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INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR
BASIC AND TRANSLATIONAL RESEARCH

STRATEGIC PLAN QUESTION 2 PLANNING GROUP

CONFERENCE CALL

SEPTEMBER 27, 2013

The Strategic Plan Question 2 Planning Group convened via conference call at 11:30 a.m., Susan Daniels, Ph.D., *Executive Secretary*, IACC presiding.

PARTICIPANTS:

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PROCEEDINGS:

Dr. Susan Daniels: Hello, and welcome, everyone, to today's phone call of the Question 2 Planning Group. We are going to be meeting to discuss a number of items regarding the Strategic Plan update and that process.

I'd like to start with a roll call of who's here from the IACC. We have three members of this Planning Group.

Walter Koroshetz, are you here?

Dr. Walter Koroshetz: Yes, good morning, everyone. Or good afternoon, whichever it is.

Dr. Daniels: Good morning. Alison Singer?

Ms. Lyn Redwood: Good morning, Walter.

Ms. Alison Singer: I'm here.

Dr. Daniels: Thank you. And Lyn Redwood?

Ms. Redwood: I'm here, too.

Dr. Daniels: Thank you. Great. So we have all three IACC members on this call.

The Planning Group will be joined by some additional people in the coming weeks as we finalize additional expert members -- external members who will be joining the group, but for this call, it will -- it will just be the IACC members.

Welcome to all the members of the public who may be listening to this call. The materials for this call are on our Web-site, the IACC Web-site. If you go to the Meetings and Events page and look for the September 27th 11:30 a.m. call of the Question 2 Planning Group, you'll see a link for materials, and you can review all the materials that we all, as IACC members, have in front of us as well.

So we are going to be having a discussion today of the Question 2 IACC portfolio analysis documents that I sent out to the group. I also sent you guidance that provides sort of some background about what this process is going to be like for updating the Strategic Plan.

The first phone call of all of the planning groups is going to really focus on the funding information provided by the portfolio analysis over the past 5 years and give you a chance to really evaluate what you feel is the status of the completion of objectives and the distribution of funding, et cetera. So we're going to go through those documents, and the goal of the call is for you to by the end come up with sort of a feel for what you think is the status of this question

overall and of the different objectives in the question.

And then I will be asking someone to volunteer to do a draft document that would be no more than five pages. And in fact, yesterday, the Question 4 Planning Group met, and they're going to try to do it in one page. So it will be --

[Laughter]

Dr. Daniels: -- up to all of you to --

Ms. Singer: That’s great.

Ms. Redwood: Susan?

Dr. Daniels: Yes?

Ms. Redwood: When you say a draft document, I guess I need a little bit more guidance for that. Is that draft document just to look at funding, or is that --

Dr. Daniels: Yes, because that's the first -- that's part one. So that's what we're focusing on, on this call. And so, the end product after this call, you all will work on drafting a document that reflects what you feel is the status of the funding activity. And that's -- that's the only purpose for this call.

The next call is going to talk more about results and outcomes and kind of future planning.

So that's -- that's going to be part two. So we broke it into a couple of different segments before we have our big meeting on October 29th with all of the question planning groups together, the entire IACC, and all of the invited external participants. And you will be able to discuss everything in full.

Ms. Redwood: Just a quick question, though. Is there going to be an opportunity to actually drill into each one of these Plan objectives? I think there are a total of nine for this particular question.

And some of them will be really easy to sort of look at, so, for example, the one objective, which is to increase brain tissue donation.

Dr. Daniels: Mm-hmm.

Ms. Redwood: And there are only a couple of projects there. That would be one, we would be able to look at and, you know, write something, just a paragraph in terms of whether we've really been able to increase brain tissue donations or increase the community awareness or value of that.

Is there going to be a chance to actually go through these objectives, look at the projects, and determine whether -- what the status is on

each objective?

Dr. Daniels: That is something that you can discuss on this call. OARC has provided all the documentation that would enable you to do that, and so we have a couple of hours here. We can go through this. We don't expect that you'll be able to do maybe all of the analysis you may want to do on your own.

So we'll try to discuss what we can on the phone, have you start working on a draft document, and then you have all of the information in front of you that will help you if you do want to drill down further into the data.

Ms. Redwood: Yes. [Inaudible comment] Cause I know just for now, is there just sort of an expectation of we think this is what it would cost, but if something is actually answered and done, you know, we could take it off the Plan. And so, that's why I think actually looking at whether the question has been answered may be more important than looking at, you know, how much we've spent.

Dr. Daniels: Right. And so, this is the first -- you know, as the Question 1 Planning Group that was kind of working with the pilot information and

developing this process discussed, looking at the funding is really the first step. But I think everyone probably agrees that finding out what the outcomes have been is probably even more important because you can only get so far with knowing what's been funded.

So -- so this call is going to try to just focus on the funding aspect and let you look at the funding and try to make what conclusions you can based on just the funding information. And then the next call and the workshop will give you more information about the results and outcomes and status of the field, you know, as a whole.

Dr. Koroshetz: Hey, this is Walter. So I think to that point, the document, which is called 2012 Question 2 Project List --

Dr. Daniels: Mm-hmm.

Dr. Koroshetz: -- in-depth, you know, list of all the grants and projects that have gone out under the different questions. So I think that might be a focus for the next call where we dig really deeper into the science.

But we probably, because it is so extensive, we should save some time on this call to discuss among ourselves a plan for how we might do that.

And that plan will include getting help, I think.

Dr. Daniels: Well, Walter, so, actually, the next call is really going to be more devoted to talking about -- talking with the invited participants about the status of the field, and so it's not going to be looking at funded projects.

The funded projects part is supposed to be happening on this call today and as an outcome of this call. So why don't we dive into the documents and start walking through? And if you end up feeling by the end of the call you still haven't had enough time, you can do some study on your own and keep working on the draft together.

Dr. Koroshetz: Alright, but to Lyn's point, before we go, I don't see any mention in the reports of the issue of the brain donation progress. So is that correct, or am I missing it? I didn't see anything in the reports we have on that topic.

Ms. Redwood: The one that -- the one that I'm actually looking at, Walter, is the IACC Strategic Plan objectives, and then it's broken out by year -- '08, '09, '10, '11, '12. And then underneath that, it has the funding, and it has -- let's say for that particular one -- five projects. And you

can click on that. It's highlighted blue, and it will take you to those five projects for 2009, 2010.

And then I think for '11 and '12, they're actually buried in that long list that Susan sent. But there is only one project for '11, and it looks like five projects for '12 that were funded.

Dr. Daniels: Right. So, so --

Ms. Redwood: Does that make sense?

Dr. Daniels: Yeah. I think it might make sense for me to go through the documents in order so that you can really get a feel for what we've provided.

Dr. Koroshetz: Yes, makes sense. Good.

Dr. Daniels: So, so just to give you a little bit of background on the portfolio analysis, I guess we have all veterans here on this Planning Group. So you don't need that much introduction.

Over the past 5 years, the OARC has been collecting data from all of the Federal agencies and as many private funders as we were able to have participate to get an idea at the individual project level of what's being funded and how that maps onto our Strategic Plan.

Just for clarity, and this came up in

yesterday's call with some of the newer folks, the objectives didn't directly drive the research or research-related projects that were funded. It was provided to the agencies as advisory. But what we're doing is really just saying what -- what is being funded out there and how does it relate to these objectives, and are these objectives being accomplished through what is going on in the external environment through the agencies and the organizations?

So we've collected this information over 5 years. The first document that you have is a 5-year Strategic Plan Status Chart or cumulative funding chart as we've also described it. In the front of that document, we provided some background information to help you in terms of interpreting it, and I think you can -- you can take time on your own to look through all of that.

But in brief, we -- we can let you know that the red, yellow, and green color coding is there to help you understand just in terms of the funding and project status how are these objectives doing over time. And in the five columns for the year, that was based on an annualized estimate of the recommended budget,

which, you know, in some cases if the recommended budget was only supposed to extend over a couple of years, we're actually looking at every year. So it's really just an approximation, but to give you a sense of how that's going.

And in the final column, you have a total for how much was invested over the past 5 years. And if you see green, that indicates that at least as much was invested as what was recommended by the IACC. And also as a reminder that the IACC number of projects and recommended budget were described by the Committee as a floor, not a ceiling, but just what the minimum is that is required to begin to delve into this area and try to flesh it out in the way that the Committee intended.

And so we tried to provide those indicators for you to give you a sense. But I think you're going to need to look into it more carefully to make an assessment of how you think that progress has gone. In the cumulative funding chart, for 2008, '09, and '10, we've provided links to the data in the Web tool. So you can actually see project lists if you click on those links.

For 2011 and 2012, the data are not yet live in the Web tool. And so, instead, we have provided

you with a project listing that is essentially the same information, but it's static and not in the Web tool yet. So --

Dr. Koroshetz: That's really nice. That's really something.

Ms. Singer: This is an impressive piece of work, Susan. This is really nice.

Ms. Redwood: Susan, that is really nice. The thing that is going to throw me for a loop, though, in going through this are those not specific to any objectives at the bottom.

Dr. Daniels: Right. And so, you have the listing of what's there. We also -- the last document in your list that we've provided is a summary sheet. And in that, we tried to go through and give you a sense of what's in that "Other" category. We actually have done this two ways. So if you look on the summary sheet, summary --

Ms. Redwood: Hold on.

Dr. Daniels: Yeah, it's the last --

Ms. Redwood: The summary sheet -- what's the full title of it?

Dr. Daniels: IACC Strategic Plan Funding Summary Sheet. I don't have the electronic file in front of me. I'm hoping that I've named the

electronic file the same thing.

Ms. Singer: I think it's Q2 2008 to '12 funding sheet summary.

Ms. Redwood: Yeah, okay.

Dr. Daniels: Yes. So if you go to the bottom of that sheet, the last part of that is a summary of the 2012 Question 2 projects categorized as "Other" to give you a sense of -- it's not comprehensive, but it does give you a sense of the kinds of projects that are there, just to give you a snapshot before you would maybe, if you wanted to delve into reading every project title.

But the list includes face processing, cognitive control of emotion, auditory systems, neural mechanisms and basis of number of delays implicated in autism, such as imitative behavior, sensory behavior, reward motivation, et cetera. Neural networks, synapse formation, and neuroanatomy and autism.

So those are some -- some ideas that will -- or some of the types of projects that are there. But if you wanted the full detail, you would need to actually scan the list of projects, and you do have access to that as well. So that's -- we definitely knew that you would be interested in

that.

The other thing that OARC did, actually, Lyn, in response to a comment you had at the IACC in 2009 saying you had the same concern about "Other" being kind of murky and difficult to understand what's in there. OARC went back in 2010 and actually assigned subcategory codes to every project in the portfolio analysis, and now we've done that for 3 years.

