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EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND DEVELOPMENT

NATIONAL CHILDREN'S STUDY

PRE-PROPOSAL CONFERENCE

EAST-RFP NIH-NICHD-NCS-08-21E and WEST-RFP NIH-NICHD-NCS-08-21W

April 2, 2008

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND DEVELOPMENT

6100 Executive Blvd.

Rockville, MD

DR. JEFF EVANS: Good afternoon. I'm Jeff Evans, with the newly named Eunice Kennedy Shriver National Institute of Child Health and Human Development. I'd like to welcome you today to the Pre-proposal conference for the National Children's Study. I'll be your moderator today.

Let's briefly review the agenda of what's going to happen. I'm going to give you a little orientation to the technology that we're using today. After that we're going to have several technical presentations. We'll cover contracting issues, an overview of the study, and the technical requirements of the Study.

Now, I want to impress upon you that this is an interactive kind of capability. So, at any time you can ask a question. And I'll show you how in a little bit. But if you already know how, you can go ask it now.

We will have a break, after the presentations, and we will tally up all the questions and try to get them into the hands of the people who will answer them. When we reconvene from the break, we'll take the questions one-by-one and answer them as fast as we can.

Some of you were good enough to send in questions before this webcast, and we've done our best to work them into our presentations. Some of the questions were so complicated that we're going to have to our homework. And, so, we'll have to get back to you through the formal procedures that we'll discuss later on. But for most general questions, we'll answer them today.

We will end promptly at 4:00 p.m. And at about 3:45 we will try to cutoff the questions so that we have a chance to answer the ones that we have.

So, that's our agenda. Let's get to know one another. First of all, as you can see on your screen, I am talking to you from the little box up on the left-hand corner. In the big box in front of you -- let me see if I can activate my pointer -- you can see that the formal slides will appear. And, incidentally, these slides will be available through the procedures that are described in the request for proposals (RFP). So, they'll be memorialized for all time, as will a transcript of this meeting.

The question-and-answer box is over below my talking head. And everything that you type in and ask us will appear in the question-and-answer box. And, incidentally, only you and I will see these questions. For those of you who are familiar

with us you should know that we've transformed our fifth-floor conference room into a studio. And we have a whole team of experts ready to sort your questions and get them into the piles.

Now, how do you ask a question? Well, you use this box down here, this little rectangular box that is right here. Type in your organization name, your name, and the question. And we'll be able to keep them properly organized that way. And then when you're finished and you want to send it, you use this little icon here that symbolizes the return on the computer. And, incidentally, you can also use your computer's return, if you're old-fashioned. So, anyway, that's how we submit questions.

Now, let's warm up. I'm going to ask you a couple questions and just get a feel for who's out there. So, in which time zone are you located? So, if you would just vote -- the East Coast is winning. So, it's pretty much East and Central, a little Pacific. No one from the Mountain? Okay. That's okay.

Next question I'd like to ask you is: Who's with you? Are you all alone or are you with a group of people? So, if you would, submit your answer there. Let's see. Oh, a lot of singletons. Wow. Well, it's varying thing. All right. Oh, I see the rest of you are counting up your group. Oh, okay. Okay. So, it's -- most of you are all alone, but some of you are in fairly commodious groups. Thank you, very much.

Now, let's practice with the question capability. And actually we have a secret motive for this next question, because we want to develop an attendees list. So, if you would type in the name of your organization and a list of the people who are with you and send that to us, we will then have a list of who's attending the conference. And thank you. And you will now know how to work the software for this web-cast. And from this point on, please use that question box and send us your questions.

All right. Now, I would like to introduce several speakers who have technical presentations. The first thing we're going to do is talk about some contracting issues. And I would like to invite Fred Ettehadieh to come up and tell us about the contract issues.

MR. ETTEHADIEH: Thanks. Welcome to the National Children's Study Pre-proposal Conference for the 2008 new centers RFPs. These are the numbers that you see on -- you should see on the slide on your monitors. These are the two RFPs that

are, as you have seen them in the Federal Business Opportunities, where the RFPs are issued. Any amendments in the future to the RFPs will also appear on the same side, Federal Business Opportunities, FedBizOpps. I will have the link for the FedBizOpps available for you further down in my slides, which then you can; please bookmark it and have it available at all times during this acquisition period. I wanted to emphasize that all the information from this Pre-proposal conference will be available, will be issued on the FedBizOpps, probably by next week.

What I'm going to be covering today on my presentation are the point of contact for this acquisition, the purpose for the Pre-proposal conference, the acquisition schedule. It's very important for me to go over this with you, and as Dr. Evans was saying, this is an interactive. So, I want to make sure, if you have any questions concerning this matter, please address them to me at this time through the web link -- through the questions that you can submit now or in the future.

The next thing is exchanges with offers before receipt of proposals, and then technical proposal page-limit requirements and business proposal instructions, and finally type of contract that we are going to be letting in the end of this acquisition period.

I wanted to make sure that this information is available to you now on my presentation. This information is available right now on the front page of the RFPs. And I just wanted to make sure also I highlight them here. For the purpose of this acquisition, the primary point of contact is myself, Fred Ettehadieh, the contracting officer. My e-mail address is as is listed there and, of course, phone number. And the secondary point of contact is Ms. Elizabeth Osinski. And her e-mail address and phone number is listed there. This information -- again, I just want to emphasize, this information is also available on the front page of the request for proposals, which are on the Federal Business Opportunities website.

I also want to mention that, if you have any additional questions after the Pre-proposal conference, please submit them in writing by mail or e-mail and I ask you for your questions to be submitted and received by me at those e-mail addresses I've identified up on the -- above this, on the same page, no later than April 11, 2008.

This date is very important for you to -- I want you to understand this day is

very important, because this will give us time to prepare responses to any concerns or questions that you may have. And also give us an opportunity to have an amendment to the RFP in a timely manner. So, please, I ask you to consider this very important date, April 11, 2008.

As I was mentioning just a few minutes ago, we are very glad that you are able to join us on the web and by telephone conferencing. We are very interested to provide you, the potential offerors, of a clear understanding of the requirements and also to make sure that you'll be able to judge whether you can fulfill the government's requirements. So, this is going to be supplemental information, in addition to the RFP. My emphasis today, not only is going to be on all the presentations that you're going to be hearing, but I would like to really emphasize that, please -- one thing that I want to leave you with, please read the entire RFP packet. That's very important. We have all the information you would need for preparation of your proposals, your offer and how they are going to be evaluated.

One of the sections I would like to identify, Section L, which I would like to emphasize is the section that will provide you information on how your proposals should be prepared. That will cover the technical proposal, as well as the business proposals.

And also Section M, which is the evaluation factor for award – a very important section of the RFP. And, please, do not hesitate to have that information reviewed and available to you, because that's how your proposal will be evaluated. There is a list of criteria there. Also there are scores that you -- that's how they will be judged by the technical evaluation panel.

So, hopefully by going through this Pre-proposal conference. You'll have a better understanding of the requirement. You'll have a better efficiency of preparing your proposals. And also, of course, we'll spend some time on responding to some general questions that have been submitted and also will be submitted throughout this conference.

As I was saying just a few minutes ago, the acquisition schedule, as you should be seeing it on your monitors, and it is presented in this slide, it's very important to understand that this information is available to you, again, on the RFP. And this is a general time line for planning purposes. So, I'm just going to go over it now and I'm

going to identify some of them that I need you to respond some information to me when the time comes.

So the RFP was issued on March 19, 2008. Again, the RFP was issued in Federal Business Opportunities, FedBizOpps. And I'll have a website for you in a couple of slides down in my presentation. There were two RFPs issued. And, as you recall, I have this set on the cover page of my slides. One RFP is for the West, and the other is for the East. And that's how they are posted. They're all the same.

As identified on the front page of the RFP, all question cutoff dates are April 11, 2008. That is in writing, by mail, or by e-mail. And that, again, as I mentioned, the point of contact, that's where the questions need to be submitted to.

The next item is the proposal intent response sheet, which is due by April 14, 2008. This information is part of the RFP, is one of the attachments of the RFP. I want to emphasize that this is information that you may start submitting now. There's point-of-contact information on those sheets. There are two sheets available on the RFP -- on each of the RFPs. There's my fax number, my e-mail address, my point of contact on there.

This is some very important information, because we need this information to be able to start planning the proposal evaluation. This information that you're submitting is not binding; however, as I said, this will create a very efficient system for us to prepare the evaluation – the scientific evaluation process for your proposals.

A very important date is the proposal submission date, May 2, 2008 and that's the date for both of the proposals for the West and the East. That date is on the cover page of the RFP on FedBizOpps.

From here on down, this is how we are planning to move through the process of this acquisition. The contracts office will notify the offerors, whether they are in or out of the competitive range. We anticipate that the notifications will be accomplished through the month of July 2008.

During July and August 2008, we will start discussions, negotiations with the offerors in the competitive range. That is, we will submit technical and business questions in writing to the offerors in the competitive range.

And then the final proposal revision is due to us in August -- through August

or September 2008, because we anticipate multiple awards of contracts in this fiscal year, which is September 2008. We anticipate September 26, 2008 as the contracts award date -- that's what we anticipate.

So, it's very important for us to convey this information to you. I have done that through my presentation today. Also the dates, March 19, April 11, April 14, May 2, those are all available on the RFP cover page and throughout the RFP, which is on FedBizOpps.

I wanted to mention that the Government reserves the right to award a contract without discussions, if the contracting officer determines that the initial price is fair and reasonable, that these discussions are not necessary.

So, what I like to leave you with here is, the offerors' initial proposal should contain their best term from a cost or price and technical standpoint.

On this slide, I've identified exchanges with offerors before receipt of proposals. Basically it's a ground rule to -- that I would like to go over for this acquisition, which started when the solicitation which was issued on March 19. This is a full-and-open competitive acquisition procurement. So, to avoid creating an unfair competitive advantage, the presentations that we are going to be providing today, the transcripts of this conference, as well as questions and answers will be issued as an amendment to the RFP, as soon as practicable after the conference. We should be issuing this information next week. So, please, I'd like to emphasize and I'd like to make sure this is completely clear, that this information will be issued on Federal Business Opportunities, FedBizOpps. And on the bottom of this slide, I would like to point you to that URL to the website. Please have that information available to you, if you don't have it at this time. This is where we will have the amendments. This is where the RFP is now. This is the link for the Federal Business Opportunities. It is the responsibility of potential offerors to check this site to obtain communication regarding this solicitation.

