

**WORLD TRADE CENTER HEALTH PROGRAM  
SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE (STAC) MEETING  
March 22, 2016**

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**THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
CENTERS FOR DISEASE CONTROL AND PREVENTION  
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
WORLD TRADE CENTER HEALTH PROGRAM**

**EIGHTH MEETING**

**SCIENTIFIC/TECHNICAL ADVISORY  
COMMITTEE (STAC) MEETING**

March 22, 2016

The verbatim transcript of the  
Meeting of the Scientific/Technical Advisory  
Committee Meeting held on March  
22, 2016, 10:00 a.m.

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**PARTICIPANTS**

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THOMAS ALDRICH - COMMITTEE MEMBER  
ROSEMARIE BOWLER - COMMITTEE MEMBER  
BARBARA CAPORALE - PUBLIC COMMENT  
ANTHONY FLAMMIA - COMMITTEE MEMBER  
KIMBERLY FLYNN - PUBLIC COMMENT  
ROBERT HARRISON, MD - COMMITTEE MEMBER  
GREGORY HOMISH, PhD - COMMITTEE MEMBER  
JOHN HOWARD, MD - PROGRAM ADMINISTRATOR  
CATHERINE McVAY HUGHES - COMMITTEE MEMBER  
MARIAMA JAMES - PUBLIC COMMENT  
VAYLATEENA JONES - COMMITTEE MEMBER  
RACHEL LIDOV - PUBLIC COMMENT  
MICHAEL McCRAWLEY - COMMITTEE MEMBER  
ANNYCE MAYER, PhD - COMMITTEE MEMBER  
STEVEN MARKOWITZ, MD - COMMITTEE MEMBER  
GUILLE MEJIA - COMMITTEE MEMBER  
PAUL J. MIDDENDORF, PhD - DESIGNATED FEDERAL OFFICIAL  
LILA NORDSTROM - COMMITTEE MEMBER  
WILLIAM ROM - COMMITTEE MEMBER  
MARGARET RYAN - COMMITTEE MEMBER  
GLENN TALASKA, PHD - COMMITTEE MEMBER  
ELIZABETH WARD, PhD - COMMITTEE CHAIR-PERSON

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**WELCOME AND INTRODUCTION**

DR. MIDDENDORF: Good afternoon. I am Paul Middendorf. I am the designated federal official for the World Trade Center Scientific/Technical Advisory Committee. I'd like to extend a warm welcome to the committee members and the members of the public who are on the phone with us. We very much appreciate your interest in these proceedings. I need to go through a number of administrative issues here (inaudible @ 00:03:38) before we get into the meeting. First, I need to point out that we have three new members and one member who is returning to us after a short hiatus. I'd like to welcome Annyce Mayer, Margaret Ryan, and Greg Homish to the committee and also re-welcome Guille Mejia. I'm looking forward to working with each of you over the next few years, along with the other members of the committee.

Since we're talking about the committee members, I'll remind you that we currently have an announcement out soliciting for new members for next year. That announcement is available on the committee's website for anyone who is interested. If you are interested in nominating someone, including yourself, please visit the committee's website to find the information on how to nominate someone. The solicitation is open until March 31.

For those of you who have signed up to provide public comments, those are scheduled to begin at 1:30 this afternoon and that's Eastern Time. For our public commenters, your phone is muted until it's your turn to comment. At that time, the operator will unmute your phone and you can provide your comments at that time. When your comments are finished, your phone will be muted again.

It's important for us all to remember why we're here and to set the appropriate tone for the meeting, so let's just spend a few moments in silence to remember those who were killed in the attacks on 9/11, those responders and survivors who have since died because of those attacks, and also those who have died in other terrorist attacks around the world, including those who were killed in the Brussels attacks this morning.

[Moment of silence.]

Okay, thank you. Let's go into our roll call now, and for our roll call, I'll call out the name of each member and ask you to let me know that you're on the line. Just as a reminder, if a member needs to leave the call, please let me know when you leave and when you return so I can be certain that we continue to have a quorum. In addition to whether you're present or not, I'll ask you to state whether or not there have been any changes in your employment or other interests that would affect your conflict of interest statements. And lastly, I just want to be sure that you can access the website so let me know that too. So there are three things I'm asking you to tell me. First off, that you're present, secondly, whether or not there have been any changes to your conflict of interest statement, and then if you're able to access the website. Let's start in. Tom Aldrich?

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DR. ALDRICH: Yes, I'm present, and I have no changes in my employment or other interests that would affect conflict of interest, and I can access the website.

DR. MIDDENDORF: Okay. Rosemarie Bowler?

DR. BOWLER: I'm present. I've had no changes in employment or conflicts of interest.

DR. MIDDENDORF: Okay, are you able to see the website?

DR. BOWLER: Oh, I'm supposed to—this is the first time I'm on one of your calls like that. Am I supposed to have the website open?

DR. MIDDENDORF: It would be much easier for you because we'll be using that as our workspace as we craft changes to any of the recommendations.

DR. BOWLER: All right. You can certainly go on and I'll try to access the website.

DR. MIDDENDORF: Okay. Anthony Flammia?

MR. FLAMMIA: Anthony is present, there are no changes, and I can access the website.

DR. MIDDENDORF: Great. Bob Harrison? Okay, apparently not present. So Greg Homish?

DR. HOMISH: Present and I have no changes as they relate to my conflicts of interest and I'm able to access the website.

DR. MIDDENDORF: Great. Catherine?

MS. McVAY-HUGHES: Here and I have accessed the website and no changes and you should have received the form. Thanks.

DR. MIDDENDORF: Okay. Vaylateena Jones?

MS. JONES: Present, I can access the website, and no changes in employment.

DR. MIDDENDORF: Okay. Steven Markowitz?

DR. MARKOWITZ: I'm here. No changes. I'm on my laptop actually at the NIOSH headquarters in Washington but my laptop's not cooperating. I'll work on it but you should continue.

DR. MIDDENDORF: Okay. Annyce Mayer?

DR. MAYER: Present, I have no changes, and I am viewing the website.

DR. MIDDENDORF: Great. Mike McCawley? Mike, I'm seeing you on the website. Are you not dialed into the speaker line? If not, you may want to check your emails. I sent you the information on the passcode for the speaker line and I'll come back to you in a minute. Guille Mejia?

MS. MEJIA: Present, I have no changes, and I do have access to the website.

DR. MIDDENDORF: Great. Lila Nordstrom?

MS. NORDSTROM: Present, no changes, and I'm on the website, yes.

DR. MIDDENDORF: Great. Bill Rom?

DR. ROM: Yes, I'm present, no changes in conflict of interest, and yes, I'm on the website.

DR. MIDDENDORF: Okay. Margaret Ryan?

DR. RYAN: Yes, I'm present, no changes, and I'm on the website.

DR. MIDDENDORF: And Margaret, while I'm speaking with you, did I hear you during the orientation meeting say that you're referred to as Megan?

DR. RYAN: Oh yes, sir. That's (inaudible @ 00:09:24) yes.

DR. MIDDENDORF: Okay, I just want to use whatever is comfortable for you, so thank you. Glenn

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- Talaska?
- DR. TALASKA: Here, I'm on the website, and there are no changes.
- DR. MIDDENDORF: Okay, and Liz Ward?
- DR. WARD: I'm here, no changes, and I can see the website.
- DR. MIDDENDORF: Okay, great. Mike McCawley? Okay, not hearing anything from Mike. We'll assume he's not here, but Mike, if you're hearing this, when you call back in let us know. I just want to remind the committee members that when you begin to speak, just make sure you identify yourself so we can get an accurate transcript and attribute the comments to each of the individuals accurately. And before I turn this over to Dr. Ward, our chair, I'll just remind you about the motions and voting procedures. When a member of the committee is developing a motion, I will type it here so it's visible on the screen, and each of you should each be able to see it, but I'll also read it so that it's into the transcript verbatim. When the chair calls for a vote, I will have to do a roll call vote and will ask each of you in turn to say yes, meaning you are voting for the motion that has been put to the committee; or no, meaning you are voting against the motion that has been put to the committee; or abstain, meaning that you are not voting on the motion. If someone has been recused for a specific motion, I'll note that also. Also remind you that, according to our bylaws, a majority of those voting determines the outcome. So with that, I'll turn it over to you, Liz.
- DR. WARD: Thank you.
- DR. BOWLER: Can I just ask one question—or maybe we're getting it, I'm having someone help me. Sorry, apologize. I should be able to get on there.
- DR. MIDDENDORF: Okay.
- DR. McCAWLEY: Paul? This is Mike McCawley. I am back on the right line now.
- DR. MIDDENDORF: Hey, Mike. Okay, great. And can you see the web?
- DR. McCAWLEY: Yes, I can see the web and I have no changes in my conflict of interest.
- DR. MIDDENDORF: Great, thank you very much.
- DR. WARD: John, would you like to say a few words?
- DR. HOWARD: Sure. This is John Howard. I just wanted to say welcome to everybody, and again, thank you so very, very much for taking time from your busy schedules, all of you, to participate as members of the committee. I want to thank those new members for joining, we welcome you, and thank Guille for coming back to us, thank you very much. And to Liz, who serves as our chair, thank you.
- DR. WARD: Hi, this is Liz. I'll add my welcome, especially to the new members. It will be really delightful to meet you in person, I guess next June, at our in-person meeting in New York.

**PRESENTATION OF CHILDREN'S RESEARCH WORKGROUP REPORT**

- DR. WARD: So I think we can get right to business. The main topic we'll be discussing today is the Children's Research Workgroup report and I'll just give a little bit of background, especially for the new members. We were asked by NIOSH to give

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recommendations regarding research in populations that were children and adolescents and preconception individuals at the time of the 9/11 event. And the committee has had a couple of opportunities to discuss this as well as formed a workgroup, a separate workgroup to develop recommendations in more detail. So a great deal of what you'll see in our recommendations and report is a result of the discussions that we had during our in-person meeting where we brought in experts in pediatric research and in 9/11 exposures and outcomes to discuss with us this very specialized area of research. We also had two workgroup calls. The workgroup has had an opportunity to review this draft report and give comments and everyone has agreed that the report was ready to be presented to the committee.

The charge to the workgroup was really quite broad, it's, "What are the most important physical, psychological, and developmental health outcomes to target and in which groups of children?" And I think as most of the members of the committee recognize, this is a difficult question to answer, particularly at this point in time, because it's quite some time after the initial exposure and therefore we are somewhat limited in what we're able to do, both in terms of identifying populations exposed at young ages and also in terms of characterizing their exposure and characterizing many outcomes that we would be interested looking at such as early childhood developmental outcomes.

So one of the things that we did in this report was essentially, in the introductory material, we really were addressing two issues. One is, is it important to study children and why? And I think one of the things that struck me and many other members of the committee is, you know, when we started research on people who had been exposed to 9/11 in various ways, I don't think anyone realized the extent and the severity of the health effects that were going to be identified in the exposed populations. And so at that point in time, it probably appeared to many that the likelihood of substantial enough exposure to cause health effects in young children might not be that great. I think that our perspective has really changed in a number of ways, and one is that we've seen such significant health effects in older populations.

Secondly, you know, we understand much better the nature, at least—I can't say that no one understood this, but I can say that one of the topics we've discussed a lot on the committee is the unique nature of the neighborhood and the community exposures, and the way children may have been exposed, including continuing to live in contaminated residences, although not all of the children did that. So I think we understand much more about the potential exposures to the children, the potential severity of health effects resulting from World Trade Center exposures, and as we heard about at the last meeting, the unique ways in which children may be more susceptible to environmental exposures and even to psychological exposures. So we did feel it was important to—even though it wasn't specifically

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asked in the charge, we did feel it was important to talk about why we think pediatric research is important and also to talk about what the potential limitations—or it's more than potential, the actual limitations of what can be done now in terms of study designs and outcomes because it's been so long since the event and the exposure.

So what we did is we wrote this fairly long introductory text and then we kind of interweaved specific recommendations within text that gives a little bit more background explaining each of the recommendations. So I think the format is a little unusual, but we want to make—you know, one of the things we want to do on this call is make sure that there's general agreement with the main body of the report and also general agreement on the specific recommendations. We haven't—you know, and I don't know that we would propose to necessarily take a vote on the priority of the recommendations. I will say, at least from my point of view, the first recommendation is kind of a fairly broad, overarching recommendation that pertains specifically to the pediatric population of the World Trade Center Registry, in part because we think that really still is, despite a lot of limitations, it's still, like, the best study population at this point in time to proceed with research. Many of the other recommendations are a little bit more general and they're really designed to be general so that it really gives both the Program and people who might apply for funding in the pediatric research area maximum flexibility to really match what might be a really important research topic with a study design that can be accomplished within a reasonable time frame and an achievable budget. So with that, maybe we should just open for general discussion and reactions on the report.

- DR. MIDDENDORF: Okay, and then just a general reminder that we need to stop at 1:30 so that we can do the public comments. And since Steven was also one of the authors—
- DR. WARD: Right.
- DR. MIDDENDORF: Maybe we ought to give him an opportunity to make any comments he would like to.
- DR. WARD: Yes, thank you. Steve? I think you're still on mute possibly.
- DR. MARKOWITZ: Can you hear me now?
- DR. MIDDENDORF: Yes.
- DR. WARD: Yes. You might want to speak up a little bit more.
- DR. MARKOWITZ: Okay. So I don't have much to add to what Liz said. This is Steven Markowitz. Our recommendations are really a potpourri, not addressing the science in depth because we didn't really have the ability to do that, but a variety of things that we thought would help move the process along.
- DR. WARD: Good. So any comments or reactions or discussion?
- MR. FLAMMIA: Hi, it's Anthony.
- DR. WARD: Hi, Anthony.
- MR. FLAMMIA: Hi. I had recommended some questions be possibly sent out to the population. Is

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- this the correct time to maybe possibly put it into that document from the last meeting?
- DR. WARD: Yes, I mean, those questions were very specific and more along the lines of designing a questionnaire. I don't know that they would necessarily be something that the committee would specifically recommend because they're so specific in relation to a study. But why don't you suggest—why don't you say what your recommendation was and maybe we can talk about it?
- MR. FLAMMIA: Actually, Paul, I'm going to send it to you so you can post.
- DR. MIDDENDORF: Okay, you're going to need to send it to a different email address then because actually I don't have access to it on this computer.,
- DR. WARD: Anthony, I don't think they're that long. We can just—can you read them?
- MR. FLAMMIA: Yes, sure. Give me a second. Basically, I had put it into a written form. Here's a suggestion, if you wanted to identify second generation spousal exposure, cases concerning potential birth injury cases, using FDNY and NYPD as a preliminary focus point for studies, limit it to only males. Once the population is identified, send a questionnaire to them at the last known address that would include: were you a 9/11 first responder or children that lived or worked in, and in parentheses, identify areas, between 9/11/2001 and 6/1/2002, yes or no? If no, do not answer any further questions. If yes to question one, did your spouse/partner become pregnant between 6/1/2001 and 6/1/2002? If yes to question two, did your spouse have a miscarriage with this pregnancy? If yes to question two, did your spouse have complications during her pregnancy? If yes to question two, did your spouse give birth prematurely with this pregnancy? If yes to question one, did your spouse/partner give birth to a child between 9/12/2001 and 12/31/2002? If yes to question two, did the child suffer from a birth defect or other abnormality? That was the email that was sent on January 15.
- DR. WARD: I was looking in the document to see, I thought we had captured somewhere the concept of looking at pregnancies among wives of first responders. So what I tried to do with some comments was to make the general comment, but not necessarily include all the detail, because, you know, there's really complex issues related to the study design. And as an epidemiologist, I guess I'm aware that studies of pregnancy outcomes are particularly difficult to do and often require very large sample sizes. So what we were hoping was to make some general recommendations about what studies would be useful and then let the investigators come in with specific methods and approaches and questions that they would use to try to answer them. We did actually, and I forget if this was from you or from Catherine, but on line 277, we specifically talked about studies of other child cohorts which might include births to from—actually that's a typo there—9/11 responders up to 18 months after 9/11, approximately—
- MR. FLAMMIA: And I'm just thinking, wouldn't it give it better depth when we submit this just to show where we're going with it?

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- DR. WARD: Well, I don't know that this—I guess what I'm saying is, what we tried to put in here were general recommendations that the entire committee could agree on. You know, we haven't debated on the specifics of sending out a questionnaire to that specific population and asking those specific questions. So I think that the comment that I inserted might have been the comment that you sent in response to our request for comments on the document. So I think that was where we addressed your comment.
- DR. MIDDENDORF: I'm wondering if the committee might take these suggested questions and send them off to the Health Registry to see whether or not it's something that they could include in possibly some of their waves or something else. The committee doesn't want to do anything more with it.
- DR. WARD: Or we could, you know—again, if the sense is we should add them more, you know, we could put them as part of the report, but I think that's a really good suggestion, that it might be something that the Registry could include in one of the follow-up waves. So really it's the pleasure of the committee. If you want, we can see if there's an email address, you can send it to Paul, so that the committee can see in writing what the recommendations are. Does anybody want to speak from the committee on...?
- DR. MARKOWITZ: This is Steven Markowitz. I'm wondering, Anthony, if you could read the lines to yourself, lines 279 through 284, and see whether that summarizes and captures what you have in mind.
- DR. WARD: Yes, it probably starts on 277 and goes up to 281, yes.
- MR. FLAMMIA: Yes, I had sent that in. I tried to capture that. I just wanted to give it more depth for when this is submitted and just to give an example of the questions, what we're looking for. I mean, it does capture it somewhat but not the whole thing. The way I'm looking at it.
- DR. TALASKA: What would you suggest to add? This is Glenn.
- DR. RYAN: This is Margaret Ryan. I wonder if I might chime in, just as someone who's done research on congenital anomalies, birth defects in children, really appreciate all these concerns and also echo the concern about it's really difficult to make these questions. So I would just respectfully recommend maybe bullet points on the topic areas rather than trying to frame the questions, because the questions are very difficult to formulate and, you know, as the National Children's Study knows, it's really difficult to address this. So I agree with getting the general concept in, but I would shy away from trying to put in specific questions, over.
- MS. MEJIA: This is Guille. I also agree with Margaret and I like Paul's suggestion that maybe these are questions that could be sent to the Registry as a way to incorporate it into their annual questionnaire.
- DR. WARD: I mean, so one thing we could do is maybe just add—and Margaret, maybe you could help with this—should we be a little bit more specific in this one, between lines 277 and 281? We didn't really talk too much about what outcomes we're

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- concerned about which is what Anthony's questions really address, is looking at miscarriages, birth defects. Is there some language you all could suggest that we could add to this and then we could certainly submit the questions separately?
- DR. RYAN: I agree. I think that that's exactly where to go, with pregnancy losses, congenital anomalies, and perhaps (inaudible @ 00:29:25) disorders as perhaps some of the broad topic areas for the kind of cohort that you're talking about as pregnancies. And then of course when you get to children who were, you know, exposed later, that's a different set of outcomes.
- DR. WARD: So we could say to include outcomes such as pregnancy losses and congenital anomalies.
- MR. FLAMMIA: This is Anthony, if I may.
- DR. WARD: Yes.
- MR. FLAMMIA: Basically the just to look at bullet point, I just basically said complications, miscarriage, premature birth, partner gave birth between a specific date, birth defect, abnormality. There's 17 of these questions.
- DR. MIDDENDORF: Yes, if you and Megan would like to collaborate, pull that together, and send it to Liz so Liz can incorporate it into the workgroup's report then... And it's 1:32.
- DR. WARD: Yes, so I think in concept we're—I think we've got a plan, you know, and I think the idea is we don't have to mention everything as long as the categories are inclusive and maybe Margaret can help with that.
- DR. MIDDENDORF: And she goes by Megan.
- DR. WARD: Megan, sorry. Okay, so let's see if there's any other major comments or concerns about the report.
- DR. MIDDENDORF: Well, I really—
- DR. WARD: Oh, the 1:30, I'm so sorry, I forgot.
- DR. MIDDENDORF: I have to do the public comments at 1:30.
- DR. WARD: No, I just forgot, I just forgot.
- DR. MIDDENDORF: So, you know, when we're done with public comments—
- DR. WARD: Excellent, perfect.
- DR. MIDDENDORF: We'll use that as our marker, that's what we're coming back to.
- DR. WARD: Okay, perfect.

