U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR BASIC AND TRANSLATIONAL RESEARCH

STRATEGIC PLAN FOR AUTISM SPECTRUM DISORDER RESEARCH UPDATE

EXTERNAL PLANNING GROUP

QUESTION 1:
WHEN SHOULD I BE CONCERNED"

TELECONFERENCE

TUESDAY, MARCH 26, 2013

The Question 1 Planning Group of the Subcommittee for Basic and Translational Research convened via teleconference at 2:30 p.m., Eastern Time, Coleen Boyle, Ph.D., *Chair*, presiding.

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PROCEEDINGS:

Operator: At this time, all participants are in a listen-only mode and will remain so throughout today's conference. This conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the meeting over to Ms. Susan Daniels. Go ahead, ma'am. You may begin.

Dr. Daniels: Hi. This is Susan Daniels, the Acting Director of the Office of Autism Research Coordination that manages the IACC. I would like to welcome everyone from members of the public who are listening in and the members of this Planning Group that was charged by the Subcommittee for Basic and Translational Research with looking into how we might go about planning an evaluation of – what has been made on the Strategic Plan.

I'm sorry. I'm getting background interference. Is someone trying to speak?

Dr. Carey: That's my son. I'm going to

put us on mute. I'll cut back in as I need to.

Dr. Daniels: Okay. Thanks. So we are going to be having a discussion today to talk about how this Group would like to mock up a possible way to evaluate progress on the Strategic Plan that's been made to date. And in the past, we have evaluated that progress on the question level through the work that we did last fall, most recently 2012 progress. And we put out or the IACC put out an update on the Strategic Plan, but it was based on the questions.

So the Committee has discussed this further and would like to do maybe more detailed work looking really at the progress that has been made on individual objectives and overall assess where the plan is going and possibly work on some prioritization.

So Coleen Boyle is going to be the chair of this Group. And this Group will come up with a model that can be presented to the IACC, the Subcommittee first and then to the IACC, for discussion as a model that the rest of the Committee can use to evaluate all of the questions in the strategic plan and their objectives.

So I don't know if Coleen would like to also welcome folks and if you have any other comments you would like to make before I do roll call.

Dr. Boyle: Yes. Thank you very much, Susan. And thank you to the Subgroup of our Subcommittee, the Workgroup of our Subcommittee. I do appreciate all of you joining in on this effort. I have been giving this some thought internally here at CDC in reaching out to some of our experts in evaluation but really want to get your thoughts.

And, you know, given the background I think that Susan has provided us that we have done each year, a review of progress at a question level and obviously taking it to the next step, which is to actually look at the individual objectives is I think a more challenging effort on our part. So I would love to get your thoughts. I will share some of mine as we go along.

Dr. Daniels: Great. Well, I'll go ahead and do roll call just so that everyone who is listening in on the phone knows who is here. So, as you heard, Coleen Boyle is here. And she is chairing our Group.

Anshu Batra, are you on the line? Yes? Is Anshu there?

Dr. Boyle: Someone's there.

Dr. Daniels: Anshu, I guess do you want to send me an email to let me know if you are there? We can't understand you if you are there.

Matt Carey?

Dr. Carey: I'm here.

Dr. Daniels: Walter Koroshetz?

Ms. Saylor: This is Kate Saylor. He will be.

Dr. Daniels: Alright, Kate. Is Walter going to be joining us?

Ms. Saylor: He will be. He is on his way.

Dr. Daniels: Okay. Great. Thanks.

Lyn Redwood?

Ms. Redwood: Here, Susan.

Dr. Daniels: Thanks.

And Alison Singer?

Ms. Singer: I'm here. Thanks.

Dr. Daniels: So we have most of our Group here, it sounds like. Walter is on his way, and Anshu may be on the phone just with a bad connection.

So, Coleen, I will hand this over to you to start the discussion.

Dr. Boyle: Thanks, Susan.

So I was just trying to pick up where we were at our last Subcommittee meeting when this idea first arose. I thought it might be helpful to clarify and have a discussion amongst ourselves as to what is it we were trying to achieve or what are the questions that we are trying to address through this process, how it relates back to what has already been done by the Office of Autism Research and Coordination. So, really, how does this complement or feed in or build upon what has come before?

And I think Susan summarized some of that. You are all I think aware of the products that have come from that exercise that we have just gone through in terms of doing the 2012 evaluation.

And then I guess the other question is really how is it – maybe the final question for me is, how does it advance the Strategic Plan, how does it help the research plan move forward, you know, thinking that we will again have to go through some reevaluation or assessment of the research plan at some point in time, whether it is next year or in the future. Obviously, using this effort to help guide that is helpful. So I thought we would start there just trying to get a better understanding of what it is that we're trying to achieve through this.

So others?

Ms. Redwood: Hi, Coleen.

Dr. Boyle: Hi.

Ms. Redwood: This is Lyn. Are you ready

to start discussion or is there –

Dr. Boyle: I sure am.

Ms. Redwood: Well, one of the answers I see to your question about how this is going to help us move forward is that right now we really don't know of these objectives that we have written over the past several years, how many of them we have actually accomplished or maybe we have accomplished just half of an objective and we need to focus on another part of an objective and that is where I think this is critical in terms of helping us to sort of narrow in and focus on the things that are still gaps in our knowledge. And that is why I think this exercise is so important.

It's been wonderful to have these updates annually with regard to each chapter. And, also, the autism research portfolio analysis that OARC has been doing for the last 3 years has been really helpful, but there has not been any effort to take those individual years and combine them to determine whether or not we have actually accomplished an objective.

That's why I think this is so critical.

Dr. Daniels: Lyn, this is Susan. I just want to add a clarification. I can't talk. That's echoing. In terms of accomplishments, you are talking more about scientific or research-type accomplishments versus the portfolio analysis has measured only accomplishment in terms of did X number of projects get funded. And so that is maybe part of an accomplishment, but you're really talking about did the research get done, regardless of whether those projects are funded, the outcomes from that research.

Ms. Redwood: Yes, exactly, Susan. But I think both. I think we need to look at whether or not we were sort of on target because each of these research objectives were written to be smart. So they're measurable. They're time-bound.

And so we should be able to look at these and say, "Did we meet that budget that we recommended? Did we go over that budget? If we had a time frame of 2 years, it was a shortterm objective. Have we accomplished that yet or not?"

So, you know, I think we need to answer both of those, the larger question, and also drill down into each of these objectives because if we're going to update this plan, if we have accomplished some of these objectives, then we need to take them out. And each year, we have been leaving them in there. We have just been sort of adding to it. So I think now is the time, after 5 years, to really see what we have accomplished.

Dr. Boyle: Others' thoughts on that? Alison, it sounds like you were in the background there.

Dr. Koroshetz: This is Walter Koroshetz. I just got on. So I –

Dr. Boyle: Hi, Walter. How are you?

Dr. Batra: Hi. This is Anshu Batra. I just got on.

Dr. Boyle: Great. Nice to have you, Anshu.

So, Walter and Anshu, we just started our discussion. And the primary question right now is, so what is it we are trying to achieve through this review? I am going to summarize what Lyn just said to us.

And, Lyn, if I am misstating it, please correct me, but essentially what have we accomplished at the objective level? And this will help us. If we understand that we have actually achieved our objectives for a number of the different objectives in the plan, it will clearly condense the plan and make it a leaner plan. It will help us to be able to focus.

And I think when she is talking about accomplishment based on a clarification from Susan, it is accomplishment in terms of, you know, the overall funding and whether we funded three projects, but that is the way that the objective was stated. But it is also reflecting how we potentially move the fields forward. So if we said that we have developed a screening cast, you know, that screening has something that is starting, making its way into translation.

And, Lyn, I may be just putting a few more words in your mouth than you wanted. I guess I was trying to think about, you know, if there is added value to what we have accomplished through the objectives.

Dr. Daniels: Coleen, just another clarification. In terms of the numbers of projects that have been done for every objective, that has already been done by OARC.

Dr. Boyle: Right.

Dr. Daniels: So you already have that information. You don't need to do it again.

Dr. Boyle: Excellent. And that’s been updated for the 2012 year?

Dr. Daniels: The 2012 year, we're still working on the data collection for that.

Dr. Boyle: Okay.

Dr. Daniels: And so that information up to 2012 is not available yet, but at least through 2010, you have the number of projects.

Dr. Boyle: So we have that. Eventually we'll have the one – what is the time frame for the 2012, Susan?

Dr. Daniels: We are still working on data collection, but as we are launching more and more projects, that is going to be -- that is starting to slow us down. And so it depends also on what else is put on our plate.

Dr. Boyle: Okay.