And so if you look in the charts that are provided that are labeled subcategory pie charts for Question 2, from 2010 through 2012, we've broken down the entire Question 2 into some scientific subcategories that might help you understand the balance of what's going on in the portfolio.

And so, that it's not just for "Other," but it also covers "Other." So it will give you a sense overall of what's happening throughout Question 2 in terms of more granular fields within the Question 2 area. So do you find that to be helpful?

Ms. Redwood: No. I have -- I don't see it in here, Susan. There are so many different documents. I see the guidance document,

subcategories, cumulative 2011 project list, 2008 ASD pie chart. Is that it?

Ms. Singer: Subcategory. It says Q2 Subcategory Pie Graphs.

Ms. Redwood: Q2 Subcategory --

Ms. Singer: It's the fourth one from the bottom.

Dr. Koroshetz: It looks like the yellow pie.

Ms. Singer: Yeah, it's like a series of beige pies, pecan pie.

Dr. Daniels: I know that in the title it should say something about subcategories or subcategory.

Dr. Koroshetz: Yeah.

Ms. Singer: Yeah. It says Q2 Subcategory Pie Graphs. It's the fourth attachment from the bottom.

Ms. Redwood: Mine don't come in like that, though, Alison. They're all on a line.

Ms. Singer: Oh.

Dr. Daniels: Yeah, I'm sorry. I know that there are a lot of documents, but we wanted to try to provide you with the detail that the Committee wanted.

Ms. Redwood: Okay. Found it.

Dr. Daniels: You found it? Okay.

Ms. Redwood: Yes, got it.

Dr. Daniels: So if you open that up, you'll see that there are three pie graphs provided for 2010, '11, and '12. And I don't know, maybe '12 might be the most relevant because it's the most recent.

It gives you a breakdown of all of the projects within Question 2 broken into scientific subfields that gives you a sense of what's in the portfolio. It covers "Other," but it also covers the rest. And if -- if you needed it for some reason, you could also, within the Web tool, pull down just the "Other" category divided by subcategories, if you needed to. So --

Ms. Redwood: Is there a way to say how you broke out these different subcategories, like molecular pathways? I'm just wondering when we looked at it before, Susan, a lot of the "Other" projects were MRI, MRI-type studies. And I'm just sort of curious how you fit -- I'll go dig through it. Never mind.

Dr. Daniels: So -- so, yes. So when we were doing the subcategory coding, we realized that many of them were MRI studies. However, in the

past 5 years, MRI has gone from being kind of a focus of research to just being a technology that's used to answer scientific questions.

And so in the subcategory coding, we tried to get at what scientific question was being answered rather than the methodology that was being used to answer it. So there could be MRI studies throughout this pie chart. We didn't selectively just isolate the MRI because MRI could be looking at any number of important scientific questions.

Ms. Redwood: Gotcha.

Dr. Daniels: So if you were interested in MRI, the way you would get at that is by doing a keyword search. But --

Ms. Redwood: Okay.

Dr. Daniels: Same with iPS cells. At first when iPS cells came out, that was, in itself, a topic of study. But now iPS cells are going to be or they are being used to answer various scientific questions. So again, we tried to make the subcategories really focus on the question that's being asked.

Ms. Redwood: That makes sense.

Dr. Daniels: So -- so I hope that this is somewhat helpful in kind of breaking down in a

different way than the objectives what is in that portfolio.

[Pause]

And I think that, actually, this was much quicker than yesterday's call. We've pretty much gotten through I've explained kind of what the documents are that we have. And so, these are the data that are available, and so what would be good to do is for us to be able to go through the objectives in this question area to find out what your sense is based on some of this information as to the status and health of the efforts for each of these objectives.

[Pause]

Dr. Koroshetz: Looks good.

Ms. Singer: This is amazing.

[Pause]

Why do some of the studies have zero dollars against them?

Dr. Daniels: Oh, okay. So that is because some agencies do their funding by giving a lump sum in the first year, and so the out years may not be directly getting dollars in those years. But the project is still ongoing with funds that were provided earlier.

So in those cases, we just -- it's zero dollars, but the project is still ongoing and is still funded.

Ms. Singer: Okay. Wow.

Ms. Redwood: Susan?

Dr. Daniels: Yes?

Ms. Redwood: If we were wanting to, say, dig a little bit deeper, like I'm looking at the 2008 document for this one over here, one in here that was interesting that was a primate models of autism.

Dr. Daniels: Yes.

Ms. Redwood: And the funding was support at least four research projects to identify mechanisms, blah, blah, blah. And this was funded to David Amaral and Melissa Bauman, and it was back from 2008. So if I'm wanting to know whether or not there was a publication that actually came out of this, because I don't think that I've really seen a lot in terms of primate models, how could I find that out?

Because that's sort of -- I guess what I'm asking is what's the status of the project? Is it completed, and what were their findings? Were their findings published? Has it advanced the

field? That's what --

Dr. Daniels: Right. And that's really the subject of the next call -- is really to talk about findings, but we don't have all of that tabulated for you in an easy-to-grab format of every single publication that's come out of all 5,500 projects. Unfortunately, it was just a little bit more work than we would be able to do.

With the NIH-funded projects, if you wanted that information, you could use the link in the Web tool to go to NIH RePORTER's Web-site, and in RePORTER, in many cases, they do have links to publications. But for you to do that for all --

Ms. Redwood: Okay.

Dr. Daniels: -- however many projects are in this question would probably be too much. So if you have a particular project you want to find that information for, if it was NIH funded, there is a way for you to get some of that information.

But if it's from another agency or organization, I don't know for certain if there's a direct way to do it without doing some searching on PubMed.

Ms. Redwood: Okay. And this one was NIH funded. So I should be able to then go in and dig

this one out?

Dr. Daniels: Yeah. So it's a 2008 project?

Ms. Redwood: Yes.

Dr. Daniels: I'm not sure which one you're looking at. So what you would do is then, if you're in the Web tool, if you've used the link to get to the Web tool, the Web tool does have a link, I believe, to NIH RePORTER. And then you would go in there and then click on further tabs in NIH RePORTER to try to find the publications. I don't have the Web-site open in front of me, but I do know that there --

Ms. Redwood: Gotcha.

Dr. Daniels: -- there are links in there to help you identify publications, but it might not be completely comprehensive.

Ms. Redwood: Okay. So that's the Web tool that's actually back on the IACC Web-site? I can't access it from any of the links that are embedded in the documents that you sent?

Dr. Daniels: Well, so the cumulative funding document, I believe -- those links go right to the Web tool. Correct? Yeah. They go to the Web tool. So if you clicked on -- which one are you doing? Is this 2.S.A? Or is it the first --

Ms. Redwood: Let me go back -- let me go back to where I was. Just let me go back one more. Hold on; let me open up the document I was in.
I was in the cumulative funding, the Question 2, cumulative funding 2008, and I clicked on 18 projects. Okay? When I went to the 18 projects, it takes me to --

Dr. Daniels: Oh, I see. So I was just looking at it on one of the laptops in the room here. I have the OARC team gathered in the room, and I don't have my desktop computer in front of me.

It looks like, actually, from that particular link we've linked to the project list, but it's static. But within the Web tool, if you were to go into that project, you would have to, I guess, type in the project or something in the Web tool or put in David Amaral's name. You could find that project.

And then if you went from that project to further information, there is a link to RePORTER. But unfortunately, from that static list --

Ms. Redwood: Okay.

Dr. Daniels: -- you can't get to it.

Ms. Redwood: Okay. That was what I was trying to find out.

Dr. Daniels: So that -- yeah. So it is in the Web tool, but you would have to get to it a different way.

Ms. Redwood: Okay.

Dr. Koroshetz: Yeah, I can get to RePORTER off of the -- from that document. If I just keep going, I can get to the RePORTER system.

Dr. Daniels: So it's -- it might be a few clicks.

Dr. Koroshetz: A few clicks, right.

Ms. Redwood: So after I clicked on, say, David Amaral, to get to RePORTER, did you click on National Institutes of Health, Walter?

Dr. Koroshetz: Ah, I just lost it.

Ms. Redwood: I'm sorry. Just wait a second -- primate models of autism -- maybe it's down here at the bottom.

[Pause]

Dr. Koroshetz: On the IACC Web-site, it's the link that says Web link 1. Oh, wait. No, that was -- hmm.

[Pause]

Ms. Singer: 2009? The 2009 projects? Wow.

Dr. Daniels: Lyn, if you go into the 2009 portfolio, I believe that the project has a link

out to RePORTER -- the same project. So you should be able to get to it that way.

Ms. Redwood: Okay.

Dr. Koroshetz: Yeah. So it goes out to RePORTER. Once you're in RePORTER, there's an option at the top, which says "Results." And if you hit “Results,” then you get the journal articles --

Ms. Redwood: Okay.

Dr. Koroshetz: -- to go with the grant. We could spend years on this one. This is amazing data.

Ms. Singer: This is unbelievable -- be here all day.

Dr. Koroshetz: Data, yeah. So the issue is how to think it through.

Dr. Daniels: Right. And --

Ms. Singer: So one thing -- one thing that would be interesting was -- I mean, this list of funded projects is very long. It would be interesting to see how many of the projects resulted in a publication and compare that to other disease groups. You know, are we doing better or worse?

Because, you know, it's going to be tough to

have any sort of objective measure. I'm trying to think of something that would be an objective measure.

Dr. Daniels: Right. And actually, OARC did attempt to do something like that when we were working on the publications analysis that we released last summer. But what we found was that there's a real problem with -- with investigators at times not citing the grant when they publish.

And so we found that there was only about 50 percent of the publications that were able to be linked back to grants, and so it's really just not accurate at all. So therefore, we weren't able to do that analysis.

Dr. Koroshetz: What percent did you say? Was it 50 or 15?

Dr. Daniels: I think about 50.

Dr. Koroshetz: Fifty percent.

Ms. Singer: Wow.

Dr. Daniels: I believe. Don't quote me because I don't have the report in front of me. We cited a number in the report, but I believe it was something along the lines of 50 percent. It was not -- not high at all, and it wasn't adequate for doing even a reasonable analysis.

So we found that to be one of our major findings in the publications analysis was how it would be really helpful to encourage the research community to be more vigilant about citing their grant support when they are publishing. And this is a -- that's a problem that's pervasive throughout grant funding for all disease areas, not just in autism.

Dr. Koroshetz: Oh, you're right. Absolutely.

Ms. Redwood: I wonder if there would be a way to sort of assess it through PubMed? If you typed in certain keywords to get a little bit better idea of the status of, you know what the state of the science is.

Dr. Daniels: In PubMed. So we did the publications analysis last summer, and that gave a sense of how the publication trends have changed over time, and that's the document that is available to you, and you could look at it from both the lens of Question 2.

Ms. Redwood: Yeah. Well, I was just thinking if you did something, let's say, where one of the objectives was launching three studies that specifically focus on the neurodevelopment of females with ASD. So if you did, you know, autism,

females, you know, neurodevelopment, and put in those keywords to see what -- you know -- what has been published.