**PUBLIC COMMENTS**

- DR. MIDDENDORF: So we are now starting the public comment portion of the agenda. Each of our public commenters has signed up on a first-come, first-served basis and each of them will have up to five minutes to present. At four minutes into your presentation, I'll just butt in briefly to let you know that you have one minute remaining and make sure that you have the opportunity to make your final point. I also want to point out that you have the option of submitting late comments to the docket of this committee. The docket is number 248-E. Information on how to submit comments is on the NIOSH docket webpage. The last thing to do before beginning the public comments is to make sure the commenters are aware of the

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redaction policy for public comments. The policy is in the Federal Register Notice for this meeting and on the committee's webpage. The policy outlines what information will be kept and what information will be redacted before it's posted to the docket. So with that, operator, if you would let Kimberly Flynn into the call, I would appreciate it.

DR. WARD: (Inaudible @ 00:32:10). You can't access the internet?

DR. MIDDENDORF: Kimberly, are you speaking?

MS. FLYNN: Hello? Yes, can you hear me?

DR. MIDDENDORF: We can hear you so please go ahead.

MS. FLYNN: Oh great, okay. Thank you for the opportunity to speak. I make these comments on behalf of the World Trade Center Health Program Survivors Steering Committee which I chair. We greatly appreciate the work of the Children's Research Group in creating this report. We highlight, however, the urgency of moving forward quickly to enable better research on children before the opportunity to capture information is lost as this population disperses beyond our reach. We agree that research to better understand the physical and mental health impacts of in utero and childhood and adolescent exposures to 9/11 is of high priority. And we agree with the emphasis on physical health, especially given that certain physical health effects with implications for future health remain less well understood. From the beginning, the community has pressed for an assessment of mental and physical health impacts on children. Many of the research needs that STAC has been discussing were raised at a 2011 public hearing, the first that NIOSH held following the passage of Zadroga in 2010. It is clear that the current discussion on children was hampered by the absence of an environmental pediatric expert on the STAC. In order to bear fruit, these discussions must continue with this expertise at the table. A pediatrician should be appointed to the STAC in the environmental health specialist slot. The steering committee plans to nominate someone highly qualified.

Survivors Steering welcomes the recent STAC focus on children in the spirit of better late than never. Whether these discussions will lead to a just-in-time intervention depends entirely on whether NIOSH is willing to devote the attention and especially to commit the resources required to address the research needs of those exposed as children. On February 12, 2016, NIOSH issued a funding opportunity announcement, or FOA, that sets out the requirements for research proposals for the next five years. The FOA includes a new area of interest, quote, "Characterizing alterations in health and development for those exposed to 9/11 as children," close quote, which we applaud. However, we find it unfortunate that this announcement was released before the STAC could issue its recommendations. NIOSH has stated to us that the funding distribution in the FOA is appropriate to a maturing research portfolio. It is clear to us and to the STAC that especially with regard to children's post-9/11 physical health, we do not

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have a maturing research portfolio.

We approached the STAC's recommendations on research direction by dividing them into two columns: those that can be accommodated under the current FOA funding levels and those that cannot. We will start with those that cannot. We strongly endorse the more ambitious recommendations for a coordinated research consortium, for an NHANES type study that would follow a cohort of those exposed as children longitudinally; for creation of a blood bank to preserve specimens for analysis by techniques that become available in the future. We ask that NIOSH explain what funding outside of the current FOA could be made available for these pressing projects.

In the other column are projects that can operate under the FOA. The priority should be to fund follow-on studies to research already under way. Given that some of these projects are at an earlier stage of development and have ongoing recruiting needs, researchers should be able to include in their proposals a justification for a larger award amount. Smaller scale efforts should include the feasibility studies exploring the creation of other child cohorts. Of the highest importance, given the limited resources and the limited WTC Health Registry pediatric cohort, are workgroup recommendations that researchers join forces to collaborate to avoid duplicating research efforts and risking exhaustion of the cohort. Under the current FOA, we endorse a coordinated approach with a limited number of researchers with demonstrated expertise who are highly credible in their respective research areas and who have the trust and cooperation of the community.

DR. MIDDENDORF: One more minute, Kimberly.

MS. FLYNN: Researchers who study the 9/11 responder population are working on ways to collaborate and share their respective cohorts. The expanded pool of subjects will lead to better research and stronger findings, as well as conserve the cohort. This approach also offers the best way to study complex comorbidities. For child study, the Health Registry and NIOSH should encourage, incentivize, and coordinate collaborative research using the Registry child cohort, a critical resource that, despite its limitations, must be conserved. Because the Registry is known to enrollee families, it is important that the Registry plays a key role in the recruitment effort for external researchers.

And I'm just going to skip to a final recommendation. I'll send in other recommendations in written form. Finally, we strongly support a formal study of what went wrong with respect to research on children and developing a roadmap for the future. We believe the WTC Health Program and its steering committees are in an ideal position to formulate lessons learned into guidelines. Thank you.

DR. MIDDENDORF: Thank you very much, Kimberly. Operator, if you would bring in Rachel Lidov.

Rachel, are you on?

MS. LIDOV: This is Rachel Lidov. Can you hear me?

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DR. MIDDENDORF: Yes, we can. Please go ahead.

MS. LIDOV: I am representing Concerned Stuyvesant Community. As the parent of a 16-year-old who was exposed to the WTC disaster at Stuyvesant High School on 9/11, I can say that for the past 14 years we have been advocating for an assessment of how all children in Lower Manhattan have been affected physically (and mentally @ 00:38:27) by the disaster. Many state and federal agencies whose first goal was to get Lower Manhattan back to work worked lock in step to deny the dangers of the dust and smoke, even for children. In the days and months after 9/11, they refused to protect our children from preventable exposures, especially indoor exposures. They quite simply did not want to know, but how could we not? Parents reported that their children were coughing themselves to sleep at night. Our early demands for a screening program for our kids fell on deaf ears. As we joined forces with parents in nearby schools to repeat our demand and urge the need for clinical studies of physical health, nothing changed. The first study looking at physical health impacts to children living or attending school downtown was published in 2004 by Dr. Tony Szema. He analyzed the medical records of kids being treated for asthma at the Charles B. Wang Clinic and he found clinical deterioration. The next study by the WTC Health Registry from its pediatric survey was not published until 2008. We learned then that the new-onset asthma rates had soared among Downtown residents and school children who were under the age of five on 9/11. By the time the Zadroga Act passed in 2010, despite these earlier findings, there were no further studies. Even after NIOSH took charge of the Health Program and research, there was still no attention to the yawning gaps in knowledge about physical health impacts. NIOSH told us to recruit pediatric researchers. The Pediatric Environmental Specialty Unit now might have been a place to look, but after 9/11, they put out so-called fact sheets that echoed the full safety assurances issued earlier by the EPA. In doing so they had disqualified themselves in our eyes from involvement in the research. In 2011, pediatrician and researcher Dr. Leo Trasande joined the WTC Pediatric Program. After treating sick kids, he was able to generate some strong hypotheses which he shared with the Survivors Steering Committee. When he applied for funding and didn't get it, we learned that NIOSH had no pediatric expertise on its peer review panel. More egregious, it dawned on us that the lack of baseline information on the level of certain long-lived chemicals in children's blood was held against him by reviewers, but since no clinical studies had been done on the physical health impacts right after 9/11, such an expectation was completely unacceptable. We, as parents, rejected this reasoning utterly. So did the Survivors Steering Committee and the three Lower Manhattan Community Boards. While we were pressing NIOSH for a more appropriate review process, Dr. Trasande completed a successful pilot study on the WTC pediatric clinic

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population and is now conducting a study on a cohort entirely drawn from the World Trade Center Health Registry.

So let's address how to move forward. If NIOSH is attempting finally to do right by those exposed as children, then the STAC's pediatric discussion must be ongoing. This means that a pediatrician with environmental health expertise must be appointed to the STAC. We appreciate the scope of the STAC workgroup's recommendations. We support having a broad portfolio and even believe longitudinal studies of both mental and physical health are essential, but the current research budget which covers all Zadroga populations is insufficient for such broad, ambitious research recommendations. Hence, there has to be funding allocated immediately because, as the workgroup understands, this population is dispersing rapidly. The youngest are now 14. Finally, we need to— Rachel, you have one more minute.

DR. MIDDENDORF:

MS. LIDOV:

Thank you. We need to capitalize on all our resources. We endorse those researchers who have demonstrated the expertise and capability to study the Registry cohort, and who have the trust and confidence of the community, to continue in their respective research areas. It is incumbent upon them to join forces and collaborate with each other, thereby strengthening the research validity of the findings, while maintaining the cooperation of families enrolled in the Registry. Therefore, we expect both NIOSH and the Registry to encourage this approach. It is not only in the best interest of the cohort, but in the best interest of those who lived through 9/11 as children and adolescents. Thank you for the time to speak to you.

DR. MIDDENDORF:

Thank you very much, Rachel. Operator, if you would allow Mariama James into the call, please.

MS. JAMES:

Hello?

DR. MIDDENDORF:

Hello, Mariama. Are you ready?

MS. JAMES:

Yes, this is Mariama.

DR. MIDDENDORF:

Okay, please go ahead.

MS. JAMES:

Hi. Again, I'm Mariama James. I'm a Southbridge Towers resident and a parent and a member of Community Board 1. On the morning of September 11, 2001, I was eight months pregnant with my third child. From my company's offices in Queens, I saw the first plane hit. As the day progressed, my father picked up my two children from school in the Village as I walked to Lower Manhattan from Queens. We all arrived at our apartment blocks away from the World Trade Center covered in dust. At Southbridge Towers, we had no power, water, or phones, but at daybreak, when the sun came out, we could see that our home was also coated with dust.

Soon we were told the dust was safe and to remove it ourselves, and we did. At eight months pregnant, I got down on my hands and knees and pulled up the carpet in my children's room. I started to vacuum with a non-HEPA vac, who

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knew? The EPA said there was no problem and my kids actually helped clean throughout the whole process. Not long after 9/11, the City Health Department put out an advisory to residents that recommended we clean up the dust ourselves with a wet rag. I remember also that it stated that pregnant women and young children did not need to take additional precautions. You can understand why any medical or scientific experts who aligned themselves with that official story do not have the trust of our community.

My daughter, born on October 23, was diagnosed with asthma at the age of 10 months. And my other children, none of whom had health problems before 9/11, developed the typical WTC illnesses. For years, all three of my kids ended up on a long list of medications for sinusitis and asthma. There were no programs to treat kids who were sick from 9/11. I had to beat the bushes to find a pediatric pulmonologist, and for a long time, my kids needed to see her at least once a month. Other parents consulted her as well. Once there was a WTC Pediatric Program, we went. All three of my kids were treated for WTC asthma, sinusitis, and GERD. I am so pleased to say that they are far better now, but they still have chronic WTC physical health problems.

When Dr. Trasande became a WTC pediatrician, my kids saw him and he was great. Dr. Trasande is now leading the research to get answers about our children's' medical health and he should be. One of the outcomes he is looking at is cardiovascular issues. It's something that has shown up in my son.

Looking at the workgroup recommendations, we are calling for collaboration and we believe that this is best for the research. It is in the best interest of the families in the Registry. When people are contacted by researchers, there is incredible confusion. You have to remember that the Registry—there is the Registry, there is the WTC Health Program, and there's the VCF. Add researchers to the mix and parents wonder, "Who is contacting me? Who is contacting my child? And why?" I have heard parents at the community board express frustration and irritation. Some say they will withdraw their family from the Registry. The Registry should play a major role in study recruitment and that will help everybody, including the Registry.

Obviously, we agree that the Registry is a precious resource, but that doesn't mean it doesn't have problems. The fact that they didn't capture enough of the child population is a problem. The lack of diversity is a problem, and with the attrition over the years, it's become a bigger problem. We have yet to see the Registry respond to a STAC member's request for the demographic breakdown. We want to see a table that shows income, race, ethnicity. Then there needs to be a discussion of ways to address that problem in recruitment for studies using the Registry, because as we all know, researchers prize that baseline data. NIOSH should also fund projects to explore pulling together other pediatric cohorts, whether an NHANES type study would be carried out with the Registry

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cohort, another cohort, or both, we support that idea. We need good cooperation among researchers in the study of mental and physical health impacts that will follow our kids across decades.

Finally, we do need a formal study of how it happened that children ended up being the least-studied of the 9/11-affected population. We need an honest account and we need to make sure that none of the mistakes are repeated in a future disaster. Thank you.

DR. MIDDENDORF: Thank you much for that. Thank you very much, Mariama. Operator, would you let Barbara Caporale in, please?

MS. CAPORALE: Can you hear me?

DR. MIDDENDORF: Yes, we can hear you, Barbara. Go ahead.

MS. CAPORALE: Okay, hi. My name's Barbara Caporale. I'm a Lower Manhattan, Lower East Side resident living approximately two miles from the World Trade Center site inside the original frozen zone that went up to 14th Street. I have a now 18-year-old daughter who was just under 5 on 9/11. Walking my daughter to her first day of preschool on East 9th Street, we heard what I thought was a huge truck backfire. I dropped her off. And on my roof, I watched the towers burn and then collapse. I filled my bathtub with emergency water, scrambled to buy supplies for myself and my parents, picked up my child, headed back to our apartment through ever-thickening, smoky air that smelled like a mixture of electrical and chemical factory fire and crematorium. Cars, buildings, and playground equipment became increasingly coated with grit. Our apartment on East 5th Street is on the top floor facing south towards the World Trade Center. We could not breathe in our apartment for weeks so we kept the windows closed with the AC on. My daughter would wake up every few hours coughing at night. The smoke and dust plume would change directions and conditions would vary in intensity, particularly at night with the atmospheric inversions. Our streets were closed down and my child played in the playground on Houston Street with a bandana over her face, cheering the rescue/recovery vehicles as they passed. And when the 14th Street boundary was moved to Houston Street by the end of the week, which is equivalent to 1st Street, we were told the air was perfectly safe to breathe and she had to return back to school or I would lose my meager workfare benefits. In 2002, my daughter was diagnosed with respiratory syndrome by a pediatrician at Betances, a Bellevue affiliate, which is on Henry Street. She was prescribed Singulair, Flonase, and also referred to Bellevue's allergy clinic. And that year she also participated in a pediatric respiratory study of 32 daycares below 14th Street, conducted by epidemiologists from the New York Academy of Medicine. Parents of 1,320 three-to-five year olds responded to the study in English, Spanish, and Chinese. Results showed that in an age range of a population that traditionally would have a 7% rate of asthma, there were mutually exclusive statistics of approximately 40% reporting either had never prior been

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diagnosed with asthma but had respiratory syndrome, coughs, wheezing, or had asthma with increased symptom events. 89% had been prescribed asthma medicine in the year through June 2002 and 31% had at least one respiratory-related emergency room visit. This study found a significant 9/11-related respiratory impact.

And shamefully, that was the last physical health study for which my daughter and children in our area were eligible, because the EPA and the city department of health's World Trade Center Registry established a boundary line at Canal Street, which excluded the entire area above Canal Street from EPA's 2003 cleanup or eligibility to be data studied in the World Trade Center Health Registry. This boundary excluded parts of the Lower East Side and a huge chunk of the Hispanic and Chinese populations, and lower income persons with less access to healthcare, the very families who could not afford to leave the area to go elsewhere when the fires burned for months.

So I'm speaking in support of recommendation 12. The exclusions and omissions and outright falsehoods that got in the way of studying what happened to our children from their exposures to the World Trade Center disaster must be carefully examined. The science, specifically on the physical health impacts, was either non-existent or has been biased. The idea that the area above Canal Street was not part of the zone of impact was absolute political fiction with no scientific basis whatsoever, and it is infuriating that we as parents have gone for so many years without good science on how kids' physical health was harmed.

So many impacts that our children are experiencing were suspected by the doctors at Bellevue to be linked to the environmental disaster, but such studies were never funded. From the basic headaches, migraines, and allergies to the neurodevelopmental problems that have impacted my child and our children's school attendance, academic and social performance, their selection of quality schools, and their educational careers in general, my child and this population were and are more susceptible to seasonal illnesses and events such as H1N1, the mold from Superstorm Sandy, etc. Endocrine impacts which now may be manifesting in our population of adolescents and young adults are finally beginning to be and should be further studied. Is the extra breast tissue of my friend's son and my daughter related to their exposure? A lessons-learned study is important. The refusal to look at health impacts for a full two-mile radius from the World Trade Center has resulted in excluding a part of our affected population from the healthcare that is provided at the World Trade Center Health Program. (You have @ 00:53:06) one minute.

DR. MIDDENDORF:

MS. CAPORALE:

Again, merely a financial decision done in Washington DC. So what was wrong with the research must never happen again. Medical experts and community advocates who struggled to understand what this disaster was and what it was doing to our children should work together to build the right roadmap, setting

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response precedents for precautions and care in the future. We are playing catch-up and pediatric research must be well-funded in every research cycle, and the proposals should be reviewed by experts in the specific fields proposed. Thank you.

DR. MIDDENDORF: Thank you very much, Barbara. That's our last public commenter and I want to thank each of them for coming to the meeting, providing their perspectives and their thoughts. I think these are perspectives and thoughts that many of our members don't have an opportunity to hear or see, so it's very important and I really do thank you for coming and taking the time to present them to us.

**DISCUSSION OF CHILDREN'S RESEARCH WORKGROUP REPORT**

DR. WARD: Thank you. So we wanted to talk—I wanted to see if there were any more general reactions or comments. I do think that we probably should at some point break from general comments and go through the slides that Paul has given us online to speak about the specific recommendations. And Paul, were you intending for the committee to take votes on these or...?

DR. MIDDENDORF: Yes.

DR. WARD: Yes, okay. So I'd like to open the floor for any general comments, and then when we conclude those, we'll look at the specific recommendations, have brief discussion, and then vote.

PARTICIPANT: So you want to vote on which recommendations in particular?