Dr. Daniels: But we are still in the process of collecting those data. And so numbers, projects depend on getting the data verified.

Dr. Boyle: Okay.

Dr. Daniels: So NIH has not released their 2012 data yet publicly. And so OARC doesn't have access to that yet.

Dr. Boyle: Okay.

Dr. Daniels: We are still awaiting that release that we hope will happen in the next few weeks or so.

Dr. Boyle: Alright.

Ms. Redwood: Susan, aren't we also getting 2011 because right now we only have '8, '9, and '10?

Dr. Daniels: Right. And so we have collected the 2011, but the data verification process usually takes about 3 months. And we don't even have all of the data yet. And that is if we have the amount of time that we need to work on it and we're not being assigned a lot of other projects that will take us away from doing the analysis.

Ms. Singer: This is Alison. I wanted to propose something else. I think, you know, in the past, we have collected data on the numbers of projects and the numbers of dollars. So when we wrote the strategic plan, we wrote it from the point of view of individuals with autism and their families. That's why we came up with the question system, questions that people would ask.

So it would be great if somehow we were able to also evaluate the outcome of the plan based on whether or not the objectives and the funding that has gone against the objectives has actually provided real value to real people. And I know that is hard to do, but I was thinking maybe if there was some kind of survey or some kind of qualitative assessment, we could determine what the public feels about how this plan has been implemented.

Ms. Redwood: I would think you could do an RFI, Alison.

Dr. Daniels: So if you do an RFI – you can do an RFI. We are talking about – we were just talking about OARC finishing the portfolio analysis. If we launch an RFI and get thousands of comments, then we would either need the Committee to sift through those thousands of comments and organize them and analyze them, or if OARC begins doing that, that will slow down the portfolio analysis.

So it's a matter of – this was one of the things that I talked about in January, we're just a little bit limited on how many different projects we can be taking on at the same time.

And so we can certainly collect the data, but the meat comes down to actually analyzing it all because even if you have a mountain of thousands and thousands of comments, someone has to make sense of what is in there.

Dr. Boyle: Alison, one alternative perhaps is that we can engage family members and people with autism as part of whatever process that we are using. And however, you know, we do evaluate the objectives, we can evaluate from the perspective of what value it has provided to individuals.

Ms. Singer: I think that that would be great. And also maybe I don't know if it is possible to specifically encourage people to comment during the period for public comment at the IACC meetings about the Strategic Plan, whether that is allowed, but at least that way we would start to get some feedback from families.

Dr. Daniels: This is Susan.

Ms. Singer: I agree with Coleen, I think. You know, as long as we include some sort of qualitative assessment on the outcomes for real people, as opposed to just counting publications, which I don't know any family members who respond by counting journal publications. I know it is important. And I get that. But that is not how we as stakeholders measure progress.

Dr. Boyle: Right.

Dr. Daniels: This is Susan. We could do kind of a town hall meeting, where you would be hearing the comments and listening to them where we're not really doing an electronic data collection exactly. But if you are hearing the comments, we also do have the mechanisms from just the normal public comment process, although if we are inviting more than the usual amount, that means we would have to set aside more time to be able to listen to the public comments that are coming in or collate them for the regular meetings.

Ms. Redwood: Susan, the only thing about doing a town hall meeting is that autism parents are strapped financially. They're not going to be able to travel and, you know, provide child care for their children to be able to get there to make public comment. That is why something like an RFI really reaches a lot more people. And I know in the past, you know, different reports that we have done, like this Autism Spectrum Disorder Research Publication Analysis: The Global Landscape of Autism Research was outsourced to, what, Reuters?

So, you know, in the past, we have used outside contractors to help us be able to collate these things. Could we not do that with an RFI to take some of that burden off of your Office?

Dr. Daniels: The process of putting together a contract is really long in the Government. It took us many, many months to get that contract together. We planned it far in advance. Basically, I don't remember exactly how much. It took probably at least 6 months to 9 months for us to get that contract in place before we could start the work. And so because we were planning ahead, we had it.

But if you want us to start pursuing a

contract now, you wouldn't be getting to do this until next spring. And I think your timeline is shorter. You want something done in the immediate future.

We can put together an RFI. But I guess is this Group willing to do the analysis of the data if we bring in all the data and sort it?

Dr. Boyle: Susan, this is Coleen. One thought is I think we need to go -- I think we need to make sure that we have a component here that clearly is reflecting the community. And we heard a number of suggestions about how to do that. And we'll circle back to that.

But I guess one thought on the RFI is that we could do that and then provide that information to – you know, if we were to bring in expert groups around each of the questions to actually dig down to the objective level, similar to what we were trying to do in the fall, when that meeting ended up getting canceled.

You know, we could provide the feedback

from the RFI. And it may be sorted by question. You know, so that would be the minimum amount of work that the OARC or maybe our members, we take on ourselves. And then that is provided to the experts. That is just one thought.

Dr. Daniels: Yes. That definitely can be done. And if an RFI is done, I think the question level is probably the most detailed you'd want to get. I don't think that you would want to ask an RFI that had 78 different questions in it because –

Dr. Boyle: No, no. I agree. But I was thinking we could have the question level that – maybe synthesize was actually in the objectives so that, you know, whoever is responding could perhaps respond objective-wise or just get a sense of what the objectives are in, again, a very, you know, more growth way.

Dr. Daniels: In our past RFIs, we put out general requests for comments on the questions. And then they always have a tab where somebody can look at the objectives –

Dr. Boyle: Okay.

Dr. Daniels: – that question, but there's no additional description. They would just have to click into the objectives and look at them. And then if we have working groups centered around each of the questions, they could receive the data from their questions and just go through it. You know, that is definitely doable.

Ms. Redwood: Susan, if you look at each of the questions and, Coleen, every question has an aspirational goal except for question 1, the aspirational goal was children at risk for ASD will be identified through reliable methods before ASD behavioral characteristics fully manifest.

So that would be one of the things that we could look at globally to give it value. As Alison says, it's whether or not we met that aspirational goal. And that would be a question that we could also put out to the public.

Dr. Koroshetz: This is Walter. I think we really need to – if we are going to do this in any kind of a reliable way, that we need to get information that tells us what actually has changed, with regard to each of these aspirational goals, how is it different from – I guess our starting point is 2006.

And I think that it is really easy to make a Gestalt statement, but that I don't think is going to be helpful to anyone. I think the only thing that is going to be helpful is you dig down, analyze what was done, how far did it get, what was the problem. That is the only way it is going to shine a light moving forward.

So I think we really need to go into each of these questions and get a really wide input from not only the autism community but the researchers in terms of what was done and what, you know, stopped progress or what were the stumbling blocks, what are the hurdles that they – that prevented them from going as far as they wanted.

And I think this is – I mean, if you are going to do this seriously, I think you really have to dig down in each of these areas. You have to read the 50 or 100 papers that apply to each of these goals and to try and understand exactly where the science is.

I think if we do this in a very kind of superficial manner, it is going to turn into an opinion piece, and it's not very valuable. So I think we really do need an RFI that is targeted at these populations that gets us the information we need to move forward.

But, as I said, I think this is a daunting task, but it's worthwhile doing.

Dr. Daniels: So, Walter, this is Susan. On March 6th, you all talked about convening panels of experts and consumers to do some of this work. And I think in a way, they would be able to potentially synthesize some of the information, rather than going all the way to collecting raw data and then having this Group do all the synthesis, which would take a lot of effort.

What do you think about inviting, you know, a group of experts and inviting a group of community members, probably a significant size that would be able to give you a distribution of information from across the community, both in the research community and the public?

Dr. Koroshetz: I think that – you know, I think that is the only way to deal with the data, but I still think an RFI is very valuable because it reaches out globally. You can, you know, send that RFI to large groups who would potentially have the interest in putting together a scholarly reply to your questions. And that can inform your panels. Otherwise, you know, the danger is you have a panel that has its own, you know, view on things. And so you don't get that kind of global look.

Ms. Singer: But if we combined the RFI with the panels –

Dr. Koroshetz: That's what we have generally done. You have the RFI, collect the data. Give it to the panel. And so they have to look at the global RFI that they're getting, as opposed to, you know, just again going through -- you know, it's easy for people to go to just give their opinion when they have particular viewpoints. RFI is a good idea, followed by panels.

Ms. Singer: Yes, I agree.

Dr. Daniels: In the past, when we have given you RFIs, it has generated thousands of pages of information. Do you think that these groups will have the time to actually read all of it and go through it or do you expect that folks will be able to do it because we would want to definitely use the information from an RFI if we're going to take up the public's time in responding to something like this, make sure that it is actually used?

Dr. Koroshetz: To do that in the past, what we have had to do is have internal people collate into particular areas so that when the panel sees them, they're not so chaotic, but they're binned into particular areas that they can go after.

Dr. Daniels: Well, so what I am seeing with OARC's staffing situation, we can't do an extensive analysis beforehand, but what we can do is put out an RFI that is already electronically binning things. And so hopefully the question 1 then will only correct question 1 information, although normally OARC would go through all the thousands of entries and verify that we didn't get an entry in the wrong category and we would move it to the right categories so that the data were cleaner.

But in this case, given what we're up against in terms of our other projects, I don't think we're going to have time to do that. But we could provide the binned data the way it comes out from the electronic format.

Dr. Boyle: Walter, this is Coleen. That would be modest information for these panelists to go through.

Dr. Koroshetz: Yes.

Dr. Boyle: And not only that. I mean, we would also be requesting of them to sort of get a good sense of what has been published, produced, what tools have been developed, really getting a good sense of sort of the state of the science and the art for all of the products related to the objectives under a question. It is a big task.

Dr. Batra: This is Anshu. I am still a little bit unclear in terms of the objectives. In my mind, I was thinking that after 5 years, – this wonderful document has been published yearly – to notify the public about what is out there, what has been funded, what is new, to help the public, right?

And so, you know, I am the public. I looked over the document. I was involved in generating parts of the document. And I am still puzzled in terms of where is my money going, how does it help me, and, you know, as a parent and as a clinician.

And so, Lyn, I was looking at the document you sent. And basically, you know, it was astounding to me to see how much money has been spent on genetics, you know, for question 3, genetics and epigenetics. And, you know, for question 3, I would like to see, well, how do those things merge? And, you know, what information, what research, what information do we have that's helped us, you know, bring those two things together to help us, you know, clinically?

I am not sure, again, what an RFI is. Is that just a survey that you send out within the Government?

Dr. Boyle: It's a request for information.

Dr. Batra: Request?

Dr. Daniels: Basically, it's not actually a survey. The RFI is a different category, but it's sort of like an open-ended question/survey, where you just say, "Please provide information on X." And it doesn't ask overly specific questions.

Dr. Batra: I mean, I worry when you ask an open-ended question, you get a lot of information. And I worry. I mean, unless we have a very specific question to ask, I think it gets a lot of information. And then I think it muddies the water a bit.

You know, I think this very specifically asks a question and say, you know, "What has this – how has this affected you or, you know, has this helped?" For question 1, you know, how has this helped us identify, you know, up to six features earlier, you know?

I can't remember all the questions at this moment that – you know, how has this helped us clinically identify children with autism earlier? How has this helped us with treatments to help quality of life?

I guess I am concerned about sending out another survey to get a lot of information that – I feel like a lot of public responses are that. You know? And I have enough difficulty going through all of those and do enough due diligence, you know, to people's opinions that they send to us before our Committee meetings. And my patients email me all the time. And I try to answer. So I guess

I'm a little puzzled about –

Dr. Koroshetz: Let me just try and take that. So I think your question is critical. So there's a lot of money been spent –

Dr. Batra: Yes.

Dr. Koroshetz: – and purportedly to answer these questions. And here you are on the Committee, and you don't know where the money went and what we got.

Dr. Batra: I don't.

Dr. Koroshetz: We have an obligation to answer that for you, so that you understand where the money went, what happened with it, and –

Dr. Batra: And how has it benefited me? How has it benefited me as a parent with a child with autism? And how has it benefited me day to day?

Dr. Koroshetz: Alright. Well, let me just hold you there because that I think – you know, for somebody who has been in science a long time, I can tell you that we put a lot of money into science for people that we have never helped.

And so the only way to appreciate this is to see the stepwise progression and to know where the stumbling blocks were because the expectations are frequently much higher.

So when we discovered Huntington's disease in '93, we thought we would have a cure in 10 years. And we have nothing. You know, sickle cell anemia, we have nothing. So these conditions are not that easy to fix, but for people to understand where the money goes and why it's valuable or not, you have to really see what was the research that was done, what did the research lead to, and what is this big gap and why is there this big gap.

But I think if you seriously want to do an evaluation of all of the money spent, you have to answer the question that you asked, where did this money go and what did it do? And, you know, you need to face the reality of what actually happens over these years.

Dr. Batra: Yes. I mean, this is – I was going through the questions, Lyn, on the documents you sent. I was astonished at how much money has been spent over the last 5 years on genetic research and epigenetic research, which is terrific.

Then, you know, I think about what I do as a clinician. I mean, when patients come, families come to me, I think, "Yeah. I guess I do a microarray." And, yeah, you know, they ask me about toxins and mercury and phosphorus and this and that. And I can't really pull out a whole lot of research to support or refute, you know. And so, I mean, yeah.

And my other comment is I am really hesitant to get a panel of experts, you know, that – you know, I am not convinced the experts are really the experts. And so I am concerned about getting a panel of people that then may not really be able to, you know, really give us the information we are really looking for or the perspective we are looking for.

Anyway, I am struggling with how to make this so it really, you know, hits the point, really is not wasting a lot of time or a lot of money and really -- you know, so we're doing, really, what we need to do and –

Dr. Koroshetz: Your question, ask the people who got the money, "What happened to the money? Where did it go?" And you get your answer.

And I think that's how you evaluate science. You've got to track the money and try and track what happened with each of these grants, what was the progress that was made. I mean, it's a really – I mean, if you don't do it and get in the weeds, then it's all a mystery.

Dr. Daniels: Walter, this is Susan. I know that OARC can help, but the first step of that, which is where the money went, we already have tracked all of the projects.

Dr. Batra: Right.

Dr. Daniels: So, for example, for question 1, if you want a list of every project funded that OARC is tracking, we can give you a listing of those. We have project descriptions. We have the PI names. We have the amount of money. And that's a starting point.

In terms of what actual science came out, that would be what you all would need to take on in figuring that out and whether you want to talk to experts, dig yourself and figure out what all has been published.

I know that OARC actually undertook as a part of its publications analysis an attempt to see if there was any kind of an automated way for us to be able to, for example, grab publications that matched with these grants.

But we found in our process that the citation data is too poor to do it in an efficient way. And so we weren't able to do it that way. So, really, it would require somebody either knowing about it or manually going in and looking at all of these projects, but it's a lot of projects.

Dr. Koroshetz: We could send the RFIs to the and have them submit their answers to our questions that Anshu comes up with.

Ms. Redwood: I like that idea. The other thing, Susan, like the report is online is wonderful. And you can drill down. Like for that question 1, the very first objective, you can look at 2010 or 15 funded projects. You can click on each of those and find out how much money they were funded.

And I think going back to them, if they were funded to answer the very first objective of question 1, what essay developed with existing tools to efficient diagnostic instruments, send something out to all of the people funded and say, "What is your progress on this? Have you developed an instrument?"

Dr. Koroshetz: Right.

Dr. Batra: Yes. And, Lyn, this is Anshu.

Ms. Redwood: I'm sorry?

Ms. Singer: Autism Speaks has a tool for that. And we looked at it, and we thought it was great. And so we are actually using it as well. It's very good for measuring qualitative output of grants, the value of grants.

That might be something that this Group

wants to take a look at in terms of a template to send out to the funded researchers. And that way there would be some consistency in the responses. There would be specific questions that they had to answer. We would be able to compare and contrast.

Dr. Koroshetz: Right. That –

Ms. Redwood: I think that's better than an expert panel, I think, hearing from the people that we have actually funded. And then we can sort of synthesize that material ourselves when we look over the responses.

Ms. Singer: Well, no. I think, I mean that's one way or this data could feed into the panel. I mean, I think this would be another good source of data, in addition to content from the public at large to also have content from the funded researchers to then be evaluated by the panel. I mean, someone is going to have to take a look at it and say from a scientific standpoint as well as a stakeholder standpoint whether there has been value added.

So I would see it more as also feeding into the panel.

Dr. Daniels: This is Susan. So there are two caveats, things that I would need to look into. One is that if we ask for information from grantees, that it may be voluntary. We may not be able to require people to respond to this. And so we may only get part of the information we're looking for. I don't know that there is a way for us to make it mandatory that everybody has to respond to this.

And the second piece is I would just need to check that we wouldn't be breaking any Government regulations by doing something that would be considered a survey. And I would need to find out if that is possible for us to do.

Dr. Koroshetz: Yes. We've dealt with this before. So my understanding, yeah, we are prohibited from sending out to grantees anything that they have to fill out and send information back. That's considered a survey and would have to get approval from, you know, downtown.

