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NATIONAL INSTITUTE ON CHILD HEALTH AND DEVELOPMENT

NATIONAL CHILDREN'S STUDY

COORDINATING CENTER

PRE-PROPOSAL CONFERENCE

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PROCEEDINGS (1:05 p.m.)

Agenda Item: Welcoming Statement

MS. DESEAU: We are here to talk about the National Children's Study coordinating center request for proposals that was recently advertised in the Federal Business Opportunities. The purpose of today's meeting is for an exchange of information. It's three fold. First, we want to be sure that everyone that is here, and this will all be transcribed, and so everyone that is here and everyone reading the transcript will understand our requirement.

It gives us an opportunity to discover things that we might want to change, clarify, or even add to the requirement that we had not anticipated before.

The third thing is to allow offerors, or potential offerors, to judge whether they can meet the requirements of this solicitation. That's an important one, so keep that in mind.

My name is Virginia DeSeau. I'm the contracting officer who will be overseeing both projects, the coordinating center, as well as the vanguard centers. We have two other contracting officers, contract specialists who will be working on these projects also, and you have seen their names in the RFP; but their names will also be on the screen before the end of this program today.

Since the release of this solicitation, the contracting officer must be the focal point for all communications concerning this project. That's a statute; that's a regulation. That's the way it is. So, even though you see people you know maybe up here on the podium or in the front row here, they have been restricted in their communications with you at this point until proposals are received.

So, for the next few months, don't ask them any questions that they won't be able to answer. Ask all your questions through the contracting office. And again, we'll give you that information, although it's in the RFP, and it's in the cover letter that is on the request for proposals.

The reason for that is that as the contracting officer, one of our responsibilities, is to make sure that everybody has fair and equal opportunity. And to make sure that there is no unfair competitive advantage, that we create an environment in which we can get the best buy for the government.

So, by going through our office, if there are technical questions, we go back to the program office anyhow to get the answers for those questions. But we are responsible, we being the contract officers, are responsible for making sure that everybody has the same information. So, just be nice to your friends. Talk to them in a couple of months.

Dr. Peter Scheidt will be giving you the Web link to the National Children's Study Web site, which is also in the RFP in a number of places. And that Web link will be your source for a lot of information that results from today's meeting, as well as tomorrow's meeting.

We recommend that if you can, you become very familiar with the responsibilities of the vanguard centers, since these two are closely linked, the coordinating center and of course the vanguard centers, and we hope in years to come the study centers. So, be as familiar as you can be with both, because it will enhance your understanding of the project.

You probably have an agenda someplace, and Dr. Scheidt will give a presentation of the overview of the study, and following that today, Dr. Galke will give you—he is the project officer, but again, you're not allowed to talk to him and ask him questions—but he will present to you more of the technical information related to the studies.

For the conduct of today's conference we were not going to be accepting any verbal

questions. The way we want to handle this is all written questions. So, please write legibly. When you have a question, you can hold your hand up or raise the piece of paper, and people that are here who have on name tags, those are our runners, and they will come. There are some in the back over here. They will come to collect your questions.

Those questions will go to our triage table, because we don't want to be answering the same question over and over and over again, unless there really is a problem with our answer, in which case we may need to regroup and come up with a better answer. But Sarah, Dawn, and Teneshia, who are over here, will go through the questions and try to consolidate so that our panel members or myself can answer your questions in total.

Now, if you find that there is a question you have that we are really not answering today, please submit it anyhow, and we'll let you know that we can't answer it today. We'll get back together, and again, you look to the NCS Web site, and you will find an answer to it eventually, hopefully within the next week or two.

Or if it's a substantial question or a substantive question we will put it through a modification to the RFP, which we anticipate to be released—the modification—by the middle of December. We are asking after you leave this meeting, and you may think of other questions that you have not yet asked, you can certainly send those to us also. And send them in writing. And we are asking for all questions to be provided by December 9. That will give us time to consolidate our answers, and to get the modification to the RFP out.

This is also for comments. If it's not even just a question, but if you want to say we really think you could do this better by doing X, Y and Z, we are willing to accept those suggestions at this time. It's a comment period. And we want to get the modification out by the middle of December, so that you have time to prepare your proposals in total, including all of the changes that might be made as a result of these conferences.

And we are assuming today in the questions that will be asked that everybody has read the RFP. And we are assuming—the statement of work we know is long. We know that it may have a lot of technical information in it, but we'll do our best to answer those questions now.

So, I told you the final date for submitting the questions, suggestions, or comments is December 9. And we hope to have the modification out by the middle of December, around the 16th.

And then some people have sent in questions ahead of time to ask when is our next round, when will the study centers—when's the next round of solicitations for the study centers? And we'll get to that today too. We think it will be during the year 2007. We want to get the coordinating center up and going. We want to get the vanguard centers up and going.

In terms of the RFP itself, this is a new acquisition. It's a competitive acquisition. This is not set aside for small businesses. The statement of work you will find the Section C of the RFP, if you don't already know that. And the Section L is a really important part of the request for proposals, so read that thoroughly. It will tell you how to do your business proposal. It will tell you how to do your technical proposal.

And it also gives some very useful notes to the offerors. Please read those. They will help you in understanding how we made some of our assumptions. It will help you understand what directions we are anticipating this going. This whole project is a work in progress. We know that some of the things that we may try right now may not be where we land, but we also think that there are valid reasons for trying the approaches that have been put into this request for proposals, into this statement of work.

The evaluation criteria are very important. Read those in Section M of the request for

proposal. That's how you will be evaluated. The reviewers who are chosen to evaluate these proposals are told specifically, don't evaluate on information that you know about an offeror, evaluate on what they have provided to us in their proposal. So, please read the evaluation criteria, and try to be aware of how that ties in with the statement of work, because they were derived from the requirements in the statement of work.

There is another RFP, as I have mentioned, the vanguard centers RFP. That one is again so closely tied to what the coordinating center is going to be, it would be important for you to know what their requirements are too. The study plan is in that RFP, and the study plan feeds into all of those plans that you have read about that are in the coordinating center statement of work, so make sure you understand what their requirements are also.

The coordinating center requirement, there is one requirement that we don't want you to miss. It's on page 105–106 of the RFP, and it's a requirement from small business utilization. I have the Web site for you. I can tell you what it is, but it's on those pages of the RFP. I'll tell you just so if you want to write it down, it's http://dsbs.sba.gov/dsbs/dsb_dsbs.cfm.