DR. WARD: Okay, so the vote will be—so in the report itself, you'll see little boxes with—

PARTICIPANT: Right.

DR. WARD: With recommendations, but then Paul has also sent out, and we'll be showing on the slide, each of the recommendations in a PowerPoint format, and we'll vote on each of those. So I just wanted to make sure that there were no comments on the overall report or any general concerns before we turn to the specific recommendations. So Paul is opening Recommendation 1 now.

DR. MIDDENDORF: But I can go back to the report if we need to.

DR. WARD: But we can go back if we...

DR. MIDDENDORF: Yes, I can go back and forth. Not a problem.

MS. MEJIA: Liz, this is Guille Mejia. I just have a question, and I'm coming in at the tail end of this, so part of the narrative refers back to various studies. Is there a way for the sources of those studies to be highlighted, like who did the study, when, and—rather than it be in general terms? So wherever in the text they reference a study that was already done, is there a way for you to identify the actual source of that study?

DR. WARD: Can you give a specific example?

MS. MEJIA: Well, let's just look at page three. I just happened to pull this one up. Page three, line 99, it says here, "These complex inter-relationships...have been observed in many studies of World Trade Center-exposed..."

DR. WARD: Yes.

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MS. MEJIA: So my question is what are you referring to?

DR. WARD: So I think one of our recommendations gets to your point, but a little differently. I'm trying to see where it is. Paul, didn't we put it—wasn't there a recommendation in there about... Or maybe that one didn't become a recommendation. It was just a comment. Because, you know, one of the things we found, Guille, was when we were reviewing the literature on, you know, pediatric studies as well as the adult studies, the literature on the World Trade Center health effects has become really voluminous.

MS. MEJIA: Mm-hm.

DR. WARD: And, you know, we made a determined effort in the workgroup, and I specifically did, even to come up with, like, a really comprehensive summary list of all the childhood studies and which cohort was studied and what the outcome was. And it just became—it's very hard. You really have to dig. So with the specific references, like a comment like that, there's probably, if this was a scientific paper, there might be five to ten sentinel studies that you would cite for that point, but it's a lot of work to go back and choose them. I mean, I think there is a lot of evidence that, you know, there are concomitant physical and psychological comorbidities. There's clusters of physical comorbidities that go together. Some of this information I think is in the research report that has been distributed to members of the committee and maybe we could send it out again. But I'm thinking that maybe we missed that specific recommendation. When we made the recommendations, we may have missed a specific one that had to do with the committee asking NIOSH, you know, that in the future they consider...

DR. MIDDENDORF: Liz—

DR. WARD: Providing more formal literature review to have (inaudible @ 00:59:15)—

MR. FLAMMIA: This is Anthony, if I may.

DR. WARD: Yes.

MR. FLAMMIA: I had recommended a one spot and I think this is what she's alluding to, is having one spot for the actual documentation of all these studies, and I had recommended a—you know, basically to drop the literature in a digital format somewhere as an information-sharing type environment. And I think Paul and I went back and forth on it as to, you know, you can go searching on the CDC and NIOSH website, but that's going to take, you know, a lot of time and a lot of effort. But the onus is on the NIOSH and CDC to provide the information in one spot.

DR. WARD: Well, I think that's true, Anthony.

MR. FLAMMIA: And I think it should be an information-sharing network—

DR. WARD: Yes.

MR. FLAMMIA: For it to be accessible for the World Trade Center studies in one spot so someone can access it, even for practitioners.

DR. WARD: I think that that is one recommendation, although truthfully, I think what we've come to—I think the last time I looked, there's, like, a thousand studies and each

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of them is complicated and... So, I mean, I think that's one approach, but honestly, I think a more—a better approach or a more useful approach would be to—you know, if we're going to have a—you know, if the STAC is going to undertake a major review like we did for the pediatric literature, then I think it would be really helpful, you know, to maybe have a contractor—and government agencies do this all the time. They can have a small contract for a contractor to just really come up with a nice, concise summary of the existing studies and whether the different publications—

MR. FLAMMIA: It's just a matter of migrating all the hyperlinks into one spot.

DR. WARD: Well, I guess what I'm questioning is whether that's useful or not. Now, maybe it's something that can be done. The other thing is whether there are publishing restrictions. You know, for a lot of journals, you have to pay for access to scientific articles. So the question is, are you talking—you're talking about something that would be open to the general public and I don't know if there's restrictions on what NIOSH can provide.

MR. FLAMMIA: Well, the published data, of course. I mean, that's the information sharing network. You can information share—

DR. WARD: No, you—

MR. FLAMMIA: I mean, the stuff that's publically out there as far as studies.

DR. WARD: I don't know.

MR. FLAMMIA: I understand the confidentiality of the other stuff, I understand that.

DR. WARD: Well, there's restrictions. For example, if I want a copy of a certain scientific article as an individual investigator, some journals will say you need to pay \$30 if you want to see this article. So that's one restriction. But let's just go back for a second because if you look at line 336, we actually addressed this and we didn't specifically make the recommendation of putting all the articles in one place, but we really talked more broadly about the need for a dedicated and integrated review of the topic, and also more broadly about NIOSH communication of the results of the research programs. And I think, truthfully, that would be more helpful to everyone than just putting the articles in one place.

DR. MIDDENDORF: Yes, what I'm hearing is there is a general recommendation coming from the STAC that it needs more support to be able to analyze and provide substantive recommendations on issues such as children's research.

DR. WARD: Right, right.

DR. MIDDENDORF: So I think that's a recommendation back to the Program, but it's not a recommendation about children's research.

DR. WARD: Right.

DR. MIDDENDORF: And that's something that I will take out of this and I will work on separately.

DR. WARD: Although, I mean—

DR. HOMISH: Hi, this is Greg Homish. I had one comment. On the World Trade Center website, there actually is a listing of all the publications related to this that has hyperlinks to

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abstracts or full articles, where available. So it's on the homepage if you go down to the bottom-right. So, I mean, that first step seems to be done. I think that Paul's suggestion about a more integrated review is a great second step, but the first step, I mean, there's 21 different pages here of all the relevant articles that have been published to date.

- DR. WARD: Right, but some of them are abstracts only and I think there are—it's only the ones that have been supported by the World Trade Center Health Program.
- DR. MIDDENDORF: I think it's largely those.
- DR. WARD: It's largely those, so there are some that are not there, but I think the, you know, abstracts, some of the articles where there's abstracts only, it's because they're not freely available to the public.
- DR. MIDDENDORF: Yes. And I think the point is well-taken that the STAC needs more support, it needs for the Program to help provide it with more detailed information so it can do its work. And that's something I think that we can take back and I would like for the committee to focus more on the children's research needs at this point.
- DR. WARD: Right. But, I mean, again, it's in our report and it certainly is registering with—
- DR. MIDDENDORF: Yes, it's there.
- DR. WARD: Yes, we didn't leave it out. I think maybe Recommendation 10 could be maybe stated a little more clearly, but we'll get to that when we get to that (inaudible @ 01:04:38).
- MR. FLAMMIA: I just think it should just be a little bit more transparent. I mean, that's what I think. I'm getting also it just could be a little bit more transparent and forthcoming with the information, being what had happened, you know, with the EPA back on 9/11 of '01, what they said, and it just should be more transparent going forward.
- DR. WARD: Okay.
- MS. NORDSTROM: Also, aren't a vast majority of the studies that are on that website—sorry, this is Lila Nordstrom—aren't a vast majority of them solely mental health studies? There aren't really that many, like, I just wanted to point out just back...
- DR. WARD: I don't think so. I mean, you know, and I've done independent PubMed searches too. I mean, you know, there's a lot—again, it's not—we're talking now about the entire World Trade Center literature and there's a lot of articles on pulmonary effects and other physical health effects now. So, I mean, there's quite a bit there. It's very hard—I mean, even if you have all the articles and the abstracts, to me, the trouble is really digesting it and, you know, especially for people who are not—you know, if you were a pulmonary expert, you might be able to digest all the pulmonary articles and come to a good understanding, but as someone who isn't—as anyone, even if, you know, you're a scientist, if you don't have expertise in each of these areas, it's very, very difficult to comprehend the full meaning of the research that's been completed.
- DR. MIDDENDORF: And I'll say that I'm hearing this very clearly. I will definitely take this message back to the Program, and if you want to want modify one of the recommendations

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to make it even clearer, that's fine, but I really would like us to focus in on the children's research now.

DR. WARD: Okay, yes. So shall we move on then and talk about the specific recommendations? And obviously, if we're talking and anyone, you know, does feel that they have a burning comment that they didn't get a chance to make in this first discussion, please let us know and we'll certainly listen. Because I think the idea today is to really finalize the recommendations on children's research so that we can get this report to NIOSH and they can take appropriate action. So we've got Recommendation 1 and does anyone have any—well, we'll vote on if any is, everyone is agreed to it, but also does anyone have any specific suggestions for changes?

DR. TALASKA: This is Glenn Talaska. I move to accept the recommendation.

MR. FLAMMIA: Anthony Flammia seconds it.

MS. McVAY-HUGHES: Yes, I support it too. Catherine.

MS. NORDSTROM: This is Lila. I support it as well.

DR. MARKOWITZ: I'm sorry, can we still have discussion?

DR. MIDDENDORF: Yes.

DR. MARKOWITZ: This is Steven Markowitz. So I just want to comment on this. This is a very important and somewhat out-of-the-box recommendation that has a number of different components. And it, I think, resonates—I think the first public commenter actually made several comments in essence relating to this. This idea of a coordinated approach would involve multiple researchers who at present are probably working separately. The reason for that is in part because there aren't that many kids to study and they're not easy to find and most of them seem to derive from the same source, which is the World Trade Center Health Registry. So unless NIOSH encourages multiple researchers to work together, it's going to be problematic to achieve what needs to be done. If that coordinated approach is successful, then the idea on the fourth bullet point really is to expand the scope of what the current studies really have addressed, meaning expand both the physical health and the mental health domains of what's already been studied.

The issue of a funding mechanism is also very important because, as I read the current RFA, I don't see how it could accommodate, frankly, a coordinated approach involving multiple researchers and a broader set of issues combining physical and mental health, in part because the maximum grant is \$600,000, which is very generous, but wouldn't cover the waterfront as envisioned in our recommendation. So, you know, it's unfortunate that we're working in parallel with the development of the RFA, but this is—does endorsement of this recommendation constitute a challenge to NIOSH to kind of figure it out in terms of the funding piece for such an approach?

So I just want to emphasize that this is kind of an unorthodox thing that we're recommending, but because of the particular situation, and here we are 15 years

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later, relatively few kids have participated recently, the difficulty of finding additional kids—I'm sorry, the kids are now pretty much teenagers and adults—this approach is justified.

MS. NORDSTROM: Can I make maybe a suggestion or maybe just a comment? This is Lila speaking. But I wonder if we can add something as—you know, as a lot of these commenters talked about, this RFA doesn't really accommodate a lot of the sort of scope of what we're talking about, but is there a way to emphasize that, in talking about a coordinated approach, we're maybe also advocating for, like, a cooperative approach or, you know, something that sort of emphasizes that if the funding doesn't come through that could support this kind of recommendation, that we want to recommend that researchers find a way to sort of work cooperatively towards these goals, as opposed to just sort of, like, coordinating from, you know, their different ends? Because that way, you know, they can sort of consider using a lot of the same pool of—you know, the same research subjects and things like that, where I feel like this reads much more vaguely and doesn't necessarily encompass that spirit.

DR. WARD: Well, I mean, this is primarily recommendations to NIOSH and so I think both the second bullet and the third bullet are really making recommendations to NIOSH about, you know, a coordinated approach and creating a funding mechanism that would allow the collaboration and a consortium investigator. So it sounds like what you're saying is more to make even—you're kind of saying, well, if that doesn't happen, we still can encourage collaboration, but I think that's more directed to the investigators rather than to NIOSH. But if you want to make a specific proposal as to what to add...

DR. MIDDENDORF: Yes, and if you want to suggest different wording, let us know what it is.

MS. NORDSTROM: I mean, I'm not entirely certain that I know the correct wording for, you know, a recommendation like this. I was just wondering—and maybe someone else on the committee has a suggestion or maybe no one else on the committee thinks that this is a relevant issue—something that sort of indicate—I just don't necessarily see a lot of researchers sort of spontaneously coming to the conclusion that they should work together, especially when they're in separate fields. You know, there's been a lot of discussion on the committee in the past about there seems to be a sort of, like—you know, two sort of—there seems to be a sort of mental health and a physical health component to this that often don't necessarily cooperate or aren't able to collaborate with the way that the, you know, the funding and work now and the way that they've developed separate subject pools that—and maybe this recommendation isn't the right place to put that. Maybe there is a recommendation later on that more realistically could sort of, like, address this, but something about encouraging a—I don't know if cooperative is the right word, but...

DR. MARKOWITZ: So Lila, Lila?

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MS. NORDSTROM: Yes.

DR. MARKOWITZ: This is Steven. I agree with you. Let me suggest in the second bullet we substitute for the word "coordinated", we say "highly collaborative".

MS. NORDSTROM: Good, I like it.

DR. MARKOWITZ: Because "collaborative" to researchers means that they are really working together.

MS. NORDSTROM: Excellent, I like it.

DR. MIDDENDORF: Can I throw out an idea for you? In the third bullet, maybe possibly say something like, "Would allow and encourage..."

MS. NORDSTROM: Sure.

DR. MIDDENDORF: Is that what you—

DR. MARKOWITZ: How about just "encourage"?

DR. MIDDENDORF: I'm sorry?

MS. NORDSTROM: Perhaps even one step further and say, "Foster and facilitate collaborations".

DR. MARKOWITZ: Well, the researchers have to decide that themselves as they prepare a collaborative proposal, but I think if you put the word "encourage" instead of "allow", that's a lot stronger.

DR. WARD: Yes, I think that's good. Good. Well, shall we vote on this version, or any more discussions?

DR. MIDDENDORF: Yes, any more discussion?

DR. MARKOWITZ: I accept the amendment.

DR. MAYER: This is Annyce. I just have a question. With bullet one, it says, "Efforts to sustain and renew," and I get that 15 years later it's really hard to find new people, but would there be any kind of mechanism, like, through school records or a similar resource that might allow for a larger cohort? As it stands, 10% to 15% is a pretty limited percentage of the estimated affected children.

DR. WARD: Yes, and I think this particular recommendation is our specific recommendation relative to the research in the World Trade Center Health Registry population. And I understand it, that population is closed, but there are other areas of the recommendations where we talk about the possibility of identifying other cohorts including feasibility and pilot studies. So we kind of address that in their other recommendations.

DR. MARKOWITZ: Number seven in particular.

DR. MAYER: Yes, yes.

DR. WARD: Yes. And any further points or comments on Recommendation 1? So are we ready to take a vote on the recommendation as stated on the screen?

PARTICIPANT: Yes.

PARTICIPANT: Yes.

DR. MIDDENDORF: I need to read it into the transcript.

DR. WARD: Okay.

DR. MIDDENDORF: Did somebody else have something else they wanted to say? Okay.

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- MS. MEJIA: I'm sorry, this is Guille. I just, I have a quick question. Maybe someone can elaborate on the relationship between the World Trade Center Health Registry, which is a city-run program, and the World Trade Center Health Program, which obviously is a federal program, and how—I mean, this recommendation basically puts the World Trade Center Program and Registry (inaudible @ 01:17:36) of funding... You know, in a way that it's going to be funded if it collaborates with other groups that are looking at adolescents and children who had exposures. I'm sorry, I may not be explaining myself properly, but I'm just concerned about the relationship between a city entity and then the federal program, and how those two relate. And is this something that then—where the Registry will get continued funding so that they can engage in some of these collaborative efforts?
- DR. MIDDENDORF: Yes, I mean, the World Trade Center Health Registry, while it is a city organization, they have received the funding from NIOSH through the World Trade Center Health Program, and that funding is being, I guess, competed, a renewal is coming up very shortly.
- DR. WARD: But one of the things we've discussed, Guille, and we discussed this in the subgroup and also in the main meeting, is that at this point the World Trade Center Health Program itself does not include very many children. There's only one site that sees children and there's a limited number of children. So for the World Trade Center Health Registry, with this being a relatively large population of children, you know, in any program. And there was—you know, and we had a presentation on this, again though, there's some limitations. You know, there was a very systematic recruitment effort that went into identifying the children who ended up being in the Registry. So in terms of a feasible study population where studies could be ready to go in a reasonable period of time, it really was the only one of any substantial size that we could identify.
- MS. MEJIA: I guess, Liz, I'm sorry, I don't mean to raise this. I was just wondering whether the World Trade Center Registry is considered a data center like the FDNY has a data center and the Health Program has a data center.
- DR. MIDDENDORF: It's in a different category than the data centers. The Zadroga Act funds the Health Registry and then it also funds data centers, so there are differences between them. I don't know exactly what they are.
- MS. MEJIA: Thanks.
- DR. WARD: Does that answer your question, Guille?
- MS. MEJIA: Not really but that's fine. We could take a vote on this. I'm fine.
- DR. WARD: Okay.
- DR. MIDDENDORF: Okay, so do we have a motion? Does somebody want to make a motion?
- PARTICIPANT: I move to approve the recommendation as currently stated.
- MR. FLAMMIA: Anthony seconds it.
- DR. MIDDENDORF: Let me read that into the transcript. Children and adolescent survivors enrolled in the World Trade Center Health Registry are an extremely important resource for

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understanding the health effects of World Trade Center exposures. Recommend that the World Trade Center Health Program: make substantial efforts to sustain and renew participation in surveys and special studies; consider a coordinated approach that could examine a broad range of mental and physical health outcomes in the Registry population; develop a funding mechanism that would encourage collaboration between the Registry and a consortium of investigators with diverse expertise; and conduct an analysis of the feasibility and usefulness of a standardized health assessment approach, similar to NHANES, that could examine a broad range of mental and physical health outcomes in the Registry population prospectively.

MR. FLAMMIA: Paul, what's NHANES?  
DR. MIDDENDORF: National Health and...  
DR. WARD: It—survey.  
DR. MIDDENDORF: And Nutritional Examination.  
DR. WARD: Survey. Yes.  
MR. FLAMMIA: Thank you.  
DR. MIDDENDORF: Okay. Okay, so we'll do a roll call vote. Thomas Aldrich, can I hear yes, no, or abstain?  
  
DR. ALDRICH: Yes.  
DR. MIDDENDORF: Rosemarie Bowler?  
DR. BOWLER: Yes.  
DR. MIDDENDORF: Anthony Flammia?  
MR. FLAMMIA: Yes.  
DR. MIDDENDORF: Bob Harrison, not on.  
DR. HARRISON: Paul, I wanted to let you know that I had joined the call earlier. I have been silent and part of this discussion, and my vote is yes.  
  
DR. MIDDENDORF: Okay, thank you. Greg Homish?  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine Hughes?  
MS. McVAY-HUGHES: Yes.  
DR. MIDDENDORF: Val Jones?  
MS. JONES: Yes.  
DR. MIDDENDORF: Mickey Kelly, not here. Steven Markowitz?  
DR. MARKOWITZ: Yes.  
DR. MIDDENDORF: Annyce Mayer?  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike McCawley?  
DR. McCAWLEY: Yes.  
DR. MIDDENDORF: Guille Mejia?  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila Nordstrom?