The hint that I give you is, when you go to this site, you may register to get notifications. That way, when you register on this site you should be able to receive notification to an e-mail that you designate, when you register at this site. That way you don't have to check it that often.

So, the second bullet on this slide I wanted to emphasize that. As I

mentioned, I am the primary point of contact for this acquisition. The contracting officer must be the focal point of any exchange with potential offerors. As I said, this is very important, because this is a competitive acquisition. So, please submit your correspondence directly to the point of contact information that you have.

Also, please identify the RFP number, the one that you have seen on my first slide, that of the West and the East, in your correspondence. That would be very helpful.

The remarks and explanation provided today do not qualify the terms of the RFP. The information provided at this conference is for informational purposes. So, this is supplemental to the RFP only and does not override the terms of the RFP.

For any ambiguities or conflicting information, the offerors shall refer to the RFP. And then it is very important for me to say this and make sure everybody understands, the changes resulting from the conference are official only if issued through an amendment to the RFP. And that's what we're planning to do. And any future amendments to RFP will be issued to the Federal Business Opportunities website. And that's the website that I wanted to leave you with.

As I mentioned, one of the items that I wanted to cover was technical proposal page-limit requirements. This information is identified in the RFP. One thing which was not in our RFP, which I'm identifying here, is the margins. And as several bullets down from the top in this slide, it says, margins must be set to one half inch on each edge of the paper. Hopefully that helps with some of the individuals who had questions about this.

So, starting from the top, the technical proposal is limited to 25 pages. Attachments and other information, including resumes, data sharing plan, letters of commitment, human subject documentation, etc., are limited to an additional 75 pages. The entire technical proposal is limited to 100 pages.

I want to make sure that I convey this message, that pages that exceed the page-limit requirements will not be read, evaluated, or considered for review. So, this very important for potential offerors to look at the page-limit requirement, which is addressed in the RFP. And then the paper size should be a standard, not to exceed 8.5 by 11 inches. The font size shall be no smaller than 11 point. Margins, as I said, half

inch. And two-sided pages will count as two pages.

On the business proposal side of it, I'd like to say that offerors must submit a complete, separate business proposal for each Location proposed. And then there are templates for preparing your budgets, the budgets that you are submitting with your business proposals. There are templates available on the Section J of the RFP, which is attachment 24 of the RFP. And those are live -- if and when you go and pull this up, these are active links available there for you to upload this Excel spreadsheets that we are asking for you to submit when your proposals are arriving on May 2, 2008. And there's information about submission, and the number of copies, and the format, everything available in the package and the receipt of the RFPs.

And the next item is for assisting for preparation purposes -- I'd like to bring your attention to Section J, Attachment 9, titled, estimate of effort. This information is available to assist you in the preparation of your proposal. This information is for guidance only and is not to be considered restrictive for proposal purposes.

The other item is very important for any acquisition over $550,000. I'd like to make sure that the potential offerors are aware of this. And, again, this is identified throughout the RFP. And specifically Section J, Attachment 23 will provide an example of such a plan. The plan is titled, Small Business Subcontracting plan. So, any potential proposed contract or offer over $550,000, the offerors shall prepare a Small Business Subcontracting plan.

Now, I want to make sure you are aware that this plan is not required to be submitted with your initial business proposal; however, this plan will be requested from the offerors who are in the competitive range. And I wanted to identify where in the RFP this is available, which is in the Section L of the RFP, Item C, like cat, the letter C, Item 6. And there you will have the information of the U.S. Department of Health and Human Services anticipated minimum subcontracting goals for this RFP.

What I'm trying to do now, I'm trying to just clarify that in our RFP there is a Small Business Subcontracting plan. And also there is extent of small disadvantaged business plan. Those are two separate requirements in Section L of the RFP.

The first one, Small Business Subcontracting plan, shall not be submitted with your initial business proposal. However, the small disadvantaged business participation

plan which is, again, on Section L, must be submitted with your business proposal.

The extent of small disadvantaged business participation plan is in Section L. And I want to bring to your attention that that is in Section M, evaluation factors for award.

Type of Contract and number of awards – It is anticipated that multiple awards will be made form this RFP on/about September 26, 2008. It is anticipated the award from this RFP will be a multiple year cost reimbursement type completion contracts with a period of performance of five years, and incremental funding will be used. Unlike a grant, the individual cost categories may be shifted during the performance of a contract. So, you're not restricted to keeping the funds in one cost category. That's after the contract is awarded and during the performance of the contract. Thank you.

DR. JEFF EVANS: Thanks, Fred. That was Fred Ettehadieh. And next I'd like to invite Peter Scheidt, who is the Study Director. Dr. Scheidt is going to tell you all about the overview of the Study and introduce you to some of the technical people on staff.

DR. SCHEIDT: Good afternoon. And welcome to this Pre-proposal conference about the National Children's Study and the procurement for additional centers for the National Children's Study.

My role this afternoon is to orient and introduce the National Children's Study to those of you for whom this is a new undertaking and a new interest. In doing this, I will give a very brief overview and history of the Study and how it evolved, review with you the structure of the National Children's Study, how it's organized and its various components, I will point out the time line and the milestones of this Study, as it has come to this point. But most important of this entire afternoon, is the opportunity for you to ask questions and seek clarification of issues that you may have with the procurement.

The origins of the National Children's Study began with the response of the President of the United States and the Administration to concerns during the 1980s and 1990s about increasing awareness of environmental exposures, and the risks of environmental exposure to children, and various diseases and conditions that children experience.

In so doing, the President appointed a task force to develop national strategies to control environmental risks to children. This task force, titled the President's Task Force on Environmental Health and Risks to Children, appointed in 1998, found that existing studies were far too limited to provide the needed answers. And that a longitudinal Study designed to answer these important questions was needed. Such Study should be bold and identify effects to ensure safety of our children.

Following this in the fall of 2000, Congress authorized an NICHD to proceed with conducting a national longitudinal Study of environmental influences on children in the Children's Health Act of 2000. These acts point out that this Study was called for by national leaders, both in the Executive Branch and from Congress at the very origins of this Study.

Then, as the National Institute of Child Health and Human Development, and its sister lead agencies began to plan this Study, and as it's carried out to this day, the concepts of the Study are that it aims to identify the potential environmental effects that may be harmful to children or may not be harmful to children. It aims to identify, for those important conditions and diseases that children experience, the potential preventable causes. And in so doing, this Study aims to provide a valuable national resource for future studies for decades to come.

From it's very conception, this Study was envisioned and it was felt to be important that it be hypothesis driven, that it be concerned with exposures early in pregnancy and throughout pregnancy, and that it have the power to study important, even if infrequent, high-priority conditions that our children experience. Therefore, it must be large enough on the order of 100,000 participants, and must be able to study how genetic factors interact with environmental factors. As I have mentioned, it will provide a national resource for future studies.

The process of planning for the National Children's Study began with an Inter Agency coordinating committee of the lead agencies, which consisted of the National Institute of Child Health and Human Development, the National Institute of Environmental Health Sciences, the Centers for Disease Control, and the Environmental Protection Agency. And these agencies and senior scientists in these agencies continued to provide oversight and leadership at a high level for the National

Children's Study.

The planning process included a Federally Chartered Advisory Committee that continues to provide on-going advice to the Study. Under that advisory committee were a number of working groups that focused on identifying important hypotheses and the associated measures and methodologies that would be needed to answer those hypotheses.

With this planning process, a series of workshops, of literature reviews, white papers, and pilot studies were undertaken. The reports of these planning activities are available on the National Children's Study website.

Since 2003, a staff of scientists and professionals in the NCS Program Office at NICHD have continued the planning and implementation of this Study , joined in 2005 with investigators from the various centers that have been participating in the National Children's Study.

The hypothesis related priority health outcomes and exposures are far too many to address in this presentation, but they may be organized according to priority exposures and priority outcomes that give an overview of the span and scope of the issues that this Study addresses. Priority exposures include those of physical environment, of chemical exposures, biologic environment, such as infectious agents and nutrition genetic factors, psychosocial factors, such as family structure, and exposure to media and violence. All priority exposures aim to study how they may affect priority outcomes of pregnancy, of neurodevelopment and behavior of injury, and obesity, and growth, and development.

Early in the decision-making process of this Study, we confronted the decision of who would participate and what would be the sample of participants. Extensive deliberations and study concluded with the decision that a national probability sample was correct and important for the sample of the National Children's Study, in order that the exposure outcome relationships uncovered and identified by this Study apply to and reflect the experience of all the major groups of our children experience. That can only be done with a representative sample of US children.

In addition, it was recognized that the wide variety of exposures included in the National Children's Study are distributed differently throughout the population. In

order to assure that key exposures are not missed, a representative sample is the best way to assure that all important exposures are captured.

In addition, in order to understand what happens in communities and neighborhoods, it was felt that a clustered-sampling design would be important, to be able to identify the attributes and characteristics of the community and to make the logistical implementation easier.

However, it was also felt that centers of excellence would be important to implement this Study. And that's why you are in the audience. We are seeking centers of excellence to help us carry out the Study in Locations that would be participating. The centers of excellence are necessary for both scientific input for the engagement and identity with those communities that would be included, and to provide the expertise and facilities to carry out this complex Study. This strategy of a representative sample carried out by centers throughout the country is a unique combination that had not been undertaken on this scale before, and, indeed, requires considerable flexibility and adaptation of the centers to the scientific design. That is what this procurement and these procurements for centers to help us carry out this Study are all about.

In developing the sample, leading sampling statisticians at the National Center for Health Statistics worked with the Program Office to actually develop the sample. Starting with all of the primary sampling units throughout the United States, consisting of 3,141 counties, representing all births in the country, from which 105 Locations as primary sampling units were selected as the National Children's Study first-stage sampling sample. From each of these primary sampling units, or counties, we call them Locations, neighborhoods will be selected as segments for the second stage of the sample. From each of these segments all or a significant portion of the households within these segments or neighborhoods will be invited to enroll in the National Children's Study, when those households contain an eligible woman of child bearing age with some probability of becoming pregnant. That is the sample. The map of the Study Locations portrays the various stages in developing this sample that have taken place thus far. It's a little complicated, but when we walk -- briefly walk through it, you will see how this reflects the stages.