Although that's going to be an easy one to sort of assess because there were so few projects. Even if there's -- just to see what the science is saying.

Dr. Daniels: Sure. And that's really more of the focus, again, of the next call. This call was really --

Ms. Redwood: Oh.

Dr. Daniels: -- looking at funding. I just want to make sure that you all stay on track to be able to complete the goals of this call to, at least based on the funding, make a general assessment of what the status is of these objectives, whether at least you know whether the agencies have funded an adequate number of projects or you identify that maybe projects are not being launched in that area.

If you can identify possible barriers that might have prevented agencies and organizations from being able to really address that area, those would be some important things to establish during this call.

Ms. Redwood: So are you suggesting we run through each of these objectives and look at funding across the board and just answer that one question -- question, whether or not funding has been adequate.

Dr. Daniels: I think that would be a good start.

[Pause]

So, for example, for 2.S.A, you can see kind of the trajectory over the 5 years of the number of projects that have been funded. You can see the recommended budget was over $9 million and that the total that was expended was $16 million.

You don't know, without knowing the exact projects, do you have a sense that that one is in potentially reasonable shape? Although you would need to look through the projects to see what the coverage is of the different topics that are in Question -- or in 2.S.A.

Ms. Redwood: Well, it appears if we're just addressing the issue of funding that that one seems to have been adequately funded --

Dr. Daniels: And if you -- if you --

Ms. Redwood: -- based on our recommendations, you know? Not saying that that's -- just based on

what our recommendations were for funding.

Dr. Daniels: Right. And if you look through the project listing, for example, the 2012 project listing, and you glance through it, whether it looks like the kinds of projects that are in there are addressing some of the questions that the Committee really was interested in?

Ms. Singer: I mean, to me, the interesting thing to think about is that more than half of the funding was outside of the objectives. So, you know, how did that happen?

Did some of the -- did the agencies and the private funders have different goals and objectives? Did they not like the goals and objectives? Did they not agree with them, or I mean that -- to me, that's a question we need to look at.

Dr. Daniels: So the Strategic Plan --

Ms. Redwood: Yeah, I agree, Alison.

Dr. Daniels: -- the Strategic Plan, when it was set up, was really targeting areas that were in need or that had been potentially previously neglected or were new, emerging areas. And so it was really addressing gaps, and so what's in "Other" may be addressing the mainstream things

that were already going on. And especially when you --

Ms. Singer: Okay. That makes sense.

Dr. Daniels: -- consider Question 2, before the Strategic Plan even came along, NIH already had a pretty large portfolio of biology research. And so, largely, I'm imagining that a lot of the Question 2 "Other" might be some of that, but there also were many other foundations funding research and so forth before the Strategic Plan came along.

But you would be interested, of course, in knowing whether the gap areas you identified are starting to be addressed by now, now that it's been 5 years, or if some of them maybe have been well addressed. And if there are some that are really not off the ground, why?

Ms. Redwood: The other thing, Susan, if you look at what you're saying about that category of "Other" --

Dr. Daniels: Mm-hmm.

Ms. Redwood: -- it looks like the funding has sort of been steadily increasing, you know, in that "Other" category. And maybe that's just a trend of overall funding increase in ASD research.

That would probably be another interesting chart to have -- is just, you know, the total overall funding in ASD research from 2008 to 2012.

Dr. Daniels: So we provided the pie charts for overall funding as well. It's not a line graph or a bar graph, but it is a pie graph series.

Ms. Redwood: Is it for each year?

Dr. Daniels: For each year.

Ms. Singer: Did you have -- Susan, did you guys have data that looked at the proportion that was funded by the Government and the portion that was funded by private funders?

Dr. Daniels: We did for each year. We have that information. For 2011 and 2012, I don't think we've prepared those graphs yet. Those would be part of the upcoming Portfolio Analysis Report.

But we have the graphs for 2008 through 2010. They weren't included in this packet because that wasn't one of the questions that was identified, but we have that information and can provide it.

Dr. Koroshetz: I'm just looking -- just -- people have been looking at the other projects, you know; you can pull up the names of the projects. And they're like really important. I mean, they sound really important. Just to give

you examples, you know cerebellar anatomic and functional connectivity in autism, social and effective components of communication, understanding perception and action in autism. So they're right -- they're right down the alley in terms of important research necessary for autism.

So I'm not -- I mean, we should look at them, but they seem to be the kind of things that we want to happen. They may not fit, or maybe they should be -- maybe they should be reallocated. But they seem to fit what's needed.

Ms. Singer: I think the point that Susan was making before, if I understood correctly, was that when we wrote the objectives, we were focused on gaps. And so to the extent that the “Other” --

Dr. Koroshetz: Right.

Ms. Singer: -- represented what was or what already -- we already knew needed to be funded, it wouldn't be reflected in any of the specific questions.

Dr. Daniels: That's right.

Ms. Singer: Okay. So it's not that this “Other” is ancillary or unimportant, it's probably more mainstream than what's in the seven

questions.

Dr. Daniels: Right.

Ms. Redwood: And also I see like, for example, the first one with looking at mechanisms of metabolic, fever, immune interactions that sort of came from the science that was building, that pointed to there may be abnormalities here. So this is drilling in, you know, more deeply into areas that might have pay dirt in terms of better understanding, you know, what did cause this to happen or how to understand better what's happening, especially with regard to abnormalities in the immune system.

So to me, it's almost focusing the research and the science.

Dr. Koroshetz: Yeah. Some of this stuff is, you know, on the comorbidities; here's one: evaluation of sleep disturbances in children with ASD. So --

Ms. Singer: I think what we're getting at in that the term "Other" here, usually "Other" sort of refers to things that can't be categorized or are less important. In a sense, you know, what we have in the “Other” category here are the more mainstream studies, things that we knew we had to

be studying before we wrote the Plan. Maybe we need to rename “Other” to something else that reflects that it was known as an area of need for funding prior to writing the gap objectives. You know what I'm saying?

Dr. Koroshetz: Yeah. Or at least we can be explicit when we write the report if that's the case.

Ms. Singer: Right.

Dr. Daniels: Right. And I think in the Portfolio Analysis Report, OARC usually does put in an explanation, but it probably ends up being kind of the fine print that nobody reads.

But that's a point well taken because “Other” sometimes does give that impression that it's not important, and I don't think that when you look at the content here that this research is unimportant. In fact, many of those items are extremely important and have been a foundation for research on autism, so, point well taken.

Dr. Koroshetz: Right. Right.

Dr. Daniels: And if the Committee decides they want us to call it something different, we're happy to try to accommodate that.

I wanted to answer your question regarding

Federal and private funding. You don't have this document directly in front of you, but in the 2010 Portfolio Analysis Report, the breakout for Federal funding versus private funding in the entire portfolio was 82 percent Federal and 18 percent private.

And I don't have the figures yet for 2011 and 2012, but we probably will soon. And if the Committee wants that information, we're happy to get it out to you soon.

Ms. Singer: What was the breakdown for Question 2 for Federal versus private?

Dr. Daniels: Oh, so we never did it by question. We only did it for the overall. But if you want that information, I think that we could do it for 2012. So is that something you want us to follow up and provide to you?

Dr. Koroshetz: I mean, I don't know. I'm not crazy --

Ms. Singer: I don't know. I would say let us look --

[Inaudible comment]

Ms. Singer: -- before you go do all that work. I mean, you've done so much. There is so much data here. It's hard to think that we might need more.

[Laughter]

Ms. Redwood: Yeah, exactly. Hey, Susan, I'm still back in that category of "Other," and I was running through the list here. And some of these, I mean not the majority, but some of these are very global, and I don't know that they're specific for autism. Learning and compression in human working memory? You know, I don't know how that got assigned to autism.

Dr. Daniels: I don't have that in front of me. Who's the funder?

Ms. Redwood: Hold on. This one that I'm on, it doesn't say. It just says, let's see -- George Alvarez, Harvard University, is the institution principal investigator. It says -- the page that I'm on, it doesn't -- it doesn't show the funder. It's just the list, 246 projects.

Dr. Koroshetz: Yeah, it's NIMH. I have it on --

Dr. Daniels: So NIH has research category -- disease category systems -- for it's basically a computer algorithm that checks all of the grants for relevance to autism. And then that information is checked by program officials, and they confirm what belongs in the autism portfolio. So based on

those determinations, that was in NIH's autism portfolio, and they submitted those data to us.

Dr. Koroshetz: So, Lyn, in their abstract, they say -- so they're talking about this general area of learning and working memory, and then it says, "How can these influences be exploited as tools to enhance cognitive processes in those with learning disabilities, for example, autism?" So they actually -- so it's a simple science area --

Ms. Redwood: Gotcha.

Dr. Koroshetz: -- that they are posing as, you know, maybe someday relevant to autism education.

Ms. Redwood: Okay. I was just curious how those were assigned to the --

Dr. Koroshetz: They have -- my understanding, Sue, is that there's basically a computer analysis of the abstracts that tosses them into different areas.

Dr. Daniels: Right.

Dr. Koroshetz: You have autism in your abstract you're going to probably end up in an autism bin. But those bins are not -- they're overlapping.

Dr. Daniels: Right. And at NIH, they generally have the program officials also confirm that

things are relevant to the disease area it was assigned to. So they try to weed out anything that mentioned autism in passing as, you know, something that was not relevant necessarily to that project, but to something else.

So -- so usually those things get weeded out. But each agency submits data to OARC, and OARC does check the information. And if we find that something looks awry, we usually go back to the agency and ask questions.

And, but ultimately, the agency decides what's in their portfolio. So we try to work with them to ensure fidelity of the data.

Ms. Singer: Do they ever assign the same grant and dollars to more than one disease?

Dr. Koroshetz: Yes.

Ms. Singer: Do they split it in half when they do that, or do they double-count it?

Dr. Koroshetz: I think they double-count.

[Pause]

Dr. Daniels: In the past, they had a proration system, but that system has been abolished now. I think with the categorical funding, I thought it was mostly mutually exclusive, but at least at NIH -- I mean, this doesn't apply to all the other

organizations and agencies. They all may have their own systems.

But the NIH system, because Congress had had a concern about double-counting, I think that the current system now doesn't do that anymore, the system that's been in place for the past 5 years.

Dr. Koroshetz: That system is called RCDC.

Ms. Redwood: Hello? [Laughter] Hello?

Dr. Daniels: Yes.

Ms. Redwood: Hello?

Dr. Koroshetz: Yes, hi.

Dr. Daniels: We can hear you.

Ms. Redwood: Okay, great. I'm sorry. It's Lyn. All of sudden, my phone just went to a busy signal, and it disconnected me. So I had to dial back in.