And what that Web site is, after all that—and you'll find it on those pages, that's why I thought I'd give you the pages specifically—what you will find there is a list of small businesses and their capabilities. That Web site is created by the Small Business Administration. And since there is a requirement for use of small businesses in this proposal, we are asking that if you don't already know a lot of small businesses who can participate, that you go to that Web site at least as a source to find other small businesses.

The reason that this is not set aside for small businesses is that it's a very complex project, and we recognize that. We were able to speak with the Small Business Administration and agreed that we would make this a requirement within our request for proposals to be in compliance with them, which would give us the best of both worlds, the use of small businesses, as well as being able to open this up for full and open competition. So, have a look at that Web site. It's a good resource.

Section K of the request for proposals is reps and certs. The section L that I mentioned before, which tells you how to put together your business and your technical proposal, will reference it, but you have to fill that out. And your business offices will know all of that.

There is also a late proposal clause in Section L, and you should read that. The clause virtually says that proposals must be received by the date that is listed both in the cover letter and in the RFP. If a proposal is received after that date and time, it can be accepted if it hasn't yet been assigned to the reviewers, but it would be at a disadvantage to the offeror, because it may be decided that it will not be accepted if the proposals have not already been assigned the reviewers, or if there is no competitive advantage to us to accept a late proposal. So, the solution to this is just get them in on time.

So, with that now, I will open the floor to Dr. Scheidt, and he will give you an overview of the study. Does everyone understand though how the questions will be submitted? Okay. We'll take a break after Warren and Peter give their presentations so you can write your questions. We'll give you a little bit of time to think about it. And then we'll come back, and the rest of the afternoon will be devoted to questions and answers.

Agenda Item: Overview of the Requirements

DR. SCHEIDT: Thank you, Ginny.

Welcome and good afternoon. I want to emphasize how pleased we are to come to this point, and be able to go forward with concrete steps in initiating the National Children's Study,

and how pleased we are to have the opportunity to get feedback and help from you about how to make it the best coordinating center, and the best study possible, and how pleased we are to be able to help you develop the best proposals that can be developed.

Given the assumption that you have read the RFP documents, as Ginny said, I'm only going to do a very brief overview of just certain aspects and development of this study, just for emphasis, and hopefully to anticipate a few questions that you are likely to have.

Just very quickly, a couple of slides on the background for specific emphasis. You know that the proposal for this study didn't come from a couple of feds sitting in a little office building saying hey, I think this will be a neat study to do.

It came from a very high level task force of the president of the United States, chaired by secretary of Health and Human Services, and the administrator of the Environmental Protection Agency, with seven other cabinet officers in the late 1990s, who were charged by the president to propose national strategies for reducing and controlling the risks of environmental exposures to children.

This concern stems from the understanding of how vulnerable children are to environment risks, environmental exposures compared to adults, as exemplified by numerous examples that we are all familiar with of lead, fetal alcohol syndrome, and so on.

Also combined with the fact that we know about many exposures for which we have concerns, but insufficient information to understand whether there are real risks, and then the convergence of knowing that that are a number of conditions such as autism, diabetes, cerebral palsy, you name it, for which there are suggestions of environmental contributions and causes to these conditions, but insufficient information to answer these questions.

Given the convergence of these numbers of factors, the task force began to tackle the question, and quickly came to the realization that there was not sufficient information to answer a whole series of important questions about our children's health and development.

Consequently, they realized that in order to provide these answers, it was required to embark on a kind of study that could answer these important questions across a wide variety of known exposures and important conditions. They proposed this large longitudinal study to address these concerns.

For those of you who may not have heard this as well, then the task force set out to reaffirm that this was an appropriate and reasonable undertaking, and brought in representatives from virtually all of the recent and existing large longitudinal studies around the world—the Scandinavian cohort studies, Framingham, Women's Health, Collaborative Perinatal Study, and a number of others.

And this consultation with these experts reaffirmed that it was reasonable, appropriate, doable, should be undertaken, and should be undertaken boldly, and they recognized that it would require the input of multiple federal agencies, and extensive input from scientists around the country. And that was the beginning of the planning for this study.

The lead federal agencies who have funded this planning process in HHS—NICHD and National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention—and the U.S. Environmental Protection Agency then dedicated staff and resources to begin the planning.

In the fall of 2000, Congress passed the Children's Health Act that authorized NICHD to plan and carry out this longitudinal study. This legislation and the report of the task force emphasized that environment should be defined very broadly. And the study should address itself to the wide spectrum of children's conditions and development.

So, as the planning for this study has been carried out, the concepts that have guided us in undertaking this planning are listed in these two slides. First, that it be a longitudinal study of children; not only children, but include extensive information about their families and their environment; that it be national in scope; that it be hypothesis-driven.

That "environment" be defined very broadly—not only chemical exposures, but physical environment, behavior, social, and cultural exposures as well; that it be able to study relatively uncommon but important environmental exposures in the range of those seen with infantile autism, with diabetes, with cerebral palsy, which require a sample size on the order of 100,000 children.

That the study concern itself with exposures early in pregnancy, and therefore, observations should begin as early as possible in pregnancy; that it include the ability to understand how environmental factors interact with genetic expression, and capitalize on the advances gained with the human genome project, and therefore include extensive genetic information.

That it be a state-of-the-art technology study that embraces technological advances in tracking and measurement, and the ability to handle large and massive data sets; that it involve in the planning and the implementation of the study, all of those federal agencies that have a stake in both the exposures and the outcomes of the children, and it be very much an interagency collaboration.

And in addition, that it also include public/private partnerships, both for support, and especially for adjunct studies in addition to a federally funded core study. And finally, understanding that it is hypothesis driven, that it be planned in a way that recognizes that such a large and extensive study will collect information and samples to enable hypotheses and questions to be addressed for decades to come, and it should be planned and carried out in a way that optimizes that potential.

Well, those are the guiding principles that we have used in undertaking the planning of this study. In the carrying out of the planning we have used a number of organizational elements and processes for developing the science of the study. It began, as I mentioned, in the spring and summer of 2000 with an interagency coordinating committee comprised of senior scientists from the agencies that I have mentioned. And this committee has and is still responsible for operational decisions regarding the overall operation of the study.

Early on, the coordinating committee recognized the need for extensive both broad and in-depth scientific input and ownership from the scientific community and the stakeholders around the country. And the committee proposed and received a federal charter for a federally chartered advisory committee that provides advice to the study, and manages a number of working groups.

Those working groups—there have been 22 of them defined thus far—consist of non-federal and federal scientists and investigators, and have been responsible for developing and proposing the majority of the hypotheses and the design and measures that have been used in the planning of this study. And those working groups provide consultation and findings to the advisory committee, that in turn reviews and provides them as advice to the institute director and to the interagency coordinating committee.