The orange dots, these are seven of them, are the Vanguard Locations that

were established with awarded Centers in 2005. These Vanguard Centers worked with us for several years in helping develop the protocol and move the Study forward.

Last year, in 2007, Wave 1 Locations were added through a similar procurement that we are carrying out today. And those are the 33 red stars that were awarded last year as Wave 1 Locations.

At the same time, 14 additional Locations designated by blue triangles were awarded for future Waves, Wave 2 or Wave 3. This leaves the 58 centers that are available for this procurement, and that we're discussing today.

It's important to be clear about what is a Location and what is a Center. The Locations are cites are those geographic Counties from which participants will be recruited. They're selected by a stratified probability sample of primary sampling units. There are 105 Locations. Centers are the entities or institutions that will carry out this Study at the Locations. They are selected by a competitive process. Each will cover, on the average, more than one location. And there will be 30 to 50 of them. We're estimating approximately 40.

Why did we choose to use a contract mechanism? As you're aware, this is a rigorous, uniform national Study with a core protocol that will need to be carried out in all locations. To assure that this consistent and rigorous core protocol is carried out in all sites, we felt that a contract mechanism was particularly important.

It also assures that the Study remains true to the goals of the funding agencies that have led the implementation of this project. However, I point out to you that on the continuum between the maximum independence, as with research grants, as shown in this scale, and the maximum control as with contracts. It is our intent that the National Children's Study be operated as close to a cooperative agreement as possible, but reserving the options to carry this out when needed as a contract.

Let's talk about the key entities in the organization of the Study. The Inter Agency Coordinating Committee that is responsible for federal oversight of this Study. There is another, larger and broader federal Consortium that includes most of the federal agencies that are concerned with children's health and the environment with which we meet with periodically to update and to obtain input from broader federal agencies. There is the Advisory Committee that provides review and advice. The NCS

Program Office is necessary to carry out the day-to-day scientific and operational management of this Study. There is a Steering Committee comprised of Center Principal Investigators and representative federal scientists who engage in the primarily -- in the primary scientific deliberations, as the Study goes forward, a Coordinating Center responsible for data management and clinical coordination, and a not-yet constituted, but planned, Data Safety Monitoring Committee (DSMB) that will be responsible for monitoring the data and advising on when interventions providing information is necessary based on the findings of the Study.

Principal Investigators of all the Centers will be included and participate on the Steering Committee. Let me quickly review the roles and responsibilities of the Steering Committee. The Steering Committee is responsible for identifying problems and best practices that arise in the conduct of the Study. It's responsible for scientific input and expertise to support decision-making. It will make recommendations regarding scientific content of a study component. It will review -- provide review and approval regarding adjunct and add-on studies, in addition to other entities that also will be providing review and approval. It will be engaged in decision-making about non-direction changing and budget neutral issues related to the protocol and the manual of operating procedures. And it will be involved in proposing changes to the protocol based on its experience in carrying out the protocol.

The various components of the Study I've already mentioned. They include the scientific support of the various reviews, the information technology development contractor that is working on a state-of-the-art information management system. There are the Vanguard Study Centers, the initial seven, and then the additional center, the 24 (17 new ones) that were awarded in 2007. This year there will be the Wave 2 Study Centers. Then in 2009 will be the specimen repository and laboratory services coming on line.

We are frequently asked about what are the policies, with regard to access to data and publication. Our guiding, overriding principle is that there be maximum use and publication of the data from the National Children's Study. And that is a guiding principle. The primary hypotheses and primary outcomes of this Study will be analyzed and published through the center PIs and other participating investigators. We do plan

for a data use and publications sub-committee. Actually there is a separate publications sub-committee and a separate data use committee that will provide oversight about publications and access to data respectively. A specimen oversight committee, as a guardian for the use of the valuable biospecimens is being formed. And public use data sets are to be available with each phase of this Study, as per NIH guidelines and confidentiality requirements. In all of these, the federal statutes and contractual agreements will prevail.

Adjunct studies will involve a portion of the sample using some of the National Children's Study infrastructure and data to address additional or in-depth questions. Examples might be in one or a couple of centers, to do a more in-depth study of functional neuroimaging of an exposed subgroup for mechanisms of effects on children's development. Funding for such studies will be by other mechanisms, not directly out of the National Children's Study funding. The process for review and approvals has been established. It is important to point out that specific proposals for adjunct studies are not a requirement of this solicitation.

The time line and milestones of this Study include: from the very beginning, have -- has been planning and various pilot studies and methods developments; then the initial contracts for the Vanguard Centers and coordinating center in 2005. Congressional appropriation of $69 million as a line item for the National Children's Study in 2007; completion of the first phase of the Study protocol and award of the Wave 1 Study center contracts in 2007. In 2008, Congress appropriated for this year $110.9 million, which enabled us to go forward with this procurement. Also through this year we expect the input and guidance from the various reviews including Scientific Peer Review by the National Academy of Sciences, the review of the protocol under the Paperwork Reduction Act by the Office of Management and Budget and various IRBs.

We are undertaking additional Center and Location procurements as we speak in 2008 and 2009. We will begin the pilot cohort at the Vanguard Centers at the end of 2008 or into the beginning of 2009. 2008 into 2009 will be the repository and laboratory procurements. In 2010 we will begin the full Study at the Wave I Centers with additional waives following each year. We anticipate first-Study results, at least of methodologic results, not outcome data, by 2011, with the first full data set being

available in 2016.

And with that I'd like to thank you for your attention and turn the podium over to Dr. Ruth Brenner, who is the director of the Study Centers of the National Children's Study, who will provide more detail about this procurement.

Dr. BRENNER: Thank you, Peter. And I'd also like to welcome you to the Pre-proposal conference.

The goals of this presentation are to first review some central components of the Study design, to review the purpose of the solicitation and the mandatory requirements, to answer some general questions that were submitted in advance of this meeting. I want to remind you that some of the specific questions will actually be addressed in the amendment to the RFP.

Beginning with a broad overview of the Study design, we plan to enroll and follow 100,000 children from before birth to 21 years of age. The children will be enrolled primarily through enrollment of the mothers. The mothers, in turn, will be enrolled during or prior to pregnancy to allow assessment of early in-utero exposures.

Our goals are that children in the National Children's Study will be representative of all US children. And as Peter has described, we used a multi-stage probability sampling approach to achieve this goal.

In the first stage of sampling, 105 geographic areas were selected as the areas from which participants will be recruited. We refer to these as the Study Locations. The Study Locations are in general single counties, or in some sparsely populated areas, groups of adjacent counties are joined to form a single-Study Location.

This is a slide that shows the 105 study locations that were selected by our colleagues at the National Center for Health Statistics in 2004.

The primary method of recruitment is through household screening. Once women are enrolled in this Study, we will follow a standard protocol that will include interviews, physical examinations, observational assessments, collection of environmental samples, and collection of biological specimens. The participants include mothers, fathers and children. So, that's a really, high level, broad overview of the Study design. Additional details about the Study are available in Attachment 4, which is the overview of Study, design and methods. There's additional detail also available at

that NCS public website. And in particular, I call your attention to the research plan.

That does bring us to the first question, which was submitted prior to this conference, which is: How should we reconcile the RFP with the research plan document? The research plan contains data collection tasks and other activities that are not in the RFP.

And the answer to that is that, where there are inconsistencies, the RFP takes precedence.

Turning now to some of the specifics of the procurement. The goal of this procurement is to award contracts to organizations that will be responsible for data collections at specified Study Locations. These specified Study Locations include 58 of the 105 Study Locations that were shown on the previous map. Again, contracts have already been awarded for data collections for the 47 other locations. And this is included in Attachment 11, which lists the Study Locations, as well as a map.

I think Peter touched on this, but I'll go over it again briefly. We received questions about the difference between a Study Location and a Study center. The Study locations are the 105 geographic areas that were selected in the first stage of sampling. The Study centers are the organizations or entities responsible for carrying out the data collections.

The NCS is being implemented in three Waves. The anticipated dates for initiation of household screening in each of these Waves is shown on this slide. There are about a third of the counties in each of the Waves. The Wave 1 Centers will begin household screening in January of 2010, Wave 2 in 2011, and Wave 3 in 2012. Again, the goal is to achieve a sample that is reflective of all births in the United States with each Wave of implementation.

I want to add that these dates are the best dates that we have right now. They are contingent on a number of factors, including receipt of requisite approvals and continued funding of this Study.

This brings me to the clarification to the RFP. In the statement of work, in the last paragraph of the first page of the statement of work, there -- it stated that field work for Wave 1 will begin in 2009. The clarification is that enumeration and screening of households for Wave 1 locations is scheduled to begin January 2010 as described in

the overview of Study design and methods, as shown on the previous slide, and also shown in the Study time line, which is Attachment 10.

Some additional specifics about the Waves of implementation. For Wave 1, contracts have already been awarded for 34 of the 37 Study Locations. This includes the seven Vanguard locations, as well as 27 Wave 1 locations that were awarded in 2007. The current procurement includes the three remaining locations to be implemented with Wave 1. And there are separate documents, particularly in some of the attachments that discuss the time line for implementation for the Wave 1 locations versus the Wave 2 locations.

Contracts have also been awarded for 13 other locations, to be implemented in either Wave 2 or Wave 3. The remaining 55 locations are the primary subject of the current procurement.

So, this brings me to a second correction to the RFP. The 55 locations have been grouped into strata. These strata appear in Section M of the RFP with specific targets for the number of awards within each of the strata.

The first amendment to the RFP was issued about -- within a week of issuing the RFP. One of those lists of -- one of those strata incorrectly listed Warren County as Warren County, New York and that was corrected to Warren County, New Jersey. Again, Attachment 11 shows a study map and a list of locations. The counties are all correct as listed on Attachment 11.