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MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill Rom?

DR. ROM: Yes.

DR. MIDDENDORF: Megan Ryan?

DR. RYAN: Yes.

DR. MIDDENDORF: Glenn Talaska?

DR. TALASKA: Yes.

DR. MIDDENDORF: Ms. Ward?

DR. WARD: Yes.

DR. MIDDENDORF: Okay. That is 16 yeses. Motion carries.

DR. WARD: Good. Moving on to the next recommendation. So this recommendation is really a very short, general one: recommend that the World Trade Center Health Program include the general area of childhood and adolescent health in their requests for proposals. Is there any discussion on this recommendation?

MS. MEJIA: I'll make a motion to accept. This is Guille Mejia.

DR. TALASKA: Seconded, Glenn.

DR. WARD: So for the record, no one would like to discuss this? We can move to a vote.

DR. MARKOWITZ: This is Steven. I just have a quick question, because I remember one of the public commenters referring to this, but having some critique of how the RFA addressed it. I don't recall the details. Does anybody else? Okay.

DR. MIDDENDORF: Yes, I remember, I agree with you that there was discussion by one of the commenters, I just don't remember exactly what they had to say. Unfortunately, we don't have the written comments in our hands at this point.

DR. WARD: I mean, I guess what I'm assuming is that, since that RFA was written before our recommendations were finalized, that our recommendations here would pertain to a subsequent RFA, not the one that's already published, which is out of the barn.

DR. MIDDENDORF: Yes, but if we were able to look back and—

DR. WARD: Yes.

DR. MIDDENDORF: At those comments, we might be able to craft this in a way to help the program focus their funding announcements in the future.

MR. FLAMMIA: Hi, this is Anthony. I would actually maybe possibly add "physical and mental health".

DR. WARD: (Miguel @ 01:25:43), is there any chance that you—

MS. McVAY-HUGHES: Hey, this is Catherine here.

DR. WARD: Yes.

MS. McVAY-HUGHES: I have a quick question. I realize in Recommendation 1, we had "mental and physical health", and I want to be—I don't know if we have to be consistent in how we do it and I don't know if this committee would agree that we put physical before mental health consistently in the dozen or so recommendations, because there's been always so much more attention to mental health rather than physical health when it's ever come to children, in terms of research and studies and everything

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else.

MS. NORDSTROM: I would agree with that. That was Lila.

DR. MIDDENDORF: Sounds good.

MS. McVAY-HUGHES: Thank you. I'm sorry, even though we did a vote on Recommendation 1, if we can just make it consistent; it's always "physical and mental". Thanks a lot.

DR. WARD: Okay, so as we go through the recommendations, we'll take a look at that and—

DR. MARKOWITZ: So Liz, Liz.

DR. WARD: Yes.

DR. MARKOWITZ: It's Steven. Let me just throw something out, because this recommendation is very plain, and I'm wondering whether we—I'm not sure myself, but whether—I'd like peoples' opinions on whether we should amend it to say that the WTC Health Program include this area, but also say that: ensure that significant resources are devoted to funding this area, you know, if meritorious proposals are...

MR. FLAMMIA: I wouldn't say that—this is Anthony. I wouldn't say "devoted". I would say "allocated".

DR. MARKOWITZ: Okay, whatever, but whatever the particular verb is, whether we want to add that idea to this.

MS. NORDSTROM: And is this the appropriate recommendation to discuss the idea that these proposals be reviewed by pediatric experts or people with expertise in the field, as opposed to just...?

DR. WARD: I think we should—I think that's another...

MR. FLAMMIA: Number three—

DR. MARKOWITZ: Number three has that recommendation and covers funding.

MS. NORDSTROM: (Inaudible @ 01:27:44). Right.

DR. WARD: Yes, I think that is a danger so, yes, so thank you. I think—does it cover funding too?

DR. MARKOWITZ: Yes, it does.

DR. WARD: I know I saw the specific pediatric review section, but I didn't remember that we covered funding because I wasn't sure it was in our purview but that, I mean, I think if we...

DR. MARKOWITZ: If you look at number 3, the first sentence in number 3 says that a specific pediatric study section be created under the funding mantle of the Zadroga Act.

DR. WARD: Yes, but it doesn't specifically say the amount of funding—it doesn't specifically address the funding allocation—

DR. MARKOWITZ: No.

DR. WARD: Being adequate, and that's the part that I'm thinking we didn't include anywhere, you know, in our recommendations.

DR. MARKOWITZ: And I thought that was on purpose too, that the subcommittee looked at it and said that that wasn't in our purview to decide how much funding.

DR. WARD: Yes, I suspect it's not in our purview. I mean, a lot of our recommendations indirect—you know, as I think one of the public speakers said or someone else

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said earlier, you know, to really fulfill, you know, to fully fulfill the recommendations that we're making would probably require more funding than is in the current budget, so it's sort of we got at it indirectly, but we didn't make any specific recommendations about funding. So, I mean, but if there is a sense in the committee that we want to put something in, I think this is an approp—I don't think there's going to be a more appropriate place than this. So we can look at the language that is proposed and see if there's any changes.

DR. MARKOWITZ: Well, this is Steven, we could say, end the sentence by saying "and make this an area of priority for funding" which gets to the same point but doesn't really...

DR. WARD: Right.

DR. MARKOWITZ: Not quite as strong.

DR. ALDRICH: This is Tom Aldrich. I agree, making it a priority is reasonable, but I don't think there should be a set-aside specifically for any one particular area. The best quality research should be funded and should not be denied funding because there's a low quality proposal that comes in for an area of a set-aside. So high priority is fine and adding a priority for—because this is an important area, which it is—is reasonable, but not a specific set-aside.

DR. ALDRIDGE: This is Tom Aldridge. I agree. Making it a priority is reasonable. But I don't think there should be a set-aside specifically for any one particular area. The best quality research should be funded and should not be denied funding because there's a low quality proposal that comes in for an area of a set-aside. So high priority is fine and adding a priority because it's an important area, which it is, is reasonable, but not a specific set-aside.

DR. WARD: I mean, so I think this wording is probably agreeable to everyone. Or, I mean, it sounds like this would be agreeable to you, Tom.

DR. ALDRIDGE: Me? Yes. This is Tom Aldridge again.

DR. WARD: And I think, you know, the specific set-aside is probably where we would—there might be some areas of political disagreement about what's the best approach to—if there is a limited pot of money what's the best approach to allocating it, but I think this is a good comprise.

DR. MIDDENDORF: So is there a motion, then, to accept this wording?

PARTICIPANT: Could you just read the wording?

DR. MIDDENDORF: "Recommend that the World Trade Center Health Program include the general area of childhood and adolescent physical and mental health in their requests for proposals and make this a priority for funding."

MS. NORDSTROM: I'll move to accept it. This is Lila.

PARTICIPANT: Seconded.

DR. MIDDENDORF: Second. Okay. We can do a roll call vote then. Tom Aldridge.

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie Bowler.

DR. BOWLER: Yes.

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DR. MIDDENDORF: Anthony Flammia.  
MR. FLAMMIA: Yes.  
DR. MIDDENDORF: Bob Harrison.  
DR. HARRISON: Yes.  
DR. MIDDENDORF: Greg Homish.  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine Hughes.  
MS. McVAY-HUGHES: Yes.  
DR. MIDDENDORF: Val Jones.  
MS. JONES: Yes.  
DR. MIDDENDORF: Steve Markowitz.  
DR. MARKOWITZ: Yes.  
DR. MIDDENDORF: Annyce Mayer.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike McCawley.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille Mejia.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila Nordstrom.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill Rom.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan Ryan.  
DR. RYAN: Yes. Sorry.  
DR. MIDDENDORF: Glenn Talaska.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz Ward.  
DR. WARD: Yes.  
DR. MIDDENDORF: Okay. Sixteen votes for it. The motion carries.  
DR. WARD: Great. So moving on to the third recommendation. Do you want me to read it? I guess you can all read it to yourselves. We're fixing the view. Okay. So this is a very specific recommendation about creating a distinct pediatric study section. And if that weren't possible the alternative of including pediatricians or other relevant health professionals with expertise in childhood environmental health as primary and secondary reviewers. So is there any discussion on this recommendation? Does anyone want to make a motion?

PARTICIPANT: I move to approve.  
DR. MIDDENDORF: Is there a second?  
PARTICIPANT: I second.  
MS. McVAY-HUGHES: Sure. Catherine here.  
DR. MIDDENDORF: Okay. So let's do a roll call vote. Tom Aldridge.

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- DR. MIDDENDORF: Second. Okay. We can do a roll call vote then. Tom Aldridge.
- DR. ALDRIDGE: Yes.
- DR. MIDDENDORF: Rosemarie Bowler.
- DR. MAYER: I'm sorry. A question.
- DR. MIDDENDORF: Yes.
- DR. MAYER: It seems like there's—who makes the decision as to whether or not there's a distinct pediatric study section created? Because this is really kind of two separate things.
- DR. MIDDENDORF: Creating a distinct pediatric study section would be done by the World Trade Center Health Program in concert with the Office of Extramural Programs. They would have to look at the recommendation, evaluate it, see what they can and cannot do, whether or not it makes sense to do it.
- DR. MAYER: So it's not our place to weigh in which is the two we think would be better?
- DR. MIDDENDORF: Which are which two? Oh.
- DR. MAYER: Well, the first bullet is a distinct pediatric section and the second part is, if it's not created, then recommending primary and secondary reviewers in the NIOSH review process.
- DR. MIDDENDORF: Well, it sounds to me the way this recommendation is worded is that the priority from the committee is a distinct pediatric study section. And if that can't be done then an alternative is to recommend primary and secondary reviewers. So if you would prefer a different approach then we need to word it differently.
- DR. MAYER: Well, the one thing I will say, and having had the experience to participate in the review process is that there is a lot of people with different backgrounds at those sessions. And to the extent that having additional expertise there that can weigh in both from a pediatric perspective as well as the wealth of knowledge from the other people participating, I think has the opportunity not only to help enrich these studies that focus on pediatrics but also potentially on the other studies. And, you know, there have been some studies proposed that have been somewhat limited in focus and population under study. Some of that stems from a biologic approach but not all of it. And to the extent could some of these other studies even feasibly include children in them. I just think that having everybody incorporated as part of a broader (request @ 01:36:42) because we've already in Recommendation #2 said that we're going to make it a priority, so it's not like they're going to get shoved in a corner and lost in a larger review section.
- DR. WARD: Yes, so I think one thing we should do, and is in many cases there is text that kind of explains the rationale for each of these recommendations like in the actual document, right, more? And I think what was expressed in the various meetings was that, you know, there was a feeling that pediatric proposals were ranked lower compared to responder proposals or—because, you know, the responder proposals would have so much more background information in previous studies. And so I think most of the sense of the workgroup, and it was certainly a comment

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that was made by a number of pediatric experts who came to talk to us, that there was a concern that the pediatric proposals are not really getting evaluated fairly because they were being compared to, you know, other proposals in different populations. It's hard for me, you know, as someone who hasn't been inside the process. You know, certainly that was a feeling and a concern that I think many members of the workgroup resonated with. And so I would say it did become kind of a majority sentiment in the workgroup. But I also wanted to call attention just because of the recent comments. If you look at page—and so a lot of that is laid out in the text of the report which is one of the reasons why we're not just making the recommendations where we added the text. But we also did—and this is a soft recommendation. We didn't put it in a bullet. But on page 225 we said—

DR. MIDDENDORF:

It's line 225.

DR. WARD:

I'm sorry. Line 225. Thank god there's not 225 pages. "We encourage NIOSH to consider a set-aside of funds during the next grant cycle that will specifically target meritorious"—and it did say meritorious—"pediatric research, especially since the window of opportunity to access these populations at younger ages is rapidly closing." So that was part of the rationale text, but it wasn't in a specific recommendation that we're voting on. But, anyway, that's a little bit of the background. So maybe some other members of the workgroup could weigh in on their sense of how strongly the workgroup felt about the pediatrics study section recommendation, and then we could have some more sessions.

MS. NORDSTROM:

This is Lila here. I just want to kind of reiterate that point, that that is something that at least sort of as part of the survivor community and part of the survivor steering committee, like that's a sentiment that has been widely expressed and something that was a priority of ours because it felt like part of the reason that pediatric studies not getting funded was because they were—you know, we believe here that pediatric studies don't have, you know, they don't have the sort of like enough participants and they don't have any way of accessing the participants, and there's this, you know, no one did any research early enough to create a cohort that they could study effectively over long periods. But it still is very important that we study this population. The pediatric population is never going to live up to the same kinds of sort of organization that the respondent population has because we weren't, you know, in unions and we weren't, you know, we weren't sort of organized according to something that could follow us through to adulthood. So a lot of members of the pediatric population itself—like myself—or people who, you know, are part of this survivor community have felt in the past like this was something that the pediatric study population needs to sort of be considered according to its own merits and its own standards because, you know, because it's a rapidly dispersing population that we do sort of like have a need to study despite its lack of—the lack of sort of early intervention in that regard.

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DR. MARKOWITZ: This is Steven. You know, this is pretty straightforward. At a minimum the community should have confidence that the proposals that are put in are being reviewed by pediatric experts in environmental health. That's the normal way we always do things. And I'm not sure what's happened in the past. But, in any event, if there's been any deviation from that that's pretty straightforward to correct.

Dr. WARD: So I guess the two alternatives is do we want to propose an alternative to this wording and vote on that or do we want to vote on the existing wording with the opportunity for folks to either abstain or vote against? So are there any suggested amendments to this? I'm not hearing any. I think we have a motion on the table to accept this. It was seconded, and we began the vote taking. I want to clarify this. Annyce was it you who started the discussion on this?

DR. MAYER: Yes.

DR. MIDDENDORF: Great. I just want to make sure we have that for the transcript. So what I'll do is I'll start back at the beginning of the voting list just to make sure that after this discussion that Tom's vote hasn't changed any. So Tom Aldridge.

DR. ALDRIDGE: My vote does not change. It's still yes.

DR. MIDDENDORF: It's still yes. Okay. Rosemarie Bowler.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony Flammia.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob Harrison.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg Homish.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine Hughes. Catherine, are you on mute? Catherine? Okay. I'll come back to Catherine in a minute. Val Jones.

MS. JONES: Yes.

DR. MIDDENDORF: Mickey Kelly is not here. Steven Markowitz.

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce Mayer.

DR. MAYER: I abstain.

DR. MIDDENDORF: Okay. Mike McCawley.

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille Mejia.

MS. MEJIA: Yes.

DR. MIDDENDORF: Lila Nordstrom.

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill Rom.

DR. ROM: Yes.

DR. MIDDENDORF: Megan Ryan.

DR. RYAN: Yes.

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DR. MIDDENDORF: Glenn Talaska.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz Ward.  
DR. WARD: Yes.  
DR. MIDDENDORF: Okay. Coming back to Catherine Hughes. Catherine? Are you still in the meeting, Catherine? Okay. No vote. So one, two, three, four, five, six, seven, eight, nine...fourteen. Fourteen out of—14 votes out of 14 cast. So the motion carries.  
DR. WARD: Now we'll move on to discussion of Recommendation 4. Is there any discussion or amendments to the recommendation as stated?  
DR. MIDDENDORF: And as stated it says, "Recommend that the World Trade Center Health Program fund pediatric research that emphasizes multi-system impacts, examining a range of World Trade Center physical health effects including respiratory illness, cardio-metabolic (including blood pressure), endocrine, neuro-development, autoimmune and cancer impacts."  
DR. HOMISH: This is Greg Homish. I just had one question why physical health was getting kind of its own category and mental health wasn't getting a similar one. I mean, it seems we're to prioritize one over the other. I think we need pediatric research in both of those areas.  
MR. FLAMMIA: Physical and mental. Correct.  
DR. HOMISH: That's correct.  
MR. FLAMMIA: Yes. This is Anthony.  
MS. NORDSTROM: I think the reason I would agree but I also think the reason it was done this way is because there is a relative paucity of physical health research on pediatric populations as compared to the mental health research. That that was something that in the past there has been very little physical health research done so far.  
DR. WARD: Yes, and actually that was what a lot of people thought. Go ahead.  
MS. McVAY-HUGHES: Hi. Can you hear me? I'm sorry. I was on the phone and I said yes a couple times, but it didn't seem to work. So I dialed back in again. So I just want you to know I voted yes on the prior resolution.  
DR. WARD: Thank you.  
DR. MIDDENDORF: Okay. Thank you. We have...  
MS. McVAY-HUGHES: Sorry for the technical difficulties on my end.  
DR. WARD: I'm sure it wasn't your end. I'm sure it was the Ethernet.  
DR. MIDDENDORF: Who knows?  
DR. WARD: Okay. So I think that really was the sense on the, you know, from the workgroup discussion is that there had been much more work on mental health effects and that physical health effects has had very few studies done and a real need for additional work. So that was the rationale. But I think in most of the recommendations we are addressing both mental and physical health, and this is the only one we're really calling out physical health specifically.  
DR. ALDRIDGE: This is Tom Aldridge again. I have a problem with requiring the funding of specific

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research areas. I think we could encourage applications in these areas or we could prioritize these areas, the proposals could get extra points.

DR. WARD: Yes, I agree.

DR. ALDRIDGE: But I don't think we should require that these areas be funded because if there's no quality proposal that comes in, then the low quality proposals should not be funded just because it's the requirement.

DR. WARD: So if we change "fund" to "prioritize," or something?

DR. ALDRIDGE: That's my view. Other people may have different views about this.

DR. WARD: No, I think it was just an inadvertently strong statement for editorial reasons. I mean, it's just the way it was written. I don't—

DR. ALDRIDGE: Okay. Can we make it "prioritize funding of," I guess?

DR. WARD: Yes. Yes.

DR. BOWLER: Good. Good.

DR. WARD: Okay. So is everyone ready to vote on the rephrase recommendation? Can we have a motion?

MS. McVAY-HUGHES: Motion moved

DR. MIDDENDORF: Any further discussion before we go? Okay. I'm not hearing any. Who made the motion?

MS. McVAY-HUGHES: Catherine.

DR. MIDDENDORF: Catherine made the motion. Is there a second?

MR. FLAMMIA: Anthony seconds it.

DR. MIDDENDORF: Anthony seconds. So the recommendation as written is: "Recommend that the World Trade Center Health Program prioritize funding of pediatric research that emphasizes multi-system impacts, examining a range of World Trade Center physical health effects including respiratory illness, cardio-metabolic (including blood pressure), endocrine, neuro-development, autoimmune and cancer impacts." So we'll do a roll call. Please vote again.

DR. ALDRIDGE: One more thing. This is Tom Aldridge again. I'm not sure I exactly understand why there has to be an emphasis on multi-system impacts.

DR. WARD: Steve, can you take that one?

DR. MARKOWITZ: No, I don't—I'm with Tom. I'm not sure what it means here actually.

DR. ALDRIDGE: And I would say eliminate "emphasize multi-system impacts" and make it "examines," that it "examines a range of..."

DR. WARD: Yes. I mean, that would be fine with me. I think someone suggested multi-system impacts, but I can't defend it too strongly either. Is that okay with everybody in the workgroup? Does anyone want to speak up in favor of keeping it the way it was?

DR. MARKOWITZ: Unless somebody can define it, then I think it's correct. Yes.

DR. WARD: Okay. Good.

DR. BOWLER: I have a question on why only neuro-development and not mental? I mean, there's so much that we are learning with neuro imaging and so on. To leave out the mental all of a sudden and just have it be neuro-development I don't understand

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that.

DR. WARD: Well, I think this was a—the bullet was specifically relating to physical health effects. So...

DR. BOWLER: Well, neuro-development is really more—really is mental development, isn't it? And particularly with kids. That's a very important area.

DR. HARRISON: There's definitely an overlap, but you can have physical health neuro findings.

DR. WARD: Yes, I mean, I think—I mean, I do think that, you know, I always have trouble when we make these lists of outcomes because I'm never—you know, it's always really a matter of splitting hairs how do you categorize things. All I can say is that the intent here was—and I don't know that everyone agrees with it—that there have been lots of studies looking at mental health and emotional impacts of 9/11, and not so many studies looking at physical health effects. So I don't think there was any really deep discussion of neuro-development as an outcome. I think that this list was derived at to try to cover a spectrum of outcomes that people thought were important to look at under the category of physical health effects.

DR. BOWLER: Well, I mean, this just is so, it's a little (doubtful area @ 01:52:17) where it's like, it's too many things in one. There's affect and mood and personality development. Then there are the stages of childhood mental development. And, as I said, right now we are getting more and more associations with neuro imaging. So that seems too sloppy a category, neuro-development, unless you're talking about infants or something like that. But later on that's interconnected, the growth and mental function being on target with your age group, and all this.

DR. HARRISON: The recommendations are for mental health assessments and longitudinal studies are in number 5.

DR. BOWLER: But then—

DR. MAYER: Perhaps being broken out into neuro-development—

DR. BOWLER: Yes. Well, just to have a clarification what do we mean here with adolescents, that we're talking about neuro-development where now the young kids are adolescents. Or are we talking about kids that were exposed in utero? I mean, then they would be adolescents. That's where I'm confused by this.

MR. FLAMMIA: Actually, this is Anthony, I would say also brain development. Would that cover neuro-development?

DR. BOWLER: I'm sorry. What development did you say?

MR. FLAMMIA: Brain development.

DR. BOWLER: Yes, that would be more specific. Yes.

DR. WARD: Someone else was trying to say something.

DR. MIDDENDORF: I think that was Catherine.

DR. WARD: Catherine, was that you? Or Megan?

DR. MAYER: It was Annyce

DR. MIDDENDORF: Sorry.

DR. WARD: We're going to have learn your voice.

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DR. MAYER: Sorry, and I should've said my name. I was just going to say that perhaps instead of neuro-development we use neurologic.

DR. WARD: Ah, brilliant.

DR. BOWLER: Neurologic. Yes. Yes, that would be fine.

DR. WARD: Yes, I think that—and neurologic development just neurologic.

DR. BOWLER: Right.

DR. MAYER: Yes, just neurologic.

DR. BOWLER: Neurologic dysfunction. Right, right. Or abnormalities. Dysfunction is enough.

MR. FLAMMIA: Abnormality sounds great. Anthony.

DR. BOWLER: That's strong but...

DR. WARD: I think it's fine to just leave at it—because it's consistent with the way the rest of the verbiage is.

DR. MIDDENDORF: Neurologic impacts.

DR. WARD: So I think that's good. Great. Thank you. That was a great solution. I mean, we know that development—you know, I mean, just in general we know that developmental effects are going to be very hard to study when you don't have—when you can't access the kids during the period of their early development. So this is really helpful. Any further discussion?

DR. BOWLER: I can't hear anything.

DR. WARD: You can't? Oh, I'm sorry. Is there any further discussion or are we ready to hear a motion? Does somebody want to make a motion? Can somebody tell us if they hear us?

MS. McVAY-HUGHES: I'll make the motion. Catherine.

MS. NORDSTROM: This is Lila I'll second the motion.

DR. MIDDENDORF: Okay. Let's got into a roll call vote. The motion is to accept Recommendation #4 as "Recommend that the World Trade Center Health Program prioritize funding of pediatric research that examines a range of World Trade Center physical health effects including respiratory illness, cardio-metabolic (including blood pressure), endocrine, neurologic, autoimmune and cancer impacts." So we'll go to a roll call vote. Tom Aldridge.

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie Bowler.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony Flammia.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob Harrison.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg Homish.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine Hughes.

MS. McVAY-HUGHES: Yes.

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DR. MIDDENDORF: Val Jones.  
MS. JONES: Yes.  
DR. MIDDENDORF: Mickey Kelly's not here. Steven Markowitz.  
DR. MARKOWITZ: Yes.  
DR. MIDDENDORF: Annyce Mayer.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike McCawley.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille Mejia.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila Nordstrom.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill Rom.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan Ryan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn Talaska.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz Ward.  
DR. WARD: Yes.  
DR. MIDDENDORF: Okay. Sixteen votes. It carries.  
DR. WARD: Okay. So the next recommendation is simple as stated. It's "Recommend that the World Trade Center Health Program commit, to the extent possible, to longitudinal studies of physical and mental health." But if you look back at the text that was supporting this recommendation it really is attempting to broaden. I mean, while we do think that the World Trade Center Registry probably represents the best opportunity or the most feasible opportunity to do such studies, there's also other opportunities some of which, you know, involve restructuring cohorts from studies that have been done previously and so on. So we didn't want to preclude opportunities to develop longitudinal studies from some of the previous studies, which is why we wrote this specific recommendation. Any comments or discussion?

DR. MAYER: This is Annyce. Don't know if "commit" might be a place where we might want to put "prioritize."

DR. WARD: I think it's a good suggestion. I think, you know, one of the concerns is that it's the way the grant funding works is often, you know, there's a maximum term funding that makes it difficult for, you know, there to be a commitment to a real, like, a ten-year study. So I think the idea of "commit" had something to do with finding a funding mechanism that would allow planning of long-term studies. But, I mean, "prioritize" probably conveys that well enough.

MR. FLAMMIA: This is Anthony. Maybe both present and future for the present and future studies.

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DR. WARD: Longitudinal inherently means long-term.

DR. MIDDENDORF: Yes. Going into the future.

DR. WARD: Yes. Going into the future.

MR. FLAMMIA: Okay. I just wanted to clarify that. Okay. Thank you.

DR. WARD: Okay. Is everybody happy with the revised wording? Further discussion?

MS. NORDSTROM: Should we say somewhere in this that we're talking about pediatric populations or some—I mean, is this recommendation just meant to—that the health program—or that the World Trade Center Health Program prioritize any longitudinal studies or are we talking specifically about the pediatric—or not pediatric but the former pediatric population? I don't know how to exactly frame that. And maybe I misremember because again—

DR. WARD: Yes. It's just a question of whether it's understood or not, but we can certainly make it more specific: ...longitudinal studies of physical and mental health of pediatric survivors. Would that be a way...?

MS. NORDSTROM: Yes, I think that language would work for me, but maybe if one of the doctors could—

MR. FLAMMIA: It's Anthony. Pediatric survivors of who?

DR. WARD: Period. All.

MS. NORDSTROM: Just any impacted non-responder population. Right?

MR. FLAMMIA: Responder and non-responder?

MS. NORDSTROM: Well, there are no pediatric responders. So anyone's who got secondary is a survivor, right? Am I right about that? Anyone who's been influenced by secondary...

DR. WARD: So maybe that's not the right word then: pediatric—of populations or of pediatric—

MS. NORDSTROM: Impacted population or something?

MR. FLAMMIA: Pediatric populations of both responders and non-responders?

DR. BOWLER: I think that would be good because that would also then include like the Tower survivors. The children of the Tower survivors.

MS. NORDSTROM: But anyone who is not actually a responder on the day is in the survivor population, aren't they?

DR. BOWLER: Pediatric non-responders and non-responders. Right. But they're always left out.

MS. NORDSTROM: But there were no child responders. There's only the children of responders and aren't they in the survivor population? Am I wrong about that? I could be, but I think this implies that this would include studies of child responders and child survivors or people who were children at the time. There were no responders that were children.

DR. BOWLER: It's their parents. Their parents who were non-responders. Children of parents who were non-responders.

MS. McVAY-HUGHES: But perhaps more broadly is affected pediatric populations.

DR. WARD: Yes, thank you.

MS. NORDSTROM: Yes, I think that's a better idea.

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DR. BOWLER: I couldn't hear. What is the better idea?

MS. McVAY-HUGHES: Affected pediatric populations. And sorry, this is—

DR. BOWLER: I'm sorry, I have a very bad connection.

MS. NORDSTROM: She said affected pediatric populations.

DR. MIDDENDORF: Yes, if you can see it on the screen at the top.

DR. BOWLER: Okay.

DR. MIDDENDORF: It's on the screen now, Rosemarie, if you can see it there.

DR. BOWLER: Thank you.

DR. WARD: Yes, I like that suggestion because, you know, there is some debate about populations that are officially covered and not covered under the Zadroga Act, but...

MR. FLAMMIA: Or could be covered.

DR. WARD: Or could be covered. Right. So this kind of leaves it broad enough that we're not trying to over-define it.

DR. MIDDENDORF: Is there a motion?

MS. NORDSTROM: I'll make a motion. This is Lila.

DR. MIDDENDORF: And what is your motion?

MS. JONES: I second. This is Val.

DR. MIDDENDORF: What is your motion, Lila?

MS. NORDSTROM: Oh, to vote on this.

DR. MIDDENDORF: Accept the Recommendation 5 is your...

MS. NORDSTROM: Or to accept the recommendation. Yes. Sorry.

DR. MIDDENDORF: Okay. And, Val, did you second it?

MS. JONES: Yes.

DR. MIDDENDORF: Okay. So Recommendation 5 as currently written is: "Recommend that the World Trade Center Health Program prioritize, to the extent possible, to longitudinal studies of physical and mental health of affected pediatric populations."

DR. WARD: And I think we have to take out this "to."

MS. JONES: Right. Yes. After "possible."

DR. BOWLER: Right.

DR. MIDDENDORF: So it is: "Recommend that the World Trade Center Health Program prioritize, to the extent possible, longitudinal studies of physical and mental health of affected pediatric populations." Okay. It's a roll call vote. Tom Aldridge.

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie Bowler.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony Flammia.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob Harrison.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg Homish.

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DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine Hughes.

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val Jones.

MS. JONES: Yes.

DR. MIDDENDORF: Steven Markowitz.

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce Mayer.

DR. MAYER: Yes.

DR. MIDDENDORF: Mike McCawley.

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille Mejia.

MS. MEJIA: Yes.

DR. MIDDENDORF: Lila Nordstrom.

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill Rom.

DR. ROM: Yes.

DR. MIDDENDORF: Megan Ryan.

DR. RYAN: Yes.

DR. MIDDENDORF: Glenn Talaska.

DR. TALASKA: Yes.

DR. MIDDENDORF: And Liz Ward.

DR. WARD: Yes.

DR. MIDDENDORF: Okay. Sixteen votes for it. The motion carries.

DR. WARD: Great. So the next recommendation, Recommendation #6 is a very general recommendation and as, you know, as we said earlier, in relation to the first recommendation it's a very important concept, and so I think that's why it's called out separately from the first recommendation and also because we felt that if, in fact, another cohort besides the Registry cohort was identified and proposed it would be optimal for a similar coordinated approach to studying that cohort. So any discussion? We have a motion?

DR. MARKOWITZ: I'm sorry. It's Steven. Just a quick note. We changed the word "coordinated" to "collaborative" in the previous recommendation, #1. And if this echoes that then we should probably do the same.

DR. WARD: Good. Any other discussion? We have a motion?

DR. BOWLER: So is that not a single pediatric cohort any more?

DR. WARD: Ah, very good point. And it's true—you know, and I just noticed—it's funny how you write these things and then you see flaws in the way they're written. We're not saying there can be only one pediatric cohort. We're saying that we would, you know, that any pediatric cohort that we encourage a collaborative approach to research on any un-pediatric cohort.

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DR. BOWLER: Yes, that's better than single.

DR. WARD: Yes.

MS. JONES: Right. On, yes, any.

DR. BOWLER: Or pediatric cohorts, plural. Then you avoid the any...

DR. WARD: Yes, I don't even know if we totally need this recommendation, honestly. But...

DR. BOWLER: Yes, the "any" is not so good. You could—so cohort and put "s" in parentheses.

DR. WARD: Or could say, "Recommend that the WTCHP encourages collaborative research approaches in pediatric studies."

DR. BOWLER: Yes, that's better. Although that's different.

DR. MIDDENDORF: What was that again?

DR. WARD: "Recommend that the WTCHP encourages collaborative research approaches..."

DR. MAYER: But isn't the collaboration on the cohort development?

DR. WARD: I think we'll—I mean, that could be part of it. And so it could be "encourages collaborative research approaches in pediatric cohort development and study design." And in pediatric cohort development and (inaudible @ 02:09:03)

DR. BOWLER: Well, wouldn't it be "approaches in developing pediatric cohorts to study." Is that what you're trying to say?

DR. WARD: Well, it's development and then conducting pediatric research.

DR. BOWLER: Oh, I see.

DR. WARD: And developing pediatric—pediatric cohort development and study.

DR. BOWLER: How about just "to study" or...?

DR. WARD: How about "pediatric cohort development and research and proposals?" And we can maybe take out research. "Encourage collaborative approaches in pediatric cohort development and research proposal."

DR. BOWLER: Yes, that's better.

DR. MIDDENDORF: Sorry, what was that again?

DR. WARD: Let's take—it's too many researches.

DR. MIDDENDORF: Take this out.

DR. WARD: Yes.

DR. MIDDENDORF: "Collaborative approaches in pediatric cohort development and research."

DR. WARD: Yes, I think that's good. I mean, I think it says something that's a little bit more...

DR. BOWLER: Yes. Yes. Going with the prior longitudinal approach.

DR. WARD: Do we want to say, "research proposals" or just "research?"

DR. ALDRIDGE: Well, you've taken out the word "funding" now, I noticed. Or "fund."

DR. WARD: Yes.

DR. HOMISH: I'm sorry, this is Greg Homish. I had a question about how this doesn't overlap with Recommendation #1 where we talk about the collaboration and the consortium.

DR. WARD: It does overlap, and I think the distinctive thing here is that we didn't want to only respect the importance of this approach to research using the Registry. So we're talking about the possibilities of developing other cohort studies or other study

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opportunities. But I think the point still stands even if it's another study, even if it's another population it's still kind of a scarce resource, and you'll certainly want to make the most of opportunities if you're going to contact people and enroll them in a study. You want to make sure that, you know, you at least think about whether there's other outcomes besides a specific one that you might be interested in.

PARTICIPANT: Yes. The recommendation also doesn't say anything about the World Trade Center, this being a World Trade Center cohort.

DR. WARD: Well, I think everything in this document relates to pediatric research related to the World Trade Center.

PARTICIPANT: Yes.

DR. MIDDENDORF: Or any of the 9/11 attacks sites.

DR. WARD: Right. Okay.

DR. HOMISH: Would we want to make a recommendation that encourages data sharing plans for ongoing research? Because that would get at this collaborative approach, and then it would also get at instead of asking partici—having two investigators ask the same participant multiple questions, if there was one bigger study that had a data sharing plan in it other people could access that in a collaborative fashion.

DR. MIDDENDORF: I can tell you that there's another effort within the federal government to require data sharing for funded research. So I think that's taken care under another venue.

DR. HOMISH: Okay.

DR. BOWLER: Right. And it has been—the Registry has been engaged in this data sharing, but it's been an incredibly long process. I think it took me six months to get—it was different from before. The police just (inaudible @ 02:12:40) I have, there's no problem. But the Tower survivors took over six months to get, and tremendous amount of work. I don't how many researches carry through with that unless it gets changed.

DR. WARD: Yes. I think this is general, but I do think it probably covers potential data sharing because someone could write a proposal to use data—partly use data from an existing study. So I think it's covered under the umbrella anyway.

DR. MAYER: This is Annyce. I'm sorry. What exactly is a research consortium?

DR. BOWLER: What exactly is the what?

DR. MAYER: Research consortium.

DR. BOWLER: Oh. Group of researchers who are engaged in some joint research. Right?

PARTICIPANT: Uh huh.

DR. MAYER: So it's nothing more formal than that?

DR. WARD: Right. I mean, I think in some instances it could be, but I think the—really the idea—and we've moved away from that a little bit—we've moved away from the language—is have a group of investigators, some of whom might be experts in mental health, others in physical health or respiratory health, collaborate together to develop the methods for a study of exposed children. So it is kind of a planning,

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a common planning effort. So it's more than data sharing. It's actually developing an approach (inaudible @ 02:14:32) together.

DR. BOWLER: Right. Approach different.

DR. MAYER: So it just seems that the language in the original recommendation was stronger.

DR. WARD: You mean in recommend—

DR. MIDDENDORF: Yes, this wording (inaudible @ 02:14:43)

DR. MAYER: Collaborative research consortium.

DR. WARD: I think it is stronger. I guess the question is, is it too specific in the absence of a study population or plan, and I think that's...

DR. MIDDENDORF: You want it to send the message that this is one idea of how you would do collaborative approaches. You could—

DR. WARD: You could say "such as."

DR. MIDDENDORF: "Such as." So you can include it in the second set of words if you choose to.

DR. WARD: Yes. (Inaudible @ 02:15:34) oh, nice. Nice. Good. Does that look good to everyone, informally?

DR. BOWLER: It's fine.

DR. MIDDENDORF: Is there further discussion on that suggestion?

DR. WARD: We could be more specific and say, "such as by funding..." or "through funding such as..." "by funding" or "such as..."

DR. MAYER: Funding a research consortium.

DR. WARD: How about "such as encouraging proposal by research consortium?" Because I think there's a—I mean, "such as requesting proposals." Aye?

PARTICIPANT: Yes.

DR. WARD: That looks good to me. Does that look—I mean, does anyone have any comments on that recommended change?

DR. MIDDENDORF: Give folks a second to read it—we didn't digest it—and think about it.

DR. ALDRIDGE: I'll go back to what you just had which was the funding. I think that's a stronger statement than "requesting proposals." Because "requesting proposals" doesn't mean you have to do anything with them.

DR. BOWLER: Right, right.

DR. WARD: I mean, obviously, and it goes back to what Tom's been saying, you can't fund something if you don't have any meritorious proposals.

DR. ALDRIDGE: Right.

DR. MIDDENDORF: You could request or you could encourage. There are a number of different ways of stating that.

DR. WARD: And you probably want to say "research consortium" not "a research consortium" because there could be...

DR. MIDDENDORF: True.

DR. BOWLER: Would you want to get into multi or interdisciplinary?

MS. McVAY-HUGHES: Although I thought the point of this was to have a collaborative effort to use multiple sources to develop a pediatric cohort as opposed to different cohorts.