Dr. Daniels: Oh, no problem. I actually just got the data for 2012, the Federal versus private. It's pretty much the same as what was going on in 2010. So it was 78 percent Federal and 22 percent private. Just --

Dr. Koroshetz: It's in RCDC, and it says that the research categories are not mutually exclusive. Individual research projects can be included in multiple categories. So amounts

depicted within each column of the table do not add up to 100 percent.

So I think they -- they're not mutually exclusive categories.

Dr. Daniels: Thanks for looking that up, Walter, and getting that verification. We'll be sure to take note of that in case it comes up on other calls.

[Pause]

Dr. Koroshetz: So what does the Group think about how we would assess the funding based on the information we have here, which looks pretty complete?

Ms. Redwood: You mean just for 2.S.A, Walter?

Dr. Koroshetz: Sorry, Lyn, I didn't hear.

Ms. Redwood: You mean just for that one objective, 2.S.A?

Dr. Koroshetz: No, I'm just thinking in general terms, how would we -- do you want to go through each one, and then -- I'm just not sure of what process we use to make our --

Dr. Daniels: I think it might be helpful for you to go through each one and give, you know, a general sense for what you think, based on the information you have here. And then you can drill

down further as time permits and as you see fit.

Dr. Koroshetz: Okay.

Dr. Daniels: So, for 2.S.A, what is your sense of that? You might be wanting to glance through what's in the 2012 Portfolio Analysis Project listing, as well as kind of take in those numbers.

Do you feel that from a funding perspective that there is coverage of the kinds of things the Committee was looking for?

Dr. Koroshetz: I would -- in my mind, I was thinking, just throwing this out, that the funding has been pretty stable across the years for this, whereas it seems to me that the scientific opportunities have increased.

But again, statistically, it's not significant because we have been as high as five. Now we're down to three in 2012. I mean, that would be the only caveat I have is that it seems as though the interest in this area is increasing. The funding is not. But the numbers are, you know, reasonable. Anybody else have any thoughts?

Dr. Daniels: Walter and all of you, something to keep in mind is that you might see some spikes in funding in 2009 and 2010 due to ARRA –

Dr. Koroshetz: Right.

Dr. Daniels: the Recovery Act. So that's something just to keep in the back of your mind -- that you might see a little bit higher level there because there was an infusion of additional funds.

Ms. Redwood: Walter, I overall agree with that. I was just sort of looking through to see whether or not, you know, if you actually drill in a little bit deeper into that to break it down into, you know, immune system interactions, metabolic, fever, those types of things in that question, are all of those represented would be part of another question to ask, too.

Dr. Koroshetz: Right.

[Pause]

Ms. Redwood: But that's going to definitely take some time –

[Pause]

Dr. Koroshetz: [Inaudible comment] mitochondrial disorders few (studies), but not extensive.

Ms. Redwood: Right.

Dr. Koroshetz: And microbiome and gut-related changes on immune system. I don't see that. Maternal immune activation, I think that's a, you know, very hot topic. I see one, two – three

(studies).

[Pause]

Also I think that it is kind of a gap area because we're so "brain centric" that missing a more systemic problem in metabolism or more systemic illness affecting the gut or the immune system, we would really have to put emphasis on it because people wouldn't necessarily move in that direction.

[Background noise]

Ms. Redwood: I think that's really true, Walter. I think that's an observation that's worthy of including in our -- in our write-up.

Dr. Koroshetz: Okay, any other points on that one?

[Pause]

Ms. Redwood: You're a lot faster than I am going through these charts.

Dr. Koroshetz: Okay.

Dr. Daniels: And of course, we don't expect you to go in that great of detail for every single thing in just one phone call. But you know, hopefully, you're getting a sense for that.

So overall, in summary, do you have a feel for this particular objective and where it is?

Dr. Koroshetz: I think Lyn and I are on the same page.

Ms. Redwood: Yeah, and I think we need more research in this area.

Dr. Koroshetz: Okay.

Dr. Daniels: So then maybe you could independently work on this outside of the call and then add information about that to your write-up.

Dr. Koroshetz: Okay.

Dr. Daniels: So then we just want to give you a chance to discuss on the call anything that you want to discuss about these objectives. If you move to 2.S.B, what is your feeling for that one?

Ms. Singer: 2.S.B.

Dr. Koroshetz: This is research on neurodevelopment of females with ASD, basic to clinical research. So there are basically five projects that we can look at.

Ms. Singer: It -- I mean, that's a little misleading, though, because one of the projects is an ACE center, right? So --

Dr. Daniels: Right. And that ACE center, though, is focused on this particular objective, actually.

Ms. Singer: Right. No, I know. And that's what

I'm saying, is that the number of projects, looking at the number of projects may be misleading because some projects are $5,000 in funding and some are $5 million in funding.

Dr. Daniels: Right.

Ms. Singer: And varies across.

Dr. Daniels: Absolutely, and that is something that, you know, the other group yesterday also pointed out. That more projects is not necessarily better. Sometimes more well-funded -- fewer well-funded -- projects sometimes make more of a difference than lots and lots of tiny projects.

But in other cases, maybe a more distributed approach is needed, and so, so that's something that you all can get a sense for.

Ms. Singer: No, I mean, when you think about this is definitely an area that people are talking about more. There's been a lot more research coming out. There is a recognition that it's an emerging topic with the funding of the ACE centers. I mean, this is one where I feel like progress is moving -- we are moving forward.

Dr. Koroshetz: What was the last word?

Ms. Singer: There are only five projects. But the feeling is that there is recognition now that

the girls are different than the boys and that we need to understand why.

Dr. Koroshetz: Yeah. Yeah, so I'm looking at the Lauren Weiss one. It's a Simons Foundation grant that looks like it's right down the alley, recruiting as many females as possible, looking particularly to identify female genetic susceptibilities.

[Pause]

Ms. Singer: Now this one is definitely moving forward. I mean, I know we're talking about money, but I know that up at -- up at Yale -- they're opening a clinical center just for women with autism. So it's definitely -- this one's moved forward.

I mean not done, but at least there's -- I mean, you can sort of see it. It went from red to yellow, yellow, yellow, and now it's green.

Dr. Koroshetz: Yeah. No, let's make that point.

Dr. Daniels: Right. And when you move to the next call and the workshop, you'll probably find, because a lot of that funding just came in the past year or so, that there may not be a lot of publications yet. There may not be a lot of new

data as yet because it's all new, but -- but you would be able to say that the field is moving forward, that there has been some research attention given to this, and you're expecting results will be coming out in the future.

Ms. Redwood: Susan, is anybody taking notes on this call for us, or is that something we should be doing?

Dr. Daniels: Yes. We have someone taking minutes for this meeting, and so we will -- we will have that for you.

Ms. Redwood: Great. Thank you.

Dr. Koroshetz: So, Lyn, are you good with what's been said on this one?

Ms. Redwood: Oh, yeah. Absolutely, and I know this is an interest of Alison's. So I defer to her opinion.

Dr. Koroshetz: Okay. The next one seems easy to me, 2.S.C. I guess -- I guess the question here is, are we going to assume that it's correct that there's still a huge shortage of brain tissue? So then we can just state that, you know, the effort just isn't meeting the need.

Ms. Singer: So I can't find this page anymore, but I do know something about this topic. Wait let

me see if I can get back this way.

So I was looking at the two projects that were funded in 2009, the year that's green, and I mean, one was to process the library samples, which didn't really increase the number of donations. It just -- I mean, it did -- it --

Dr. Koroshetz: It made it more useful.

Ms. Singer: It made them more useful, yeah. I mean, but it was for the existing samples. That's also important.

And then the other one was for skin cells. So, I mean, that's important, too. So stem cells. But, and then there's one project in 2010, enhance tissue procurement. I'm not sure what -- what that one was. But basically, you know, last year when we talked about this question, we actually said this is an area where we have regressed. Because of the freezer malfunction, we have fewer tissue samples in 2011 than we did in 2008. So we actually identified this one last year as moving backward.

You know, in 2012, the Simons Foundation is now funding two big projects in this area. One is to create a network of banks and to encourage them to standardize the collection and the processing

so that the tissue is more easily used by a wider network of researchers.

And then there is also funding for an awareness campaign targeted at families of kids with autism to try to encourage them to register to become donors. So, you know, that's happening.

Dr. Koroshetz: Do we have -- for those projects, they are probably not research projects. So would we have any idea of the money that's associated with them?

Ms. Singer: I do. I mean, one is to us. So that one I know. And we started in 2012. David Amaral got, I think, $1 million to start to work on the network to network the banks, but that's 2013 funding.

Dr. Koroshetz: I see.

Ms. Singer: So that wouldn't be reflected here.

Ms. Redwood: You know, I worked several years ago with the Autism Research Institute. They -- one of the shortcomings that we identified for being able to collect tissue was the lack of freezers. So ARI purchased several freezers. I want to say they were like $10,000 or $12,000 each.

And we were outreaching to the actual medical examiners in different States to get them to include on their intake questionnaire the question of whether or not the child had been diagnosed with an autism spectrum disorder. And you know, that was one of the outreach projects, was to get parents to go to their State medical examiners and increase awareness of the need of tissue donation that way.

And I could check back with Dr. Edelson to see what the status is. I know that here in Atlanta, I personally met with the medical examiner. They were onboard, very excited to help. We created these beautiful posters, you know, with a picture of a child, you know, and the importance that were mailed out to different medical examiners to put in their offices.

And we created a trifold brochure along with the NICHD Brain and Tissue Bank at the University of Maryland. And you know that was a good effort.

I don't know if it's sort of fallen off. Those were distributed at different conferences for parents, along with magnets. I know the people at the University of Maryland Brain and Tissue Bank would actually come and set up booths and set out

little key chains with brains, and then they'd get parents to sign up at conferences.

So that was another way of doing outreach. But I think those types of creative projects really need to be happening more, and I hope that that's something -- I don't know what you're planning, Alison, in the project that you're funding, building awareness.

Ms. Singer: It does include outreach to doctors in the -- in the PICUs. It includes outreach to medical examiners and training for medical examiners. This is part of the funding that David has for what's going to be called the Autism BrainNet, which is starting with four nodes for collection -- MIND Institute, Mount Sinai, University of Texas, and, oh, what is the fourth one? I think it's Children's Hospital in Boston.

But the Maryland Brain Bank was invited to be part of it and has not, unfortunately, yet signed on. But these four are going to have a sort of a governing body that determines how the tissue is collected -- harvested, collected, processed.

And it's going to be really categorized in conjunction with the IAN network. So that when we get samples, when someone actually donates tissue,

there is a rich history in terms of the diagnosis of that person, the medications that he or she may have tried, the interventions, the parent experience. Everything that's in IAN will be linked to that tissue.

Ms. Redwood: The only -- I know we're getting off topic here, but Alison, one of the things we ran into, which is hugely problematic, was control tissue. Not only having adequate control tissue, but you didn't have that rich history associated with it.

Ms. Singer: Yes, that's definitely a problem. Yes.