RFI, we use the RFI as a get-around because an RFI is public. You put the template on the RFI. And then you notify all the grantees about the RFI. It's still going to be voluntary. We can't force them.

Dr. Daniels: Right. So we could probably do that. I would just – just as part of my job, I have to make sure that everything we do is legally being done. So I have to just check on that.

Dr. Koroshetz: I have to go through an RFI. That's the only way we have been able to do it.

Dr. Daniels: Right. I don't know that we would be able to do a formal survey. And I am pretty sure that we can't require people and especially people that have been funded through private organizations. Certainly we couldn't require them to do additional work that they didn't want to. So it would be on the basis of whether they feel they have the time and are interested in helping us out.

Dr. Koroshetz: They want another grant.

Dr. Boyle: Susan, another possibility is to work through, at least within the Federal system, agencies to get us to do like we provide you information about the grants we fund and the dollar amount. We can do an assessment of what has come out from that as part of our – in addition to the portfolio review.

Dr. Daniels: So we could work in that way.

Dr. Boyle: We wouldn't know what publications. I mean, we could do the work internally.

Dr. Daniels: With something like that, we could ask Federal programs to provide information on progress that has been made with regard to publications that have come out or particular findings that have come out based on their portfolio.

Dr. Boyle: Right.

Dr. Daniels: But, for example, NIMH I know has more than 100 grants per year in autism. That would be a significant amount of work for that program to take on to have all of their program offices providing progress information.

I don't know how much of that information is publicly available during the period of the grant, but they would have to provide that information. So I don't know what all the hurdles are. We could look into that. But it is a possibility if it wouldn't be breaking any rules.

Ms. Singer: Can I ask Walter a question? If you can't require the grantees to respond and you can't penalize nonresponse, are you only going to get positive responses? I mean, what is the incentive to submit a report saying, "It didn't work out the way we thought" or "The results were not what we had hoped"? Are you going to only see –

Dr. Koroshetz: I think the pride of the investigator is always, you know, "This is what we did." You know, they want to usually publicize what they did –

Ms. Singer: Yes. Okay. Alright.

Dr. Koroshetz: – and it's harder to get the honest answer about what the obstacles were, although I think that, you know, if they are interested in getting further funding for research in this area, they may be quite honest about what they think the next steps would be to get over the obstacles that they encounter.

So I think you could get a lot of information by phrasing it in that fashion. And then I think you also want to get to, you know, the caregivers, the pediatricians, at least for question 1, to get some of the answers not only from the parent side but also from the physician side, in how things have changed over the last 5 years.

Dr. Batra: Walter, this is Anshu. I think I love that idea because, first of all, I am astounded that, you know, I hold my 18-year-old accountable for the money I give him, you know, before he asks for more money that – I can't believe we can't hold researchers accountable for the money we give them.

You know, we are held accountable by the Government, you know, through our taxes. So, you know, again, I think that is the system that we maybe change looking at moving forward.

But I think that specifically – what you said about asking the people who then use it and apply it, asking them, "How has this helped you be more efficient, better at identifying, diagnosing, and treating?" et cetera, as well as, you know, the parents, you know, which again I think we get a lot of the parents' feedback because that's – you know, the parents are the biggest advocates and have the biggest need, but I think asking, you know, the pediatricians, the family practitioners, the nurse – whoever is in the first line, that, you know, what tool do we have to diagnose early? What do we spend? And how is that changed? How has it helped you?

And that maybe could be sent through the American, you know, Academy of Pediatrics or, you know, the medical boards

Dr. Koroshetz: Right.

Dr. Batra: – or hospitals or, you know, where you have physicians that are, you know, on staff there. I mean, again, and I think that would really help target specifically the application.

Dr. Koroshetz: Right. You have got some good answers. I think if you get a group like that who then really kind of does a lot of background work and prepares their response, they're like "Yeah." If we can get the American Academy of Pediatrics to really take the question seriously, go out to their members, get – you know, they can do a survey and come back with information that would help us. I mean, Autism Speaks can do a survey.

Dr. Batra: Yes. That's what I was thinking, Autism Speaks. And, you know, they may be able to send out a survey through the AAP.

Dr. Koroshetz: Yes.

Ms. Redwood: What about the IAN Network, too? I would think that we could survey the parents through the IAN Network.

Dr. Daniels: Those would be two possible sources for the grantees. This is Susan. Would bringing grantees together just in a meeting discussion format possibly help you get the key information without taking up their time filling out an RFI, just in concern for their time doing research?

And I know that you all don't want to really take them away from actually doing the research to fill out – I mean, maybe you do, but –

Dr. Koroshetz: Yes, I think we do.

Dr. Daniels: – paperwork.

Dr. Koroshetz: I think we do.

Ms. Singer: The Autism Speaks outcomes report is two pages. It's not that intense. I mean, it will take them 2 hours. I don't think it is that –

Dr. Boyle: I like the idea of sending it out, that out, to an RFI. I think most people would take the time to provide that information. And, you know, that is a very organized way to collect the information. And we could do it by questions.

Ms. Redwood: And if we bring people together, then we are also adding the additional cost of travel and a hotel, and we are taking away from the research.

Dr. Koroshetz: Yes. I think a panel that helps – you know, the panel I think should be working for us, not – you know, so they should be helping us digest the information. I mean, to tell you the truth, I don't feel comfortable with – because I am not a pediatrician, you know, with knowing the answers to these aspirational goals. You know, what was it like in 2006 compared to now? I think I would really like to hear, from the pediatricians who have been involved in this, what they say.

So I think we need that kind of expertise on the panel. But I think the panel is more an extension of our Group.

Dr. Boyle: Right.

Ms. Redwood: One of the things I think would be really helpful to get going is if we can take the information that we have now that has already been collected by OARC and start compiling that. I know that each time another month or two goes by, we are getting closer and closer to the date where this particular Committee will sunset. So that is why I am really pushing that we get started with something now.

And, Susan, when do you think that 2011 data will be available and 2012?

Dr. Daniels: I don't think it's going to be available until the fall.

Ms. Redwood: Can we start compiling '8, '9, and '10 together in terms of one sort of comprehensive document and then add that in when it is available?

Dr. Daniels: I don't know what you mean by a "comprehensive document." Do you mean just – I saw that you did your own version of cumulative funding. If you wanted some document like that that attempts to look at cumulative funding, you could try to put something together, also pointing out what all of the caveats are about looking across the years. But we can put that together. Is that what you are talking about, or are you talking about something different?

Ms. Redwood: That would be really helpful, Susan. I mean, as Anshu said, I did that for question 3. And it was a real eye opener to actually look at where the money had gone in those different categories of questions. Some of them had no funding. Some of them were three or four times over what we had projected as to what funding would be adequate.

So I think that information is really critical. It is available to us now. It is just not compiled in any way where we can look at cumulative funding. It is individual years, which isn't as helpful.

Dr. Daniels: Right. And the reasons that OARC didn't do that – actually, we would have liked to have done cumulative funding, but the objective changed so much the number of funders and the fact that new objectives were being added – for example, in 1 year, if you have five grants in one objective and then the next year you have a new objective, three of those grants might have moved to the new objective. And so it makes it a little bit unreliable when you are looking at how that funding moves because of the changes to the plan.

It doesn't mean you can't look at it, but you just have to look at it through the lens of knowing that we have had different funders come in and out. We have had different objectives created along the way. And the timelines and budget numbers have also changed over the years in terms of the recommended budget. Sometimes if the Committee rewrote one of the objectives and added three more things to that objective, then the recommended budget was different that year.

So, with all of those things in mind, it was just a moving target. It was hard to get really reliable information.

So we can provide you with information, but you would have to be aware that it is not going to be a clean, linear progression because of all of those changes along the years.

Ms. Redwood: Well, if you do it in columns with the year, then if you can see in 2008, there were just several objectives. And then in the 2009 column, correlating with that, there are some new objectives. That is one way to lay it out where you can actually see or you can put an asterisk and put "New objective added" such and such a date.

So you can put that information into this document to make it less confusing.

Dr. Batra: This is Anshu. I like that idea. That was –

Dr. Daniels: The objectives themselves are the same objectives as the three written, has slightly different language the next year that includes a few more things than it may be included. So you can also mark that something has changed, that this – there are so many different things you would be marking, it would make it really hard to look at. But we can try to do something like that.

Dr. Boyle: This is Coleen. I was going to try to just summarize where we are in terms of our discussion. And then maybe we can continue to flesh out the rest of the process. And going back to what it is that we're trying to tease, in some ways, we could say it's value added by all of the research over the past 5 years, so 5 years from – maybe it's from 2006-7 and that's the timeframe we are going to be looking at.

So, you know, bottom line, what have we accomplished? And how has that helped us move forward, both from a scientific as well as a community perspective? So that is the big frame.

In terms of trying to generate information that will help with that evaluation, we just talked about getting cumulative information on grants and dollars that have been aligned to these different objectives, reaching out to both the scientific as well as to the broader autism community, using an RFI process, and potentially using a structured way of collecting information, the Autism Speaks portfolio review metric, and then perhaps another metric for the providers and families, and individuals with autism.

And then this information would be evaluated. And, again, this is where I think we need to start to focus some discussion by an expert panel, including both scientific representatives and community representatives. And they would be essentially an extension, which, as I heard it, an extension of the Subcommittee or the Workgroup for each of the questions.

And that's where I feel like maybe we could spend the last half hour if everybody feels comfortable with what I have outlined. I would be happy to write this up in some way.

Ms. Singer: I just want to clarify

Dr. Boyle: Sure.

Ms. Singer: – because Autism Speaks has a lot of metrics. And one is actually called the portfolio analysis. The one that I was thinking of is something called the grant outcomes report.

Dr. Boyle: Grant outcomes report. Okay.

Ms. Singer: Yes. It is a very specific template. So if we ask Geri for it, I want to make sure we are asking for the right thing.

Dr. Boyle: Okay.

Dr. Carey: Coleen?

Dr. Boyle: Yes?

Dr. Carey: This is Matt. This is Matt. There is one aspect of this I don't think we can get, but it's pretty critical, which is we don't know who has been applying or not applying for grants and how grants – you know, whether some areas get funded more. You know, if a grant goes through in area A, is it more likely to get funded than in area B? We don't know if area A is getting more applications in there, you know, if there is just nothing coming through in area B, those kinds of things, right? And then I don't think we're allowed to get that information.

So, I mean, that is actually in some ways trying to work out how we got to wherever we are. That is a key piece of information that we just don't have. And I don't know if there is any way around it.

Dr. Boyle: Well, I guess I want to reach out to Susan and Walter. Is it public information how many grants, how many people apply for specific funding? I mean, you do have that information public from NIH, right?

Dr. Koroshetz: We can't release any information about the applications that are not funded.

Dr. Boyle: How about the number?

Dr. Koroshetz: Numbers are usually fine.

Dr. Boyle: Yes, yes. That would be something that we could start to address. If there is a specific FOA, Matt, we can tell you how many people who have applied, responded to that FOA.

Dr. Carey: Okay.

Dr. Boyle: We wouldn't be able to tell you anything about them beyond that.

Dr. Koroshetz: I mean, personally I guess I am just kind of thinking that focusing on where the money went is probably the first step. And then, you know, once you look at that, then you can ask questions about, you know, are we engaging the right group or some solution to the problem?

I'm not sure that spending a lot of time on applications that didn't get funded is going to get us too far.

Dr. Carey: Well, we got the data Lyn sent out, right? There is a huge disparity in, you know, sort of – you know if you look at, say, genetic versus environmental funding, there is a disparity just overall in funding and a disparity in how much funding there is compared to what IACC asked for. And so then that is where that question came up. So, I mean, I guess I am saying --

Dr. Koroshetz: Oh, I see.

Dr. Carey: In one respect, you know, I have kind of gone through this one time.

Dr. Koroshetz: Okay.

Dr. Carey: That was a question that came up.

Dr. Koroshetz: Okay. I'm just thinking about question 1. So, I mean, we are just doing question 1. So, I mean, yes, I guess you are right. There is a definite issue, but I don't see that in question 1. Are there any other kinds of disparities, issues with regard to question 1 that we need to –

Dr. Daniels: And, Matt, this is Susan. I understand what you are asking, but in order to be able to measure that, we would have to be coding grant applications. And we don't do that.

Dr. Koroshetz: Yes.

Dr. Daniels: That is something because – the IACC really can't request it because it's not public information anyway. And so there is really not a lot of point in us going out to code grant applications because we wouldn't be able to give the data back to you.

Dr. Koroshetz: Yes. I mean, there might be a way. I would have to investigate. We had a tool. It was like a computer-based reading of grants that would try to pinpoint where they are. We have used it on funded grants. We have never used it on unfunded grants. Whether it is legal to do, we would have to check.

You know, I mean, there is a question with regard to question 1 that we would need to do that with. I could certainly explore it, Matt.

Dr. Daniels: I think that what is being asked is maybe with regard to certain objectives, whether there are unfunded applications that came in that would have been related to that objective. But that would require actually analyzing the applications that were unfunded or that were never funded and determining whether they would have fit in the Strategic Plan.

And that is just another huge undertaking that I'm not really sure what the – although I can understand why you would want to know that information, it is also dealing with a set of applications that we can't really share with the public anyway.

Dr. Carey: Yes. I mean, I prefaced the whole thing with I think that this is impossible, but I do think that it is – you know, when we start drilling down into this, it is kind of very important information. It would be great if we could. If there is any way anybody could come up with, it would be great to find out.

But I do understand. We have gone through it. I do understand that this level of data is impossible or, you know, unlikely for us to get. But if we're going to ask and we're going to start doing these comparisons, the natural question is going to come up.

You know, it is great to come up with comparisons, but then how do we go forward with that? And if going forward means if – we can't just say, "Well, we'll just put a lot more goals in the Strategic Plan on this area." It won't happen. I mean, if we're putting goals out that aren't getting funded, putting more goals in that area isn't going to work. We don't have the tools to make some of these things happen.

So, you know, Lyn was mentioning, "Well, maybe there are areas where we need to ramp down funding." Again, we don't do the funding. So how? We can sort of say perhaps we shouldn't be as much on this area, but we can't really control it.

Ms. Redwood: But making our recommendations, Matt, once we assimilate all of this information together and we start drilling down into it, if we see things, these big disparities, then I think one of our recommendations as a Committee could be we need to look at mechanisms that we can use to try to increase funding in those particular areas.

So maybe it's putting out a specific RFA to answer a question. Maybe those types of recommendations we as a Committee could make, or maybe it's the fact that, you know, there's a much larger number of genetic researchers than there are environmental researchers. So maybe we could look at trying to accomplish ways of moving people into environmental research or trying to get more researchers interested in that type of work.

So I think there are some recommendations we could make without having a lot of that information just based on what we are able to get back from doing this analysis.

Dr. Koroshetz: I think you could target. You know, those are the kinds of questions that you could go in depth around if you isolate a gap area, trying to understand what is at the core of the gap. And then NIH does that all the time. And, as you said, they do RFAs to try and fill in gaps.

Ms. Redwood: Right.

Dr. Koroshetz: Well, we could certainly do that.

Dr. Boyle: I guess, trying to be mindful of time and moving us along, it sounds like, Matt, we will keep this issue and maybe think it through because I think you bring up a really good point. And I think Lyn's creative suggestions might be some ways of dealing with that.

But thinking about the actual process of the expert panels. And, Walter, I guess I am going to ask you maybe to give some thought to help us think this through since it sounds like you have been through this with the expert panel.

They will have two sort of bodies of information: one on the dollars and the grants and hopefully up through 2012, although from Susan, it sounds like that might not happen until the fall. So we will have to talk about what to do moving forward.

And then they will also have the information from the RFI. And that will use the Autism Speaks grant outcomes report to hopefully summarize the progress and outcomes relative to the individual-level grants per question.

And then I guess, Walter, help me understand how it has worked in some of your prior reviews. So, you know, are we going to be asking folks to again use some type of metric to align progress relative to their evaluations? And then just give me your thoughts there.

Dr. Koroshetz: I think I am just trying to move quickly from what we have done in other areas to here. I would say the first thing you want to do, so we take question 1. We should break it down into specific areas of research so you just – and I think the aspirational goals, I agree with Lyn that that looks like a good structure. And then basically make sure we have the expertise on the panel that covers the spectrum.

So just going through the aspirational goals, you would like to have somebody who is an expert in screening instruments, somebody who is an expert in diagnosis of autism, and somebody who is interested in this idea of detecting incremental changes in ASD characteristics.

So I think that is how I would structure the panel as to add expertise where we need it with regard to some structure coming out of question 1, which I am just kind of jumping on Lyn's aspirational goals as a structure, and then feed them the RFI information. We work with them and then try to develop a product at the end, which is, you know, on this aspirational goal.

This is the state of the art in 2006. These are the kinds of things that have changed since then. You know, these are the studies that were funded. This is what they turned out. And then, you know, have a realistic assessment of where the gaps are and to the point where it is actually benefiting the families. So that is how I put out a structure.

Dr. Batra: So, Walter, this is Anshu. So can you clarify to me, I guess, when a researcher is awarded a grant, let's say, a million-dollar grant for in, I guess there is a timeframe, right, 2 years, 3, whatever it is, how are they held accountable for the money they got to answer the question that they got the money for.

Dr. Koroshetz: Yes. So that is an interesting question. So there are different ways in which these grants are awarded. On the one hand, there is a contract grant. And that is a statement of work. And they have to produce the statement of work. The next level is where I –

Dr. Batra: I'm sorry. I didn't hear what you said. Statement of work? What did you say?

Dr. Koroshetz: The contract would be the most specific where there is a statement of work that has to be delivered.

Dr. Batra: Okay. Statement of work.

Dr. Koroshetz: The next level is what is called a cooperative agreement, in which there are usually some milestones that the institute is working with the investigators to attain. There are commonly clinical trials-type grants called cooperative agreements.

Then there is the R01 grant, which is an investigator-initiated grant in which the investigator presents ideas that they will pursue. But it is expected that the investigator as times change can move their science.

And so the only accountability there is that they are required to submit progress reports every year. And they are reviewed by program directors to make sure that the money is being used appropriately.

And then the real accountability comes when they resubmit after 5 years for a second grant because then reviewers will look at their ability to perform and factor that in with the decision whether to fund the next grant.

Dr. Batra: Who are those reviewers? Who are the reviewers?

Dr. Koroshetz: The reviewers are, again, the peer review panels that are set up to review grants. And they are usually topic specific. So if it's autism grants, there will be autism reviewers.

Sue, do you want to add anything from – I'm just thinking from NINDS. Do you have any other additional points to make from NIMH?

Dr. Daniels: I don't think so, Walter. I think that you have covered it. So there is a lot of internal accountability. But a lot of that information isn't publicly available. So the program officers who run those portfolios are responsible for ensuring that progress reports are coming in, that people are making progress on their research, et cetera, but most of that process is not a public process.

Dr. Batra: Susan, this is Anshu. So those progress reports, they are not available to the public. Is this because they just haven't been available or they are not allowed to be available?

Dr. Koroshetz: They are not allowed to be available.

Dr. Daniels: They are not allowed to be available. They're internal information.

Dr. Batra: I mean, is that something that

– oh, gosh. I hate to put – is that something that internally that could be aggregated for the various, you know, grants that have been.

Dr. Daniels: I couldn't hear you. Sorry. What was that?

Dr. Batra: I think those benchmark progress reports would be critical for this process because they would – you know, test what kind of progress is being made and ultimately is the money – you know, are you getting the most bang for your buck? Are we getting the most bang for our buck? So I guess, you know, that –

Dr. Carey: Are we just trying to re-create what they have already done but without as much information?

Dr. Koroshetz: Alright. I would say we want to get better information than what is in the progress reports, but I think in a sense, you know, that the RFI is a potential – we could think of it as a way of getting, you know, more targeted progress report information back from the PIs.

The progress reports, I mean, I have seen a whole bunch of them. I am not convinced that they are as informative as you would like them to be. So I think we can probably do better by structuring the RFI to get the same and maybe even better information.

Ms. Redwood: Would it be possible, too, Walter – this is something I think Susan mentioned previously or maybe Coleen – to go to the individual institutes, like you said, that NIMH has funded over 1,000 grants. And there are certain program officers who are over those particular grants who are reading the progress reports – and see if we could get the program officers to sort of synthesize that material for us and say, "This is the progress that is moving forward."

And it wouldn't be specific to any one particular grant in this entire area, let's say, of question 1. And that way, you know, we wouldn't be dealing with the volume of data if we were relying on the program officers to try to pull together for us just what progress is occurring.

I know that wouldn't help for the private grants, but, you know, a majority of the funding well, you know, maybe I can't say that anymore, but, you know, a lot of the funding is coming from the Federal Government. So at least if we have that information from the program officers, that would be a way to get that.

I would hope that they would be included in these meetings as well in terms of some of the people either in the audience or on the panel.

Dr. Koroshetz: I think that's a good idea, yes. The program directors would be able to – I think what they can't do is go through each – you know, they have, you know, 300 grants, to go through all 300 grants and fill out a form on each grant. But they could give a high level, their high-level opinion on how things have – what progress is made in these areas.

Ms. Redwood: Right.

Dr. Boyle: So, Lyn, this is Coleen. Were you suggesting that instead of the RFI –

Dr. Koroshetz: No. In addition.

Dr. Boyle: In addition. Okay.

Dr. Koroshetz: Yes.

Dr. Batra: Yes. This is Anshu. I think that to me, again I don't know the process or the system, but it just sounds like, you know, you target a survey or RFI to the individual grantees.

And then you ask the people who then are held accountable to sort of gather, you know, to hold these people accountable. It sounds like your progress report. But whether at the Committee or whether it is an individual person I don't know how it works.

And then to see where there's – whether it's equitable and "equitable" is the wrong word. You know, whether it is sort of – whether there is a gap there or whether it seems like it is keeping with individual grantees are sort of pointing in terms of the progress and what the assessment is by the program offices. Do that make sense?

Dr. Koroshetz: I kind of lost –

Dr. Batra: Did I just confuse everyone?

Dr. Boyle: I mean, I don't think the project officer is going to get Anshu to the grants level. I think that probably would take a body of grants but then each question maybe?

Dr. Batra: But is that how that works? The program officers, are they – again, I don't know how the system works. Does the program officer – are they responsible for a certain aspect of that research for that area or are they –

Dr. Boyle: Generally, yes.

Dr. Batra: Are they given, you know, "Okay. One through ten, here, you take it. You know, 11 through 20, you take it"? How does that work?

Dr. Koroshetz: Each grant has a program office. And they generally, program offices, have expertise in certain areas. And so grants in certain areas coalesce with certain program offices.

I know in NINDS and I'm sure at NIMH, right Sue, there are certain program offices who are getting autism grants.

Dr. Daniels: Right. I could see realistically we have about 20 different institutes. Those of you who have looked at our portfolio analysis in detail, gone on into the Web tools to look into how NIH is distributed, there are about 20 different institutes of the 27 that have grants in autism.

And if we were to send a request to every institute and say, "Out of these seven question areas, can you please provide a summary of your portfolio," but this is not going to be getting you extremely detailed information about exactly what publications came out, exactly what findings, et cetera. It would be a high-level overview. That is something that would be possibly doable if you think that is useful, but if you are really looking for very granular information, I don't think that that is likely to be something you can get easily.

Dr. Batra: How do you get that granular detail? I mean, how do you get to that point? That is what – I'm trying to wrap my brain around this process.

Dr. Koroshetz: Well, the problem is the law states that if NIH funds a grant, the data belongs to the PI. So the investigator is the owner of the data. So no one can make them do anything with the data. So it all has to be voluntary. So that's the issue.

Ms. Redwood: I thought that with the ARRA funding, Walter, that there was something in there that all of the data has to be able to be accessed into the – oh, what is it? What's the network that –

Dr. Daniels: The NDAR.

Ms. Redwood: Yes, yes. I mean, there may be some of it we would be able to get because it has to go into NDAR.

Dr. Daniels: That's research data, though. And that's like people's brain scans and things. And you would only be able to access that if you are a registered researcher that has a reason to be accessing the data.

Dr. Koroshetz: Raw data.

Ms. Redwood: But I think the other thing, guys, we need to be realistic in that if we want to accomplish this by – when does the Committee end, Susan, September?

Dr. Daniels: Two thousand fourteen, September 30th, 2014.

Ms. Redwood: Right. So we've got to be a little bit time-bound, too, in what we can accomplish in that period of time. And I think we can drill in by looking through the reporter and each of these projects funded to see if there's any status report or if there are publications pending or publications that are out there already under that investigator's name. We can do that.

I think the overview from the program officers would also be really helpful for us.

Dr. Koroshetz: Yes.

Dr. Daniels: Well, my understanding was when this all began, this was a part of your

2013 update to the Strategic Plan, in which case, I mean, unless you are going to have this going on as an overlay while you work on the update, but by law, you are required to put out an update to the Strategic Plan this year. So that needs to be done by December. So I had understood earlier that this process was going to be feeding into that and that you would have a document done by December.

Dr. Batra: This is Anshu. You know, maybe what we need to look at is really whatever data we can accumulate for 2010 and have that as almost an accountability report for those specific areas of research that were identified and see where has that taken us, where has that money been spent, and how is that – what has that gotten us.

I don't know if that's feasible in 9 months.

Dr. Daniels: Anshu, can you explain that a little bit more? I don't think I understood.

Dr. Batra: Yes. I think I am having a hard time understanding it myself in terms of

– bottom line is I just want to know – I mean, from my standpoint, I want to know what has been done out there, how is our money being spent, and then what outcome has it given so that it helps me, you know. And so I don't know the process that we're in, how that can help answer that question.

Dr. Koroshetz: How about if we – so, Sue, it should be possible, right, to get a list of all of the grantees who came under question 1?

Dr. Daniels: That's available on the Web tool, at least for 2010 data.

Dr. Koroshetz: Yes. And then we develop an RFI for those people. It's a Web-based public, but we basically send emails out to each of those grantees.

Dr. Daniels: Actually, as far as I understand, we don't send RFIs out to individuals. We have to post the RFI publicly.

Dr. Koroshetz: That's what I meant. You put it an RFI out, but then you send an email to each of the grantees saying, "We have this RFI out. And we're interested in evaluating, you know, autism research in this area."

Dr. Daniels: I think that that would have to be the programs that – basically all of the funders that participate in our portfolio analysis. We would have to contact them and say, "Please let them know that this RFI is on the street and that it would be great if they could respond to it." And so we could put a notice out to each of the institutes to have their program folks –

Dr. Koroshetz: Correct.

Dr. Daniels: – let their grantees know. But that is not something – OARC could not directly send information to grantees.

Dr. Batra: Is it something our Committee can do or is that – is there some protocol that it has to be geared to?

Dr. Daniels: RFIs are supposed to be posted. And then people are supposed to come to them voluntarily. So if somebody wants to do a notification to those individuals, it would be whoever has access to those individuals.

Ms. Redwood: Anshu, it could be accomplished by the same way Susan sends out the request to get information to all the different funders. We could send a request out to those funders, the same people you contact already, Susan, on an annual basis to contribute to the research portfolio analysis saying, "We have put out an RFI," like you said, and ask them to distribute that –

Dr. Daniels: Exactly.

Ms. Redwood: – with their funding. So that is how we can get that accomplished.

Dr. Daniels: But then those people, I can't require that they do it. I can't require that –

Ms. Redwood: Yes.

Dr. Daniels: – they do it in a certain way. So they may not choose to send individual emails to everyone. They might decide to just put it on their Website or do something else to get the information out. We really can't require people to do it a certain way for us. We would just ask for their assistance and say, "Can you please get the word out that this RFI is on the street? It closes on such and such a date and we would like to have feedback."

Ms. Redwood: I think we're so close to having the 2011 and 2012 data, that that needs to be included, instead of just the '08, '9, and '10 because if you look at it, it is already 2013. We would be 3 years behind. I think it is worthwhile to wait and incorporate that information into it, too.

Dr. Daniels: Alright. Can you repeat that? I didn't quite understand.

Ms. Redwood: I heard Anshu say to look at 2010, that what we already have available now – I think what we can do would be to start looking at the cumulative document. I think, Susan, you said earlier you could do this with 2008, '9, and '10 funding for each individual objective –

Dr. Daniels: Right.

Ms. Redwood: – and then have that tie into the reporter, where you can look at each of the projects funded for those years but also incorporate into that as soon as we can the 2011 and the 2012 grants, too.

Dr. Daniels: Twenty eleven and 2012 grants, as I said, they are not going to be available probably until the fall. And the more projects that the Committee generates and puts on OARC's plate, the more we are going to be slowed down in the portfolio analysis process. So I am trying to – I want to get the portfolio analysis done, but we also need time to work on it.

So we can provide this cumulative funding document to you. It's not something that I would incorporate into the Web tool because it is not going to be a reliable type of document that would lend itself to the database format, but we can provide it as a static document that our Office can put together. And I can do that for question 1 to give you a start. And then you would see what that is going to look like.

But please remember, everyone, that any

process you come up with, it has to be approved by the full Committee. So you can come up with a process and then propose it to the full Committee through the BTR Subcommittee. But I think that we can probably do that via email.

If you have a written plan that you all agree on as a Planning Group, send that to the BTR Subcommittee. And I think if they are okay with you forwarding it on to the full Committee, then the full Committee can consider it. And then they will have discussion and feedback and may modify whatever you propose.

Ms. Redwood: Susan, I am on the agenda for our meeting on the 9th to present sort of a proposal to the full Committee for what we are wanting to do.

Dr. Daniels: Yes. I am planning for that.

Ms. Redwood: Okay. Could the document combining 2008, '9, and '10 projects be ready by that meeting to share?

Dr. Daniels: For question 1. So you're

talking about projects, or are you talking about funding?

Ms. Redwood: Well, both. I mean, it would be combining the three –

Participant: Grants and dollars.

Ms. Redwood: – analysis that we have, the –

Dr. Daniels: This is Susan. Grants, are you just talking about printouts, like, for example, if we went into question 1 and you just want a printed document listing like an Excel spreadsheet of all the grants or you want this cumulative funding table?

Ms. Redwood: Cumulative funding.

Dr. Daniels: Yes. It's only 2 weeks away. So but that is something normally that I would say that we could provide. And I would like to try to provide that for you. It's just a matter of that it is only a couple of weeks away. And we are trying to get the meeting planned. But I will do my best to have that for you.

Ms. Redwood: Okay. If not, I can work on it, Susan, like I did with question 3.

And, Matt, you were really helpful, too. Would you want to help work on it?

Dr. Carey: Sure.

Dr. Boyle: This is Coleen. Why don't I take a stab at writing up a summary of our call today. And then if, Susan, it is okay to share with the Workgroup here and then we can refine it before we share it with the larger Subcommittee?

Dr. Daniels: That sounds fine. And then, Coleen, I would ask, you know, as long as it is okay with the BTR Subcommittee for you to be able to talk about this on the April 9th date with that group?

Dr. Boyle: Either that or Walter. He seems like he has a lot more experience than me.

Dr. Koroshetz: Well, just you have to be there.

Dr. Daniels: So it sounds, part of the summary here, it sounds like you are talking about four possible major data sources: So an

RFI that would be created for researchers who have participated in autism research to date, for them to respond about progress that has been made in the field based on their research.

For you to do a general RFI to the public to ask for feedback on the plan, probably very similar to how we have done those RFIs in the past.

Autism Speaks is doing some kind of a survey. And I kind of am not sure if I remember who the target for that survey would be; and then IAN doing a survey for the community.

Dr. Boyle: Yes. So I guess for me, this is what I have: cumulative information on grants and dollars. And that sounds like it will only be available through 2010, although maybe we can somehow append '11 and '12 on in a static way. I guess I missed that conversation. So I apologize.

And then two RFIs: one that's tailored to the grantees that will obviously be something that agencies and funders would encourage or at least make grantees aware of; the project officer's overview –so we would contact the project officers for the bundles of grants that each agency or organization examines – and then the IAN Network. And I wasn't sure about Autism Speaks. I didn't have that on my list.

Dr. Koroshetz: Yes. Autism Speaks has the – remember, they have the tool for evaluating research that was mentioned.

Dr. Boyle: Yes. I have that part, but I didn't think they were doing their own survey. No. I have that part as the tool. But those are the four or five inputs that would be used by the expert panel.

The expert panel represents both community representatives and science representatives, and it would be composed to reflect either the aspirational goals or the bundle of objectives, however they were – if there was a different way of bundling the objectives relative to the actual overall goal.

Sometimes if you read the objectives for some of the questions, they don't necessarily align with the aspirational goals, but that can be a larger discussion.

Dr. Daniels: This is Susan. The only thing I understand that you would want in terms of an actual mockup by the time of the meeting on April 9th is cumulative grant information for question 1. And the rest of it would just be proposals on paper for the Committee to consider.

Dr. Boyle: Yes. Yes. I mean, we could try doing a mockup for the RFI using the Autism Speaks grant outcomes report.

Dr. Daniels: Would you be doing that?

Dr. Boyle: I could try.

Dr. Koroshetz: I can help with that.

Dr. Boyle: Okay.

Dr. Daniels: Okay.

Dr. Boyle: So I'll write up the process. And we can go back and forth on email and clarify it.

Dr. Batra: Walter and Coleen, this is Anshu. I would like to help in that process, not that I can be any help in terms of the actual process but I think the way I am envisioning this in terms of the questions that are asked that may be more relevant to the community.

I don't know how these RFIs are structured, but I know from my point of view, I would like certain questions to be asked as a parent and as a clinician to the researchers so that – at least then maybe we could figure out if there is a disconnect, why there is a disconnect or if there is not, then great. You know, then at least we are both merging together and heading in the right direction. Is that –

Dr. Koroshetz: That makes sense to me.

Dr. Daniels: With the RFIs, would you be working on drafts for RFI questions for both the RFIs for grantees and the RFIs for the public or just one or the other?

Dr. Batra: I'm sorry. I'm assuming they

would be a little different because _

Dr. Koroshetz: Yes.

Dr. Batra: – for the researchers or the grantees, it would be just I think more in detail for the grant. And then for the public, I guess it would be a little less detail in terms of, you know, asking what is needed, what is relevant, how has it helped. Is that right? So it would be two different documents, Susan?

Dr. Koroshetz: Yes.

Dr. Daniels: Yes, they would be two different documents. I can also –

Dr. Koroshetz: Who's going to work on the one for – Coleen, are we doing both or are we doing the –

Dr. Boyle: I was just going to do the one for the researchers, but if others want to – I don't know if, Matt, Anshu, do you want to take that on? Then, Anshu, I will be more than happy to work with you on the ones for the researchers as well. They may have dropped off the call.

Dr. Batra: No. I'm here. I'm still here. I'm still thinking about how this is going to happen.

I mean, I think, you know, I am new to the process. I don't want – you know, I have a huge learning curve. And if someone has already been through this and understands the process, if they could help me through it, I would be happy to take it on, you know, like Lyn or Alison or whoever else, Matt. I would be hesitant to take it on, though, knowing that I would have to sort of learn the process and that takes time.

Dr. Boyle: Susan, you did the RFI for the public prior to (unintelligible conversation). Could we start with what you did last time?

Dr. Daniels: Yes. I was just trying to put that forward, that what I can do is by email circulate back to you from our Website what we have in terms of structure for the questions out to the public from the past couple of RFIs. And so that is something that – and anyone who is listening in the public, that is on our Website. If you go to the menu item about requests for public comment, our previous RFIs are there along with the responses we received to RFIs.

So I can send the Planning Group the links so you can look through the structures from previous RFIs and see if something similar would meet your needs or if you have something completely different in mind.

Dr. Batra: Yes, Susan. That would be great if there is already something in place. I mean, we could just tweak it.

Dr. Koroshetz: And just make it just relevant to question 1, get it –

Dr. Batra: Exactly. Exactly. So, again, I hear that there are two different documents: one for the grantees, one for the public. And Coleen and Walter and whoever, myself, whoever else, could have some input in that.

And then for the public, I am more than happy to assist in that, but I can't take it on as the primary producer. So if someone would like to help in that?

Dr. Carey: Yes.

Dr. Daniels: Sounds like Matt. Matt and Anshu, then you'll work on the RFI for the public.

Dr. Batra: Okay.

Ms. Redwood: Susan, I would think that the one you did before, like you said, could easily be tweaked. And you wouldn't need to reinvent the wheel.

Dr. Daniels: Exactly. So that is why I thought it would be important for –

Ms. Redwood: Why don't you share that one with Anshu and see what – you know, whoever wants to work on that question and see what they think.

Dr. Daniels: I'll circulate it to the entire Planning Group. And you can just look back through. But basically the way it works is I think it asks three questions per a question of the Strategic Plan: I think what progress has been made, what gaps remain. I can't remember all three questions. What are the new opportunities in that field?

And so it asks those same three questions for all seven of the questions of the Strategic Plan. And then it was open-ended. And the public just provided us with input.

And because it is structured in a Web form, the Web form set it all into bins already. So that really helped expedite things a little bit so we could potentially just do something similar where we are asking the same set of questions for every question.

But I would encourage you to keep it a little bit limited because you have seven question areas for the whole Strategic Plan and some member of the public coming in. If you are going to ask them 20 questions about each question, it will just get really long and laborious for them. So try to –

Dr. Batra: Susan, I absolutely agree. I know most people have the attention span of a flea. And so I think to be very targeted would be very appropriate.

I would say that the additional question I would want to have asked me is, how has this helped me? How has this been relevant? How has it, you know, enhanced my knowledge and my application?

Dr. Daniels: And so I think it is keeping it to maybe about three really focused questions per question area and then something that we could just put out. And then members of the public if they are only interested in question 2, they could come in and answer questions for that. And then exit the RFI. And those who want to answer questions on all seven of the questions of the Strategic Plan could, but they wouldn't be totally overwhelmed.

Ms. Redwood: Right. And when you did that before, Susan, I know all of that information was distributed to the Committee.

Dr. Daniels: Yes.

Ms. Redwood: It was a lot to look through, but it was doable. I mean, I read through all of them in maybe 2 hours.

Dr. Daniels: Yes. It was a pretty thick set of notebooks. I think one year we gave you two giant 3-inch binders. And, you know, I don't know if there is a way for us to get the information to you electronically instead, rather than, you know, killing as many trees as it takes to put together huge binders of information. But we would want to get you that information so you could look through. It would take your time to read it all.

Ms. Redwood: Yes.

Dr. Koroshetz: For clarification, the community RFI would include the practitioners, right, as well as parents and patients/persons?

Dr. Daniels: It would be open to the vast public.

Dr. Batra: But as a community practitioner, I mean, this is the first I have heard of this process. And so I guess how do we – you know, how do people like me find out that this is out there?

Ms. Redwood: I like the idea of going to the American Academy of Pediatrics.

Dr. Koroshetz: So that's the key with any

RFI. You put it up on the Web. It's useless. Everything depends on outreach to the organizations and the people who you need input from, not useless, but it's not –

Ms. Singer: Anshu, maybe the local AAP branches, you know, maybe – I just don't know the process enough to give you –

Ms. Redwood: Just to their members, Anshu? I mean, couldn't we get them to put it in their enews? How does the AAP communicate with its members?

Dr. Batra: Yes. It's through newsletters. Yes. It's – well, I'll be honest. We get so much that I think everyone sort of looks at things, which happens if it's worth it based on time and interest.

Again, I would have to think about how we can best get the information from the most people, you know. I am not sure if an AAP bulletin is really the right avenue. I don't know if it needs to be more localized.

Ms. Redwood: What about developmental pediatricians?

Dr. Batra: Yes, developmental pediatricians, but the problem is that the Society for Developmental Pediatricians is very, very small, a small subset of individuals who see kids. It's really the pediatricians and family practitioners who are seeing them. And those are the people you really want to target. It's the general peds who see the kids, who see the babies in the hospital, who see the babies 12 times in a year.

You know, let me think about it. Let me think about what the process is.

Dr. Koroshetz: Yes. We need an outreach to coincide with this work.

Dr. Batra: I mean, let me think about what works for me. And I think that would be pretty much what works for most pediatricians. So I will have to get back to you on that.

Just to clarify, are we going to have this information ready to then present at the April 9th meeting? Is that correct?

Dr. Koroshetz: The plan, the plan.

Dr. Batra: Okay. So that means we have to take the 2 weeks, then, to get this information to synthesize and then present. Okay. That makes –

Dr. Daniels: If you're really planning to have – I wasn't expecting you to have all of that done by the time of the April 9th meeting. It's something that you want to disseminate to the – I guess you could do it in a slide presentation if you want to have drafts of your information to give to Coleen and if she is going to make a slide set. Then you would just have to turn in your slide set by the time of the meeting so that we could put it up for people to look at.

Dr. Boyle: And we don't necessarily have to have that, I mean, Anshu. We can give people a sense of where we are with this because, you know, they may change the process on us.

Dr. Batra: I agree. That at least gives me a framework to what the expectation is for the next 2four weeks.

Dr. Boyle: Yes. I mean, first, we have to go back to the Subcommittee. And we have to bring it to the full Committee. And I think it needs to be fairly fluid until so we get buy-off from everybody.

Dr. Koroshetz: I have to drop off here.

Dr. Boyle: Yes. Me, too.

Dr. Koroshetz: But this sounds good, very encouraging.

Dr. Boyle: Okay.

Dr. Koroshetz: So I'll start sketching out something form the RFI. And we can go back and forth, Coleen?

Dr. Boyle: Yes. That would be great. And I will write up the notes at least in terms of summarizing them.

Dr. Koroshetz: Yes.

Dr. Daniels: This is Susan. I will plan to work on that cumulative funding table for you all. And if I run into any problems, I will talk with Lyn and see if I do need any help. I doubt that we will need help, but if we do, we will let you know.

Dr. Boyle: Okay. Alright.

Dr. Batra: And, Susan, this is Anshu. You are going to send out an email in terms of what the RFI looks like?

Dr. Daniels: Yes, I'll forward that to you. I'll forward you the links.

Dr. Batra: Alright. Thanks so much, everyone.

Operator: This concludes today's conference. Thank you for your participation. You may now disconnect.

(Whereupon, at 4:12 p.m., the Basic and Translational Research Question 1 Planning Group adjourned.)