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DR. WARD: I don't know that that was necessarily true. I mean, I think the idea was—I mean, part—and, again, I'm not sure how well it's translated into the recommendation, but I think the idea was that there may be other cohorts that would be amenable to study. Although it seems like from what we heard that it's going to be difficult. But if there were opportunities to study other cohorts that I think the main point was that a research consortium approach be considered. Maybe this is not—I don't know. This may not be the strongest recommendation. Maybe we—I'm not sure it stands on its own as a recommendation or maybe...

MR. FLAMMIA: Hi, this is Anthony. I'm just playing around with the words in my head here. I'm thinking recommend that the World Trade Center Health Program study multiple outcomes and collaborative approaches, for example, as requested—I'm just playing with it right now. Yes. That the World Trade Center Health Program encourage multiple outcomes.

DR. WARD: Yes. I mean, and I...

DR. MIDDENDORF: Do you see another recommendation where you would pull this into it?

MR. FLAMMIA: I'm looking at line 288 on page 10.

DR. WARD: Yes, and maybe we really were at that point trying to get it making one large cohort out of all the different cohorts, although that seems really ambitious.

MR. FLAMMIA: I mean, because it says on number 288 about—it says about the optimal and to study multiple outcomes.

DR. BOWLER: On the single cohort.

DR. WARD: Yes, I almost think, you know, just keeping it very simple and saying "encourage collaborative approaches in pediatric research," period.

DR. MIDDENDORF: Yes, I think that makes sense.

DR. WARD: Because I think, you know, we said it really strongly in the first—relative to the Registry cohort, but I think that comment kind of carries across to any other research that's proposed.

DR. ALDRIDGE: This is Tom Aldridge again. Would it be reasonable to say something like incentivize the collaborative—or creation of collaborative research consortium?

DR. WARD: I think that's a good way to put it. And, again, but keep it pretty general like that.

DR. MIDDENDORF: Can you say that again, Tom?

DR. ALDRIDGE: I didn't have it very well-formed syntactically. But I wanted to say something like the World Trade Center Health Program should incentivize the creation of pediatric consortium for collaborative research. I'm sure somebody can come up with some better wording.

DR. WARD: Incentivize the creation of consortia for collaborative pediatric research. I don't think we want pediatric consortia to open a day care center. I like that.

MR. FLAMMIA: Yes, that's actually simple.

DR. WARD: Yes, that's great. So is there any further discussion or modifications of that?

MR. FLAMMIA: I like that one.

DR. BOWLER: That's fine.

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DR. MIDDENDORF: Okay. Do we have a motion?  
MR. FLAMMIA: I motion to accept. Anthony.  
DR. MIDDENDORF: And a second?  
DR. MAYER: Annyce seconds.  
DR. MIDDENDORF: Who was that?  
DR. MAYER: Annyce.  
DR. MIDDENDORF: Annyce. Okay. So as worded the recommendation is: "Recommend that the World Trade Center Health Program incentivize the creation of consortia for collaborative pediatric research." We'll do a roll call vote. Tom Aldridge.

DR. ALDRIDGE: Yes.  
DR. MIDDENDORF: Rosemarie Bowler.  
DR. BOWLER: Yes.  
DR. MIDDENDORF: Anthony Flammia.  
MR. FLAMMIA: Yes.  
DR. MIDDENDORF: Bob Harrison.  
DR. HARRISON: Yes.  
DR. MIDDENDORF: Greg Homish.  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine Hughes.  
MS. McVAY-HUGHES: Yes.  
DR. MIDDENDORF: Val Jones.  
MS. JONES: Yes.  
DR. MIDDENDORF: Steve Markowitz.  
DR. MARKOWITZ: Yes.  
DR. MIDDENDORF: Annyce Mayer.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike McCawley.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille Mejia.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila Nordstrom.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill Rom.  
DR. ROM: Yes.  
DR. MIDDENDORF: Margaret Ryan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn Talaska.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz Ward.  
DR. WARD: Yes.  
DR. MIDDENDORF: Okay. Sixteen votes. Motion carries.

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- DR. WARD: So we'll vote on these separately. So Recommendation 7 really relates to the possibility of identifying additional groups of children to study and it specifically is suggesting that the World Trade Center makes funds limited to short-term grants to identify a potential cohort. So is there any discussion of this?
- MR. FLAMMIA: This is Anthony. Just out of curiosity why short-term?
- MS. McVAY-HUGHES: Anthony, can I make a comment here?
- MR. FLAMMIA: Sure.
- MS. McVAY-HUGHES: After 15 years we don't want necessarily a project that's going to take 5 years to go through from beginning to end necessarily for kids who have been (inaudible @ 02:25:43) not a whole lot of attention for the last 15 years. So at least there should be some possibility for some short-term results because the turnaround on all this data it takes forever.
- DR. MIDDENDORF: And that's Catherine? Is that correct?
- MS. McVAY-HUGHES: Yes.
- MS. NORDSTROM: Also, isn't the point here to just attempt to find, you know, to figure out whether we can expand the research cohort with the pediatric population by giving out grants that are specifically focused on trying to sort of expand our study population?
- DR. WARD: Right.
- DR. MIDDENDORF: That was Lila, by the way.
- MS. NORDSTROM: Yes, that was Lila. Sorry.
- DR. WARD: Yes. And I think that's the thing. I mean, I think that, you know, people aren't going to be able to compete for a full grant, and so the idea would be to set aside funds for these short-term grants that people could say, "I want to look at the possibility of re-contacting Stuyvesant students or talk to the Board of Ed. again about the Hoven (inaudible @ 02:26:44) or you know, any—but without the funding people just don't have the resources to do that kind of work. And unless they can do that kind of work, they can't really write a full grant proposal for funding. But then (inaudible @ 02:27:05) it long-term is it doesn't take five years, it takes a year, hopefully. Go ahead. Sorry.
- MS. NORDSTROM: This is just essentially an attempt to sort of like give pediatric studies the possibility to compete on equal footing with steady populations that are much more well-developed. Right? That's the...that's the narrow intention of this—of this recommendation.
- DR. WARD: Part of it. But I think the other idea is the one last chance. I mean, we already know that we've lost lots of opportunities. Is there an opportunity out there that we could possibly use to identify another pediatric population to study?
- DR. BOWLER: You know, here is something I've wondered about in the pediatric area, and since you have like, you know, I'm not familiar with the schools that had most of the—have or had most of the children who were involved. Why aren't there any reports on achievement test results for those schools? That's publically available.
- MS. McVAY-HUGHES: There's a lot of people who don't put that much faith into achievement tests. They

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- consider them somewhat biased. This is Catherine.
- DR. BOWLER: Oh, but it's certainly—nevertheless it would be—
- MS. McVAY-HUGHES: That would be a heavily—
- DR. BOWLER: Nevertheless, it's a knowledge—the knowledge base they respond to it and it's to some extent mental development, even if it's not perfect.
- MS. NORDSTROM: But children (inaudible @ 02:28:37).
- DR. WARD: I think what you're saying, though is—
- MS. NORDSTROM: Don't go to their school for their entire education. So you don't really have a study population to follow through from beginning to end because people that were in elementary school at the time of the attacks did not necessarily go to high school in the area and the people that did go into high school in the area are either attending a highly specialized math and science high schools or they're attending another school that draws largely from outside of the neighborhood for its population. So there's not sort of like a population to follow through long-term in terms of the test results anyway.
- DR. BOWLER: But that's what could be followed and that would be of great interest if there is something organic going on in the kids. There would be a difference between those and another group, and that's relatively inexpensive compared to a big study testing kids.
- DR. WARD: Well, I think she's saying, Rosemarie, that this isn't really what this bullet is about. I mean, this bullet is about if somebody has an idea of either a study population or a source of records that they can apply for funds to investigate it. You know, I know that there have been issues with getting, you know, records from the Board of Education. And, you know, one of the great possibilities was to follow up on the Hoven's study population, but that population was collected in such a way that it couldn't be followed longitudinally. So, but I think that's what this is intended to cover. If somebody has an idea about it, a resource for a study that has not been tapped, this is to provide funding feasibility and pilot studies to evaluate that opportunity.
- DR. ALDRIDGE: Tom Aldridge. Once again I think this should not be "fund," it should be "encourage the submission of" or something like that.
- DR. WARD: I almost think, though, that this would almost have to be a very specific RFP because otherwise it will never, ever—don't you think this would almost have to be (inaudible @ 02:30:51)?
- DR. ALDRIDGE: Well, I think it may turn out to be impossible and so you can't fund something that's impossible.
- DR. WARD: Say it again.
- MS. NORDSTROM: But at least someone would try.
- DR. ALDRIDGE: No, somebody should try, sure, but if it turns—I mean, you have to write a grant that's feasible and if it's totally unfeasible then it should not be funded.
- DR. MARKOWITZ: This is Steven. Maybe it should say that, "recommend that the WTCHP develop a

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- DR. WARD: funding opportunity” or “develop a grant opportunity” instead of—  
Yes.
- DR. ALDRIDGE: Yes. Yes, exactly.
- DR. WARD: Yes. Good.
- DR. ALDRIDGE: But if it turns out to be totally impossible this does not soak up funds that would otherwise be available for meritorious research in pediatric or other areas. That’s my view. I’m not suggesting wording change.
- DR. WARD: Yes. I mean, these would have to be evaluated just like—I mean, it would be a separate funding opportunity for smaller amounts of money for shorter time periods, but it would have to go through a merit review just like any other. So it wouldn’t compete directly against—but you can’t evaluate something like this against a full grant proposal, is what I’m saying. You’d have to have a separate evaluation mechanism.
- DR. MIDDENDORF: It wouldn’t compete.
- DR. MAYER: Right.
- DR. MARKOWITZ: Regardless, it’s more appropriate for us to recommend the funding opportunity than for us to recommend funding. So...
- DR. WARD: Yes. Yes. We could say “funding opportunity” because it doesn’t even need to be a grant.
- DR. MAYER: This is Annyce. I would just add “expedite cohort identification” to emphasize this is something that needs to be done quickly.
- DR. MARKOWITZ: This is Steven. You know, the short-term kind of covers that because that means limited—you know, the funding will be limited to a year or something, so that that will be expedited.
- DR. WARD: Yes, I think we have maybe—maybe that is attempt is better just because it’s not—I mean, we recognize that this may not come to anything. I mean, “expedite” kind of implies that we believe that there are cohorts out there (inaudible @ 02:33:46) sure, but we certainly want—it’s really, you know, uncovering the last stones in terms of if there is an opportunity out there that’s been missed or overlooked we want people to have some funds—to be able to apply for funds so they have the resources to look, I think.
- MS. McVAY-HUGHES: It really should be “expedite the attempts,” but...
- DR. WARD: “Expedite attempts.”
- MS. McVAY-HUGHES: “Expedite the attempts.” Oh, but then I guess it doesn’t work for cohorts. But it just seems like this is an important question that the answer may well be no, but to recognize that this isn’t an option and to focus on other avenues would be helpful in addition to if they were actually able to identify a cohort.
- DR. WARD: Yes, I guess—I think the problem I have with “expedite” is it assumes that it’s going to happen, but slowly. And I think if we don’t do this that it won’t happen. So it’s not really expedite. Expedite, to me, means make faster. So, but, anyway, does anyone else have a strong preference on “expedite” or...

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MS. McVAY-HUGHES: Or how about the “WTCHP expedite the development of grant opportunities?”

DR. WARD: That’s good. I think that gets at the sense better. Anyone else have any further comments? I am mindful of the time. We had a scheduled break at 3:00 which we did not take, but we are...

DR. BOWLER: Right.

DR. MIDDENDORF: Right. Yes, I think we might want to. After we finish Recommendation 7, why don’t we take a quick five-minute break.

DR. WARD: Okay, but—

DR. MIDDENDORF: And I mean five minutes, not...

DR. WARD: But we are—it’s now 3:37 and we had scheduled only until 4 o’clock for this.

DR. MIDDENDORF: So we can move into the reauthorization stuff. That should only take five, ten minutes at the most.

DR. WARD: Okay. But, anyway, we do need to keep, you know, an eye on the time so we don’t run out of time to discuss the last recommendations. Okay.

DR. MIDDENDORF: But we also want to make sure that we get full discussion of each of the recommendations to make sure it’s what the committee wants.

DR. WARD: Right.

DR. MIDDENDORF: We’re balancing here.

DR. WARD: Yes. No, it’s just that the time—the countdown is beginning to the end of the meeting.

DR. MIDDENDORF: Yes.

DR. WARD: So Recommendation 7, any further discussion or motions?

DR. MIDDENDORF: A motion?

MS. NORDSTROM: This is Lila. I’ll start a motion to accept it.

DR. MIDDENDORF: Okay. A second.

DR. RYAN: Megan. I second.

DR. MIDDENDORF: I’m sorry.

DR. RYAN: This is Megan seconding.

DR. MIDDENDORF: Okay. So Recommendation #7: “Recommend that the World Trade Center Health Program expedite the development of the funding opportunity for limited short-term projects that attempt cohort identification, location, and willingness to participate in studies to answer outstanding questions about whether unexamined opportunities to learn more about childhood effects of 9/11 can be addressed 15 years after the event.” That was a mouthful. We’ll do a roll call. Tom Aldridge.

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie Bowler.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony Flammia.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob Harrison.

DR. HARRISON: Yes.

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DR. MIDDENDORF: Greg Homish.  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine Hughes.  
MS. McVAY-HUGHES: Yes.  
DR. MIDDENDORF: Val Jones.  
MS. JONES: Yes.  
DR. MIDDENDORF: Steven Markowitz.  
DR. MARKOWITZ: Yes.  
DR. MIDDENDORF: Annyce Mayer.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike McCawley.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille Mejia.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila Nordstrom.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill Rom.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan Ryan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn Talaska.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz Ward.  
DR. WARD: Yes.  
DR. MIDDENDORF: Sixteen out of 16. The motion carries. Five-minute break?  
DR. WARD: Yes.  
DR. MIDDENDORF: Okay. Five-minute break. And I do mean five minutes.  
[Break.]  
DR. MIDDENDORF: Hello, everybody. Let's try to get back together again.  
MS. McVAY-HUGHES: Catherine here.  
DR. MIDDENDORF: Hi, Catherine.  
MS. JONES: Vaylateena here.  
DR. MIDDENDORF: Okay. I'll tell you what, I'll go through my roll call list and we'll see who we've got.  
Okay. I heard Val and I heard Catherine, and how about Tom Aldridge? Are you back?  
DR. ALDRIDGE: Yes, here I am.  
DR. MIDDENDORF: Rosemarie, are you back? We'll, come back to you. How about Anthony?  
MR. FLAMMIA: Anthony here.  
DR. MIDDENDORF: Okay. Bob?  
DR. HARRISON: Yes, I'm back.  
DR. MIDDENDORF: Okay. Greg?

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DR. HOMISH: Here.

DR. MIDDENDORF: Okay. Steven?

DR. MARKOWITZ: I'm here.

DR. MIDDENDORF: Annyce?

DR. MAYER: Here.

DR. MIDDENDORF: Mike?

DR. MCCAWLEY: Yes, I'm here.

DR. MIDDENDORF: Great. Guille?

MS. MEJIA: I'm here.

DR. MIDDENDORF: Lila?

MS. NORDSTROM: I'm here.

DR. MIDDENDORF: Bill? Bill Rom? We'll come back to you in a second. Megan?

DR. RYAN: Here.

DR. MIDDENDORF: Glenn? Liz, are you here?

DR. WARD: I'm here.

DR. MIDDENDORF: Okay. Let's go back to the top again. Rosemarie, are you there? How about Bill Rom? Glenn Talaska? We have 13 members at the moment. We do have a quorum and I'd like to keep moving on this. We're up on Recommendation #8.

DR. WARD: Recommendation 8 is a very specific one: "That the World Trade Center Health Program consider use of appropriate incentives to the World Trade Center children cohort to enhance their ongoing participation."

DR. ALDRIDGE: It's Tom Aldridge. Specific yes, but kind of vague nonetheless. I mean, what's the meaning of "appropriate incentives?" Are we talking about money or are we talking about whips and chains?

DR. WARD: I think "incentive" has a positive connotation.

MS. JONES: I think that when we had one of the people who presented to us who said—this is Val—that she had a long-term research project and what she said she used as incentives was really basically explaining to people how it was purposeful that they participate in research and I think she said she may have, in the end, developed some type of manual or some type of report, and that was how she got a large population to participate.

DR. WARD: Yes, and I think the concern, I mean, it sprang out of the discussions about the Registry population, is, you know, as time goes on people no longer are responding to questionnaires or wanting to participate in surveys. And, you know, sometimes incentives—whether they be financial or other kinds of positive reinforcement—will help the response rate and the retention rate especially if we're trying to do longitudinal studies.

MS. NORDSTROM: Also especially for this population. It's a population that really very much dislikes talking about this topic. So I think there's that incentive to offer this incentive program as well.

MR. FLAMMIA: This is Anthony. I think the other incentive—and everything what everybody said is

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great—or actually route to take is go through the unions; go through all the organized unions between the uniform and non-uniform people. And, you know, they have the best access to all the active which are dwindling in numbers as far as being exposed to 9/11 but also the retirees as well which have the outreach through the United States, not just the metro area but also throughout the United States that has that outreach to the retirees.

- PARTICIPANT: But the problem is that the children really, I mean, some of them may be in unions, but most of them probably not who were children at the time.
- MR. FLAMMIA: I'm sorry, you cut out. I lost you there for a second. I'm sorry.
- PARTICIPANT: Those who were children on 9/11, most of them are not currently in unions.
- MR. FLAMMIA: No, but the parents of.
- PARTICIPANT: Maybe.
- DR. BOWLER: Well, not necessarily; not everyone is a union member.
- MR. FLAMMIA: But you also have, you know, that's one route is through the unions. I understand you want to have the children. Yes, that's—yes. But also with the responders. You know, this is like a two-prong thing here is the responders, the children of the responders, and also the children that were exposed to Lower Manhattan and we—
- PARTICIPANT: I guess my issue with this, is it seems like, first of all, it's got three vague words in there: "consider" and "appropriate." I mean, well, okay, two vague words. But we either should be specific and say they should be paid or we shouldn't say it. I'm not sure that we should be telling the researcher how do their jobs unless it's a change in policy. Is it currently policy that people who are subjects of research programs are not allowed to be paid? If that's the case, sure it makes sense to say in this case it should be paid. But I'm not sure that we should do this at all. It seems to me that we're just telling the researcher how to do their job and they know better than we do.
- MS. MEJIA: This is Guille. I really do have a concern about this recommend—first of all, I'm not being facetious here, but, I mean, who is getting the incentive? Is it the parents? And you know, there we have the other groups, the responder group that, you know, we have retention problems. We have major retention problems with that group. So I think the issue here is to address retention and not incentives.
- DR. WARD: Yes, I think, you know, this...
- MS. MEJIA: That people are not sticking and responding. You know, maybe the methodology that's being used needs to be changed, it needs to be refreshed. So I'm...
- MS. JONES: I think what she said was that the research—and I think she did mainly public schools and she had did it longitudinally—was basically written and verbal incentives not monetary. It was written and verbal.
- DR. WARD: But here's the question. I mean, I like—we addressed the same point specifically in relation to the Registry cohort and we basically said that we recommend that

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the WTCHP makes substantial efforts to sustain and renew participation in surveys and special studies. And I think, in a way, we're saying the same thing here, and maybe it's not necessary. And it really isn't the role of the World Trade Center Health Program to—you know, it's the role of the investigators to propose incentives or other mechanisms of outreach that they need funding for. So I guess the question is: do we need this specific recommendation? And, if so, do we want to make it a little bit more general. Because "incentive" often, you know, often means a benefit whether it be financial or something like that whereas I think we're really talking about lots—any possible method of outreach or feedback, or any method to encourage ongoing participation in studies for the pediatric population. But, again, it's not really a recommendation to the World Trade Center Health Program. It's more to the researchers who are conducting the studies and the role of the World Trade Center Health Program would be to allocate funding, if necessary, to create those incentives or mechanisms.

MS. NORDSTROM: Is there a way for us to sort of, if it's not our role, to sort of—to kind of tell researchers how to do their research, but we are sort of helping create the larger set of priorities that the funding, you know, the funding then sort of like gets divvied up on the basis of is there a way to stress that this is—this is sort of, it's an especially difficult subject that historically, you know, we've had a difficult time getting interested people to participate in studies of because it's so unpleasant to talk about and unpleasant to think about, and that also on top of that we, you know, we've waited until this population is very dispersed to even try to find them. You guys know that I think that it's possible to find study cohorts in the pediatric population, and that I'm a member of that population, and that's not an impossibility. But I think that the reason that this recommendation is there is because it is so difficult to get—it's so sort of unpleasant for the participants to participate in these studies, and it's because we're dispersed it can be quite inconvenient, and maybe this is sort of like an important thing specifically with this population to consider because it's not just something that like, you know, 20-year-olds can necessarily do easily, but it's important that they do. I mean, I'm not sure that I'm phrasing that all that articulately. But I think that the reason that that is there is because this is an especially difficult subject to get people to talk about in the first place.

DR. WARD: So maybe we could just say, "Recommend that the WTCHP encourage use of appropriate incentives."

PARTICIPANT: I like that a lot better than "consider."

DR. WARD: Yes.

PARTICIPANT: Yes.

DR. HOMISH: Most definitely.

DR. BOWLER: Uh huh.

MS. NORDSTROM: I agree.

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- DR. BOWLER: Well, they have to get something out of it. And we do this in various ways by giving them a monetary incentive for their time or in—well, usually in the form of a gift card to avoid the social security issues about it. And I always give them an individualized feedback report to tell them how they scored and if there's any concern who they should talk to. So, but that's not done so much, I believe, that they get that kind of feedback. And then, you know, what is an incentive? I mean, you need to think of incentives to get them to come. I don't blame them.
- MS. McVAY-HUGHES: Catherine here. I just want to make sure that we state somewhere that the researchers make sure that they do provide the research back to the individuals that participated in their study. Because I have spoken to residents over the years and the data never got back to them, and they didn't even know that the data was actually published. And it's more than just a courtesy, but people want to know that their time was helpful. So there almost should be a requirement in the RFP.
- PARTICIPANT: Good point, Catherine.
- DR. BOWLER: Yes, yes. That would be something very important and useful to add because it is surprising how that isn't done very much.
- MS. JONES: And that's what that researcher said. She said that that was what they found very useful, was the fact that she explained to them how it was going to be used, the importance of it and that they got something written when it was completed. And I think for—
- DR. BOWLER: It's usually in the consent form we'd say that, that they sign to do the research. So we...
- MS. NORDSTROM: But a lot of—
- PARTICIPANT: I think that's a general requirement of—
- MS. JONES: But I think beyond a consent form—you know, I think there's certain populations that are very leery of research and especially when it is completed and you don't get anything, and you remember that you signed something, and you... you know, I just thought that when she explained that I says, "Okay, I understand that and I understand the purposed of that, and I can see where someone might think twice about doing some research if that was stipulated to them that this is the purpose and this is going to be the outcome, and the outcome is going to be written."
- DR. WARD: Okay. I have a suggestion in order to move things along. I don't know, this could be a second sentence in Recommendation 8, so we don't have to add a recommendation, but it could be: "Recommend that WTCHP require researchers to provide individual study results (where appropriate) and overall study results to study participants."
- DR. MIDDENDORF: Okay. I got about half that.
- DR. WARD: Okay. "...require researchers to provide individual study results (where appropriate)"—because sometimes it's not...
- PARTICIPANT: And, actually, that's really good.
- DR. WARD: "...and overall study results to study participants."

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DR. BOWLER: Yes, maybe, you know, to provide a feedback either to the participants...

DR. WARD: Yes. I think that gets (inaudible @ 02:58:58)

DR. MAYER: This is Annyce, and maybe it's obvious in here, but the way I interpret this was ongoing participation and because it was in the same box as #7 was that if we identify a cohort for a study now is there some additional incentive that we can provide that will encourage them to continue to participate over the years?

PARTICIPANT: That would be included in Recommendation 8.

DR. MAYER: Okay.

PARTICIPANT: I mean, that's just a special case of #8. So that would be covered.

DR. MAYER: Right. Okay. Didn't know if it should be, you know, including just to make it a little more clear it includes both.

MS. JONES: You know, I don't—one of the people who gave public testimony, I don't know if this would fit here. But one of the things she was saying was that also that in terms of identifying who the researcher is initially. I think one of the public presentations was the fact that I think the Victims Compensation Fund is a World Center program and there's a Registry, and that when contacted wasn't clear as to who exactly was contacting, and that some of the parents were thinking about taking their children out of the Registry because it wasn't clear as to who was contacting them to participate. I'm not sure if that would fit here, but I thought that was an important point when someone was saying that, you know, they thought about taking their kids out.

DR. WARD: But I think we kind of covered that...

MS. JONES: We did? Okay.

DR. WARD: In the collaborative research. Because the idea would be rather than three different studies recruiting people separately that you have one, you know, you have some coordinated, a collaborative approach to—yes. So I think...

MS. JONES: Okay.

DR. WARD: Yes.

MS. JONES: Okay. That sounds good.

DR. WARD: I mean, I think it's—the two sentences are connected, they—you know, we could wordsmith and make the connection stronger, but, I mean, I think it captures what we want to say.

MS. JONES: Okay.

DR. WARD: Right.

DR. MIDDENDORF: I agree with you there; we should have a cohort.

DR. WARD: Yes, I agree, especially—so is there any further amendments to this recommendation or further discussion? Do we have a motion?

MS. JONES: I make a motion—this is Val. I make a motion that we vote on Recommendation #8.

DR. WARD: Do we have a second?

PARTICIPANT: I'll second.

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MS. JONES: I see.

DR. MIDDENDORF: Okay. The wording on Recommendation #8 then is: "Recommend that the World Trade Center Health Program encourage the use of appropriate incentives to the World Trade Center children cohort..." Is that children's cohort?

DR. WARD: I think maybe we're talking about the Health Registry cohort there, but...

DR. MIDDENDORF: Okay. "...incentives to the World Trade Center children cohort to enhance their ongoing participation. Recommend that World Trade Center Health Program require researchers provide individual study results (where appropriate) and overall study results back to study participants." I'll let you think about that for a second and then we'll go to our voting list. Tom Aldridge.

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie Bowler.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony Flammia.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob Harrison.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg Homish.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine Hughes.

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val Jones.

MS. JONES: Yes.

DR. MIDDENDORF: Steve Markowitz.

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce Mayer.

DR. MAYER: Yes.

DR. MIDDENDORF: Mike McCawley.

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille Mejia.

MS. MEJIA: I'm going to abstain.

DR. MIDDENDORF: Okay. Lila Nordstrom.

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill Rom.

DR. ROM: Yes.

DR. MIDDENDORF: Megan Ryan.

DR. RYAN: Yes.

DR. MIDDENDORF: Glenn Talaska.

DR. TALASKA: Yes.

DR. MIDDENDORF: Liz Ward.

DR. WARD: Yes.

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DR. MIDDENDORF: Okay. Fifteen out of 15 votes cast. Okay.

DR. WARD: Okay. Recommendation 9. "Recommend that the World Trade Center Health Program support blood banking and preservation of cells from WTC-exposed children using state-of-the-art methods so that DNA, RNA, proteins, and long-lasting toxins can be studied in the future." Any discussion?

DR. ALDRIDGE: This is Tom Aldridge. I'm no expert in that area, but isn't this kind of late to be collecting this material? I understand the DNA maybe be all right, but all these other things, 15-year lasting toxins, I'm not so sure.

DR. WARD: Tom, I mean, there are some.

DR. TALASKA: There are a few things that may—from the exposure that maybe have long enough lasting—many of the dioxins would still be in somebody's blood, probably in their lipids.

DR. WARD: And then we did talk about epigenetic effect.

DR. TALASKA: Exactly.

DR. ALDRIDGE: I think it's up to the researcher who proposes this to justify it and I don't think we should say we're going to support—that the program is going to support it. Support it if it's a good proposal, but demonstrates the likelihood of success.

DR. WARD: But I do think it's a general...

MR. FLAMMIA: This is Anthony. What about past medical records that identify that there are certain abnormalities?

DR. ALDRIDGE: I can be pretty confident that there are no such—I mean there's no saved, there's no bank blood on these individuals and an ordinary blood test would be no good whatsoever.

MR. FLAMMIA: What about a full panel?

DR. ALDRIDGE: I think we're talking about a very specialized test that will not be on any kind of panel (inaudible @ 03:05:45)...

MR. FLAMMIA: Oh, no?

DR. ALDRIDGE: More than a handful of these. Like I said, I'm no expert, but that's my understanding.

DR. WARD: But there's two separate—I guess there's two separate questions. One is what we're basically saying here, I think, is that we would encourage the World Trade Center Health Program to support the blood banking and preservation of cells. But then the rationale for that is the belief that even doing that at this point in time will possibly yield—there will be then meritorious study proposals for analyzing those samples to identify potential either biomarkers of exposure or biomarkers of effect.

DR. ALDRIDGE: Do you really think that there is that potential this many years later?

DR. TALASKA: Certainly. Certainly. There's no doubt there will be dioxins in several of the long—the halogens. Halogenated hydrocarbons will still be in people's lipids and there may be markers that we don't even understand yet that would do the epigenetic effect. So to encourage them to just keep samples in a well-preserved way makes

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- a lot of sense to me.
- DR. WARD: Yes, especially in the context that, you know, we're kind of talking about, you know, at least for the Registry population bringing kids in for a physical health exam where very likely blood would be collected. And so the question is here—you know, so it's not doing this, I think, as an independent effort, but it's one potentially important component of a study where people are—where are kids are brought in for medical exams, and blood is drawn presumably for a physical health assessment.
- DR. ALDRIDGE: Each one of these individuals who was a child on 9/11 has had hundreds of thousands of other exposures since then and any finding now is, in my view, hopelessly compromised by all the subsequent exposures that they get from living in New York City or wherever. To me this is a very low yield potential study that's extremely expensive, and if somebody can justify it with the right science there's the mechanism already there to do that, I don't think we should add a specific encouragement for this kind of work. That's my view.
- DR. WARD: Well, I mean, that's good. I think it's healthy that, you know, we have a range of opinions on this in the committee, and I think, you know, you've just expressed I think a very cogent rationale for why one would not support this recommendation. I don't know if anyone else would like to speak in opposition or speak in—
- MR. FLAMMIA: I think the benefit of the doubt—this is Anthony—should be given to the responders and the children of Lower Manhattan of the children. I think we should—whether it's 1 or 1001—we should be giving the benefit of the doubt and have the studies done regardless of cost.
- DR. ALDRIDGE: There's not an unlimited amount of money. The money should be spent where it has the most impact.
- MR. FLAMMIA: Well, if you want to talk about the bill specifically, the bill it's been for a very long time and we're going to do what we have to do and if we have to go back for money we'll go back for money, and we should be given the benefit of the doubt—whether it's one or a thousand and one. Do you want to take that risk?
- DR. MARKOWITZ: Well, the thing is, is that—this is Steven—it really boils down not so much to money but to scientific merit and there is a process in place to address that. So I think we're—
- MR. FLAMMIA: So we should go down that road. We have to go down that road.
- DR. MARKOWITZ: Yes, we're okay in that respect.
- MR. FLAMMIA: We have to go down that road.
- DR. TALASKA: Encouraging them to hold on to samples seems to make sense to me. And not to collect samples and have them go away. That seems to make sense to me regardless even if they don't analyze them themselves.
- DR. ALDRIDGE: I wish those samples had been collected 15 years ago, but I don't think it's likely to be fruitful to look at them now.
- DR. TALASKA: Depends what the question is.

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- DR. MAYER: This is Annyce. I agree with the concern that Tom raises. And I, too, don't have any expertise in that area. If it were clear what would still be relevant and helpful from this information then I would support it. And I'm wondering if it—I don't know what the mechanism is in regard to a working group, but would it be appropriate for people who this is their area of expertise to provide more information on the feasibility of this?
- DR. WARD: I mean, one middle ground I could say is, you know, if we wanted to make it softer and get more—you know, one is we can vote on it as it is and the vote does not have to be unanimous. The other thing is, you know, we could say "Recommend that the WTCHP consider the scientific rationale for blood banking and..."
- MR. FLAMMIA: I wouldn't use the word "consider." They have to do it.
- DR. WARD: So, I mean, if we make a recommendation that WTCHP supports it, it's still, there's still a couple of layers. That doesn't mean they do it, it means that, you know, a consortium could propose it as part of a study proposal and ultimately the program can go back and evaluate—do their own evaluation of this, the merit of this particular recommendation. And, you know, and I agree. You know, I know that there are long-term effects that we could see—very likely could be (inaudible @ 03:12:14) and so on, you know. If we got an expert panel together today I'm not sure, you know, what their consensus would be on whether this is a high priority relative to everything else. But, clearly, in this workgroup there was broad agreement that it was a priority—
- MS. NORDSTROM: And I think it's also a major priority of SSD and a lot of the survivor community as a whole. I think we get used to being told that things aren't scientifically feasible and that's why we didn't get to study children 15 years ago. You know, it was like well, it was five years later so everything's—there's no data and we can't do anything about it. But that's the rationale that we get told repeatedly as a reason that we can't study elements of the survivor community especially a pediatric cohort. So I think that is why at least keeping the discussion open on this topic is important to survivors and I think probably the responder community as well. I mean, Anthony certainly is making good, you know, case for it. So I think that's something to consider as we continue talking about this. This is kind of the idea that, you know, that things aren't—that there's no scientific rationale for something so we should just stop talking about it has kind of started to—it irks those of us who are not on the medical side but have been hearing this rationale applied to, you know, the survivor community in numerous ways for like the last 15 years, and it's always been used as a reason to not start studies that we will have the scientific ability to deal with later on. So...
- DR. WARD: So I would recommend in the interest of time that we vote on this motion and that, you know, people have the option of abstaining or voting no.
- MR. FLAMMIA: I'm sorry. Just to add to the state-of-the-art methods. I believe one of the methods that was brought up is the study of the teeth. I don't recall the name of the study or

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anything like that. But I think there was a study of the teeth.

DR. WARD: I think we mentioned it. In the text we did not make that specific recommendation.

DR. ALDRIDGE: If there is good scientific rationale for doing those studies that rationale should be used to make a proposal and any of the other eight recommendations that we've already voted on.

MR. FLAMMIA: We owe it to the responder community and we owe it to everyone in Lower Manhattan. We owe it to everyone. We owe it to America.

DR. MCCAWLEY: This is Mike McCawley. I have a little bit of experience with both blood banking and with also genetic information. And it can be extremely useable, but it's a two-edged sword remember because you're banking genetic information on each of these people, and now you have to safeguard it and make sure that it does not get too public because otherwise it can be used against the people that we're trying to help. So, really, this needs to be (centered @ 03:15:32) very, very closely that whatever we profit from this we don't lose as well on the other side of having all of this genetic information of all of these people stored somewhere that people know that it's there. It's a privacy issue too. And I don't...

DR. TALASKA: Will those concerns be addressed by the IRBs of the people who propose the studies?

DR. WARD: I would think so.

DR. TALASKA: I would think so, too.

DR. ALDRIDGE: Absolutely. IRB is required to consider that.

DR. MCCAWLEY: Yes. But IRBs are people. And views change, times change, and court orders change because a court order can override an IRB. And that's what you have to remember with genetic information. It's only as safe as the lawyers you have protecting it.

DR. WARD: So, I mean, I think there's only two obvious alternatives. One is we can leave it and support. The other is we could soften it a little by saying, "consider supporting." And, I mean, I'm just posing those alternatives. I don't have a strong feeling. So if anyone wants to make a motion.

DR. TALASKA: I move to approve Recommendation 9.

MR. FLAMMIA: I second it. Anthony.

DR. MAYER: This is Annyce. Could we change it to "biobanking" so that it's a little more broad if things like teeth are to be included?

DR. WARD: Good suggestion. Yes, that's good.

MR. FLAMMIA: Very good, Catherine.

DR. TALASKA: I'm happy with that.

MS. McVAY-HUGHES: That was Annyce but...

DR. RYAN: This is Megan. I was going to make the same suggestion and sort of the same thing about the last clause, that is them being specific about RNA, DNA, proteins, long-lasting toxins to more generalize it since it's probably not that specific so that—I had the words before—chronic health effects can be studied in the future,

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something more general like that.

DR. WARD: I feel like that's getting at something different than the intent here. I mean, the intent of what was dis—you know, what the subcommittee and the committee discussed before. Glenn, what—Glenn and Steve. I think we were really talking really about biomarkers other than necessarily chronic health effects.

DR. MIDDENDORF: You can specify—or just say biomarkers then rather than specify these elements.

DR. RYAN: But the outcomes are chronic health effects. You're biobanking...

DR. WARD: Not necessarily. I mean, you could be looking at DNA adducts of something or there's a lot of things that you would look at that might be indicators of a genotoxic exposure or something like that where you don't really know that it's a health effect, but you can demonstrate a difference in an exposed population compared to an unexposed population and possibly tie it to health effects.

DR. RYAN: I concede this point—

DR. WARD: Well, we could say so that biological markers of exposure or effect can be studied in the future.

DR. TALASKA: But you also should include long-lasting toxins because those are not biomarkers usually.

MR. FLAMMIA: I would say—it's Anthony—biomarkers and exposure can be studied now and in the future.

DR. MIDDENDORF: Okay. What did you say? And can be studied...

MR. FLAMMIA: Now. Now and in the future.

DR. WARD: I think we want now and in the future. And I think we probably want to say "support collection, biobanking." You know, collecting...

DR. ALDRIDGE: But that phraseology doesn't that assume that you're only collecting cells and not, for instance, teeth?

DR. TALASKA: How about if we just say materials instead of cells?

DR. WARD: Biological materials?

DR. ALDRIDGE: Yes.

DR. TALASKA: Yes. Preservation of materials—of biological materials. Yes.