Ms. Redwood: So there was control tissue for autism studies of a child who is 14 and committed suicide. And you know, that, in my opinion, shouldn't really be a control brain. So, you know?

Ms. Singer: No. I hear you.

[Inaudible comment]

Ms. Singer: No, I mean, it's a long-term -- it's not a 1-year project. It's going to go on. The first year we're targeting families with kids with autism. After that, it will targeting for control tissue.

And it will involve outreach to the medical

examiners and pediatricians as well to try to get families to register -- and not just families that have kids with autism -- but other families and to release their medical records if there should be a tragic accident that results in a tissue donation.

So yeah, I mean, I think there is definitely recognition that we have to have better phenotyping on all of the donors, not just the kids with autism, but the control brains as well. So you're absolutely right.

Ms. Redwood: Right.

Dr. Koroshetz: Okay, so just listening, so from the discussion, it sounds like the things that are hitting me are that this is an area that still requires attention, that in the period of time that we're looking at, we believe that we've actually regressed instead of made progress.

However, I think it's also probably important to state that there are major efforts now ongoing to address the situation and that the numbers that we have here don't reflect the overall nationwide efforts to improve brain donation.

Ms. Singer: I think that's -- I think that's well said.

Dr. Koroshetz: Okay.

Dr. Daniels: Walter -- and that's something that I was going to add is that -- I think these types of projects, like increasing awareness and so forth, they may not be very well captured in a project like a portfolio analysis where we're collecting really grant funding, and many of these things might be done through other mechanisms other than grants and contracts. They may be done through -- in the Government RMF funds or other types of funding mechanisms that private groups use.

And so it will be important for you to maybe list some of those other activities you know about, but that are not necessarily reflected here.

Dr. Koroshetz: And I think we also have to say that, you know, although we know that there's redoubling of the effort in 2013, we don't know if it's sufficient yet. Is that fair? We don't really know, do we, yet in terms of whether we've made improvements in the numbers that are coming in? I mean, from what you've said, Lyn, that there's lots of work to be done here.

Ms. Singer: Yes, but we're on track. I mean, we just fielded a sort of a “pre-wave,” we call

it, to get base-level awareness.

Dr. Koroshetz: Uh-huh.

Ms. Singer: And then we'll be able to measure after the awareness campaign is released, 6 months out, 12 months out, if there's been an increase in awareness.

Dr. Koroshetz: That's great. Do you want to go on to the next one then? So --

Dr. Daniels: Yes. Alright, 2.S.D.

Dr. Koroshetz: -- biological pathways of genetic conditions -- fragile X, Rett, tuberous sclerosis.

[Background noise]

So I would think, just for my sense, is that this has -- this has been one of the most productive areas because you have these defined genetic markers to go after. So I don't know how well you can generalize, but we've made a lot of progress, I think, on understanding each of these disorders.

And the funding is, you know -- there's never enough funding. It looks like it's been going upward, which I think makes sense, given the fact that the scientific opportunities are kind of ballooning in this area.

Ms. Redwood: Wasn't there something that just came out this last week about Rett syndrome, not being a purely genetic syndrome? I'll have to send it around, but it was interesting.

Dr. Koroshetz: I was actually talking to one of the people from the Rett Society. He was telling me an amazing story about the Retts' girls, and they have horse therapy. So they ride horses, and it just increases all their emotional tone, and he said it's just an amazing effect.

Ms. Redwood: There are a lot of kids with autism that do that, too, Walter. Equine therapy, it helps with balance and coordination and --

Dr. Koroshetz: I hadn't heard that.

Ms. Redwood: -- yeah, I got mine funded, and I don't know that I could say it was a really -- you know, I think it was more recreational and getting outside and doing something and all those other things that go along with it. It's fairly popular.

[Pause]

I agree with what you said, Walter.

[Pause]

Dr. Daniels: Alison, do you have any comments on this group?

Ms. Singer: No. I'm looking through the 2012

list right now. There's a lot of data here.

[Long pause]

Dr. Koroshetz: You said you're looking at the 2012 list? Actually --

Ms. Singer: Yeah, I was looking at the 2012 project list of 83 projects. I mean, in terms of the number of projects and the dollars, it looks good. I mean, there's not a lot of -- we haven't looked at outcomes, but the number of dollars and the number of projects look good.

Dr. Koroshetz: Yeah.

Dr. Daniels: And it looks like overall the investment in this area has -- it looks like it's kind of doubled since 2009. So there's definitely been more of an emphasis there, which might mean that you would expect your outcomes to be a little bit later since some of that is new.

Ms. Singer: Well, I think a big chunk of that has got to be the tuberous sclerosis ACE center, right? So, yeah. I mean, I think we should talk about we have two ACE centers in Question 2.

Dr. Koroshetz: Yeah. That's good, though. We like that.

Ms. Singer: No, I agree. I think that's something to point out.

Dr. Koroshetz: NINDS funds those.

Dr. Daniels: So then from what I'm hearing overall is it sounds like based on just the funding information, you feel that this one is pretty much on track with what the Committee was hoping for?

Ms. Singer: For the funding? I'd say yes.

Dr. Daniels: The funding aspect.

Ms. Singer: Okay, yeah.

Dr. Koroshetz: I agree, yeah.

Dr. Daniels: So then can we move to 2.S.E?

Ms. Singer: Yeah. That one, too, I was looking at that one, and that one, I mean -- I mean, in terms of the funding and the number of projects, and I also think when we start to talk about outcome, I think there's definitely been over the last 5 years more awareness of co-occurring conditions and a better job of getting the word out to medical professionals that they need to include this in anticipatory guidance. So -- let me just see this list.

Dr. Koroshetz: But the money has been fairly constant, right, year in, year out.

Ms. Singer: Yeah.

Dr. Koroshetz: Since 2009, but it seems to me

that the emphasis at the IACC on this area has increased substantially over the last 4 years.

Ms. Redwood: I would like to see more funding in looking at a lot of those co-occurring conditions because I think they can also seep back into some of the underlying biology where there is shared mechanisms, such as injury. And when you look at the overall – like, let's say go down to not specific to any objectives or the "Other" category, which we sort of determined was a lot of the basic science, and you have $201 million total, and then you go up and you look at the co-occurring conditions and it's $16 million. You know, I think it needs to be -- I think we need to continue research in that area and actually increase the funding.

Ms. Singer: I think we can also take a look at the subcategories within this question. It looks like there've been a lot of studies of gastro, sleep, and epilepsy, but we may be able to point out some additional co-occurring conditions that have not been as well funded.

Ms. Redwood: Yeah. I think metabolic and immune would fall into that category.

Ms. Singer: So that may be a way to look at

these data.

Dr. Koroshetz: Yeah.

Ms. Redwood: And also the wandering and elopement behavior -- that's something that was, you know, newly added. But still, you know, some of that may very well be precipitated by some of these other conditions.

Dr. Koroshetz: Yeah, would that be in any of the other questions, the elopement issue, Sue? Would that --

Dr. Daniels: I don't believe --

Dr. Koroshetz: -- something else?

[Several speakers]

Dr. Daniels: -- a specific objective for wandering. I think this is where we put it in.

Dr. Koroshetz: The wandering would have to be here, huh?

[Several speakers]

Ms. Singer: Yeah.

Ms. Redwood: You know, I also wonder whether or not we should put something about that -- this is off topic, but in-services because I really think that, you know, training is a big key to that in terms of prevention.

Ms. Singer: So I don't see a lot on the

autoimmune disorders in here, just scanning it.

Dr. Koroshetz: No, you know, that's in the 2.S.A, the -- which is the mechanisms of fever, metabolic, immune system interactions with the central nervous system.

Ms. Singer: Oh, because it also is listed in the objective here. It says “co-occurring conditions including seizures/epilepsy, sleep disorders, wandering, and autoimmune disorders.” So --

Dr. Koroshetz: Oh, I see. Familial -- I see -- so not as a cause of autism.

Ms. Singer: They may have -- they may have all been categorized in 2.S.1.

Dr. Daniels: Right. And that is one of the things that is a little bit tricky about the Strategic Plan is that there are some overlapping areas, and so there are cases where there may be projects that got categorized to another objective that are also relevant here. But in order not to be double-counting any dollars, we only put projects in one place.

Ms. Singer: Right.

Dr. Daniels: But you can always make note of that, that if you look through the list for 2.S.A

and you think that many of those projects would also fulfill part of this, you could make a note of it.

Ms. Redwood: And when I think of familial autoimmune disorders, I also think more of risk factors. You know, more like in Question 1, or I'd have to go back and look, or maybe even somewhere in Question 3, what caused this to happen and can it be prevented?

Dr. Daniels: Right. So there could be overlaps with some of the other questions as well.

Ms. Redwood: Yes, but that's, you know, definitely something that we see quite a bit of in our family histories.

Dr. Koroshetz: I just scanned 2.S.A. I don't -- it all looks like research on autoimmunity leading to autism, as opposed to a co-occurring condition.

Ms. Redwood: Yeah, I think that the familial autoimmunity is more a risk factor with regard to genetic vulnerability.

Dr. Daniels: Well, perhaps that's a gap that you're seeing then in this particular objective, [pause] in the projects that are funded for this objective.

Ms. Redwood: I'm just wondering whether familial autoimmune disorders really deserves to be included in with underlying biological mechanisms.

Ms. Singer: Well, we aren't supposed to change the objectives here.

Ms. Redwood: Yeah. Okay.

Ms. Singer: We have to just sort of say where we think they are, but not --I know what you're saying, though.

Dr. Daniels: And that was just a general challenge, I think, for the Committee --

Ms. Singer: Yes.

Dr. Daniels: -- as they were coming up with the Plan. It's really hard to categorize these things because they all do interconnect with each other.

Ms. Redwood: So I think sort of like, Alison, what you were saying was the studies looking at women with autism, it's the same. You know, we're moving forward, but there needs to be more.

Ms. Singer: Yes. I was saying that in this one, where it looked very green and well-funded, we should just look through the list and make sure that the funding is spread among all of the

conditions that were identified in the objective.

And it looks like seizures and epilepsy is, sleep disorders is, gastro is, even though it's not listed here. Wandering has one study, but I think that study has a strong outcome.

The only one I had a question about was the immune disorders, and that is captured in 2.S.1. We can just make a note of that. So I'm good with this one.

Ms. Redwood: But I don't know if it's really familial that's captured in 2.S.1.

Ms. Singer: Oh, okay. I didn't look at 2.S.1. I thought Walter had said he was looking at 2.S.1.

Ms. Redwood: Walter, do you see anything there about familial autoimmune?

Dr. Koroshetz: No, I didn't. No. No, it's all immune mechanisms that could cause autism in 2.S.A.

Dr. Daniels: So another consideration as you look at these is if you feel that some of these objectives may have been somewhat met in terms of the Committee's current recommendation, but if you see that the field is changing and that you still think that there is more that needs to be done and that further emphasis needs to be made on this

area even though the initial recommendations may have been somewhat met, you can always say that in your report as well.

And say that we have come a certain way with this, and we have fulfilled what our initial recommended budget area -- budget recommendation was, but we feel that more work needs to be done in this area, as needs are increasing or opportunity is increasing or whatever you think.

Ms. Redwood: One of the things I think would need to be done here that I don't see captured is for this systems biology approach to these co-occurring conditions, where you look at overlaps in terms of whether or not some of the immune abnormalities might be driving the metabolic abnormalities or the metabolic abnormalities might be driving some of the immune system abnormalities.

So the overlap between the biology of these co-occurring conditions -- I want to make sure they're not looked at in silos. So we're not looking at GI as separate from immune because so much of our immune system is in the gastrointestinal tract.

Dr. Koroshetz: Right, really good point. So,

but yeah, it's not a budget issue, but it's a scientific issue. So we should keep that in mind as we get to our second step. That's really important.

Ms. Redwood: Right, yeah, and not to look at these in silos. Because I think sleep, when you look at what's going on in the brain of these children, too, I think that's, you know, one of those mechanisms that's causing the abnormalities. Or it could be that they have esophagitis, and they're refluxing, and they're burning at night. And they're waking up because of the pain.

Dr. Koroshetz: Yeah. Okay. So are we ready to go on to the next one?

Dr. Daniels: Yes, let's move on to 2.S.F.

[Pause]

Ms. Redwood: hmm.

Dr. Koroshetz: So two studies. One is intramural; one is Kaiser.

[Pause]

I think this has been a really tough nut to crack, from what I've heard. Trying to get people in time and documenting the regression and it’s been really difficult.

Ms. Redwood: [Inaudible comment] [Laughter]

There's not a whole lot listed.

Dr. Koroshetz: Yeah. We say to launch two studies, and they launched two studies. And it went from zero to 400K.

Ms. Redwood: You know -- But the budget was $4.5 million, and you know, I just think this is a really important area. I just remember, you know, a decade ago when nobody believed parents when they said that their children regressed because the thinking was autism was present at birth. And now the numbers are, what, something like 40 percent of children have regressive autism?

You know, and it really wasn't even acknowledged until that 1-year birthday party video study. So I do think this is an area that really deserves a lot more attention than what it's received in funding.

So we satisfied the objective of two studies, but -- but it's such an area that --

Dr. Koroshetz: More.

Ms. Redwood: Yeah, it could really help to advance the field if we were to dig into this, and I think it would be so important to actually capture children during that process of regression and look at what's going on. You know, I would

love a study where kids would be actually hospitalized and, you know, all different specimens collected and, you know, different studies performed during that period of regression. I think that would really tell us a lot.

Dr. Koroshetz: Yeah, so maybe what we're saying here is that, you know, this remains an important question. You know, we went from zero to two projects, but we just haven't, you know, been able to crack it and needs more work.

Ms. Singer: I think we should also recognize the procedural barriers here.

Dr. Koroshetz: Yeah.

Ms. Singer: I mean, it would be great to do what Lyn is describing, but I don't -- I don't know how practical it is. It may be the case that researchers have had difficulty designing a study that would adequately and accurately capture this.

Dr. Koroshetz: I think that's --

Ms. Redwood: We were following like high-risk sibs, Alison.

Ms. Singer: What?

Ms. Redwood: You know, looking at the siblings, the high-risk siblings.

Ms. Singer: Yeah.

Ms. Redwood: You know, they're being followed up fairly closely, and the parents are enrolled in the study. And they would say something like, "Listen, I think something is going on," and you know, "Billy is doing the same thing as Bobby did."

I think it -- I think it could be done. I think it, you know --

Dr. Koroshetz: I mean, Sue Swedo at NIH -- I think that's exactly what you said -- is exactly what she wanted to do because they can actually admit people here and just put them in the hospital and study them. So it was just hard to get people. So it's maybe more of a logistic. It may just be just a big -- it may be like brain donation, a huge logistical problem.

Ms. Redwood: The other thing that I think would be important to maybe make a recommendation is not just regression, but to look at the difference between the children whose parents reported, you know, autistic behaviors at birth versus the one that regressed in terms of, you know, what are the differences in terms of outcomes?

You know, and then what are the differences in terms of what some of the comorbidities that might be associated with the groups that are regressive autism versus the groups that, you know, have symptoms of autism present at birth? I think they're sort of very different phenotypes.

And we talk about all the different types of autism. This might be a way to sort of break them out and categorize them better, and I think the better they're characterized, the more targets we have for treatment.

Dr. Koroshetz: Well, if you could find a trigger for regression, then, you know, the hope is that the opposite of that trigger helps people, or you could prevent the trigger or something like that.

Ms. Singer: Right.

Ms. Redwood: Or it's a two-hit trigger.

Dr. Koroshetz: Or a two-hit trigger, right.

Ms. Redwood: Yeah, that would get into prevention. That's another reason why it's really important.

So we're all pretty much in agreement that more needs to be done with this particular objective?

Dr. Koroshetz: Yeah, I think so. I think we can talk to, you know, the people, the experts when they get on and see if they confirm that what the problem has been here. Is it logistics --

Ms. Singer: Hey, Susan? I'm sorry, Walter. I didn't mean to interrupt.

Dr. Daniels: Yes?

Ms. Singer: No, I was just going to ask who are the experts on this question?

Dr. Daniels: We're still working on that. We're working with the subcommittee chairs to get that all done, and many people have various schedule conflicts and can't participate. So we're going to have to just go through and get them all together. But we'll be updating the Committee as soon as we have a group in place.

Ms. Redwood: If you still need any -- like if there are people that aren't available, Judy Van de Water is really good with the immune portion. I don't know if she was recommended or not. But if you have vacancies in terms of people, Judy would be a good addition to this question to help with some of the immune.

Dr. Koroshetz: Yeah, we had David Amaral last time, and she works with him, if I remember right.

Ms. Redwood: I don't know that; is David still at UC-Davis MIND?

Ms. Singer: Yes.

Ms. Redwood: Okay.

Dr. Daniels: So if we do end up with a situation where we didn't have enough names, we'll come back to the Committee for further nominations. But we did have the list from last year, as well as all the new nominations you sent in. So we have a pretty good pool to go from, and we're just trying to get all of that worked out.

Dr. Koroshetz: Okay, guys, how about 2.S.G -- genotypes with functional or structural phenotypes?

Ms. Singer: So we actually have a -- oh, no. That's a little one. That's not really an ACE center.

Dr. Koroshetz: A lot of money in this one.

Ms. Singer: Yeah. I mean, there are two ACE pieces in here. A lot of this is the -- the Simons project. The Simons VIP Project is a lot of money sort of broken up over a lot of sites here.

Dr. Koroshetz: How much is that project altogether?

Ms. Singer: We can add it up. It looks pretty

--

Dr. Koroshetz: Lot of money, yeah.

Ms. Singer: It's a lot. I mean, look at this. Go through this list. Just looking at 2012.

Dr. Koroshetz: Yeah.

Ms. Singer: There's -- the core alone is $2.5 million. I'm going to say it's probably about $4 million in here. Where's the other list?

Ms. Redwood: There's $41 million total, and we had recommended $22 million over 5 years, and we're at $41 million. So we're almost double in terms of what the IACC has recommended in those areas.

Ms. Singer: Why isn't that page --

Dr. Koroshetz: Sounds like it's because Simons Foundation really put a big investment here --

Ms. Redwood: Simons typically focuses on genetics-type research.

Ms. Singer: Oh, cumulative funding.

Dr. Koroshetz: -- but they're doing the imaging and the phenotyping associated with it, which is what --

Ms. Singer: Yeah, all of that's in here. All of that's in here. So --

Ms. Redwood: Are they including medical

phenotypes or just behavioral?

Ms. Singer: No, medical. They're getting -- they're getting blood from all of their kids.

Dr. Koroshetz: Are they collecting like morbidity data?

Ms. Singer: On the dollars, it looks good. On the number of projects, it looks good. I mean, we should point out that it's -- a lot of it is a single funder with a big project and a commitment to this area.

Dr. Koroshetz: Yeah.

Ms. Singer: But in terms of if we're limiting ourselves right now in this discussion to financial, it looks pretty good -- genotypes with functional or structural phenotypes including behavior and medical. Yeah. And cognitive, yeah, they have all of that data in there.

Dr. Koroshetz: Okay. You want to go on to the next one?

Ms. Singer: So we're on 2.L.A now?

Dr. Daniels: 2.L.A.

Ms. Singer: So this is longitudinal. Okay.

Ms. Redwood: This is interesting. Look at the projects went from 49 the first year down to 6, 6, 5, and then 10.

Ms. Singer: So, yeah, 49 projects --

Ms. Redwood: So the year that we --

Ms. Singer: -- 49 large-scale longitudinal projects?

Dr. Koroshetz: No, I don't think so.

Ms. Singer: That must be a situation where the objective changed.

Dr. Koroshetz: Or the classification changed.

Ms. Redwood: No, well --

Ms. Singer: Forty-nine long-term, large-scale longitudinal projects.

Dr. Koroshetz: Here's one: fMRI evidence of genetic influence on rigidity in ASD.

Dr. Daniels: In the coding, it's required that the project meet at least part of what the objective calls for because we don't expect that every project will meet all of the parts, and so when you're seeing 49 projects, most likely those projects had portions that met some of the requirements of the objective but may have not met all of them.

Dr. Koroshetz: How could it have jumped so much down in 1 year, Sue?

Dr. Daniels: I don't -- I don't have the computer in front of me to look at the projects

right at the moment. But I can look at --

Ms. Singer: I'm going to say --

Dr. Daniels: -- but I can look at the 2012.

Ms. Redwood: When I'm looking back at the first-year funding that had so much, I just question whether or not they were really fitting. Like one of them is understanding perception and action in autism.

Ms. Singer: Well, because I'm going to pull out the 2008 Strategic Plan, but I think we've changed this objective.

Dr. Koroshetz: Oh, okay.

Ms. Singer: And so, that's why whatever was captured here in 2008 is not -- those studies are not necessarily against the objective as it's currently written.

Dr. Koroshetz: Yeah, I looked at the 2008. They didn't look -- they looked like completely different projects.

Ms. Singer: Yeah. I think that's it. Let me see if I have the 2008 plan in one of these piles here.

Dr. Daniels: Something else to keep in mind is that as the Plan grew, because we started out with about 32 objectives, I believe, and now have 78,

is that projects that might have been coded to this objective initially might have gotten split up over all the new objectives as they were created.

Which is another -- you know -- one of the things that makes a little bit of this longitudinal look a little bit hard to do.

Ms. Redwood: Did you find your 2008, Alison? I guess you could get -- is it still on the Web site, Susan?