To actually do the work of carrying out the study and doing tasks such as RFPs that you are becoming familiar with, the program office was staffed at the National Institutes of Health and is responsible for actually carrying out the operations of the study. It is now comprised of: pediatric epidemiologists; environmental epidemiologists; behavioral scientists; developmental

toxicologists; environmental exposure assessment specialists; a sampling statistician; geneticists; and an expert in information technology. Some of these people are detailed from other agencies. And then there are a number of other experts that have been available to the program office from other offices at NICHD and the other agencies, such as obstetricians and gynecologists, and other specialists. So, the input even within the federal circle has been very broad.

Mechanisms that we have used in developing and sort of amassing the information used in developing these RFPs have included a total of 27 workshops that have been completed, 12 pilot studies, 9 scientific reviews and analyses. And if you add up all of the people from all of these activities, on that list, many of whom are among yourselves sitting in the audience, a total of 2,425 individuals have contributed to the science of this proposal from all of these processes.

Along the way there are a number of major steps and decisions that we have had and continue to have to make. And for emphasis, let me just explain a few of these that may be helpful. The first I have already alluded to, to have an advisory committee and a series of working groups. We understood this, as I mentioned, for the purpose of providing broad and detailed scientific input and consultation to the planning of the study.

And also, for the scientific community, and the wide range of stakeholders, to gain an awareness and develop support for the study. The advisory committee and the working groups alone comprised a total of 478 scientists and other individuals.

Now, there has been somewhat of a pause of the advisory committee over the past several months, which will continue into the spring. And the reason for that is the necessary distance from the scientists involved in developing the RFPs that you are here to talk about today in order to protect those who have been involved, who would be involved, and who also would have an interest in continuing to contribute on that side of work.

However, let me emphasize that the advisory committee is being revitalized, and will continue, and will carry on in a re-energized fashion dealing with the important aspects of the study to include ethics, scientific considerations, community engagement and other appropriate roles of the advisory committee. So, it's important to realize that there will continue to be an advisory committee, and it will be important for the coordinating center staff to interact with and recognize that.

A second major decision is to use hypotheses, and how we use hypotheses, and why they are important. We felt in setting to lay out this study that hypotheses were critically important to provide the boundaries, the framework, and the structure. In order to plan the study some guidance would be needed.

They are also important to assure that in fact the important, big issue questions that need to be addressed by the study are in fact answerable. And if you can't define the question, you can't tell what to do about doing the science.

And thirdly, we felt that hypotheses were important if we were going to spend significant national resources to answer questions, that question should be well defined. And we set that as an obligation for ourselves.

Criteria for the hypotheses include that they are important, that they require a study of this size and design, that they are measurable with a study of this size, and that they require the long-term follow-up that would be necessary.

It's important to recognize that a certain set of hypotheses have been defined, and are available to you on the Web site, however, we understand that science will evolve and the study will evolve, and some hypotheses may become outdated. As science evolves, other hypotheses may become more important and will need to be incorporated. And the understanding and

flexibility to do that we think is important.

A third major question is why a contract mechanism? There are a number of approaches that the federal government might take to undertake a study such as this. The major reasons, after considerable consideration and deliberations, that we decided to use the contract mechanisms were basically two reasons.

To assure that there was a consistent, rigorous core protocol carried out at all sites in this national study. And secondly, to assure that the National Children's Study addresses the goals of those funding agencies, and doesn't wander off in directions that are not consistent with the important goals defined by the agencies supporting the study.

However, if you view the various mechanisms that are available for contract supporting along a continuum of a high level of control as available with the contract mechanism, or a high level of independence as is typical of grants, there is in the middle a mechanism called the cooperative agreement, which is basically a partnership between federal staff and grantees, where after competition they sit down and plan a study together with a relatively shared governance and direction of the study.

We view that the National Children's Study, as shown in this slide, is somewhere along the continuum between contract and cooperative agreement. And we have intentionally designed the RFPs and the scopes of work for the study centers and for the coordinating center to incorporate significant and meaningful input into the directions and decisions of the study from the investigators, along with clear guidance and direction from the federal agencies supporting the study.

This is probably a dynamic process where this line for the National Children's Study on this continuum will move along this continuum depending on where the study is, and the kinds of decisions and issues that are being dealt with at the time.

Another major question and issue is the combination of the sampling strategy, and the strategy to use multiple centers to carry out the study. And I title this sampling and—but not versus—center strategies, because a number of people view that it is a decision of either a probability sample or a center-based strategy, and they are mutually exclusive. We do not think so; a little explanation.

After an enormous amount of time and consideration and effort, two years of extensive reviews, meetings, deliberations of working groups, of the study design working group, of the advisory committee, of a special expert panel and workshop the decision was made that the most appropriate sampling strategy for scientific reasons was a national probability sample.

And this is primarily because exposure-outcome relationships need to be representative of the U.S. population. Not prevalence, we're not concerned about that, although that is a potential benefit, but understanding how these exposure-outcome relationships apply to the U.S. population as a whole is the concern.

Secondly, we are concerned about a wide variety of exposures that are varied, and many if not virtually all of them with unknown distributions. And in order to be sure that we capture these exposures, the best guarantee to assure that is with a national probability sample.

However, the measures to be used in the study, and the science to be involved in the study requires the broad and continued scientific input and expertise available primarily in centers of excellence around the country.

Secondly, as the study was being designed, we realized that many of the measures require center-based expertise and facilities. And therefore, we felt it also equally compelling that we turn to centers of excellence in this country in order to be able to carry out these objectives.

The combination of combining a national probability sample with a center-based implementation strategy is unique. There are no other studies that we know of on this size and complexity that have undertaken and successfully employed these strategies together. So, it is a unique combination.

It will require flexibility and adaptation of centers to this scientific design. We understand that and we expect that. And we expect centers to respond to this with some creativity, some flexibility, and some adaptation. It will require of coordinating centers, considerable support, guidance, and back-up in order to be able to accomplish this goal.

There has been, as you are probably aware, an extensive process for scientific input into the planning of this study, and we expect that to continue. The federal advisory committee, I have already mentioned its revitalization and this pause, but it will continue with vigor, and will continue to use working groups as necessary.

Workshops will continue as well to define the series of study design and instrumentation that will be needed as the study evolves.

Through RFPs and through your input now we invite additional scientific input, and we not only welcome that, we need it. And we have designed these RFPs to encourage and incorporate extensive input from the investigators at the coordinating center and the study centers. We anticipate a continuation of both local and regional and national meetings, as we have had in the past, to provide for input into the planning of the study, into the science of the study. And the list serve, which now numbers over 3,200, is another mechanism that we continually use to get scientific input.

