U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

BASIC AND TRANSLATIONAL RESEARCH SUBCOMMITTEE

FRIDAY, SEPTEMBER 7, 2012

The meeting came to order via teleconference at 10:00 a.m., Tom Insel and Geraldine Dawson, Co-Chairs, presiding.

PRESENT:

- THOMAS INSEL, M.D., Co-Chair, National Institute of Mental Health (NIMH), National Institutes of Health (NIH)
- GERALDINE DAWSON, Ph.D., Co-Chair, Autism Speaks
- ANSHU BATRA, M.D., Our Special Kids
- LINDA BIRNBAUM, Ph.D., National Institute of Environmental Health Sciences (NIEHS)
- COLEEN BOYLE, Ph.D., National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC)
- JOSEPHINE BRIGGS, M.D., National Center for Complementary and Alternative Medicine (NCCAM)(representing Francis Collins, M.D.)
- NOAH BRITTON, M.A., Bunker Hill Community College
- MATTHEW J. CAREY, Ph.D., Left Brain Right Brain and other Autism blogs
- DENNIS W. CHOI, MD, Ph.D., Simons Foundation

NEAL R. GROSS

PRESENT(continued):

- TIFFANY R. FARCHIONE, M.D., Division of Psychiatry Products, Center for Drug Evaluation and Research, US Food and Drug Administration (FDA)
- ALICE KAU, Ph.D., Eunice Kennedy Shriver
 National Institute of Child Health and
 Human Development (NICHD) (for Alan
 Guttmacher, M.D.)
- DONNA M. KIMBARK, Ph.D., Congressionally Directed Medical Research Program, Department of Defense (DoD)
- WALTER J. KOROSHETZ, M.D., National Institute of Neurological Disorder and Stroke (NINDS)
- LYN REDWOOD, RN, M.S.N., Co-Founder and Vice President, Coalition for SafeMinds
- JOHN ELDER ROBISON, Self-Advocate, Parent and Author
- ALISON TEPPER SINGER, M.B.A., Autism Science Foundation

ALSO PRESENT:

- GEMMA WEIBLINGER, Office of Congressional Relations and Public Liaison, National Institute of Mental Health (NIMH)
- CINDY LAWLER, National Institute of Environmental Health Sciences (NIEHS)

TABLE OF CONTENTS

Roll Call and Opening Remarks Thomas Insel, M.D. and Geraldine Dawson, Ph.D	4
Overview and Discussion of Process to Update the Strategic Plan	16
Workshop Planning	
Wran up and Adiournment	112

PROCEEDINGS

(10:02 a.m.)

Operator: Welcome and thank you for standing by. All participants will be on a listen-only mode throughout the duration of today's conference. Today's call is being recorded. If you have any objection, you may disconnect at this time.

Now I would like to turn the call over to your host for today, Dr. Tom Insel. Sir, you may begin.

Dr. Insel: Thank you. Good morning everybody and I want to make sure that my Co-chair, Geri Dawson is on the phone. Geri are you with us?

(No response.)

Dr. Insel: Well, she could still be linking in. Let's go ahead and find out who is here. We will do a quick roll call and I will read out the names and just shout out so we will be able to know you are with us. Coleen Boyle.

```
(No response.)
           Dr. Insel: Tiffany Farchione.
           (No response.)
           Dr. Insel: Alice Kau.
           (No response.)
           Dr. Insel: Donna Kimbark.
           Dr. Kimbark: I'm here.
           Dr. Insel: Okay, thank you.
Walter Koroshetz.
           (No response.)
           Dr. Insel: Cindy Lawler.
           (No response.)
           Anshu Batra.
           (No response.)
           Dr. Insel: Noah Britton.
           Mr. Britton: Hi.
           Dr. Insel: Welcome. Matt Carey.
           Dr. Carey: Hello.
           Dr. Insel: Good morning. Dennis
Choi.
           (No response.)
           Dr. Insel: Lyn Redwood.
```

Ms. Redwood: Here.

Dr. Insel: Welcome. John

Robison.

Mr. Robison: Yes, I am here.

Dr. Insel: Great. Alison Singer,

I think I heard you before.

Ms. Singer: I'm here.

Dr. Insel: Okay.

Dr. Birnbaum: Hello, Tom. This is Linda calling in.

Dr. Insel: Oh, great. So we have you instead of Cindy. Excellent.

Dr. Birnbaum: Well, Cindy is keeping me company.

Dr. Insel: Okay, good. Thanks for calling in. And I assume that we will hear from a few others over the next couple of minutes. Let me just check to see if Josie Briggs is on the line as well.

Okay and Alan Guttmacher or Alice Kau from NICHD? No.

All right.

Dr. Dawson: Tom? Hi, this is Geri.

Dr. Insel: Great.

Dr. Dawson: Hi. Listen, I've been on the whole time. I think some of us were put into listen-only mode by mistake.

Dr. Insel: Okay.

Dr. Dawson: Because I know I was talking right from the beginning and couldn't get in. So I hung up and called back in and it worked the second time. So in case anyone is in that situation, they may want to do that.

Dr. Insel: Okay. So I hope that anybody who was not audible is doing just that but we are only down to a few people.

Anshu Batra, who would be calling in from the West Coast, if you are on the line and we can't hear you, just call back in and let them know that you are indeed on the subcommittee. And then Alice Kau and Tiffany Farchione and Coleen Boyle. Walter Koroshetz just joined us

here. So he is in the room with me.

Dr. Briggs: This is Josie Briggs.

I am attending by phone.

Dr. Insel: Oh hi, Josie. Great. Thank you so much.

Dr. Kau: Tom, this is Alice Kau. You got me, right?

Dr. Insel: Yes, I do now. Thank you.

Dr. Kau: All right, good.

Dr. Insel: Okay and that leaves just Coleen and Tiffany and Anshu. So if any of you are on the call -- and Dennis Choi -- If we can't hear you and you are on the call --

Mr. Robison: Anshu has emailed me to say she is stuck in listen-only mode.

Dr. Insel: Okay, so we will -Anshu if you are still listening, call back
in and let them know that you should be part
of the call.

Mr. Robison: Also Tiffany has

Ms. Redwood: Tom, I think there is a conflict with the access codes. There is a different access code that is actually posted on the webinar slide versus what we received in the email from Lina. So that may be part of the problem.

Dr. Dawson: Lyn, I don't think that's it because I did notice those two numbers and I called the one that is for speakers and I still was put in listen-only mode the first time. So I'm not sure that that is it.

Dr. Insel: So Geri, what did you do to fix this?

Dr. Dawson: I just I hung up and called back in and when the operator talked to me I just quickly told her put me into the speaker mode and then she said ah, okay.

Mr. Robison: Tiffany has just emailed to say that didn't work and Dennis Choi has also emailed to say he is stuck in listen-only.

Dr. Insel: Okay.

Participant: If you hit *0 you can talk to the operator and she can put into speaker mode.

Dr. Insel: So quickly, Dennis and Tiffany and Anshu, they will try that. And we will wait just a moment to get everybody on the line.

(Pause.)

Dr. Boyle: Hello, this is Coleen.

Dr. Insel: Hi. Welcome, Coleen.

Dr. Boyle: Yes and I also had to

*0 several times.

Dr. Insel: But it worked

ultimately.

Dr. Boyle: Yes.

Dr. Insel: Good, okay. So I want to give our other members just a moment to try that again and see if they can get through.

Dr. Boyle: Yes, it looks like a bunch of them can't.

Dr. Insel: Okay.

Dr. Farchione: Hello, it's Tiffany.

Dr. Insel: Hi.

Dr. Farchione: I'm in.

Dr. Insel: You made it through.

Dr. Farchione: The way that I made it work was by calling back using the number from Lina's email and then *0 to talk to the operator. The one when you register for the webinar, that number that they give you doesn't work.

Dr. Insel: Okay.

Dr. Farchione: So if those who are still stuck in listen-only mode would go back and use the -- it started with a seven the other number.

Dr. Insel: All right. Well this was not meant to be a test of our resourcefulness but it is good to see that people have figured out a way through the maze.

Dr. Batra: Hi, Tom! This is Anshu.

Dr. Insel: Great. Welcome,
Anshu. It's only a little after seven your
time, probably. So thanks for joining us so
early.

Dr. Batra: I have been trying to get on but I was on listen-mode only for the last ten minutes.

Dr. Insel: Great. Good to have you here at the meeting, finally. And the only person who I think we are still waiting on is Dennis.

Dr. Choi: Hello, Tom?

Dr. Insel: Okay, we're good.

We've got everybody. Thank you.

Okay, well welcome everyone. Geri

and I are going to co-chair this. So we are going to try to do this even though we are in different places. So Geri speak up and we can pass the baton or the gavel back and forth, virtually.

We have a fairly brief agenda.

Hopefully, everybody has received the email

from Lina that had the information of what we
need to cover this morning. And unless there
are any questions, we are going to plunge in.

Actually, I do need to make one announcement, which is maybe the most important thing to tell you and that is Susan did indeed have her baby on the 6th. Zara Yasmine, who is a six pound, 13 ounce girl doing fine. And she is not back at work but she will be by October 30th, the next time we meet face-to-face. And in her place, we are lucky to have Gemma Weiblinger, who has stepped in from another office in NIMH to substitute for Susan in Susan's absence.

So we are moving ahead with all of

the same things going on with Gemma helping out as time permits.

So very quickly, if we could go to the first slide of our agenda. Our agenda looks here like the overview and discussion of the process of planning the workshop itself and I think we actually will be able to complete our work this morning.

Dr. Birnbaum: Tom, this is Linda.

I'm seeing the thing. It says download

complete but nothing is coming.

Dr. Insel: Are other people having trouble seeing the slide?

Ms. Singer: After the download is complete, you will see like a little flower icon and you have to click on the flower icon to get the slides.

Dr. Birnbaum: Okay, I can't click on the flower. It says your webinar should start in a few seconds.

Dr. Insel: All right. Just wait, Linda, and see if it pops up.

Dr. Birnbaum: I mean, it has been up for a few minutes and I see raising my hand.

Dr. Kimbark: Check and make sure that it is not on the toolbar at the bottom of your screen. Sometimes it's been minimized.

Dr. Insel: Linda?

Dr. Birnbaum: Yes, I can try.

Dr. Insel: Also you should have a hard copy. There is really not a lot that was sent out.

Dr. Birnbaum: Yes, and I don't seem to have that but Cindy is with me and she is trying, too.

Dr. Insel: Okay because that was sent yesterday and it is just a handful of slides. So if you need to, you can follow on hard copy.

Dr. Birnbaum: Was one sent to me? Cindy is helping me and we will try to print it out right away. Cindy didn't get it either.

Dr. Lawler: No, I got it but you didn't.

Dr. Birnbaum: I did not get it.

I was not on the list, I guess.

Dr. Insel: Okay?

Dr. Birnbaum: Well it will be. I haven't gotten it yet but it will come, I hope.

Dr. Insel: I will talk you through it. There is not a lot in the slides that --

Dr. Birnbaum: All right, guys. I mean, I don't know.

Dr. Insel: So let's start to talk initially about just what the process is going to look like and it should be pretty straightforward.

Just to remind you that our seven questions in the strategic plan, this subcommittee is taking on five of them. And for each of the questions what we agreed to at the IACC full committee meeting was to have

some external experts who would help us, along with members of the subcommittee. we thought just for ease of moving this forward to try to get three experts for each question and ask for three volunteers from the subcommittee to work with them. The task, as we said at the first meeting was not to rewrite the plan but to focus on updates of what do we know and what do we need. that would mean looking at not only what has been reported out in the literature or discovered or developed since the last update of the plan but also where the gaps are still, either those that have been funded but not yet reported out or ones that even may be unfunded.

It is important to realize if you haven't seen it that we actually did this already once in 2011 for the 2010 portfolio for the 2010 strategic plan. So we have been through an exercise like this before and if you look at the 2011 plan that was sent out,

does include the update that was done after each question. In that case it wasn't done with the external experts. We have used members of the committee, some of whom are still on the committee to do each of the updates.

What we were going to suggest for this round is that the group can use the Portfolio Analysis that you got, as well as the Summary of Advances, as well as all of our general fund of knowledge about what is happening in autism and other areas and then also the insights of our external experts.

There are some things that you probably won't see in publication but it may have already been funded, which won't show up maybe it wouldn't be obvious in the way that you look at either the Portfolio Analysis or the Summary of Advances. And so we do want to make sure that we can contact program officers and some of the folks who are program officers at NIH are actually very involved with the

process and so they would be available to help as well.

Geri and I talked about kind of what the scale and scope of this thing ought to be. This isn't meant to be an extensive or even entirely comprehensive review of the literature. It is really kind of a 30,000 foot view of what has happened and what is happening and what we still need to do.

so we thought about roughly 1200 words but that might even be more than we need for what do we know and about the same for what do we need. When we did this before and you will see this in the 2011 plan, most of the write-ups were closer to 500 or 600 words and were fairly broad overviews. So when they talked about the genetics under biology or risk factors, it wasn't listing the 90 or 100 genes that had been reported out, you know, just saying there are roughly 100 genes that have been associated with autism, something like that. So it is kept at a fairly high

level to capture what is new and putting most of the focus on how do you understand this new information and how to put it into context.

We thought that it would be great to have one person from the subcommittee volunteer for each of the questions, just reach out to the experts. And to begin the process because a lot of this can be done by phone and can be done before the meeting, I hope actually all of it will be done before the meeting, to actually coordinate this update process. And we will go through the list in just a few minutes about who has agreed to serve as external experts and who has volunteered for questions. None of this is set in stone but we wanted to give you a straw man version of this today so you can look at it and then we can really firm up the plan and move forward.

So let me stop there. Geri, anything to add in terms of the process?

Dr. