score and the flexibility that we do have to move [the timing of implementation] within the option and bases that are proposed from a single Center and work with our statisticians to identify the most representative sample that we can come up with in each of the waves. So, that is our answer to those set of questions. I do not know if you want to add anything else?

DR. SCHEIDT: At a little higher level, it should be clear that we are trying to conduct this RFP with decisions based on merit and at the same time attempt to get to the other end of the process with as representative a sample as possible. We think this approach offers the best chance of being able to successfully have the best Centers available and as close as possible a representative sample. We think it offers a better chance and higher level of performance than had we proposed simply one-third of the remaining sites and asked offerors to compete on just

that limited one-third of the sites. That was the decision we were faced with, and we think that this is a better and stronger approach.

**DR. BRENNER: There are a couple of specific questions about the numbers in some of the attachments, particularly attachment 12, and a request for us to provide an estimate of the number of ultrasounds that would be expected.** We are not planning on provided more information than was in those tables. There are some people who have questions about those tables and think that the numbers are incorrect. We will go back and take a look at that ourselves and if there is need to publish an amendment to that we will. If you still think that the numbers are incorrect you should base your proposals, base your estimates on what you propose in your proposals, whether it is the numbers that we gave as guidance or numbers that you think are more correct for your location. The other thing I would add is that we gave estimates for an average across all locations, and there is going to be variation in some of those estimates by location.

**MS. OSINSKI: In one of the business questions, they asked about the offerors total compensation plan.** The question is what is it because it is not required with initial proposals due to the "just in time" provisions; it is required later when more details required, if you are in the successful ranges. That is to not put you to added expense.

An offeror's total compensation plan, I went to one of my auditors to check on this also, refers to your plans for your salary increases, your bonus policies, when your annual salary increases are effective, your cost of living and merit increases, and how you determine the cost resonableness of this. You would not have to supply us with all that information, but you would have to explain when you do have these, why they are reasonable. So this will not be required with the submission of initial proposals. Later, during negotiations, we will be going for the personnel action forms and the verification of salaries and things.

**MR. SONGCO:** I have been asked to announce that we are coming near the end, so this will be the last call for questions on the Web or live, okay?

**DR. BRENNER:** I have a question. **Does the base and option each need its own community advisory board?** The need for community advisory board was described in the Statement of Work and the Statement of Work applies to both the base and the options.

**MS. OSINKSKI: Are the base and the option treated as separable fiscal agents?** Yes, we will be evaluating them separately and if you are awarded the base contract and your primary location, which is part of the base contract, that will all be set out in a budget. We will have finalized a date that the option budget will start, so we will have that during negotiation, at least if it is going to start when the contract begins. We will have those set forth in the contract and we may have to set forth a range if we do not know when we are going to exercise the option. So, at that point in time, we might request that you submit separate, for the same location, option budgets, some to start at the beginning of year 2, some to start at the beginning of year 3, but we are going to wait until we are into negotiations when we are going to be sure of what we need on that. So, right now they start at the beginning of year 2 [See amendment # 2 to the RFP on the FedBizOpps].

**DR. BRENNER:** I have two questions that I think I answered, but I am going to answer again because it came in two more times. **They have to do with the existing Vanguard Centers and whether or not they can use their Center in the base proposal or if they have to go to a different Center as a base proposal.** The answer is they can construct that in any way that they think is best for their proposal. So, the base can either be the existing organization, along with the location that they pick, or it can be a different location, but if it was a different organization,

the PI has to be at the organization of the contract award. So, I am not sure if I am making that less clear or not, but if the same PI was on it, it would have to, by definition, propose their institution, their institute. [See amendment #2 to the RFP on the FedBizOpps]

DR. SCHEIDT: There are several questions that deal with enrollment through supplemental mechanisms, that is through prenatal care or community referrals, as opposed to the household sampling approach through household enumeration. **The question is: what is the expectation for the number of participants?** The reasons for the household approach are two, one to be able to obtain a representative sample as defined by geographic distribution and secondly, to be able to identify women who may become pregnant before their pregnancy, so that measures of exposure can be obtained before pregnancy. Our expectation based on projections and analyses is to have at least 20–25 percent of the sample identified through the household enumeration and enrolled prior to pregnancy.

**One question referred to the possibility of missing all of those women and enrolling completely through referrals from prenatal care providers** and we hope that would not happen. If that happens as a result of problems with the household enumeration and household screening, then we would want to examine why that was the case and hopefully adjust that circumstance.

**There is a concern about if the supplemental method is used, how to deal with HIPAA problems and that prenatal care sites may refuse to inform us of women who are pregnant because of HIPAA concerns.** Our expectation would be that the providers would approach the women and inform them so that women would understand what the Study is about and they would consent to the Study, which would preclude HIPAA concerns because they would be informed of the nature of the Study and participation in it.

DR. BRENNER: I am actually going to turn to some of the questions that came in ahead of time because I want to make sure that we get to those.

**What is the process for determining, prior to April 17<sup>th</sup>, that the Study Coordinating Center will support a particular foreign language that is prevalent in a given region?** This is a really good question. For the purpose of the proposals, you can assume that there will be translation of the questionnaires and some of the Study materials into Spanish, but assume that these will not be, just for the preparation of proposals, translated into other languages. The interpreters, which this question also gets to, are a responsibility of the local Centers and that was laid out in the RFP, so although there may be additional languages, for the preparation of proposals, everyone is starting with the same base; assume that the materials will be available in English and Spanish.

DR. SCHEIDT: **Another question, if in the course of the Study there were clinical problems identified among the women or men or children, explain what would be provided for those who participate if at all?** We will require that systems for referral and follow-through be established on the part of the Centers. We are not funded to provide direct care of those clinical problems identified through the course of the Study, but we do expect that appropriate referral and follow-through be carried out and that will be expected to be indicated in the response to the RFP as well.

DR. BRENNER: **Okay, is it acceptable for the Study Centers to do additional mailings or other types of contact to improve initial cooperation or try to convert reluctant households?** The answer to that is yes.

**Another question came in, whether or not a local Center could propose to do the initial mailing to the entire list of households prior to screening** and the answer to that is that

it is going to be done by the Coordinating Center. Again, the average is 9,000 households per location and it is more cost-effective to do that centrally.

**What information will be provided with the segment dwelling unit lists?** There will be a list of addresses provided that is based on the U.S. Postal Service delivery file and there may be maps provided also from the Coordinating Center.

**In most segments, will all housing units be included in the sample?** The answer to that is yes, it is the exception where we will be sampling housing units within segments and that is all described in the overview of the Study design and methods.

**There were some questions about the numbers of housing units.** In one place in the RFP it said 8,359 and in another place it said 9,000. Again, these are estimates based on the average location and you should feel free to adjust those to the number of housing units that you think you would need to visit in your location.

**DR. SCHEIDT: Another question: Do women enrolled through prenatal referrals need to be geographically eligible?** The answer is yes, they need to be geographically eligible in the defined locations and segments.

**DR. BRENNER: There was a question about moving and whether a woman who is enrolled, but moves prior to delivery of the child to somewhere outside of one of the selected segments, would be followed in the Study** and the answer to that is no. If a woman moves before delivery of the child to somewhere that is not included in the Study, she would not be included. However, if the child is born there and then they move, the child would be followed. If it is within the PSU, within the location, the child would be followed by the local Center. If the child moves to an area that is in a different Study location, he or she could be picked up by the other location. If the child moves to an area that is not covered, the Coordinating Center will be doing the follow up.

**DR. SCHEIDT:** Let me clarify that. If they move outside of the location, but within reach of the Center, they would still be expected to be followed.

**DR. BRENNER:** After they are born.

**DR. SCHEIDT:** After they are born, correct.

**DR. BRENNER: We had talked about telephone interviews and understood that some offerors would want to maintain the responsibility of conducting telephone interviews, but there are certain requirements to qualify for that; others would not want to maintain that responsibility, depending on what their capabilities are. So, we had a question of whether we would negotiate that before proposal** and the answer is no, you should submit what you propose that your Center will do and we are giving you the option to propose to maintain that responsibility or to not maintain that responsibility and have the Coordinating Center take over that function.

**There were a couple of questions about the eligibility criteria** and the eligibility criteria are in the Study design and in the overview of the Study Design and Methods. A couple of the questions were very specific about some discrepancies, and we will look into those and clarify if we see there are discrepancies.

**DR. BRENNER: This is a specific question, again, about whether any submissions to local IRBs are required prior to the response of the solicitation** and the answer is no, not for the contract proposals.

**Section 5.4.1 describes materials that will be left with women. Are these provided by the Study Coordinating Center?** The answer to that is yes.

**Is there a prohibition against using participants' cell phones for interviews?** The answer to that is the participants can answer the interview on a cell phone, but the interviewer can not conduct the interview on a cell phone. However, you can use cell phones for scheduling and interim contacts.

**A question concerned who would make the reminder calls.** And again, in the proposal it was assumed that for scheduling purposes, the scheduling and reminder calls would be a function of the local Centers. **Then there was another question about bids being given extra points if they propose pilot studies,** the answer to that is no.

**I have one other thing, a couple questions came in asking if we could be a little more specific about the training and the amount of travel that we anticipate would be required for staff to come from the local Centers to the Coordinating Center for training.** We will provide an answer to that in an amendment.

**I guess I was not clear on the last answer because this is a question about negotiating telephone interviews and it said in the RFP that the responsibility for telephone interviews will be negotiated independently for each Center.** Again, Centers should propose whether they would like to maintain that responsibility. There are certain qualifications to be able to maintain that and once we receive the proposals and review that qualifications, if it appears that that aspect was not met, that will be discussed after receipt of the proposals, but not before.

**This question was sent in ahead of time and resent, so I will answer this. This is about the estimated goal of the 65–70 percent overall participation rate.** What I can say is that that is our goal for participation and the information that is in the Study design document is all the information that is going to be provided on that right now. But, if an offeror thinks that their Center will have a substantially higher or substantially lower participation rate (such that they will not be possible to achieve that), they should describe that in their proposal.

MR. SONGCO: I just want to announce that we will be shutting down the pre-proposal e-mail address as soon as this event is over. So, any future questions will have to be sent to the e-mail addresses that Ms. Osinski gave you and I think what we are going to have is just automatic message; anybody that sends a question in that way will just have a kickback that says where they have to send it. Okay? So it will be shut down as soon as we are done here.

MS. OSINSKI: We want to thank everyone for coming on such short notice and we want to thank all the people who made our webcast and conference possible. Thank you for coming and we hope that we talk to you again.

(Whereupon, the conference concluded at 4:00 p.m.)

## List of Attendees

**M = Attended in Rockville; T = Attended by Telephone/Web Conference**

Mary Ann Abrams, Iowa Health Systems (T)

Kruti Acharya, University of Chicago (T)

Walter Allen, Foundation for Blood Research (T)

Debbie Amsden, University of Delaware (T)

Gary Asmus, Center of Child Development, University of Louisiana at Lafayette (T)

Leslie Athey, RTI International (T)

Jennifer Awkard, National Institutes of Health (T)

Erin Bain, National Institutes of Health (M)  
Philip Baird, Fisher BioServices (M)  
Dean Baker, University of California, Irvine (T)  
Marion Balsam, National Institutes of Health (M)  
Charles Barone, Henry Ford Health System (T)  
Martin Barron, National Opinion Research Center (T)  
Danna Basson, Mathematic Policy Research (T)  
Kathleen Belanger, Yale University (T)  
Shirley Beresford, University of Washington (T)  
Marc Berk, National Opinion Research Center (M)  
Elizabeth Blackburn, U.S. Environmental Protection Agency (T)  
Gretta Blatner, Pharmaceutical Product Development, Inc. (M)  
Ann Borders, Northwestern University (T)  
Carol Boyer, Rutgers University (T)  
Ellen Boyle, Institute for Public Research of CNAC (M)  
Ruth Brenner, National Institutes of Health (T)  
Mike Brick, Westat (M)  
Francine Buchhalter, Phoenix Children's Hospital (T)  
Alison Buckser, Women & Infants Hospital (T)  
Stephen Buka, Brown University (T)  
Thomas Burbacher, University of Washington (T)  
Alex Capshew, Indiana University (T)  
Rolfe Carlson, University of Michigan (T)  
Christina Chambers, University Of California, San Diego (T)  
Stephanie Chardoul, University of Michigan (M)  
Aimin Chen, Craten University (T)  
Jannine Cody, University of Texas Health Science Center (T)  
Craig Coelen, National Opinion Research Center (M)  
Kathleen Cole, Maine Medical Center (T)  
Valeriea Cook, Wayne State University (T)  
Kate Costella, National Institutes of Health (T)  
Lesley Cottrell, West Virginia University (T)  
Christina Cutshaw, University of Arizona (T)  
Joan Cwi, Battelle (T)  
Dana Dabelea, University of Colorado Health Sciences Center (T)  
Elizabeth Davis, National Institutes of Health (M)  
Brian Davis, California Center for Rural Policy (T)  
Angela DeBelles, National Opinion Research Center (M)  
Virginia Delaney-Black, Wayne State University (T)  
Victoria Dergileva, Booz Allen Hamilton (T)  
Andrea DeSanti, Fisher BioServices (M)  
Nancy Dole, University of North Carolina (T)  
Brenda Ecken, Booz Allen Hamilton (T)  
Fred Ettehadieh, National Institutes of Health (M)  
Mausour Fahimi, RTI International (M)  
Heidi Feldman, Stanford University (T)

Paul Fennessey, University of Colorado Health Sciences Center (T)  
Sean Firth, University of Utah (T)  
Howard Fishbein, Battelle (M)  
Joy Fisk, South Dakota State University (T)  
Alan Fleischman, National Institutes of Health (T)  
Louis Flick, Southern Illinois University (M)  
Christine Forke, Children's Hospital of Philadelphia (T)  
Alexa Fraser, Westat (M)  
Natalie Freeman, University of Florida (T)  
Sylvia Friedl, University of Tennessee (T)  
Elizabeth Gall, University of Wisconsin, Madison (T)  
Anne Gallacher, University of South Florida (T)  
Dan Gaylin, National Opinion Research Center (T)  
Jeffrey Gruen, Yale School Of Medicine (T)  
Jeffrey Hackett, National Opinion Research Center (T)  
Rickey Haith, Health Care Restoration Services, Inc. (M)  
Neal Halfon, University of California, Los Angeles (T)  
Carolyn Hamilton, National Institutes of Health (T)  
Richard Hamman, University of Colorado (T)  
Janet Hardy, University of Massachusetts Medical School (T)  
Dana Harris, National Institutes of Health (T)  
Terri Henkels, Polk County Health Department (T)  
Zhang Heting, Yale University (T)  
Jacqueline Holden, National Institutes of Health (T)  
Erin Houston, University of California, Davis (T)  
Christina Hoven, Columbia University (T)  
Audrey Ichida , ICF International (M)  
Patricia Janulewicz, Boston University (T)  
Lisa John, Battelle (T)  
Joyce Johnson, Battelle (M)  
Daniel Johnson, University Chicago (T)  
Calvin Jones, Statistical and Evaluation Research (M)  
Evonne Kaplan-Liss, Stony Brook University Medical Center (T)  
Anil Kaul, University of Oklahoma (M)  
Sarah Keim, National Institutes of Health (T)  
Hameed Khan, National Institutes of Health (M)  
Carole Kimmel, Private Consultant (M)  
Walter Knott, National Institutes of Health (T)  
Sarah Knox, National Institutes of Health (T)  
Missy Koppelman, National Opinion Research Center (M)  
Claudia Kozinetz, Baylor College of Medicine (T)  
Edward Kuczynski, Yale University (T)  
Michael Lamoureux, Booz Allen Hamilton (T)  
Philip Landrigan, Mount Sinai School of Medicine (T)  
Terry Leet, Saint Louis University (M)  
Abby Li, Exponent (T)

Paul Lioy, Robert Wood Johnson Medical School (T)  
Heather Lipkind, Yale University (T)  
Alexandria Louden, Children's Hospital of Philadelphia (T)  
Lee Lucas, Maine Medical Center (T)  
Anne Lynch, University of Colorado Health Sciences Center (T)  
William Mahle, Emory University (T)  
Mai Manchanda, University of Massachusetts (T)  
Louise Marcotte, Maine Medical Center (T)  
Lorrie Mason, Regional OD Consultant (T)  
Leigh Mathias, Westat (M)  
Pat McGovern, University of Minnesota (T)  
Allison McKamey, RTI International (T)  
Nada Mclatyre, Wayne State University (M)  
Lyannee Millar, University of Hawaii (T)  
Ricky Miller, University of Rochester (M)  
Monika Mittelholzer, Yale University (T)  
Judie Mopsik, Abt Associates (M)  
TiffanyMorre-Simas, University of Massachusetts Medical School (T)  
Jaana Myllyluoma, Battelle (T)  
Melissa Nashawati, Utah Health Science Center (T)  
Maureen Nealon, University of Rochester (T)  
Wendy Nembhard, University of South Florida (M)  
Roberta Ness, University of Pittsburgh (M)  
Christian Ong, First Five of Louisiana (T)  
Kathleen O'Rourke, University of South Florida (T)  
Elizabeth Osinski, National Institutes of Health (M)  
Alice Pagan, National Institutes of Health (T)  
Hewon Park, Georgetown University (T)  
Kathleen Parks, National Opinion Research Center (T)  
Megan Paye, Pharmaceutical Product Development, Inc. (T)  
Devon Pearce, Georgetown University (T)  
Beth Ellen Pennell, University of Michigan (T)  
Bernice Pescosolido, Indiana University (M)  
Kristina Peterson, RTI International (T)  
Judith Petty, National Opinion Research Center (T)  
Norma Pugh, RTI International (T)  
James Quackenboss, U.S. Environmental Protection Agency (T)  
Ruth Quinn, Johns Hopkins School of Public Health (T)  
Penelope Quintana, San Diego State University Graduate School of Public Health (T)  
Shawn Radcliffe, Drexel University (T)  
Jerry Rench, RTI International (M)  
Scott Rivkees, Yale University (T)  
Richard Roberts, Utah State University Early Intervention Research Institute (T)  
NoreenRobertson, Drexel University (T)  
Rebecca Roth, West Virginia University (T)  
Richard Rubin, National Opinion Research Center (T)

Pam Sactor-Litvak, Columbia University (T)  
Lynn Salo, National Institutes of Health (M)  
Sameena Salvucci, Mathematic (T)  
Jessica Sapienza, National Children's Study Office (T)  
Peter Scheidt, National Institutes of Health (T)  
Ellen Schiller, S Research Institute (M)  
Kenneth Schoendorf, National Institutes of Health (T)  
Claudia Schur, National Opinion Research Center (T)  
Amy Shende, RTI International (T)  
Stephen Smith, National Opinion Research Center (T)  
Mario Snow, SRI International (T)  
Julian Solway, University of Chicago (T)  
Judy Sommers, University of South Florida (T)  
David Songco, National Institutes of Health (M)  
Gail Sonnett, University of Michigan (T)  
Stephanie Sonnier, Children's Hospital (T)  
Sheryl Soucy-Lubell, University of California, Davis (T)  
Donna Spiker, SRI International (T)  
Lester Stayner, University of Illinois, Chicago (M)  
Warren Strauss, Battelle (M)  
Shanna Swan, University of Rochester (M)  
James Swanson, University of California, Irvine (M)  
Nigel Tameth, Michigan State University (T)  
Panisha Tate, Henry Ford Health System (T)  
John Thompson, National Opinion Research Center (T)  
Ruth Thomson, Westat (M)  
Leo Trasande, Mount Sinai School of Medicine (T)  
Jessica Vanarsdale, California Center for Rural Policy (T)  
Suzette Vanderbeek, Mount Sinai School of Medicine (T)  
Richard Wansley, OSD Medical (M)  
Clifford Weisel, University of Medicine and Dentistry, New York (T)  
Jennifer Welham, ICF International (T)  
Nedra Whitehead, RTI International (T)  
Charles Winston, National Institutes of Health (T)  
Carol Woodell, RTI International (T)