There are a number of participating entities online and planned. There is a contract entity underway for scientific support that carries out a number of reviews, analysis, and surveys. There is a contract underway to develop the information technology, as you have seen in the coordinating center. And I mentioned that the prime IT contractor in that contract has excluded itself from competing for the coordinating center; they are in a good position to interact with us and with the coordinating center as it comes online.

Over the next year of course we anticipate the successful procurement of a clinical and data coordinating center, and the initial study centers. Following that, as quickly as we can within the next year, we anticipate procurements for a sample repository. Work has already begun on that and to establish the laboratory services necessary for the study.

The projected timeline for the study—you will see several of these today. We are now in late 2004, where we have finalized at least our working set of hypotheses and developed the study plan. This is underway—to select the initial centers as the vanguard centers, and the coordinating center in late 2005. We expect during 2006 to complete and pilot the full protocol and enroll the first participants with initial centers in 2007, with selection of the additional centers in 2006 and 2007.

Anticipating the first question that everybody has, what is the status of funding for the study? I'm answering this by my way of telling you that I can't answer it. You have seen this figure. The total projected cost of the study—projected based on pre-RFP assumptions that we did about a year and a half ago—is in the range of $2.7 billion over the entire 25 year life of the study.

Anticipated fiscal year 2005 funds in the president's budget allow us to initiate these announced procurements that we are meeting about for the coordinating center and for the initial vanguard centers. Our professional judgment estimate for the 2005 budget was approximately double the anticipated funds allocated, and contract guidelines do not permit the announcing of

the amount of funds budgeted for contract procurements. That's as much as I can say about that.

These are the addresses of key individuals in the contract office to be in touch with. And it would be a good idea to write them down and use them.

I actually eliminated this slide when Ginny gave me this to be sure that I showed it; I eliminated this slide for the National Children's Study Web site, so let me tell you about it. Most of you probably are aware of it anyway. But it is http://nationalchildrensstudy.gov. It's very simple.

And with that, that's the quick overview of the process and some major issues. Dr. Warren Galke will go into a little more detail about the coordinating center RFP.

DR. GALKE: Good afternoon.

I'm going to condense what is a very long scope of work into a short presentation. I am not going to try to reiterate the entire set of requirements, but rather I'm hoping to illuminate and illustrate some places where there are rather unique requirements embedded in the 142 pages of text that you all have gone blurry eyed trying to read.

Basically, the coordinating center in the National Children's Study plays a critical and central role, and it has multiple pieces that it is playing. One is to provide scientific support to the National Children's Study program office as the study moves and follows the children.

Despite the 47 pages of the study plan, and the 100-odd pages of both procurements, we have really only focused on the first three years of the children's life. We will be doing extensive work defining what data we need to collect later in the child's life throughout the entire course of the study. Think of it as a highway construction using the design-build concept, so we will try to keep ahead of the children's aging, and things will evolve throughout the course of the study.

The coordinating center will implement and support the information management system. It will be the central tie-in to the vanguard centers originally, and then adding the study centers, also the laboratories, and the repository, and making sure that the information management system is functioning. The IT contractor will actually do the physical engineering of the IMS.

The coordinating center will facilitate the development of the detailed study documents in conjunction with people in the National Children's Study program office, the vanguard centers, and of course the coordinating center itself.

The coordinating center will develop and implement the quality assurance, quality control program for the entire study. It will develop and implement the study coordination procedures, which is pretty typical of such activities. It will do the routine data management processing and analysis. One specialized area, it will support first the vanguard centers, and then the overall study centers in the implementation of the multi-stage probability sampling that we are using to identify and enroll our study subjects.

It will also serve—and this is why you need to read the vanguard center RFP—the coordinating center needs to establish procedures to allow it to serve as a study center for children who move away from their initial sites of enrollment, or if a study center should fail and we have to put in a substitute for a given catchman area.

So, there are many, many roles that the coordinating center will play. As a result, the staffing requirements that you should consider in your proposals should reflect this complexity. And the guidance we provided in the notes to offerors about the naming of certain levels of personnel, take as a guideline, but justify whatever your final decision and your organization structure is. We are not wedded to a fixed model, because as Peter said, we are blazing several new trails, and we're trying to get the best approach that we can.

Under the rubric of scientific support, as I said earlier, we will be supporting our

decision-making about what the study needs to do as the children age. There will be specific assignments given to the coordinating center to go out and do things ranging from summarizing the important scientific content at meetings, to actually doing full preliminary studies that verify the feasibility of certain data collection approaches, and anything in between.

There is a lot of opportunity for subcontracting and use of consultants in this particular area. Certainly, remember the small business requirement. This may be a place where you can effectively use some of these alternative and additional resources.

The life's blood of the National Children's Study will be the information management system, the IMS. And I'm just going to briefly talk a little bit about how it fits, where we are, and what we anticipate the different roles of the different entities being. The life cycle, as we are approaching it, begins with the box in the upper right-hand corner. I'm sorry that it's purple, rather than blue, which it is on the screen here.

The first one in the upper right-hand corner, like two o'clock, is defining the scope of the IMS, what requirements it needs to meet, and general information about procedures.

The next step is to begin the design and the development testing procedures. Then we'll modify, maintain and enhance it in light of the better and fuller definition of what data we are actually going to collect, when we're going to collect, the particular forms that need to be handled.

We'll get into acceptance testing, where we will make sure that the design system works, at least on the small scale. Then we will deploy the system to the vanguard centers and the labs that we have up at the beginning of the study.

We'll conduct a dry dress rehearsal before we collect any real data, to make sure that the system hangs together and does not fail when instead of only having 2 sites, you have 15 or 20. And then we will lead into the main study operations.

You notice the downward arrow. We'll go back to modify, maintain and enhance as soon as our children begin to age, and we add new data collection requirements, because the IMS will evolve as the data collection requirements for the study evolve. And so, there will be a continuous updating and modification of the IMS system throughout the course of the study.

This chart should be familiar to you. It's in the RFP, and it identifies with a fair amount of specificity, the different roles and responsibilities that the entities that will be the primary users of the IMS system have. I won't bore you to tears going through block by block, but I want to make sure you realize that it is in the RFP, and do make use of it.

Here is a vertical, as opposed to a horizontal timeline, just for difference sake. In terms of the development of the information management system you can see in the lower right-hand corner that we have completed two pieces of the life cycle at this time. We have done the study process definition, and the results of that work are found in files that are attached to the RFP for the coordinating center.

So, you can see many pages of detailed thinking done by program office staff and other federal scientists working with the IMS contractor to define what we need the IMS system to do. So, that information is available to you. You just have to look in those attached files.

We are beginning the scoping requirement work. Actually, it is completed just recently. We don't have information to release at this moment.

We are beginning the process of getting content matter experts to refine the information found in the study process definition. And then you'll see a dotted line running across. All of this work is being done before the vanguard centers and the coordinating center have been awarded. The dotted line reflects the transition to the contracted organizations becoming a player in the

final development and enhancement and deploying of the initial system.

Because the IMS is going to be so critical to the overall success of the study when you think of the ramp up to 100,000 individuals, and the number of individual contacts that the IMS is going to have to handle, we are going to have to maintain a tight control over change, but definitely not say you can't change, because we know the study isn't totally defined at this point.

And this is just a kind of an illustration of the general approach that we will take. Suggestions for changes to the IMS, either because things aren't working, or if somebody may have a better idea of what might work better will bubble up from the vanguard centers, from the coordinating center, from the IMS contractor themselves, will get filtered into the program office. The program office will decide whether the IMS system needs to be changed, and then direct the appropriate entities to implement any changes that are needed.

Now, in terms of one of the key roles, is the study documents, as I indicated earlier. And these will include the study protocol, the detailed operational plans, which go on for a number of pages, and the manual of operating procedures. The development of the study documents will begin with a draft study protocol that will be given to the vanguard centers and the vanguard center investigators and the coordinating center staff from the National Children's Study project officer.

And that draft protocol—and I emphasize the word "draft"—will be developed during the course of the next year in the program office, and will be an evolutionary development from the study plan that is included in the RFP for the vanguard centers. However, once the vanguard centers and coordinating center are onboard, we fully expect a collaborative arrangement to work and develop the final study protocol that we will use to begin the study.

So, there will be plenty of opportunity for the investigators at the coordinating center and at the individual vanguard centers to participate in the science, but we want to at least have something to start from. When you deal with a study of the scope and breadth of this one, you want somebody to have at least put the first words down on paper.

Two of the operational plans that I would like to highlight in the statement of work for the coordinating center that are a little unusual are the scientific outreach program and the external data capture plan. The scientific outreach program reflects the very large investment that the country will make in conducting the National Children's Study.

We really feel it's incumbent upon us to maximize the distribution of information and findings from this study to not only the scientific community, but also the practitioner, public policy, and other potential audiences. And we have outlined a very elaborate program to maximize the utility of the findings contained within the data collected in the National Children's Study.

Things like the repository and ready and good access to the samples; public use data sets produced in a timely and periodic basis throughout the study, not waiting for the 25 years; speakers bureaus; all sorts of different things.

The other piece is the external data capture plan, which refers to the growing trend for multi-level modeling where we look not only at the individual, but the communities in which the individual lives. And data that will be captured in this context are things like routinely collected air pollution measurements, water pollution, crime statistics. We'll be developing what specifics they will be, but we are going to be collecting information not just from the children, their parents, their day care centers, their schools, but also the community at large.

Another key area for the coordinating center is the overall QA/QC function. And there are a lot of requirements built into the statement of work for the coordinating center. This

includes the definition of quality control samples to be obtained, how to obtain them, where.

It involves the oversight of the performance of laboratories and clinical testing facilities; doing field visits to the vanguard centers and study centers to insure that the data collectors are collecting data in accordance with the study protocols; doing QA/QC on the information management system to make sure that it is staying operational, that the response times are performing as specified, so that people don't say, "oh, the system doesn't work. I'm going to collect the data by hand." When you are trying to get 100,000 data points from across the country, we don't want that to happen.

And the last item I just want to point out is that the coordinating center also is going to be checked for its performance with regard to data management by an outside contractor, and will need to collaborate with that contractor.

Again, I just want to emphasize this little hook requirement, that of the coordinating center serving as a study center. This is really critical. Even assuming we have a full complement of study centers in the future, we are talking 40, 50 locations. And we all know how rapidly and far the American population moves.

We're going to have to have coverage. We're not going to lose these kids when they leave their home county. We intend to follow them throughout the 50 U.S. states, and to the extent that we can track them when they go overseas, we'll do that too.

The other point is that we'll have a call center. It will be 24/7. As you undoubtedly realize, we have time zones represented from the East Coast to Hawaii when we have the full study complement. To catch people at home these days means working on Saturdays, Sundays, and in the evenings or early mornings. So, we will need staffing throughout these times.

This call center activity will serve as a communication link to the various participating study entities, between the study participants and the study. And it will be a mechanism to collect study data, including as illustrated in the study plan, the detection of the woman's pregnancy status for women who are recruited and followed in the pre-conception cohort.

And once again, just to reiterate, here is the contact information for our contracting officers.

MS. DESEAU: Okay, a couple of points that I want to make before we take a break, and you can develop your questions. One is a question that has come to us in the past two weeks since the release of the RFP is can a coordinating center send in a proposal to be a coordinating center and a vanguard center; can one single center serve as both?

And now that you have heard Warren's presentation, and you understand a little bit more about the study, the answer of course is yes. It has to be two separate proposals, but you can, if you have an organization large enough and who can meet the requirements, that can be done.

I want you to also recognize, as we have said before I think, that this whole proceeding is being transcribed. The full transcript will be on the NCS Web site. For those who cannot attend, they will have the same advantage of the information that is shared today. Any changes in the PowerPoint presentations will be there also. That's why we have not handed out any. We want to make them equally available to everybody.

And I will make introductions of the people sitting on the stage right now, although you're not allowed to talk to them. But you now know Warren. You know Peter Scheidt, who is the director of the project overall. Warren will be the project officer for the coordinating center.

Ruth Brenner is here to answer any questions that you may have that overlap with the vanguard centers. She will be the project officer for that, Dr. Ruth Brenner. And Dr. Lew Berman is representing us today as an expert in the IT component. So, any questions that you

have today, hopefully between all of the people on the panel, and we have some other federal representatives who are here, people who have contributed extensively to the development of the project, and who can answer questions too if they come up. But you're not allowed to talk to any of them.

So, let's take a break, and we'll be back in—I have 10 after right now. Let's come back in 15 minutes. And if you have questions, hand them to the people with the name tags. They will collect your questions. And again, as we are going through the question and answer process, if more come up, just raise your hand, and they will come and collect those questions from you.

Thanks.

[Brief recess.]

Agenda Item: Government Response to Prospective Offerors' Questions

MS. DESEAU: We will start with a few questions that have already been reviewed. And we'll just use the microphones that are up here on the desk, so these guys will respond away.

DR. GALKE: The question is, is the call center required to be located at the coordinating center? There isn't a formal requirement listed in the RFP at this time for a co-location. I think I can see that a good justification could be for it not to be that way, and if you propose a non-co-located subpart of your organization team, you just should justify how you think it would work in that situation.

But do remember training requirements, do remember ease of communication as things to consider when you are establishing any satellite components to your proposal.

DR. SCHEIDT: I have another question, but let me say it's as hard or harder on us not to be able to have exchange with you, as it is for you, because I would look for some dialogue and responses to the kind of answers we give. But we'll get through this.

The question that I have is will each vanguard centers have a special focus area? For example, a focus on violence or media. And the answer is not necessarily. Critical for each center, vanguard and subsequent centers, is carrying out the core national protocol. However, a special focus is encouraged, and we have included that in the proposal for several reasons.

One is to provide a mechanism in addition to investigator input into the core protocol. We have purposely built in a sort of measured amount of uncertainty that still exists in order to incorporate input from investigators.

But also, we want to encourage the investment of intellectual energy of investigators in the project. And one additional mechanism of doing that is through special focused research, and through adjunct studies that take advantage of the core protocol.

And thirdly, we anticipate that a number of centers will have experience and capability that is well positioned to take advantage of the protocol, and we want to take advantage of those opportunities, and encourage special focus areas where it is appropriate. But it's not a requirement, and a vanguard center can have an excellent proposal that can carry out the core protocol without having a special emphasis.

MR. BERMAN: The question I have is please further clarify the responsibilities and functions of the coordinating center and the information management system contractor. And the second question is will the IMS be housed in the CC contractor's facility?

I'll answer the second question first. The answer to that is that the IMS system will eventually be housed in the coordinating center contractor facility, but primarily for purposes of testing that out during the integration tests and during pilot testing, perhaps even during the dress rehearsal. And continuing on as we go through the study with other pilot studies and things of

that nature.

In terms of clarifying the responsibilities and functions of the coordinating center and the IMS system contractor, I would refer you to the statement of work, and look carefully at the table that is exhibited there, and I think it will define that fairly well.

DR. GALKE: I have two separate questions. There is a bit of an overlap, so I'm going to handle them together, but I will read both of them first, so that you can pay attention to those parts that affect you, and ignore those parts that may not.

Please expand on the responsibilities of the outside entity doing QA/QC of the coordinating center. How do these functions relate to the QA/QC responsibilities, functions conducted by the coordinating center? And the second question is what scientific expertise is expected from the coordinating center?

The reason I'm putting the two together is that in a study the breadth and scope of the National Children's Study, it is not surprising that there may be an organization currently configured that would have an expert in all areas currently on your staff. We don't have that expectation of you.

What I would say as advice is this is a longitudinal epidemiologic cohort study of children through their entire life span. Your scientific expertise should include people and functions who would understand the scientific requirements of such a study. And in particular, the QA/QC functions that are very well detailed in the statement of work tell you there is certain scientific expertise that needs to be affiliated with your project team to be able to implement those QC activities.

However, in my experience I have found people wear amazing hats such that you can often get two bangs for the single dollar. And so, we are not pre-judging or presupposing by identifying in particular that you must have a pediatrician, you must have an environmental epidemiologist, an exposure assessment person. We are not going on that route.

But if you look at the scope of work, and in particular those activities that we are expecting you to perform on a routine and ongoing basis, you should configure your staffing plan so that you have the necessary coverage to perform those required functions. But be creative in how you implement it, because this may be opportunities for small business participation.

DR. BRENNER: I'm just going to put up some slides. There were a number of questions related to the sample and the sampling design, so I'm going to use some of the slides that we were planning to show tomorrow. But go ahead with the other questions while we're setting this up.

MS. DESEAU: Let me answer a couple of administrative questions just to throw in something a little different. There have been a couple of questions, will a list of organizations that are here today be available? The answer is no. We won't be making that available publicly, because again, it is something that has to be made available to absolutely everybody. And in this electronic day and age, we have decided that no is the answer.

Okay, what is the agenda tomorrow? A simple question. The agenda tomorrow, will the first part duplicate today's? Dr. Scheidt and I will give our same presentation essentially tomorrow, but following that will be Dr. Brenner's presentation. Dr. Galke will not be giving the same presentation tomorrow. So, if you want to come late, you can miss Peter and me, but you really don't want to miss Ruth's.

Who is the IMS contractor? The current IT contractor, this is public information that you could get anywhere, anyhow, and it's Booz, Allen and Hamilton. They will not be participating in the—they will not be competing for this acquisition.

Peter, do you want to pick up one?

DR. SCHEIDT: This one makes me smile. What is the relationship between the chartered federal advisory committee, the steering committee mentioned in the RFP that involves the PI from vanguard sites, staff for the program office, and interagency coordinating committee, and select staff from the NCS coordinating center, and IMS contractors? In short, what is the relationship between all of these different entities of the study?

And I smile, because in the interagency coordinating committee we have spent many hours examining in some detail, looking at other studies, and seriously considering who has responsibility for what, who has approval authority, et cetera, et cetera. And these relationships are not laid out causally, so I'll try to be very short.

The advisory committee is strictly advisory, however, we think it's important to serve a number of functions: to provide advice on ethical issues, and to provide some oversight and feedback on ethical issues; a forum to deal with ethical problems; to provide a forum for where proposals from a variety of other sources in the scientific community can be assured to be considered thoughtfully and advice given on the use of proposals and suggestions.

To provide feedback and oversight on the extent to which we are or are not adequately and successfully engaging communities; to provide big picture interpretation and sage wisdom about carrying out the study; and as we go forward and fill the positions of the advisory committee, we'll be looking for individuals that are especially appropriate and experienced in these categories, and there are others that I don't recall on my list.

However, the core of the consideration of once the study is underway, and the coordinating center and the vanguard centers are selected, the deliberation and the consideration of the scientific issues will be the steering committee. And that's where the primary scientific considerations will be deliberated.

The role of the interagency coordinating committee is to review, and where appropriate ultimately, if necessary, approve those kinds of decisions in the interests of the agencies that are carrying and funding the study. And we envision that appropriate staff of the coordinating center and the study centers, along with representation from the interagency coordinating committee and the program office, will comprise the steering committee.

I think that pretty much answers this. We could spend, I assure, the rest of the day on the details of this question, but I hope that gives you a sense of relative responsibilities.

MR. BERMAN: This question is, I would like clarification on the current IT prime contractor's responsibility. Are they responsible for the hardware-related issues only, or are they going to be involved in the design and development for the software also? And then the follow-up question is, who is the IT prime contractor.

Ginny answered that question. It's Booz Allen. In terms of responsibilities of the prime contractor, they will have responsibilities greater than just the hardware itself. They are actively involved, and have worked with the program office in completing the initial study process design, and are also working on the completion of the requirements and the scoping of the project. And hopefully in the next couple of months they will be moving into software design and development and integration.

We would also expect that the coordinating center contractor would be heavily involved in the testing that goes on, pilot tests, pre-tests, and dress rehearsal, along with training for these systems, and quite possibly the integration of software that they might bring into the study to support the operations.

I think that answers the question.

DR. GALKE: I got dunked because I only, like a good politician, only answered half of one of the other questions, so I'm going to try to answer the second half of the question. What about the outside contractor doing the QA/QC on the coordinating center?

What we are thinking about at this time with regard to the outside contractor is they will be responsible only for overseeing verification of the data management/data processing part of the coordinating center. Exactly where that begins in terms of stages and steps, and where it ends is at this point not totally defined.

But basically, it is to look at once a data point comes into the door of the coordinating center, be it by Pony Express, electron, light photon, or any other means to the point where that datum gets used in a statistical analysis; that is the part that we will have an outside contractor looking at. The rest of the QC functions are outside of that box, and the coordinating center will keep our eyes on the rest of the overall study.

The next question is a simple one. How are repositories associated with the vanguard and/or coordinating center? The concept at the present time is that we will have what we are referring to in the RFP as a central repository, which may be one or more physical entities. We will definitely plan to have at least a second site where we will store some of our samples away from the primary storage site just in case total disaster were to hit us, so that we don't lose everything.

We are envisioning at this time, and this is part of the detailed protocol development activity, which will be started in the program office over the next year, and then transition to the steering committee to confirm, but at the present moment we are thinking that many, if not most samples will be collected at the study centers and sent to the repository for aliquoting, and then forwarded on to the analysis labs for those samples that are going to be directly and timely analyzed. Whereas the other aliquot or the whole sample, depending on what our final decisions are, will get stored in the repository for later use.

The coordinating center will be responsible for insuring the linkages between the data collectors of the samples, and the samples arriving unharmed at the repository, and also will oversee the activities to insure that samples stored at the repository will be viable for analysis downstream.

MS. DESEAU: And that's a perfect segue to another question that has been asked, which is, as coordinating center progresses and the need for additional contracts or subcontracts arise, will the contractor for the coordinating center initiate and procure subcontractors, or will NICHD handle the additional procurements?

The answer is that NICHD will handle the contracts for the study centers, for the repositories, and the central laboratory or central laboratories. That will not be a responsibility of the coordinating center to subcontract, but they will have to interface extensively with those contractors. The government will maintain separate contracts for those entities.

Ruth has a few questions about the sample design, so this will be a prelude to tomorrow's presentation.

DR. BRENNER: I will just go through a few of the slides that I have on the sample design. The questions today were how were the counties selected for the vanguard centers? The southern region of the country appears to be underrepresented in terms of the number of study sites. And another question is about how community engagement will be related to the study design that we are using. So, I thought it was easier to look at this visually, than for me to explain it without you seeing the map.

So, as Peter described, a decision was made that the strongest, the most scientific and

rigorous way to conduct this study was through the use of a national probability sample. The National Center for Health Statistics, scientists there and statisticians, selected 96 study locations from the full list of all counties in the United States. So, all counties were included in the initial sampling frame.

Thirteen of the study locations were selected as self-representing counties, self-representing locations. These are locations that given the size of the number of units that we were selecting, were certain to be included in any sample with this number of units.

The remaining counties were placed into strata, and the strata were based on the average number of births per year, the metropolitan status, whether it was a metropolitan or a non-metropolitan county, and characteristics of the counties, race, ethnicity, and the percent of births that were low birth weight.

From these strata the counties were selected. I don't have the numbers written down right now, but I think it was 21 or maybe 20 that were non-metropolitan, 13 that are certainty units, and the remaining that are metropolitan locations.

This is the map. Most of those locations that you saw on the map correspond to a single county, however, 6 of the 96 locations include more than one county, due to the small number of anticipated births in those areas.

The question pertained specifically to the selection of the vanguard locations. So, for the selection of the vanguard locations we began with—actually, the National Center for Health Statistics began with a list of the 96 locations, and 8 were selected. And the criteria that were used in selecting them were that the country was divided in four Census regions. Two vanguard locations were selected from each of those regions.

In addition, we looked at the average number of births per year, and again, the metropolitan status, so that there was representation in all of the categories. And we ended up with two certainty units, four metropolitan non-certainty units, and two non-metropolitan locations.

And I think you have probably seen this in the RFP. These are the locations that were chosen to serve at the vanguard locations.

I think that this slide is important. The number of awards that are made is dependent on the availability of funds and the quality of proposals received. So, although there are eight locations that offerors are submitting their proposals and relationship to, we anticipate that there will be a total of three to eight awards. So, not all of those locations may end up ultimately serving as a vanguard location.

There will be no more than one award for collection of data within a single location. So, we won't have two contractors trying to recruit the same participants in a given location—only one award per location. If there are three awards, our goal is to make one award in each of the three categories of certainty, non-certainty, and non-metropolitan. And we are hoping that these awards will be made across the country such that for example if there are four awards, we would have one vanguard location in each of the four Census regions.

So, I think for the questions that I received today, I think that should answer those. And Peter was going to talk about how this relates to—how this decision to use a national probability sample relates to community involvement.

DR. SCHEIDT: The question is how is the sampling design is anticipated to encourage or discourage community engagement? And it's our anticipation that the design itself would be neutral. It would neither encourage nor discourage community engagement.

We do highly value community engagement, and the ability in the plan to engage the

community is very much a part of the expectations in the RFP. And a center's ability to do this, and to plan for it, is extremely important. We do not think that the sample selection should be a negative factor or a particularly positive factor.

Maybe others in the ICC or the program office would add to that?

MS. DESEAU: Okay, another administrative question. Can a contractor participate on both a coordinating center team and a vanguard center team? The answer is yes, as long as you have the capacity, and can justify not overextending, sure.

Another question, are the subcontractors or teaming partners of the IMS contract, the one that is currently in place, permitted to compete or participate in a coordinating center bid?

The answer to that is yes, and the reason for that is that all efforts have been made to not give the current subcontractors a competitive advantage. We have tried to advertise everything that the IMS contractor has done to date. It is included the RFPs. There is a link to the work that has been completed. And you have seen today the work that is anticipated.

So, the subcontractors who have been working with Booz Allen, we hope, and we have tried in every way, to not give them a competitive advantage. So, yes, they will be able to compete.