Dr. Daniels: The 2008 is on the Web site if you go to that link in the document I sent out. And the 2011 and '12 are in those big lists.

Ms. Redwood: No, I mean the actual Strategic Plan itself.

Dr. Daniels: What is your question?

Ms. Redwood: I was just curious whether or not the Strategic Plan itself for 2008, since we updated it -- are the old ones still on the Web site?

Dr. Daniels: Yes. All of the Strategic Plans are on the Web site. If you go to the Strategic Plan tab on the left navigation, you can find there's a little box for all the kinds of archived documents, and so you can find the 2008 Plan

there.

Ms. Redwood: The 2009 related links -- I see '11, '10, and '09.

Dr. Daniels: Oh, sorry. There wasn't -- the first Plan was in 2009. So there was no plan in 2008. But we were looking -- the first group of data we looked at was 2008 because that was our baseline to get a sense of what was happening in the portfolio before the Plan came into -- into action.

Ms. Redwood: So if you look at this section, to complete a large-scale, multidisciplinary, collaborative project that longitudinally and comprehensively examines how the biological, clinical, and developmental profiles of children, with a special emphasis on females, youth, and adults with ASD, change over time as compared to typically developing people by 2020.

Dr. Daniels: So it's pretty much the same. But if you look down the 2008 column, you'll see “N/A” in five of the objectives, and that indicates that those objectives didn't exist in 2008. And so, you can see by 2009 or in the 2009 analysis, we were using the 2010 Plan. The 2010 Plan had many more objectives.

And so, most likely, those projects got distributed out among those new objectives.

Dr. Koroshetz: One thing to note is that it's calling for large-scale projects. A number of the projects are small scale that are listed, but there are some large scale, which are the ACE networks.

What is -- do you know what this one, pediatric brain imaging, Jay Giedd at NIH, is? Does that ring a bell, Sue?

Dr. Daniels: Not without looking at it in front of me. I mean, I know of the project, but I couldn't tell you details without looking into it further.

Dr. Koroshetz: Okay. [Pause] And in terms of adults, there's one study called 20-Year Outcome of Autism, Autism Speaks funding.

Dr. Daniels: That might be related to that paper that came out recently.

Dr. Koroshetz: Those people originally were identified in the 1980s, now middle adults.

Dr. Daniels: Yeah. Yeah, there was a publication.

Dr. Koroshetz: There is one adult -- oh, that's good.

Ms. Redwood: But do we really have -- I mean, of these records in it, are there really large-scale, multidisciplinary, collaborative projects?

Ms. Singer: Well, Marsha Seltzer's study is large scale and multidisciplinary. It focuses more on social outcomes than on medical or behavioral outcomes. Well, actually some behavioral outcomes, because it talks about the percentage of adults with autism who are home as opposed to out in the community or working.

But I don't think it looks as in-depth at medical as it does at social and behavioral. But it's definitely -- I mean, she reports on them every couple of years. She's got a good cohort.

And then there is this study from University of Washington at St. Louis. I can't remember the name of the scientist, but he's a services researcher. What is his name? He came and presented a year ago.

Dr. Daniels: Paul Shattuck?

Ms. Singer: Paul Shattuck. He had -- that was a longitudinal study that look at -- also at social outcomes, not medical outcomes -- but social outcomes.

Dr. Koroshetz: There are a bunch of

longitudinal studies looking at brain MRI.

Ms. Redwood: So there's not a lot of clinical – [Inaudible comment]

Ms. Singer: We can take a look and see if there's any -- if there's anything that focuses on medical because I think what we've seen, although this may be a topic for the next call and not this one, but what we've seen in terms of publishing results is social and behavioral.

Ms. Redwood: And I think long-term medical, especially with, you know, many of the children now, you know, moving into young adulthood, I know the parents are real concerned about, you know, the risk factors for heart disease and a lot of other issues as -- as our children age. So it would be wonderful to have better information regarding what some of those problems might --

Ms. Singer: Right. So that's definitely something I think we can identify, sort of getting into the nitty-gritty of the objective, that in some areas, there has been funding and the right -- and enough -- a number of studies. But in some areas where we want longitudinal work, there is not.

Dr. Koroshetz: And in terms of large scale, I

think the numbers of patients -- we have to probably address that. Are they really large-scale studies or not?

Ms. Redwood: That's a good point.

Dr. Koroshetz: But there are not that many of them. So we could maybe take a look.

Ms. Redwood: Yeah, and I would think just by looking at -- then on the funding that they're probably not large scale. I mean, when you see this one MRI study of brain development in school-age children, and it's only $127,000?

Dr. Koroshetz: Yeah, that's about 10 MRIs.

Ms. Redwood: Yeah, exactly. And the same with this amygdala connectivity, and it's only $49,000. I mean, that's not going to be large scale.

Dr. Koroshetz: Yeah. So I would be suspicious that we're a little bit short on the large-scale projects unless there's something I'm not -- I don't see here.

Dr. Daniels: Yes, there may have been some of these studies that would be multi-site and multidisciplinary that might not have been the large scale that the Committee is looking for. So that's something that as you examine it, if you find that to be an area that needs more work, you

would want to point that out.

Ms. Redwood: Also there are -- you know, there are, what, two MRI studies in here, longitudinal MRI studies. One, Joe Piven. Well, then there's another one right above it that's also a Joe Piven. I don't know if it's the same.

Dr. Koroshetz: Same one. It's ACE network.

Ms. Redwood: It has two different funding. So there's $3 million going into the MRI. Hello?

Dr. Koroshetz: Yes.

Ms. Redwood: Sorry. My phone’s just trying to cut out. So I think it would be important to say that, you know, the medical trajectories here are missing.

[Pause]

There's another MRI study by Heather Hazlett at, again, University of North Carolina-Chapel Hill. That may be part of that, too -- that same group.

Dr. Koroshetz: Well, they were infants --

Ms. Redwood: So a lot of these are imaging --

Dr. Koroshetz: -- infants, and the other one is school age. Yeah. You know, I think it's important they're doing that, but I don't think -- you know, it doesn't look like we have, you know,

outcomes on 2000 or autism over 10 years, you know, divided along the lifespan. We don't have that kind of thing.

Ms. Redwood: Yeah, and I guess when you look at where the bulk of the money is going, and it's these pediatric brain-imaging studies -- Walter, do you know if those imaging studies also look at, combine that, with the developmental profiles and the clinical profiles?

Dr. Koroshetz: Well, I would think -- I would think they would. I mean, they're fairly intense studies. So they're usually collecting lots of data along with the MR.

Ms. Redwood: Okay.

Dr. Daniels: So I think that's the IBIS study probably. Well, I think it is.

Ms. Redwood: These, again, are not -- oh, that's funny. Some of them it will let you click on and other ones it won't.

Dr. Koroshetz: Yep, I noticed that.

Ms. Redwood: Yeah, like I really wanted to look at this NIH one. Okay. When I'm hovering over the two L.A. projects, like the pediatric brain-imaging one that's an NIH study for $2 million, when I hover over it, it won't let me click it to

go to it.

Dr. Daniels: What year are you in?

Ms. Redwood: Mmm, 2012.

Dr. Daniels: 2012 doesn't have live links to the Web tool yet.

Dr. Koroshetz: No, it has some of them. Some of them are.

Ms. Redwood: Some of them.

Dr. Koroshetz: Like below that, that goes right in. It's weird that some of them do and some of them don't.

Dr. Daniels: Oh, and so the other reason is that if it's a project that was active in previous years from 2010 --

Dr. Koroshetz: Ah, I see.

Dr. Daniels: -- then those links will be live. But if it's a new project in 2011 and 2012, because we haven't put that into the Web tool yet, it's not live yet.

Dr. Koroshetz: Right.

Ms. Redwood: Okay. Does anybody know if the 20-year outcome study by McMahon that's being funded by Autism Speaks, is that -- or they're funding in that amount for 20 years? I'll click on it because that --

Ms. Singer: Who is the PI on that one?

Dr. Koroshetz: That's --

Ms. Redwood: William McMahon, The University of Utah.

Dr. Koroshetz: So, yeah. So that's the one I was mentioning. It's a study of individuals originally identified in the 1980s, now in middle adulthood.

Ms. Redwood: Oh, so it's just one study?

Dr. Koroshetz: Yeah.

Ms. Singer: And that was retrospective, not longitudinal.

Ms. Redwood: Yes.

Dr. Koroshetz: It's retrospective from the '80s. Yeah.

Dr. Daniels: Right, and I believe that one had a publication fairly recently within the last year or so. So you may be interested in checking that out.

Ms. Singer: I'm sure it wasn't good. I mean, I'm sure the study was fine. I'm sure the data was.

Ms. Redwood: I think he was actually funded $450,000.

Ms. Singer: Okay.

Dr. Koroshetz: And so, what do people -- what's your general sense of this one, guys?

Ms. Redwood: I would say that we say that more needs to be done. I mean, look, we're way under budget on it, number one. And you know, I think we also need to look at some of those studies that are being funded, the MRI studies, Walter, but -- you know, to see how many people are in it. Are they really large scale?

Dr. Koroshetz: Right.

Ms. Redwood: So maybe drill into that a little bit more, but you know, I would really like to see more done with what the clinical outcomes are, too. I'm not certain that that's actually being captured.

[Background music]

Dr. Daniels: So if you need particular information about certain projects to help you with that determination, let us know for the 2011 or 2012, and we can help you out with getting that information. We could get you the abstracts if you need them.

Dr. Koroshetz: Yeah, okay. I think it would be good to do that.

Ms. Redwood: That would be helpful.

Dr. Koroshetz: I think we could -- if we could just get the number of patients, you know, in each of these, then we'll really know if it's large scale. My suspicion is a lot of these are going to be 40 or 50 people, not, you know, 1,000. So, but I think my sense is that we haven't really hit the large-scale longitudinal study yet, but we'll take a look.

Ms. Redwood: This would have been something where the Children's Health Study, you know, could contribute, but I don't know if that's -- [Laughter] is that actually being funded? It's still --

Dr. Koroshetz: You mean the National Children's Study?

Ms. Redwood: Yeah, has it actually gotten off the ground, or are they still on pilot projects?

Dr. Koroshetz: I thought they were off the ground. I mean, it's a good point. We could ask -- that's a good point to find out where that is in terms of what its impact on autism might be.

Ms. Redwood: Well, I know they were talking about the number of children they were enrolling and sort of predicting how many of those might -- you know, based on the current numbers -- would

develop autism. But they definitely would have the typically developing, because we have that part in there, to compare to typically developing people. So --

Dr. Koroshetz: You know what's not in here is --

Ms. Redwood: What, Walter?

Dr. Koroshetz: You know, the study in Norway where they -- they have these birth records and the pregnancy records of the mothers, and then they follow the children who develop autism over time, and they can correlate it back with what happened during pregnancy.

Ms. Redwood: Who is funding that? Is that Federal funding or --

Dr. Koroshetz: NINDS is funding. And so, it's every kid in Norway like, I don't know, for over 5 years or a 7-year period; every kid in Norway is in the study, and then, you know, a certain percentage have autism. And I think they got 500 -- is what I think they've been able to identify.

Ms. Singer: Is the EARLI Study in here, or is the EARLI Study someplace else?

Dr. Koroshetz: No, it's Poland/Norway.

Ms. Redwood: I don't think that's the EARLI

Study.

Ms. Singer: No, I know it's not the EARLI Study. But I'm just saying the closest thing we have to that, I think, here is the EARLI Study, and I don't see it.

Dr. Daniels: Right. So I think that those projects are most likely categorized elsewhere. I know that they're in the portfolio analysis, but they probably had a better fit to a different objective. So that's something you can pull up because, obviously, that's why this is more complex than just looking at the numbers completely straight because you need --

[Several speakers]

Ms. Singer: Right. The EARLI Study is a large-scale, multidisciplinary, collaborative project that longitudinally and comprehensively examines the biological, clinical, and developmental profile.

Ms. Redwood: Are you talking about the EARLI Study, Alison?

Ms. Singer: Yeah. I mean, I don't know if we fund --

Ms. Redwood: That's been canned, though, hasn't it?

Ms. Singer: Not that I --

Ms. Redwood: That's no longer being funded.

Ms. Singer: Really?

Ms. Redwood: That's what I heard.

Ms. Singer: Autism Speaks is not funding the EARLI Study anymore?

Ms. Redwood: I don't know about Autism Speaks, but I don't think NIEHS or wherever they were getting their -- that's Craig Newschaffer's study, isn't it?

Ms. Singer: Yeah, he was being funded by Autism Speaks.

Ms. Redwood: That's what I heard.

Ms. Singer: I know he was funded in 2012. So we should just see where that money -- if that money is elsewhere, we should also -- we should note that because that could also have gone here.

Dr. Daniels: So you might want some information then about EARLI and the Norway study?

Dr. Koroshetz: Yeah.

Ms. Redwood: Yes.

Dr. Daniels: And we can get you that information. I know that we have it. I do think that there were some changes in the funding for the EARLI Study, but I don't think that those are

yet reflected in the numbers we have here because that might have happened in 2013. But I'm not sure about that. We'll check.

Are we ready to move to 2.L.B? And we're kind of running out of time. So we want to make sure we close up on all of this. So what do you think about 2.L.B?

[Pause]

Ms. Redwood: Well, it's under budget, number one. You know, we did launch at least three studies, but –

[Pause]

Dr. Daniels: Are these the kinds of studies that you feel the Committee was interested in seeing?

[Pause]

Ms. Redwood: I'm sorry, Susan. I'm just now getting down to them.

Ms. Singer: I think it's promising that it looks like there are two pieces of ACE Centers that are in this -- in this objective. So that, I think, speaks well going forward.

[Pause]

Dr. Koroshetz: Lyn, what do you think?

Ms. Redwood: I still haven't gotten through. I

lost the PDF. I'm having to open it back up. Okay.

Ms. Singer: I think the numbers are low, given the budget. It's a lot of small, little studies. I think when we wrote this objective, the hope was there would be three good ones that really got at the underlying relationship there.

But on the positive side, I think having two pieces of ACE Centers is promising going forward and recognition that this is an important area.

Dr. Koroshetz: It's still a nascent area.

Ms. Redwood: Yes. When you look at what the ACE Center is looking at, it's very narrow. It's auditory perception and perceptual organization, and then --

Ms. Singer: But these are studies -- that's not what the whole ACE Center is. I mean, at the ACE Center, they have a lot of smaller studies that are part of the ACE Center but can, I think, grow with the ACE Center. So I think what I see as positive is that there is recognition that this is an emerging and important area such that it should be part of the ACE Center, not that it's the crux of the ACE Center at this point.

Dr. Koroshetz: But wasn't also the point of this one to narrow down to particular phenotypes?

They are going to be, by definition, if they focus on one of them, it's going to be narrow.

Ms. Redwood: Yeah.

Ms. Singer: Well, I feel -- I feel like the purpose of this one was to try to get at issues of predictability.

Dr. Koroshetz: Right. Or personal --

Ms. Singer: You know, treatment response categories, things like that.

Dr. Koroshetz: Right.

Ms. Redwood: When I look at these, I don't really -- I don't know. I think we need to do more. And some of it's also funded small. When you look at this, it's like one of them is just a study of autism. That's all she references about it.

Ms. Singer: I was looking at that. What is that?

Ms. Redwood: Yeah, so, oh, good -- a study of autism. So we're going to have to really dig into it.

Dr. Koroshetz: The Simons Foundation, and it's --

Dr. Daniels: That one you probably don't have the abstract for, unless it's previously funded.

Dr. Koroshetz: It says "Simons Simplex Collection repository study, collected from children with autism, propose to comb the data between autism, demographic, environmental variables. Look for clusters of individuals with similar data. Look at variety of disorders, ASD."

Ms. Singer: So one of the objectives of the Simons Simplex was to try to group them and to try to get at the issue of predictability. But from what Cathy Lord reported yesterday when she spoke at the Simons Foundation is that they haven't -- patterns have not really emerged with regard to advancing predictability.

Dr. Koroshetz: I see.

Dr. Daniels: So it sounds like you all are saying pretty much this area still needs significantly more effort?

Dr. Koroshetz: Right.

Ms. Singer: Yes. I mean, I think we all talk about how important treatment response is and giving kids the right treatment based on their cluster of medical and behavioral symptoms. I think it's proving more challenging. It's not just a question of kids with this genotype have this cluster of symptoms that will respond to this

treatment, unfortunately.

So, yeah, even though there have been studies, it's still under budget, and I think it's an area that needs more -- more attention.

Ms. Redwood: Yeah, definitely. Especially when you look at how much attention, you know, is in the other categories.

Dr. Daniels: Great. Well, can we move to any comments you might have about "Other" and then wrap up?

Dr. Koroshetz: "Other" is a big one. I'd just go back to what we said before that --

Ms. Singer: Yes.

Dr. Koroshetz: -- we can look at that and make comments on its value because it's not -- it may be missed by many people otherwise.

Ms. Singer: Are the other groups facing the same issue, Susan? Are they -- is "Other" a large category in the other questions?

Ms. Redwood: No. Uh-uh, I don't think so.

Dr. Daniels: In 2, it's the largest. And that's largely probably due to NIH having had a pretty large portfolio of ongoing research on autism before this effort started, but each question has some "Other," but 2 is the largest.

And that was what was pointed out by Lyn in 2009 that we really needed to be able to have more information to help you all assess this because there are so many projects there. So hopefully, now you have that information and can get a sense of what's in that area.

So I think that you've -- you have all successfully gotten through the entire group of your objectives and made reasonably detailed assessments, given a short amount of time, which I commend everyone on. What we need now is somebody who's going to volunteer to write this up in less than five pages.

We're going to have some minutes that we can share with you, but this would be kind of an overview. It can be short if you want it to be short. I know Dr. Insel volunteered to do Question 4, and he's going to try to get it all within a page for their objectives.

But if you all -- you can do something closer to five pages, if it would suit you better, because you had more -- a more detailed discussion. But is there somebody who would like to volunteer to do the initial draft, and then we can circulate it to everybody to comment?

Ms. Redwood: Susan, would it be possible for you to send, you know, the minutes? Because if you capture our rich discussion in the minutes, we may be able to just take the minutes and turn them into the draft.

Dr. Daniels: I'm sorry. The minutes are going to be more of a reflection of the discussion, but it won't be the same as what you all need to put together, which is really stating from the Committee perspective what you think about these things. The minutes will just reflect kind of the main points of the discussion.

Dr. Koroshetz: Yeah, I'll be happy to do it, and then can I circulate it to the group and get comments and --

Dr. Daniels: Yeah, so --

Ms. Singer: We'll all help.

Dr. Koroshetz: Okay.

Dr. Daniels: So yeah, so Walter, that's great if you volunteer to do the initial draft, then Alison and Lyn can add their comments in. And we'll try to get you the minutes within the next few days so that you have those as a backup, but you can also go from your own memory and notes to try to flesh something out here.

Dr. Koroshetz: Okay. So guys, I'm volunteering for this one because the next one is going to be much harder.

[Laughter]

Ms. Redwood: Hey, Susan, back just real quick before we go off, this category of "Other" here. When I'm looking at the total funding, you know, over the last 5 years, the "Other" category was $201 million, whereas the total funding for this whole question was $362 million.

So you know, it's a little bit less than a third of everything in here, and I'm just wondering if that -- you know, if you look at our research portfolio and you want it balanced, just like you would want your investment portfolio balanced, have we given any thought into, you know, the importance of this sort of basic science research versus, you know, some of these other things that are -- that are really important or that the Committee feels is so important?

I just wanted to throw that out there because I agree that the basic science is important, but I don't know that it -- that it deserves that much. And that's just my --

Dr. Daniels: Well, this entire question is

largely basic science. It's really the underlying biology of autism. So it's a little bit hard to quite make that comparison within Question 2, although you might want to compare with other question areas. For example, treatment would be one of those that has a more applied side to it.

This area mostly is kind of studying the basic mechanisms that underlie symptoms of autism or other features of the neural and other biological bases of what you see in autism. So, but the Committee can -- can make their determinations.

I don't know that the Committee necessarily feels that every single area has to have an equal proportion of funding. I doubt that that's true for any disease area, even if it's not autism. So --

Ms. Redwood: Right. No, not equal, but just making a decision from the beginning, like how much of your research do you want to have like be like high risk, high reward? How much of your research, you know, do you want to be more, you know, your basic science-type research? That was the question I was asking --

Dr. Daniels: Right.

Ms. Redwood: -- and if we should have that

discussion at some point in time?

Dr. Daniels: I think the Committee definitely should have that discussion if that's something that you feel is important.

So I thank you all for your diligent work on this. You've gotten through every aspect of this question in terms of going through all of the objectives at least at the level that you have, and I think that you've done a great job.

So thanks, Walter, for agreeing to do that first draft. We'll get that circulating, and we'll get you the minutes as soon as we can.

So if there are no other questions, I'll be in touch by email with further instructions about various things that are coming up.

Ms. Redwood: Walter thanks, too, for doing that.

Dr. Koroshetz: Oh, no problem. Okay.

Dr. Daniels: Thank you, everyone.

Ms. Redwood: Alright, thanks. Have a good weekend.

Dr. Koroshetz: Have a good weekend.

Ms. Redwood: Bye-bye.

Dr. Koroshetz: I hope the Government doesn't shut down.

[Laughter]

Ms. Redwood: Okay, bye-bye.

Dr. Daniels: Bye.

(Whereupon, the Strategic Plan Question 2 Planning Group conference call was adjourned.)