DR. WARD: How about sample? Materials is kind of bizarre. Is everybody okay with "materials?" I would be happier with samples, but...

DR. BOWLER: Samples just sounds better. It's more technical.

DR. WARD: Yes. Yes. So is there any further discussions or anyone ready to make a motion?

DR. RYAN: I think maybe there are some misplaced words in the last part of "exposure and effect and long-lasting toxins." Is it supposed to be "exposure and effects of long-lasting toxins?" See what I mean?

DR. TALASKA: How about—yes, just put "exposure, effects, and long-lasting toxins." Yes. How's that sound? And get rid of the "and." Yes. "The biomarkers of the exposure, effects, and long-lasting toxins." Yes.

DR. WARD: Okay. Ready to make a motion?

DR. TALASKA: I'll make the motion again.

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DR. MAYER: This is Annyce. Real quick. Biobanking is the preservation of biological samples?  
The collection and biobanking of biological samples?

DR. MIDDENDORF: You're saying that biobanking and preservation are the same thing.

DR. MAYER: Yes.

DR. WARD: Well, you know, I guess we can live with that. I think one of the things was to  
make sure that the technical message by which the samples are processed and  
maintained will allow the maximum range of potential biomarkers to be studied in  
the future.

DR. MAYER: Well, that sounds good.

DR. MIDDENDORF: Okay. So was someone making a motion?

DR. TALASKA: I'll move to accept it as amended.

MR. FLAMMIA: I'll second it. Anthony.

DR. MIDDENDORF: Okay. So Recommendation #9 reads: "Recommend that the World Trade Center  
Health Program support collection, biobanking and preservation of biological  
samples from World Trade Center-exposed children using state-of-the-art  
methods so that biological markers of exposure, effects, and long-lasting toxins  
can be studied now and in the future." So going to our roll call vote. Tom Aldridge.

DR. ALDRIDGE: No.

DR. MIDDENDORF: Rosemarie Bowler.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony Flammia.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob Harrison.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg Homish.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine Hughes.

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val Jones.

MS. JONES: Yes.

DR. MIDDENDORF: Steve Markowitz.

DR. MARKOWITZ: No.

DR. MIDDENDORF: Annyce Mayer. I abstain.

DR. MAYER: Yes.

DR. MIDDENDORF: Mike McCawley.

DR. MCCAWLEY: I abstain.

DR. MIDDENDORF: Guille Mejia.

MS. MEJIA: I'm going to abstain.

DR. MIDDENDORF: Lila Nordstrom.

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill Rom.

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DR. ROM: Yes.

DR. MIDDENDORF: Megan Ryan.

DR. RYAN: Yes.

DR. MIDDENDORF: Glenn Talaska.

DR. TALASKA: Yes.

DR. MIDDENDORF: Liz Ward.

DR. WARD: Yes.

DR. MIDDENDORF: One, two, three, four, five, six, seven, eight, nine, ten, eleven yeses. One, two nos. It carries 11 to 2 with 3 abstentions. On to 10 and 11.

DR. WARD: Okay. Ten is one which we kind of alluded to previously where we were—the text kind of gave a pretty full rationale for the recommendation, but it didn’t—the recommendation didn’t completely capture it. So I think we are open to changes in freezing. But it’s also one that, as Paul mentioned before, it’s not so much specific to pediatric research, it’s more of a general recommendation for the program and we do want to spend most of our time focusing on the pediatric recommendations. I’m almost tempted to skip 10. I just, I mean, we—if we were agreeable to it I would almost skip 10 and recommend that we vote on 11 because 11 I think is really clear and we can understand what we’re talking about. Ten is so difficult to understand that I’m not even sure what we’re trying to get at.

DR. MIDDENDORF: If the workgroup approved it to come to full committee.

DR. WARD: Oh, then we have to—okay.

DR. MIDDENDORF: I think the full committee needs—well, the full committee can vote just to strike it if they choose to. And you can propose that motion to see if people are agreeable.

MS. NORDSTROM: Can I make one suggestion that maybe it’s related to 10 or 11, I can’t quite tell which, but probably 11? I think that we in some way add that there is some sort of mechanism by which people who are being researched can also be referred to the World Trade Center Health Program if they have qualifying conditions or something that, you know, as part of the sort of like, you know, service back to the community that these findings, you know, create like that there’s some sort of pipelines, other people who qualify for treatment under the World Trade Center Health Program learn about that if they’re part of these studies. I mean, I think it’s related to, you know, that sort of like community giving back to the community how these studies—or what these findings are.

DR. WARD: Well, this is more of a procedural question. I mean, that is distinct from any of the specific recommendations that the workgroup agreed to.

MS. NORDSTROM: Okay.

DR. MIDDENDORF: Yes. I mean, the full committee can develop its own positional recommendation if it chooses to.

DR. WARD: The full committee can—and add it. Yes.

MS. NORDSTROM: Or is there language where we can just encourage researchers to—is that—I think that’s still the same thing, but encourage researchers as part of

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- communicating how these studies are coming out, that they can communicate that information about the World Trade Center Health Program as part of it or something? Anyway, maybe (inaudible @ 03:27:31), I don't know.
- DR. WARD: Well, we did make a recommendation earlier that people be notified of their individual study results and, if appropriate, and overall study results. We could amplify that a bit and referral be provided—and referral to the World Trade Center Health Program be provided.
- DR. MIDDENDORF: Yes, what I'm not sure about is whether or not the researchers would know enough about the World Trade Center Health Program and covered conditions to know when for sure someone would be eligible, and that's sort of beyond what the researchers are intended to do, that that's kind of outside scope
- DR. WARD: We could say that information about covered conditions under the World Trade Center Health Program be...
- MS. NORDSTROM: I mean, these are researchers that are going to be funded under the World Trade Center Health Program. So it feels like they should be part of the same responsibility to provide information that care is available.
- DR. WARD: I mean, I think the Registry does that, right, as a matter of course.
- DR. BOWLER: No, actually it's individual researchers. We don't get it. We just have to go on the website or ask for it, but we don't get communication like that. I mean, after five papers I know, I never got that. Five manuscripts published. But it's useful to leave it in.
- DR. WARD: Well, I think maybe this is more specific, though. We could add a recommendation that says, "We encourage the World Trade Center Health Program..."
- DR. BOWLER: Inform researchers.
- DR. WARD: To inform researchers about World Trade Center..."
- DR. BOWLER: Treatment programs available through the WTCHR.
- DR. WARD: "About treatment and coverage and covered conditions, and to provide information about, you know, the WTCHP to study participants.
- MS. NORDSTROM: I'm very happy with that process
- DR. MIDDENDORF: Might want to...
- MS. NORDSTROM: Something...
- DR. MIDDENDORF: Opine on that a little bit.
- DR. WARD: "Encourage the WTCHP to inform researchers about WTCHP treatment program and the covered conditions and provide this information to study participants." And then maybe if we want to keep the first one...
- DR. BOWLER: I'm sorry, but I will have to run off and I want to be sure that my vote for 10 and 11 is both yes, if I can do it that way, if that's legitimate and, Paul, I guess we'll be informed what comes next.
- DR. MIDDENDORF: Rosemarie, unless you're here to actually vote on the specific wording we won't be able to record a vote for you.

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DR. BOWLER: Oh, too bad. I'll wait another five minutes.

DR. WARD: I mean, do we want to just make 10 more specific to the—I still say maybe we should strike—I think the effort of trying to make this really clear is, we don't have really the full time, but I think there's a lot of consensus on this recommendation and this is a reasonably clear recommendation. So my recommendation would be we just strike the first bullet and keep the second bullet under 10.

DR. MIDDENDORF: Okay. That needs to be two separate votes. One is to strike the first bullet. So do you want to make that motion?

DR. WARD: Or we can vote on it—okay.

DR. MIDDENDORF: You want to make the motion?

DR. WARD: Okay. I can make a motion?

DR. MIDDENDORF: Yes.

DR. WARD: I didn't know I could make a motion.

DR. MIDDENDORF: Yes, you can make a motion.

DR. WARD: Okay. I recommend that we strike the first bullet because it's too unclear.

MR. FLAMMIA: I second it. Anthony.

DR. MIDDENDORF: Okay. We'll do a roll call vote. And the vote is on whether to strike the first—well, the original recommendation #10 which reads: "Recommend that the World Trade Center Health Program develop various means to communicate how the various cohorts, study methods, and outcomes inter-relate, and what the accumulated findings are to date." So, Tom, are you in favor of striking that?

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie.

DR. BOWLER: Well, so are they not going to tell them about the various study methods and outcomes, how they interrelate? Okay. Well, I would've liked to see that, but that's an idealist approach, so maybe you can scrape it.

DR. MIDDENDORF: So is your vote yes.

DR. BOWLER: Yes. You take it out. Yes.

DR. MIDDENDORF: Anthony.

MR. FLAMMIA: Anthony. Yes.

DR. MIDDENDORF: Bob.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine.

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val.

MS. JONES: Yes.

DR. MIDDENDORF: Steven.

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce.

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DR. MAYER: I abstain.  
DR. MIDDENDORF: Mike.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille. Guille.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz.  
DR. WARD: Yes.  
DR. MIDDENDORF: Fifteen yeses. One abstain votes. So the motion to strike Recommendation 10 carries.  
DR. WARD: So I make a motion that we vote on Recommendation #10.  
DR. MIDDENDORF: Is there a second?  
MS. NORDSTROM: I second that motion.  
DR. WARD: Was that a second?  
MS. NORDSTROM: Yes, from Lila.  
DR. WARD: Thank you.  
DR. MIDDENDORF: Lila. Okay. So Recommendation #10 now reads: "Encourage the World Trade Center Health Program to inform researchers about the World Trade Center Health Program treatment programs and covered conditions and provide this information to study participants." Any further discussion on that? Okay. We'll do a roll call vote. Tom Aldridge.  
DR. ALDRIDGE: Yes.  
DR. MIDDENDORF: Rosemarie.  
DR. BOWLER: Yes.  
DR. MIDDENDORF: Anthony.  
MR. FLAMMIA: Yes.  
DR. MIDDENDORF: Bob.  
DR. HARRISON: Yes.  
DR. MIDDENDORF: Greg.  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine.  
MS. McVAY-HUGHES: Yes.  
DR. MIDDENDORF: Val.  
MS. JONES: Yes.

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DR. MIDDENDORF: Steven. Steven, are you still there? We'll move on. Annyce.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille. Guille.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: And Liz.  
DR. WARD: Yes.  
DR. MIDDENDORF: So 15 yeses. Okay. Steven, are you still there?  
DR. MARKOWITZ: Yes?  
DR. MIDDENDORF: Okay. Did you vote yes on...?  
DR. MARKOWITZ: Yes, I did. I was on mute. Yes.  
DR. MIDDENDORF: Okay. So we have 16 out of 16. Great. Okay.  
DR. WARD: Okay. Is there any discussion on Recommendation #11? I move that we vote on Recommendation #11.  
DR. ALDRIDGE: I second that. This is Tom.  
MS. McVAY-HUGHES: Second it. Catherine. Yes.  
DR. MIDDENDORF: No further discussion. Recommendation 11 reads: "Recommend that the World Trade Center Health Program communication to the health care community...  
DR. WARD: Communicate.  
DR. MIDDENDORF: Communicate. Okay. I'm starting over. "Recommend that the World Trade Center Health Program communicate to the health care community up-to-date World Trade Center research findings and their implications for practice, such as through updated WTC pediatric care and treatment guidelines." So doing a roll call vote. Tom Aldridge?  
DR. ALDRIDGE: Yes.  
DR. MIDDENDORF: Rosemarie. Did you vote, Rosemarie? I'm assuming she's had to leave. Anthony.  
MR. FLAMMIA: Yes.  
DR. MIDDENDORF: Bob.  
DR. HARRISON: Yes.  
DR. MIDDENDORF: Greg.  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine.

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MS. McVAY-HUGHES: Yes.  
DR. MIDDENDORF: Val.  
MS. JONES: Yes.  
DR. MIDDENDORF: Steven. Are you on mute again? Not hearing anything, Steven. Annyce.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Guille.  
MS. MEJIA: I'm going to abstain.  
DR. MIDDENDORF: Lila.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn. Glenn.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz.  
DR. WARD: Yes.  
DR. MIDDENDORF: Five, six, seven, eight, nine, ten...thirteen yeses. Steven, give you one last chance. I'm not hearing from you so...  
DR. WARD: (We'll move on to the next @ 03:38:22) recommendation, Recommendation 12. We've actually had a little bit of discussion about this before. Is there any further discussion? I'll make a motion to (inaudible @ 03:38:37). Is there a second?  
DR. HOMISH: Yes, this is Greg. I second it.  
DR. MIDDENDORF: Okay. Recommendation 12 reads: "Recommend that the World Trade Center Health Program conduct a formal study of missed opportunities for childhood study from 9/11, including a roadmap for the post-disaster setting about how to identify and enlist exposed childhood subsets; how to approach exposure measurement; and the nature, range, and tools to use to study health effects." Going to a roll call vote. Tom Aldridge.  
DR. ALDRIDGE: Yes.  
DR. MIDDENDORF: Rosemarie Bowler. I'm assuming she's gone. Anthony Flammia.  
MR. FLAMMIA: Yes.  
DR. MIDDENDORF: Bob Harrison.  
DR. HARRISON: Yes.  
DR. MIDDENDORF: Greg Homish.  
DR. HOMISH: Yes.  
DR. MIDDENDORF: Catherine Hughes. Catherine. I'm not hearing anything; we'll come back to you. Val Jones.  
MS. JONES: Yes.

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DR. MIDDENDORF: Steve Markowitz.  
DR. MARKOWITZ: Yes.  
DR. MIDDENDORF: Annyce Mayer.  
DR. MAYER: Yes.  
DR. MIDDENDORF: Mike McCawley.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Mike.  
DR. MCCAWLEY: Yes.  
DR. MIDDENDORF: Okay. Guille.  
MS. MEJIA: Yes.  
DR. MIDDENDORF: Lila.  
MS. NORDSTROM: Yes.  
DR. MIDDENDORF: Bill.  
DR. ROM: Yes.  
DR. MIDDENDORF: Megan.  
DR. RYAN: Yes.  
DR. MIDDENDORF: Glenn.  
DR. TALASKA: Yes.  
DR. MIDDENDORF: Liz.  
DR. WARD: Yes.  
DR. MIDDENDORF: Okay. Catherine, we didn't hear from you. Did you say a vote? Okay. I didn't hear anything. One, two, three, four, five, six, seven...fourteen yeses. Motion carries.  
DR. WARD: Okay. Good, so thank you, all. We're through the recommendations.  
DR. MIDDENDORF: (To the report @ 03:40:31).  
DR. WARD: And we do have a few more agenda items. So those who can hang in would hang in that would be great.  
DR. BOWLER: I'm sorry, but I have to sign off.  
DR. WARD: Thank you. Sorry we went—  
DR. BOWLER: Thank you.

**STAC RESPONSIBILITIES UNDER REAUTHORIZATION OF ZADROGA**

DR. WARD: Paul is opening the summary of STAC responsibilities under the reauthorization of Zadroga. So you wouldn't be able to see it on your screen.  
DR. MIDDENDORF: And really, all I want to do—I just want to do this fairly quickly is just give you a head's up where we're going. As everybody is very familiar, Zadroga was recently reauthorized and that the STAC was given some additional responsibilities. The first thing I'm going to talk about is not actually a responsibility directly, but it leads into a responsibility. In the first item, independent peer reviews, basically tells the Administrator that he needs to provide for independent peer review of the scientific and technical evidence that is being used to issue a final rule to add a health condition. And the reason that I bring that up is because STAC does have an additional responsibility under (G) (II) which is the last paragraph here. And it

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says that not later than a year after the enactment of the reauthorization and not less than every two years afterward the Administrator shall seek recommendations from the Advisory Committee regarding the identification of individuals to conduct the independent peer reviews under subparagraph (F). So this is something that the STAC will have to address in an upcoming meeting. And our very strongly tentative meeting on June 2nd is when we would begin doing this. And I want to point out that upon first reading what most people think is well, what we're looking for is a list of individuals, specific individuals. But that is a very limited reading of this. The reading could be fairly broad. So the STAC may want to think about a process of how the program might identify individuals as opposed to specifying individuals themselves. But it could be either both or something in between. But that's where we're going and that's something that we'll have to deal with as a committee. And I'll be providing a lot of additional information to you as we get closer to the meeting so you can understand more about peer review, what it includes, what characteristics of independent peer review other people have identified. So we will be providing you with some background information. And as we get closer if you have specific things that you would like to—have the program provide to you let us know early on and we'll try to get that out as well. The other major responsibility of the STAC under reauthorization is that the policies and procedures that are being used by the program to add—or actually to review and evaluate whether to add a health condition to the list of covered conditions is something that the STAC will be required to review and evaluate within a year after the enactment of the reauthorization. So that will be something we will be getting to you, are the policies for adding cancer and non-cancer conditions. And if the program in the future makes any changes to the policies and procedures for adding conditions, if there are any substantive changes to them, then the Administrator is required to come back to the STAC and ask you to evaluate those policy and procedure changes. So those are the things that we will be looking at in this upcoming meeting. And we'll be providing you with copies of the policies and procedures and help lead you through what those are at the next meeting. All right. Any questions at this point? Not hearing any.

**ADMINISTRATIVE ISSUES AND ADJOURN**

DR. MIDDENDORF: It sounds like we've done all of our business and we can adjourn. And I want to thank each and every one of you for lasting through this marathon session. I think it was very helpful and a lot of good recommendations from the committee to the program. So thank you very much.

DR. WARD: Thank you, and I look forward to seeing you in person in June.

[END MEETING]

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**G L O S S A R Y**

ATSDR	Agency for Toxic Substances and Disease Registry
CCE	Clinical Center of Excellence
CDC	United States Centers for Disease Control and Prevention
CDC-INFO	Centers for Disease Control and Prevention National Contact Center (1-800-CDC-INFO)
CME	Continuing Medical Education
CUNY	City University of New York
DOE	Department of Energy
DOL	Department of Labor
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
EPA	Environmental Protection Agency
ERHMS	Emergency Responder Health Management System
FDNY	Fire Department, City of New York
FEMA	Federal Emergency Management Agency
GERD	Gastroesophageal Reflux Disease
HHC	New York City Health and Hospitals Corporation
IRB	Institutional Review Board
LHI	Logistics Health Incorporated
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIMS	National Incident Management Systems
NIOSH	National Institute for Occupational Safety and Health
NPN	Nationwide Provider Network
NYPD	New York Police Department
ODAR	Office of Disability Adjudication and Review
PTSD	Post-Traumatic Stress Disorder
STAC	Scientific/Technical Advisory Committee
SUNY	State University of New York
VCF	Victim Compensation Fund
WTC	World Trade Center
WTCHP	World Trade Center Health Program

I hereby certify that, to the best of my knowledge, the transcript of the March 22, 2016 meeting of the Scientific/Technical Advisory Committee is accurate and complete.

\_\_6/2/2016\_\_\_\_\_  
Date

\_\_\_\_ Signature On File\_\_\_\_\_  
Chair, Scientific/Technical Advisory Committee