Another question that I have is what is the applicable small business code for this RFP? That question has come into us in writing, and we will re-examine the code. And if it needs to be changed, it will be included in the modification to the RFP.

And another one is when will the transcripts from these proceedings be posted? And I'm told that it's between December 16 and 22. So, in about two weeks we hope to have these transcripts posted so that they are available to everybody. They will be posted about the same time that the modification to the RFP will be posted.

Peter still has a few questions to answer.

DR. SCHEIDT: Yes, several more. The advisory committee is sometimes called the FAC, sometimes called the NCSAC, and you have heard me calling it the advisory committee.

The answer is they are all the same. They are all the federally chartered advisory committee, chartered under the U.S. Federal Advisory Committee Act. So, I'm sorry if we are inconsistent.

Second question, will there be just one coordinating center, or will there be several regional interrelated coordinating centers? And the answer is the RFP is for one coordinating center. And we think that's important that the entire study is tied together and based on a unified experience.

The last question is, what if any role has the U.S. Census Bureau played in planning for the National Children's Study? And what, if any role will the Census Bureau play in carrying out the data collection?

Interesting question. We have met with the U.S. Census Bureau about this study, and discussed ramifications and possibilities with the Bureau. The representatives from the U.S. Census Bureau have been attendees of various meetings we've had, have attended advisory committee meetings, have participated in the assembly meetings that we have had. And we have had input from them about the design of the study.

We have discussed with them about an active role in collecting data for the study, especially because of the authority that the U.S. Census Bureau has in being able to carry out studies like this. That's not possible.

Under the authority of the U.S. Census Bureau, they can only be involved in carrying out the data if they collect and keep all of the data. So that it would be a U.S. Census Bureau study,

and it would not be able to be analyzed and used in ways that we think are absolutely critical for the NCS. So, that's not feasible, and we are envious of the capabilities the U.S. Census Bureau has for doing certain aspects of data collection.

We do anticipate using U.S. Census data, as was alluded to in Warren's presentation, as an extant data source for a number of variables that can be merged with the NCS database in order to better understand contextual environments in which children grow. And so, we anticipate that interaction with the U.S. Census data.

MS. DESEAU: Okay, I just have a couple of comments that I wanted to make. One comment that I think I need to emphasize is as Peter has mentioned, there were over 2,000 contributors to the development and the scientific input to the project. There are no competitive advantages that any of them have. I just have to emphasize that. They have contributed little bits and pieces along the way. The only conglomerate of information has been through the federal government itself, and our collaborators within the federal government.

I did say that we will not be listing the people who are attending the conference today, but I do want to encourage whomever might be a small business to get registered through the Small Business Administration. It's just sba.gov. Get registered on that Web site that I have given to you or referenced, page 105 and 106 of the RFP. If you are registered there, you will be accessible to those who are looking for small business subcontractors. You can call this SBA directly to find out any details that you may need that may not be obvious on the Web site.

And as for today, the RFP will not be changed today. As I have mentioned before, we are accumulating comments at this point, and we will continue to accumulate comments through December 9, and suggestions, and any other questions that you may think of as you are sleeping and waking up tomorrow morning. We welcome them, because they help us to rethink and make this a much more workable project, and for people to understand what is our requirement.

So, please keep thinking and let us know. After the 9th, stop thinking—no, not true. After the 9th we will really have to get something out, something that is solidified, so that everybody can keep working on your proposals. There are segments of it that are not in question, so you can obviously be working on those right now.

And I have been mentioning that any changes that do occur will be on the Web site. And I keep telling you about the National Children's Study Web site. But of course there is the Federal Business Opportunities, or what we call FBO. That of course is the source for the RFP. And if you have taken your RFP off of there, you should have registered on there to get notice of any changes to the RFP. There has been one modification already posted just this week, so you should have gotten an automatic notice that that was posted.

That is your best source for knowing what we ultimately decide on. The National Children's Study Web site may give you additional information, and it may also refer you back to the Federal Business Opportunities. But that Federal Business Opportunities Web site is your source for the information that we finally decide upon.

And again, this is a dynamic project. I say we finally decide upon, but as you have heard today we are open for changes as needed throughout the development of the project. There has been a lot of effort, a lot of work put into thinking about what is the best approach to looking at the effects of the environment on children through three years of age. We haven't gotten any farther than that.

And of course as Peter has mentioned, and Warren has confirmed, the hypotheses will change over time. The responsibilities of the coordinating center will have to be flexible enough to fit into those changes. But I think the basic concepts are there. The basic approaches have

been anticipated to the best of our ability right now.

So, go forth and write. Any other questions, just send them to us. Thank you.

[Whereupon, the pre-proposal conference was recessed at 3:00 p.m.)

List of Attendees

Abt Associates: Stacy FitzSimmons
Ansya Enterprises Solutions: Madhu Nair
Battelle: Joan Cwi
Battelle: Warren Strauss
Booz Allen Hamilton: Eugenia Guardia
Booz Allen Hamilton: Jamie Hui
Caliber Associates: Jennifer Brooks
Chiles Research Center: Kathleen O'Rourke
Children's Hospital of Philadelphia: Avital Cnaan
Collaborative Studies Coordinated Center: David Cooper
Constella Group: Rich Cohn
CSC: Bobbie Peterson
Deblar & Associates: Larry King
Duke: Suzanne Pfeifer
Duke Clinical Research Institute: Emmanuel Walter
Encompass: Todd Goeldner
Encompass: Ronna Pochter
IA Foundation for Medical Care: Kathy Schneider
ICF: Andrea Baier
IFMC: Michael Rozendaal
KAI Research Inc.: Daniel Weber
KRA Corporation: Dwight Jefferson
KRA Corporation: Robyn West
Lewin: Sharrie McIntosh
Lockheed Martin: Joseph Kelly
Lockheed Martin: Eula Payne
Mathematics Policy Research: Sameena Salvuca
McKesson Bioservices: Andrea DeSanti
Michigan State University: Ann Smith
Michigan State University: Nigel Paneth
NCHH: Jonathan Wilson
NIH: Art Bennett
NIH: Steve Corimeldi
NORC: Craig Coelen
NORC: Harrison Greene
Northrop Grumman IT: Henry Wong
PPD: Mary Wiley
Regional OS Consultants: Lorrie Mason
RTI: Ellen Marks
RTI: Diane Wagener
SAIC: Anne Imrie

SAIC: Kathleen McCormick
SAIC: Maurice Owens
Statistical and Evaluation Research: Calvin Jones
University of Chicago: Kathleen Parks
University of Pennsylvania: Jeanne Manson