I'll now turn to some of the -- mandatory criteria and other criteria specified in the RFP. Offerors shall prepare proposals to serve as a center to conduct data collections at one or more than one of the 58 specified Study Locations. This is mandatory criteria number one. Again, I'll refer you to Attachment 11.

A separate proposal must be submitted for each location in which the offeror is proposing to collect data. This is different than the way the procurement was set up last year. That is, a separate proposal is required for each location in which you are proposing to collect data.

No more than one center will be awarded a contract for data collections in a given location. That is there's no splitting of locations between multiple primary contractors. A single offeror can submit proposals for multiple locations, but, again, a

separate proposal needs to be submitted for each location.

Each proposal will be evaluated independently. Thus, the information about the center should be included in each of the proposals, even if a center is proposing on multiple locations. Again, each of these proposals will be evaluated independently. There's one exception, which is Harris County, and I'll talk a little bit more about Harris County in a couple of slides.

The Study Location must be in the same state as the Study center, in a state that is contiguous with the state of the proposing center, or in a state that is not contiguous but is separated from the border of the state of the proposing study center by no more than 100 miles. These are the same mandatory criteria that appeared last year. I think it is important to emphasize the location of the study center is considered to be that of the location of the primary institution in the proposal.

So, turning again to a couple of questions. Will proposals for collection of data in a county that is not included in the list of 58 Study Locations be considered?

And the answer to that is: No, you have to propose on the locations that are included in those -- in that listing in Attachment 11.

Can existing Vanguard and Study centers send in proposals?

Yes, they would submit proposals the same way that any other offeror would.

Turning now to the enrollment goals. Again, participants are identified through -- primarily through screening of households in the selected neighborhoods or segments. The goal is to enroll sufficient number of women, such that 1,000 live births are enrolled over a four-year enrollment period in each of the primary sampling units. Note that for both Wave 1 and Wave 2 locations, the enrollment period extends beyond the five-year contract period.

There are six exceptions to these enrollment goals. And they were posted in the RFP and are listed on this slide. The six -- for these six locations, where there are low number of births, the requirement was set at 600 births over the four-year enrollment period.

So, one question that we received is whether or not enrollment targets will be adjusted for other Study Locations that have relatively low number of births per year.

And the answer to that is: That we are not adjusting them at this time;

however, as part of the technical approach, offerors can describe the challenges that they envision in enrolling a sample of 250 births per year. If, in addition to the issues faced by all the counties, there are unique challenges for a particular county, they should suggest alternate approaches that the review panel can then evaluate.

Turning now to mandatory criterion two, this criterion applies only to Harris County, Texas for those offerors submitting proposals for data collections in Harris County. This county contains two PSUs, so data collection in one of the PSUs will be implemented with Wave 2 and data collections in the second PSU will be implemented with Wave 3. The method for doing this is by adding additional neighborhoods or segments when the Wave 3 PSU is implemented. Because we will not have more than one contractor conducting data collections in a single location, offerors that submit a proposal for Harris County must demonstrate their ability to expand and conduct these additional data collections and add these additional segments with Wave 3. The Wave 3 PSU must be submitted as an option proposal. And the option proposal would be exercised at the appropriate time, given that there's funding and the Study continues to move forward with implementation of Wave 3 locations.

I'd now like to review some of the materials that were provided. Fred's already mentioned the evaluation criteria in Section M that you should pay attention to. There also were a number of attachments. The ones that I'd like to highlight are Attachment 3, the statement of work; Attachment 7, which contains the additional technical proposal instructions; Attachment 9, which is the estimates of annual effort by annual contract year (I'll talk a little bit more about that in a minute). The time line of operational activities is Attachment 10. The estimated number of visits and telephone calls is Attachment 12. The overview of the incentive plan is Attachment 13. For those *[items on the slide]* that have stars by them, we provided separate tables and estimates for the Wave 1 and the Wave 2 centers.

Okay. Turning now to some specific clarifications. The estimates of annual effort by contract year are provided as guidance. Offerors can, and are, encouraged to calculate their own staffing needs, based on the requirements in the RFP and in the statement of work. Offerors are encouraged to explain the assumptions that they use to estimate their staffing needs.

We received a number of questions about abstraction of data from medical records. The current plan includes abstraction of maternal and newborn records following delivery of the infant. The technical and business proposals should not include work and costs associated with other medical record abstractions. The protocols for additional medical record abstractions are being worked out at this time. So, at this point you should not include technical, or business, or costs associated with other abstractions.

We received a number of questions about the biosketch versus the abbreviated CV. The additional technical proposal instructions asked for an abbreviated CV for key personnel, the principal investigator, and the Study coordinator or operational manager. It asked for a biographical sketch for other named Study staff. The biographical sketch should follow the NIH format. For the abbreviated CV, we have left it up to you as to the number of pages that you would like to include. We suggest, however, no more than six pages. Both the biosketch and the abbreviated CV count toward the 100-page limit for the technical proposal. So, you should take that into consideration when deciding the length of the CV that you include.

So, turning to some other specific questions that I would like to acknowledge. We've received a number of questions asking for the details about some of the local processing of biospecimens. We also received a number of very specific questions about the estimates of visits shown in Attachment 12.

Both of these questions came in relatively recently and we'd like to take some time to consider these. We will provide responses in the amendment that's posted to FedBizOpps.

Additionally we'll continue to receive questions until April 11 and we'll be posting questions -- answers to the additional questions as well.

So, I'd like to end with a reminder that we *[Program Office Staff]* can't answer -- we're not permitted to answer questions. The program staff really does need to refer your questions through our contracting officers. I've listed their *[Contracts Office Staff]* names and contact information, again, on this slide. Thank you.

DR. JEFF EVANS: Thanks, Ruth. That was very informative. I understand we've got questions piling up. I think we're going to take a 15-minute break to sort

through this mountain of questions. I'd like to remind everybody that, when they're submitting their questions, please type their name and organization in before the question.

So, we'll return in 15 minutes, which is about 2:30 my time. And, remember, we'll have a 3:45 cutoff for questions. So, keep them coming. They look interesting. Thank you.

(Pause in proceedings.)

Government Response to Potential Offerors' Questions

DR. JEFF EVANS: Hello. This is Jeff Evans speaking to you. We're about ready to start the question-and-answer period. We've really enjoyed your questions. I mean, they've made us think. So, we spent 15 minutes of really, really frenzied activity here.

So, let me introduce our panel. Elizabeth Osinski, who is the lead for our contract team, is joining us. Fred Ettehadieh, of course, you've already heard from him, and he is our lead contracting officer for this procurement. Dr. Peter Scheidt is the Study director. Dr. Ruth Brenner is the technical lead for the team of project officers. Later on you'll hear from Dr. Ken Schoendorf about design issues and Dave Songco about information security issues. And they'll be speaking to you from the podium.

Keep those questions coming. Remember it's a 3:45 cutoff for questions. And please do remember to list your name and organization when you're sending in a question.

Let me recognize Dr. Scheidt, and he'll kick off the question-and-answer period. Pete, what's your preference for answering questions?

DR. SCHEIDT: Thank you, Jeff. I will lead off with a general comment, because a number of questions referred to the center base and option model that was used with the Study center procurement last year, and we want to reemphasize that the center base and option model that we used last year is no longer applicable. Each location must be a separate and independent proposal and must include the center component of each proposal for a given location.

When a center, submits proposals for multiple locations, the center

description will need to be included as a component of each one of those proposals. It is perfectly fine to just cut and paste the center description for the one center into the proposal for each of the separate locations. I hope that is clear. And, if not, please let us know.

And several additional questions: Will all 100 of the randomly selected counties -- actually it's 105 counties in this sample -- be awarded and included as enrollment sites for the National Children's Study.

The answer is: The intent is to include all 105 in the full sample when all procurements are done. But that depends on funding for the National Children's Study. And that we won't know until each successive year and procurement comes up. But it's the intent to include all 105.

Next question is: When will the next National Children's Study RFP be issued? In the same manner, that depends on funding. We do anticipate a procurement for Wave 3 next year, if Congress appropriates at the professional judgment budget level judged to be required to move this Study forward in Fiscal Year 2009.

The next question is: If several counties, each as a separate location, enter as a consortium how would the Study center be configured for each location?

And the answer to this is: There cannot be a consortium of a cluster of counties. There is a consortium. It is all 105 counties, and they're all put in one large National Children's Study, but for the purposes of this procurement, each location is a separate, independent proposal. There would be no provision and no way for us to consider a consortium of linked counties.

Next question is: What provisions, if any, are being made through NICHD for women who are recruited and have no insurance?

The National Children's Study is not funded to provide clinical care, even to provide clinical care for those conditions that are identified by the Study itself. As a stipulation in this procurement, we are asking that centers describe referral networks and how they would refer and attempt to coordinate, and have patients seek medical care. But there is no provision for the National Children's Study to provide direct care, whether insured or not insured. That would have to be carried out by whatever

mechanisms are available in the local areas and for the individuals.

The next question is: Where would a data analyst be funded?

Answer: The primary analyses of data that address the hypotheses and the primary outcomes of the National Children's Study will be carried out through the data coordinating center. There may be local needs for data analysis, and when that is perceived to be the case, the justification for a local data analysis capability would need to be included in a proposal.

And if anyone else has any other additions to that, please speak up. But with that I'll stop. And who is next?

DR. JEFF EVANS: Okay. Thanks, Pete. Liz is next up.

ELIZABETH OSINSKI: Yes I am ready.

DR. JEFF EVANS: Liz Osinski.

ELIZABETH OSINSKI: Yes. The first question is on the page limits. If one 8.5 by 11 page has two letters -- I assume commitment letters or something like this -- shrunk to half size, i.e., two letters per page, will this be counted as one page or two in counting of the pages for the page limit?

It would be counted as two pages, because you have to follow the font and the size of the type that is actually in the RFP. So, it would be counted as two pages. You can't shrink the letters or shrink the type.

The second question that I have relates to one of Dr. Scheidt's questions. It's for a bid that includes a base and one option site. Again, this RFP is structured not like last year's RFP. It is structured by locations. And each proposal is submitted independently for each location and is evaluated separately for each location according to Section M, the evaluation criteria. Therefore, your center component part of the location has to be included in the location proposal itself, even if you repeat or restructure them according to each location. That is up to you. But, again, there are not base and options sites as the RFP last year was structured.

Next question: Can location staff include federal government employees?

I may have to get back to this organization. But in general, federal government employees cannot be proposed to work on the Children's Study in your proposal. But I will get back to this organization individually, because if there is

something that I don't know about your charter or something and these aren't actually federal government employees, or they're some other type of arrangement, we will talk about it.

The next question is: As part of the technical proposal requirements, Attachment 7, Page 3, Item 6, estimate of effort. It appears that in Attachments 9 and 10 will need to be completed, estimate of effort. Do these attachments need to be submitted as part of the technical or business proposal? If they need to be included in the technical, do the tables and justifications count toward the page limit?

Okay. Anything in your technical proposal is -- counts towards your page limit; however, these are just estimates of effort for guidance only. Generally an offeror might list their staffing. I would think they would, but it's up to you, in your technical proposal. You may not have each specific cost element justified in great detail in your technical proposal. This, again, is up to you. That may be part of your business proposal. The business proposal doesn't have page limits, but it's not read by the technical review committee. So, generally these are just guidance estimates of effort. Generally you don't fill them out, you propose your own estimate. Generally they are in the technical detail about a staffing plan. But that, again, is up to you. Thank you.

DR. JEFF EVANS: Well, thank you, Liz. And if I can now just move down the table to Fred Ettehadieh.

ELIZABETH OSINSKI: Oh, I'm so sorry.

DR. JEFF EVANS: OK

ELIZABETH OSINSKI: I have one more. Are we allowed to submit appendices for option counties in addition to the 15 pages?

Again, every proposal is a separate location proposal. And we're not in the same structure that we were, again, last year. And, no, there can't be appendices submitted over and above the page limits.

Also, there's a question about travel. In Attachment 8 on Page 2 of the East RFP, general assumptions were included for travel to training held by the NCS coordinating center in Rockville. But there was no break down by the type of training, interview, biospecimen, physical measures, environmental, et cetera. Would it be possible to provide more specifics so that a study center who is working with multiple

partners has more information to help determine how to divide up trips, per diem, etc.?

Okay. Different centers in different locations propose this in different ways. This could be worked out later in negotiations. At this point in time, the way you structure the travel should be your best estimate. We will be providing more details later during negotiations, but not at this time. Thank you.

DR. JEFF EVANS: Well, thanks, Liz. Fred, it switches to you.

MR. ETTEHADIEH: Thanks. Is an NIH biosketch for nonresearch staff, i.e., IT staff required?

As we explained in the RFP, we are asking for an NIH style biosketch for any named staff.

The next question is to clarify, whether the new RFP, the East RFP NIH, NICHD, NCS0821E, West and East -- equivalent?

That is correct. Yes, it is.

The next question: The previous RFP indicates the use of just-in-time concepts as marked on the cover page -- or cover sheet of the RFP. The current RFP indicates that the just-in-time concepts do not apply. Is IRB approval necessary at the time of submission?

The IRB approval is not necessary at the time of submission of the proposal.

Next question: The RFP presents an estimate of effort in Attachment 9, is the number of FTEs proposed by the offeror an additional criteria for award independent of cost?

The answer is FTE proposed by offeror is not a criteria for award. The criteria for award are only what you will see in Section M of the RFP.

The next question is: Our subcontractors are in different locations, so is a separate business proposal needed for each subcontractor?

That is correct. A separate proposal is needed for any subcontractor that a prime is proposing.

Another question about biosketches. For biosketches can we only include Part A of the NIH format to conserve space?

That's completely up to the potential offeror how they want to conserve space.

DR. JEFF EVANS: Okay. I know both Liz and Pete have new questions, but

let's move on down the line to Ruth, because I know she has a pile. So, Ruth Brenner, please.

DR. BRENNER: Thank you. So, the first question says: Why are the targeted number of awards per strata proportionately different by strata, one out of one for some, two out of four for others, and two out of five for others?

And the reason for this is to maintain the representativeness of the sample with each Wave. So, within each grouping of counties there are a number of targeted awards. I might also add that the only strata that have a single Study Location are the three strata with Study Locations for Wave 1, which are each in their own strata for completion of the Wave 1 sample, where we have much less flexibility, because most of the locations have already been awarded.

The next question says: If a woman is recruited and the pregnancy is not carried to term, does this lead to replacement recruitment?

And the answer to that is, no. The pregnancies that are not carried to term have been calculated in the estimates of the total number of households that need to be screened and women that we would need to enroll in the Study.

The next question states: How do we reflect costs and budget of combining multiple base locations with one central site? And this has been addressed a number of times. And there is no base and option structure for this particular procurement. There is only a proposal for each location. So, the center cost should be included proportionately to each of the locations. So, center costs should be included with each location.

How are we going to assure translation of the uncommon languages, languages other than Spanish, Mandarin, Farsi?

And the answer to that is: Our plan for translation of documents right now is that all documents will be provided in English and Spanish. For other languages, the Study interviews will be conducted through interpreters. The one exception to this is, we're looking into provision of the actual consent forms in additional languages. And those languages have not yet been determined. The translations will be done centrally into the Spanish. So, that should not be reflected in the center proposals and cost estimates. However, the use of interpreters to administer the data collections will be

something that needs to be reflected by each offeror.

What is the plan for following women who move outside of the US following the birth?

We will make reasonable attempts to follow children who move outside of the US, but those contacts will be by the coordinating center, and most likely will be remote contacts, either by telephone or through some other means. But, in any event, they shouldn't be reflected in the center proposals, those children will be followed by the coordinating center.

We have knowledge that a substantive proportion of the population in one of our potential Study Locations does not have access to telephones. This has implications for both the long-term follow-up of women categorized into the moderate and low probability of pregnancy groups by the NCS Coordinating Center, as well as plans for telephone and interviewing and scheduling appointments with participants. Can the government please provide guidance on what contingencies we should plan in our proposal for dealing with this particular challenge?

And my response to that is: That knowing your local needs, you should propose how this would be best addressed for your location in your particular circumstance. The estimates that we provided, both the estimates for the staffing time and other estimates, are based on an average location. We can't actually provide estimates for every single circumstance. So, again, those are provided for guidance, kind of as a base line. But we would encourage you to address things that are unique to your location in your proposals.

Okay, next question. For a bid that includes a base and one option site, when does the enrollment of Study participants begin for the base and options sites relative to each other, i.e., simultaneously or staggered, and if staggered by what time frame?

Again, there are no base and option proposals this time. All of the proposals should be for individual proposals for one of the counties listed -- one of the 58 counties listed in the procurement. There are three that begin in Wave 1 and the rest of the proposals should reflect Wave 2.

For technical proposals that include base and multiple option sites, how many community advisory boards are required?

Again, each proposal [*is separate*], there are no [*separate*] base and option components. There is just a proposal per location. And the community advisory boards are to reflect the needs of the individual communities. While it seems appropriate that each location would have its own community advisory board that is really left up to the offeror to provide their plan for community advisory boards within each of the proposals.

Here's another question: Is there a time line for option sites to be staggered by a year?

I think I addressed that in a previous question. But if there's still a question about that, I would encourage you to submit it again.

The model draft budgets provided have no lab personnel listed for processing or shipping. Can we just provide our best estimates?

And the answer to that is: You should be providing your best estimates for all of the positions. Some of the specific tasks aren't broken out in our estimates. But most of them were considered in coming up with those estimates. I would encourage you to provide your own estimates and the justification behind the assumptions behind them, particularly where they differ from our estimates.

All right. I'm not totally sure I understand this question, but I'll read it and provide an answer. And then you can resubmit it if I didn't answer what you were asking.

Should we assume a budget for Wave 2, if not already funded or listed as a plan of Wave 1 group?

I think that that is asking what the start time is for the three locations that are to start in Wave 1 and the 55 that could potentially start in Wave 2. I think the question pertains to those 55 that could potentially start in Wave 2. So, the answer to that is: That for all of those you should assume the time line for the Wave 2 group, for those 55. The only three that go on the Wave 1 time line are the three that are specified in the RFP.

The next question is: NICHD has included an incentive plan to Attachment 13. It includes both monetary and nonmonetary incentives. Should we budget for nonmonetary incentives or will those be provided by the NCSCC?

And the answer to that is: Is that the current plan is to provide a central

supply of nonmonetary incentives that centers could choose to use as the nonmonetary incentive. If they do that, those costs do not have to be included in their budget. However, we've learned from our initial work with the centers that many feel that it's important to have a nonmonetary incentive that is customized to their local community. In those cases there will be an approval process to make sure that the incentives are appropriate for the Study as a whole. And we've given the range of the value that we think would apply to those noncash incentives, but the actual funds would come out of a local center budget. So, we've really left this up to you, whether you'd like to provide non-cash incentives from the central supply or provide the nonmonetary incentives through your local centers.

Is the next question asks if we want an abbreviated CV for the location PI or just the center PI.

An abbreviated CV is required for the principal investigator named on the proposal. We'd leave up to you who is the principal investigator, but there has to be a principal investigator named on the proposal. That's who the abbreviated CV is required for. Beyond that we will leave it up to you, whether or not you think it's important to include more than the number of pages allowed in a biosketch for the location PI.

Okay, next question. This is a question regarding Attachment 9, the estimate of effort by annual contract year. Is it permissible for offerors to utilize the maximum FTE per contract year while shifting the FTE percentages in rows, such as increasing FTE by other investigators beyond recommended levels and reducing the FTEs of the hospital negotiator below the recommended maximum levels to meet the FTE allotments while ensuring the best study team for the community?

And the answer to that is: Absolutely you can shift to meet the needs of your community. Again, these are just offered as a baseline guidance, but offerors are encouraged to propose staffing that they think would ensure that the Study is successfully implemented in their communities.

Okay, next question. Please expand on comments about changes to the current RFP, regarding the requirement for stand-alone proposals for base and option sites? I believe that we've done that. If there's still a question about the base and

option sites, please resubmit it.

How will this affect the organizational framework, if the only option site is funded and not the base site?

There are no base and options this time.

The requirements about the relationship between the Study location and where the primary offeror is located, have not been changed from the last RFP. They are listed in the RFP in the mandatory criteria. The primary offeror has to be in the same state as the location, an adjacent state, or within a certain specified range. So, that hasn't changed. What has changed is that there aren't base and options this time.

How does a proposal for a center with multiple locations or sites submit an application, if each location or site submission requires a separate application?

I think we've answered that. Each location does require a separate application. The role of the center in implementing the Study should be described in each of the applications.

I think I'll take a pause and view some of the more recent questions and then I'll come back.

DR. JEFF EVANS: Okay. Thank you. Let me just give the panel a chance to take a break and consider their answers. And ask Ken Schoendorf and Dave Songco to come up and answer their questions.

So, Dave, why don't you answer a few and then we'll get back to our panelist.

DAVE SONGCO: I guess it's good afternoon, everybody. I have one question. The answer may take as long as Ruth did for her 27. I'll read the question.

In circumstances where a subcontractor is responsible for all data collection and electronic maintenance of data in conjunction with Westat and no data will be maintained by the prime Study center base, who is responsible for drafting the information security plan? If it is the responsibility of the subcontractor, is the Study center base responsible for oversight? Is a description of the information security plan required in the initial submission of the technical proposal or at time of award? What, if anything, needs to be included in the technical proposal at time of submission?

All right. Let me make a general comment first, that FISMA compliance is

complicated and it's evolving. We are tracking the latest guidance and we will provide you the latest guidance at time of award. For now, the first answer is that: It's everybody's responsibility, everybody that is on the bid that's coming in. And that the key is the data. If you are gathering data on behalf of the government, it doesn't matter whether the equipment is housed and furnished by the government, or it's your equipment, you are subject to FISMA.

So, now, the question was: If the sub is doing all the data work, who has a responsibility for drafting the plan?

Well, the first responsibility for compliance is with the prime. The prime should work with the subs to develop an IT security plan that is compliant with FISMA.

Now, what do you have to put in, in terms of your technical proposal, and what do you have to do at time of award?

What you should do for your proposal is, one, acknowledge that you have followed the link and you're familiar with the FISMA requirements and submit your current IT plan unmodified. After award we will work with you to ensure FISMA compliance based on the current guidance. That's what we're doing now with the current Vanguard Centers. That's what we'll do with the first Wave of Study centers. And that's what we'll do with your Wave.

Fortunately by the time we're ready to stand your IT situation up, we should have gotten most of the kinks out and understand the guidance. I understand it's complicated. But you really do need to follow the link that was provided in the package and become familiar with the FISMA requirements. And we will provide additional guidance as we can. And that's the only question I have.

DR. DELLARCO: Hello. My name is Mike Dellarco. I coordinate the environmental measurements here at the Program Office for the NCS. I do have one question.

The question is: Are additional resources planned to allow for an environmental characterization of each segment through a review of extant data by a person with GIS background for use in communication with the community groups, to improve recruitment, and for subsequent use and exposure characterization of the subjects?

No additional resources are going to be provided for this purpose. However, during the course of the study there will be some provisions and some guidance provided by the coordinating center for the use of extant data. Thank you.

DR. JEFF EVANS: Thank you. Next is Ken Schoendorf.

DR. SCHOENDORF: Okay. Thank you very much. I have some questions related to details of the data collection. And I will say, I'm going to answer them really only to the extent that it is necessary to respond to the RFP appropriately not to get into discussion of the merits or liabilities of the proposed data collections. There are several questions that address the handling of biospecimens, specifically blood specimens at the local sites.

The questions are, essentially: What method of freezing at a local site is necessary, whether it's minus 80 degrees or conventional freezing? And how much time can elapse between collection of the blood and processing, or refrigeration, or freezing of the specimen?

So, for the purposes of the proposal, it should be assumed that at the local sites that conventional freezing is necessary for some specimens after the initial local processing. And that's before the specimens are shipped to the repository, but that the freezers, if necessary, will be provided by the coordinating center. So, they do not need to be included in the budget proposal.

In terms of the timing, for the purposes of the proposal, assume that the processing should be performed within about four hours of specimen collection for the home visits that are in the protocol; and two hours within the collection from the clinic visits. What is included in this proposal is for a clinic visit is really only the third trimester clinic visit.

A related question is about on site procedures at the birth facility for processing and storing placenta, cord blood, cord sections. The cord blood, obviously, will be collected pretty much at the time of birth. There will likely be several acceptable technical methods for collecting the specimen. That will vary depending on the specific hospital or specific hospitals within each site. And then the specimens will be shipped to the local processing center, where they will undergo the simple processing, including the freezing mentioned previously, before shipping to the repository.

For the placenta and the cord, and for the purposes of the proposal, the plan is to ship the placenta and cord pretty much in toto from the site, unfixed, unfrozen, to a central facility where the samples will be obtained and fixed, et cetera, and the timing of this does not have to be immediate or overnight. Obviously as soon as possible is best. But currently the protocols allow up to about five days or so for shipping of the whole placenta and cord.

Also, the sites should have mechanisms for obtaining samples from placentas that are sent to pathology, so, we can't ship the whole specimen. But it's not necessary to include the capability for local sectioning or fixing at each Study site.

Next Question: will BIA, bioelectric impedance analysis machines be provided to the sites or does this expense need to be included in the proposed budget?

To the extent that these will be included in the protocol, the equipment will be provided by the coordinating center and does not need to be included in the proposal.

According to the RFP, the ultrasound, the prenatal ultrasounds, must be done by ACI, it's American College of Radiology, certified sonographer, but ACR only certifies institutions, not individuals. Would experienced sonographers or obstetricians be sufficient to provide the ultrasounds for the Study?

To be honest, we've been operating under the assumption that there was individual certification and also that obstetricians either had de facto or de jure certification. But I think this requires a little further clarification by us. And we will respond in one of the amendments more specifically.

Another ultrasound question. Should Study centers budget for interpretation of prenatal ultrasounds? Will the interpretation be performed at the coordinating center; and, if so, how will the results be returned to the Study centers?

Just briefly to go over how the ultrasounds will work, and I think this will answer those questions. There are two basic types of ultrasound. The first is the early, or first-trimester, ultrasound for estimation of gestational age or dating. And there are two options for that. The first is, if a woman has had or will have a scheduled clinical ultrasound done within essentially the first trimester, the site can obtain, or the center can obtain, either the crown rump length or the gestational age estimate from the clinical site, if this scan has been in the specified time frame and obviously gets

permission from the woman, no interpretation is needed for that.

If there are no clinical scans scheduled, then a scan will be performed under the purview of the center. And that's just for crown rump length will be measured at the time of the scan,and again, no additional interpretation should be necessary.

For the subsequent ultrasounds, the second and third trimester scans, those are for fetal growth, and the intent is for those to be basic measurements, as specified in the RFP. The technician or obstetrician will make and record those measurements specified in the protocol. The images will be saved and sent to the repository or some such place, but not routinely read. So, again, no further interpretation, other than those specific measurements, are needed.

A question regarding printed materials. What printed materials will be provided for use of this Study? This information will help us identify printing costs for promotion of the study and materials for the participants, et cetera.

I think essentially there can be zero printing costs needed at the center. The recruitment items will be provided by the coordinating center and the participant data collection items, such as self-administered questionnaires, instructions for self-collection of environmental or biospecimen collections and the like will be provided by the coordinating center, as will pamphlets for hospitals, participants, and other healthcare professionals, and other community organizations.

Here is another question rolling in right off the press. What is the time frame for processing hospital collected refrigerated frozen specimens? Is it the same as the clinics, i.e., two hours?

Yes, two hours. Thank you. And that's it for me.

DR. JEFF EVANS: Thanks so much, Ken. Now, if we can return to our panel. Let's go right down the row. Liz,

ELIZABETH OSINSKI: Okay.

DR. JEFF EVANS: -- do you have some questions and answers?

ELIZABETH OSINSKI: Yeah. I just have a few here.

Is there any benefit to submitting a number of Locations through the same academic institution?

This is up to the offeror. Many offerors do this. Yes, there could be some

benefit to this. And we would let you make that decision. But, yes, this is very typical. And we would need a separate Location proposal from the same academic institution and there could be a benefit.

PETER SCHEIDT: Let me add to that, Liz. We encourage that.

ELIZABETH OSINSKI: Oh, okay. There is a benefit, excuse me. Okay.

DR. SCHEIDT: For efficiency purposes. And, as you can see, if we're planning on approximately 40 centers and there are 105 Locations, it's clear that we anticipate several Locations per center on the average. And, so, where that's appropriate we encourage it.

ELIZABETH OSINSKI: I agree. But, again, I want to clarify, there's no separate center proposal.

DR. SCHEIDT: Correct.

ELIZABETH OSINSKI: It's a Location proposal with a center component, even if it is the same academic institution and the same center. Because I'm still getting these same questions. Okay. Thank you, Peter.

The other question is: Is a separate letter of response required for each Location or just by the Study center incorporating the Study Locations?

Again, if you're talking about the proposal intent response sheet, it's for each Location separately, not for a study center that might be included in several Location proposals. So, please submit separate proposals for each Location and separate intent response sheets with all your investigators for each Location. Thank you.

And the second page of that intent response sheet is very important, because –in structuring our review panel, we must screen it for conflicts of interest. So, we need to know relationships in advance.

I will now go back to a question on subcontracting and I want to clarify a response. The question was: Are subcontractors considered different Locations? The answer is, no, and not yes. Now, separate proposals, subcontractors, as you'll see in the RFP, does have to list all of its costs. And it can be submitted with the prime contractor's proposal for that Location. Or sometimes they come in separately, if you're dealing with commercial firms that don't want the primes to know their overhead rates, fees, et cetera. So, the answer is this, subcontractors are not considered different

Locations. Each of them do have to have a business break down of their subcontract. Many times that's part of the prime contractor's proposal for that Location. It could be a separate subcontract or proposal if that's the way you and your subcontractor deal. And that happens a lot of times in the commercial environment.

The other thing is about subcontractors. Please clarify whether the business proposal would include a section on all subcontractors being proposed with all the required justifications. Again, I think I've answered it, but the prime business proposal for each Location, whether or not they got the whole business proposal from their sub and submitted it with their prime proposal, they definitely have to list the dollar total amount in their prime Location proposal. So, again, I hope I've answered that. If not, we'll clarify it in the amendment.

The other question relates to subcontractors and subcontracting plans. That means small business subcontracting plans. Are there separate applications per each separate subcontracting plans per subcontractors? This is it. The prime subcontractor, if you're in the competitive range -- I don't want to spend a lot of time on this -- does propose a small business subcontracting plan during negotiations. For each sub they have over $550,000, the prime gets a subcontracting small business proposal from that sub submitted to them.

Again, we'll clarify this more, but this is not submitted. The small business subcontracting plans are not submitted with initial proposals. As Fred said, they're submitted after you're in the competitive range. And we'll help you on that later. Thank you.

DR. JEFF EVANS: Well, thanks, Liz.

ELIZABETH OSINSKI: Okay.

DR. JEFF EVANS: And I just want to remind people that the last cutoff for questions is at 3:45. So, do keep that in mind. It's coming up.

So, Fred, do you have any extra questions?

MR. ETTEHADIEH: I do have a couple of them.

DR. JEFF EVANS: Okay. Please.

MR. ETTEHADIEH: So, I'll start with number one.

Can you comment on what NIH expects to be a reasonable range for funding

requested over five years to meet the requirements of the contract?

What I ask you to take a look at the FedBizOpps and you may find information about last year's awards. The award information is listed on FedBizOpps. And you may search the FedBizOpps under the National Children's Study Centers 2007 and you will find that information, as far as the contractor's name, the total amount of the award. The information of the period of performance of the contract is archived on FedBizOpps. And as Jeff was saying, it was memorialized.

The estimate of effort is a point of reference as a guidance that you may look at. And that was, as Ruth and others have already mentioned, that is a -- for informational purposes and for planning your proposal, please do utilize estimate of effort by calendar year. It's available on the Federal Business Opportunities on RFP. And that's another way of preparing your business proposal.

The second question, clarification is needed about negotiation with subcontractors. What level of negotiation can be anticipated between NICHD and a subcontractor for competitive applications?

We are in the environment of request for proposal. We are asking the potential offerors to submit proposals. And it is up to the offeror to decide if they want to perform their requirement on their own, or they want to include subcontractors to accomplish the requirement of the statement of work.

The answer ,d also the answer to the other part of the question concerning the negotiation between the NICHD and the subcontractors, is: There will not be any negotiation between NICHD and the subcontractors. The discussions and the negotiations between the contracts office at NICHD will be with the prime, not with the subcontractor. The subcontractor is a responsibility of the prime. And the negotiation and any questions will be directed to the prime, not to the subcontractor.

DR. JEFF EVANS: Okay. Let's move on down to Dr. Scheidt.

DR. SCHEIDT: Good. I have several questions -- some very good questions that get to the heart of several important issues. So, let me start off with a question that asks: For the development of multiple option applications by a center, do you encourage the use of already negotiated field implementation approaches, provided necessary adaptation, although it may be repetitive in proposals that are going to be

evaluated independently?

First of all, let me dispense with the option term. It is a contract term that has very specific meaning and technically from a contract standpoint we are not using options. But I don't think that's what the questioner means here. The questioner means, when proposing more than one Location -- and they're calling them options -- let's just call them more than one Location, how about the use of their field approaches repetitively in those more than one Locations?

My response is that it may be appropriate to use the same field approaches to the extent that the Locations have the same characteristics. But the Locations are usually very different. In fact, it was the recognition of how one county or Location is different from another that led us to use the regional center approach in carrying out this Study. Failure to recognize those differences and the different approaches necessary to carry out this Study is a big problem for those who fail to do this.

Understanding the unique differences is extremely important. If one wants to use the same approaches, I would recommend justifying that strategy with establishing that the different Locations are, in fact, sufficiently similar to justify it.

I would even go so far to say that applying cookie-cutter approaches for different counties without justifying how these approaches are applicable in spite of the differences between the counties is at your peril. So, I hope that's helpful.

Second question is: Should travel be funded for the principal investigators to attend steering committee meetings? Yes. That should be included -- the necessary travel should be included in the proposals and the guidelines are provided for that.

Another question is: The RFP states that it should be a goal of awardees to form collaborations to foster the mission of the National Children's Study? Is this a general statement or are there specific recommendations to address this?

First of all, this is a general statement, but we are serious in making the statement. In my presentation where I presented the sampling strategy, I pointed out how challenging it is to take a scientifically generated representative sample and ask separate academic or other institutions around the country to do the work in those primary sampling units.

There may be many instances where those sampling units are not a

convenient Location, or for one reason or another, the institution would not otherwise have chosen to do the work there. That presents a major challenge, and the encouragement to use collaborations, partnerships, subcontracts to address this challenge is made in order to address this challenge. –In the instance in which a center is proposing to do the work in a county that is remote from that center, where they have no on-going community relationships and work going on in that county and that county does not have the research capability to carry out such a study, the Center may find it useful, rather than to create that capability de novo to instead partner with a health department in the county, or an HMO, or some entity that can complement the research expertise of the center. However, those linkages need to be clear and the mechanisms by which the supervision and coordination are carried out need to be clear as well. I hope that's helpful.

Another question: Do Locations, including multiple counties, require additional community advisory boards compared to the Locations with one county?

That would depend on the circumstances. Where the counties are cohesive, the sociodemographics are sufficiently similar, and there's an identity that crosses the counties, it may make sense to do that. Where the counties are different it may not make sense to do that. A careful examination of these kinds of factors would need to be considered to provide the answer to that question. So, the answer is: It depends.

Another question is: If the former designation of base and option sites are now required to be submitted separately, then doesn't this preclude the benefit of the Study center site?

And the answer's: No, it doesn't preclude the benefit of the Study center site. In our view and how this National Children's Study will be managed, the Study center is equally important under this procurement and this RFP as it was with the Vanguard or with the Wave 1 Centers. We see the role as the same and there should be no difference. The structural difference in this RFP is implemented to clarify the independent competition for awards strictly for the purpose of this procurement. But the roles of the center and the Locations where the Study will be carried out are the same as they were with our previous RFPs.

DR. JEFF EVANS: Ruth, take it.

DR. BRENNER: I'm going to start with this question: How many of the Wave 1 awards are Study centers, as opposed to Locations?

In Wave 1 there are currently 24 centers that are overseeing data collections in 34 Locations.

I have a series of questions that I think are related, so, I think I'm going to read all three of them and then try to provide a single answer.

Our consortium was awarded two counties in Wave 1. We plan to submit two proposals for two additional counties. We anticipate working with the same Study center leadership team. However, specific roles may be different for these two new proposals. Is it acceptable to have another member of the Study center leadership team as PI on these additional proposals, or is it expected that the Study center PI will remain the same as in Wave 1?

And second question: Since one center can apply for multiple Locations, is the center PI considered the PI of the proposal, or is the Location PI considered the PI of the proposal? Can each Location have a different PI?

And, again, the third related question: If a Study Location is working through a center, who is the PI of the proposal? Does the Study Location PI CV go in as well?

So, I'm going to group all of those and talk about the PI for these proposals. Again, for the purposes of this procurement, you should view these as independent proposals. And they require independent supporting documentation. So, the only requirement for a PI is that the PI must be employed by the primary contractor, whoever the primary organization is, that is offering this proposal. Beyond that it's up to you to determine which -- who to assign as a PI to best support your proposal. So, I don't know if anybody wants to clarify that. That would be my recommendation.

DR. SCHEIDT: You may have to have a bowl off.

DR. BRENNER: Right. So, we have required that for named personnel you include a biosketch according to the NIH format. And what we ask for was an abbreviated CV for the named PI. So, it's up to you who to name as the PI. The purpose of the abbreviated CV was to allow some additional flexibility in providing support for the expertise that the PI is bringing to the project, for each particular proposal. So, I hope that clarifies both the PI and the biosketch versus CV issue.

One clarification that I wanted to make was that we are talking a lot about not having options, which is in general true. You submit an independent proposal for each Location. There is the one exception of Harris County. So, I just wanted to put that out there, that, again, Harris County is the one exception where we are requiring an option to be submitted along with the main proposal.

One other question that I will read, but I don't have an answer at this time is: Can an exception region -- they are talking about the regions where the birth enrollment requirements are reduced, budget and plan to enroll more than 150 mothers per year, if the applicant personnel believe that this is possible?

And I will need to talk to our sampling statisticians to give you an answer to that one.

DR. SCHEIDT: I've got another question. How many steering committee meetings per year?

The full steering committee, which is comprised of the principal investigators and other representatives from the Program Office and the Interagency Coordinating Committee at least one meeting per year as a full steering committee. However, there is an executive steering committee that the PIs will participate in on a rotating basis that will meet more frequently.

DR. JEFF EVANS: Okay. Let me just remind folks that we're closing in on the 3:45 cutoff for questions, so, fire them up. While the panel's considering answers to further questions, let me invite Ken Schoendorf to come up and answer one that he's got.

KEN SCHOENDORF: Okay. It's actually several, which means, I guess, I didn't answer them properly the first time.

The first one is: It was mentioned that placentas can sit up for up to five days, which it seems like a long time. Will a subset undergo more immediate processing needs -- more immediate processing is needed for proteomics, gene expression, or infectious needs, and can we budget for that?

What I described was the the core protocol that's put forth in the RFP. The other issues that were raised here might certainly be important, but at this time period at least some would be considered as adjunct studies, and as was mentioned

previously, really should not be part of this proposal.

Are the vaginal swabs collected at the third trimester clinical exam self-collected or done by the clinic staff?

These are vaginal swabs that are self-collected. They're not cervical swabs so, they're self-collected.

Is a digital ultrasound required for the first-trimester scan? I'm assuming by "digital ultrasound" it means storage of the image that can be shipped elsewhere. For the first trimester scan, no, it is not required. It will certainly be accepted and stored, if possible, but it is not a requirement. And, again, remember that for some of the first trimester scans the Study will actually not be scanning, but just collecting the information of previous scans or scans already done in a clinical setting.

The next one isn't really a question, but it's an important issue to consider, so, I will address it here. And it follows, again, on a previous question. If a second or third trimester ultrasound is obtained specifically for the study, ethically it should be interpreted and then the results provided to the OB of record to guide care. This would need to be reimbursed.

For the purposes of the proposals, my previous answer really stands. However, it's important to recognize that there are protocols that are developed for communication with the obstetricians of record if, in fact, the woman has an obstetrician of record, and also in case there are abnormalities visualized at the time of the scan. Those protocols are being developed centrally here. They'll need to be tailored, most likely, at each individual site, depending on the circumstances of the population of the site, the healthcare system, et cetera. The RFP, though, does include the ability or a plan to refer individuals with abnormalities or other issues identified as part of the Study. And, so, I think that's sufficient for the purposes of the proposal. And that's all I have.

DR. JEFF EVANS: Thanks, Ken. We have a few more questions back to the panel. And, again, I'll remind you that the -- we're getting real close to the 3:45 cutoff date for additional questions. So, let me go back to the panel. And who's first up? Peter.

DR. SCHEIDT: This is Peter, because I'm not on the screen. I'll clarify the previous answer I gave about the number of steering committee meetings. I assume

that was asked also for the purpose of projecting travel. And the specific guidance for projecting travel is in the RFP under Number 6 on Page 2, meetings. And it specifies the travel requirements and, so, I'll leave it at that. I won't get into those details.

DR. JEFF EVANS: Fred, did you have one?

MR. ETTEHADIEH: Yeah. I have a couple.

DR. JEFF EVANS: Okay.

MR. ETTEHADIEH: Well, for Wave 2, what start date do you want us to use on the Excel spreadsheet project, September 26 or September 29?

My response to that is: For business proposal purposes, use September 26, 2008.

Do we have to provide verification of expenses at the time we submit our proposals? Such expenses would be salaries, supplies, travel, et cetera.

The response to this question is: Yes, this solicitation is not a just-in-time solicitation. So, other than this small business subcontracting plan, which is going to be required to be submitted only from the offerors who are going to be in competitive range. The technical and also the business proposal have to be complete packages. Of course, during the discussions with the offerors, who are going to be in competitive range, the contracting office will request additional information for support of the offeror's proposal.

But, again, to answer this question: The proposal has to provide justification, supporting documentation to provide the government enough information to be able to support the business proposal. So, expenses, such as salary, supplies, travel, other direct costs do require supporting documentation. An example of supporting documentation for salary would be the -- the staff salary documentation. An example for supplies would be quotes, catalogs, things of that nature. That's it.

DR. JEFF EVANS: Okay. Thanks, Fred.

MR. ETTEHADIEH: Thank you.

DR. JEFF EVANS: Liz, I see you studying something.

ELIZABETH OSINSKI: Okay. I just have one here. Can an institution applying as an NCS Study Location, but not as a center, subcontract with other potential sites; or should all subcontracts be handled by the institution submitting the NCS center

proposal?

Again, each proposal is by Location. And I really want to try to emphasize, this RFP is not the same as proposed last year. And what you have to do is propose a Location proposal and then have a center part of that proposal. And you can propose more than one Location proposal. A prime contractor can subcontract with whoever they would like to propose as part of this Location proposal. Thank you.

DR. JEFF EVANS: Okay. Back to Fred.

MR. ETTEHADIEH: I have one question. What percent inflation rate increase is allowable for budgeting each year? In past submissions two percent was used, but in reality consumers price index is increasing by 3.8 percent. Is a 3 percent inflation rate allowable for this submission?

I believe what was used last year was -- and my answer to that is: I believe the percentage that was used, which is identified in this question, is, indeed, two percent. However, I cannot provide a specific figure at this forum. So, this will be addressed in our amendment and it will be issued to the RFP.

DR. JEFF EVANS: Okay. Pete, I see you have some.

DR. SCHEIDT: Yes, I have several more.

This question addresses: To what extent is it anticipated that centers will be able to support the contributions of expert investigators at the center?

Scientific expertise will to some extent be needed to carry out elements of the protocol, and of course provide supervision and scientific input. That is relatively limited, but needed.

Scientific expertise is needed from various disciplines for on-going science development of the Study as a whole for protocol development as the cohort moves forward, et cetera. That is needed to some extent, but only to a limited extent. We do not have the funds to support large numbers of investigators at significant portions of their salary at all of the centers. We have found that it's useful to have named scientists who are available for input as needed. But the sum total of what's needed is relatively limited for each Center, generally something less than a full-time equivalent from the pooled number of individuals that might be available. However, we do look forward to obtaining that input. We are in the process of developing the scientific working groups,

teams and committees that will contribute to the science of the Study as it goes forward. But funds are quite limited for this activity at each Center. This is not a sort of faculty-support program for all of these institutions.

DR. JEFF EVANS: Pete, could I just interrupt just for a second.

DR. SCHEIDT: Yes.

DR. JEFF EVANS: I just want to point out that the question cutoff period has arrived. So, please follow the procedures of -- in the RFP for asking additional questions. So, don't try to send us anymore after this time.

So, sorry to interrupt you, Pete, but, go ahead, please continue.

DR. SCHEIDT: No, that's fine. No. Go ahead.

DR. BRENNER: Okay.

DR. SCHEIDT: That's all.

DR. JEFF EVANS: Okay. Ruth, are you considering something?

DR. BRENNER: I have a few more. It's still unclear, is the center PI or the Location PI the PI?

Again, for the purpose of this procurement, this is left up to the offeror. In general, historically, it's been the center PI that's been named as the PI on the proposal. And I don't know if either of you want to add to that.

DR. SCHEIDT: Yes, for the purposes of the composition of the steering committee and as chair of the steering committee, I will say that it is the center PI who will be asked to represent the center on the steering committee for the respective Locations as well that are part of that center.

DR. BRENNER: Do you want abbreviated CVs for the Location PI or just the center PI? Just for the named PI on the proposal. Right now there is one named PI on the proposal. So, in general that's been the center PI, but that's left up to the offerors.

Next are similar questions, should the proposal be submitted by the academic institution of the Location PI or the center PI if there are two different academic institutions involved, one for the Study center, another for the Study Location?

Again, the organizational structure that you use in your proposal is left up to you. But there is one principal investigator that should be named on the proposal.

DR. JEFF EVANS: Okay. Liz or Fred, do you have any additional questions

that you want to answer?

ELIZABETH OSINSKI: No.

DR. JEFF EVANS: Okay.

ELIZABETH OSINSKI: There are some questions; a few that we will be answering in the amendment. Fred has a few right now.

MR. ETTEHADIEH: I have one.

DR. JEFF EVANS: Okay. Fred.

MR. ETTEHADIEH: I have one. I just want to clarify that we must include copies of catalog packages, quotes, et cetera, with the business proposal. And this is the question.

And the answer to the question is: Yes, this is not a just-in-time solicitation. We're expecting the business proposals to be complete. Because as I mentioned in my presentation earlier, that the contracting officer may award the contracts without further discussions, without considered discussions. So, we are expecting your packages to be complete. And the information that they're referring in these questions, the catalog price -- the catalog packages, quotes, are in support of the costs that they're proposing. So, however, they want to support the costs that they are identifying, that's the information that is required to be submitted on the date of the submission of the proposal, which is May 2, 2008.

DR. JEFF EVANS: Okay. That's got it. Well, let me just say this; I want to recognize some people who have really contributed to this. Jim Hollahan is a wonderful producer. He made this thing really work out well. And behind the scenes, Howard Cyrus and Sarah Keim have been just wonderful as question sorters. And Beth Davis and Deb Blackshear have gotten the questions to the right people. And Barbara Worth and Darcie Smith, have just provided wonderful technical assistance. So, it's been a tremendous effort here that's been delightful for me to do this.

Let me invite the panel now to, you know, step back. You want to recant any of your answers? Do you want to clarify? Do you have any kind of closing comments? Does anybody want to step forward? Peter, I see you.

DR. SCHEIDT: My closing comment is to welcome you to the National Children's Study, encourage offerors to seriously propose to join us in this wonderful

work of carrying out one of the most exciting projects and gifts to our children that we are likely to ever have the opportunity to do. We very much look forward to working together to complete and move forward with the National Children's Study. Thank you for joining us.

DR. JEFF EVANS: Tremendous. Anyone else?

Okay. Well, then, let me just say, good luck to all of you. I know this is a competitive process. And I know that there are just tremendous amount of talent out there. So, good luck. And from NICHD, goodbye. Thank you.

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

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Cindy Ziker, University of Arizona
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Judith Aguirre, University of California, Irvine

Cheryl Herrera, University of California, Irvine
Tina Bottini, University of Florida
Mark Hudak, University of Florida, Jacksonville
Stephanie Townsell, University of Illinois at Chicago School of Public Health
Dan Benton, University of Iowa
Nancy Davin, University of Iowa
James Leaven, University of Iowa
Jeff Murray, University of Iowa
Caroline Chan, University of Louisville
Debbie Davis, University of Louisville
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Irma Ramos, University of Louisville
David Tollerud, University of Louisville
Onesky Aupont, University of Massachusetts
James Fain, University of Massachusetts
Jeanne Leffefrs, University of Massachusetts
Carla Pizzarella, University of Massachusetts
Michelle Plaud, University of Massachusetts
Sharon Sousa, University of Massachusetts
Margie Jimenez, University of Miami
Traci Miller, University of Miami
Jill Tincher, University of Miami
Catherine Wright, University of Miami
Kirsten Alcser, University of Michigan
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Angelic Howell, University of Mississippi Medical Center
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Carol Gibbons, University of Missouri
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Tracey Turner, University of Missouri
Nancy Dole, University of North Carolina, Chapel Hill
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Rebecca Rowley, University of Rochester
Shanna Swan, University of Rochester
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Shelisa Dalton, University of Utah
Jan Johnson, University of Utah
Rebecca Ourzts, University of Utah
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Patricia Butterfield, Washington State University
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Judy Mitchell, Washington State University
Valeria Cook, Wayne State University
William Lyman, Wayne State University
Nada McIntyre, Wayne State University
Adrienne Hoey, Yale University
Lisbet Lundsberg, Yale University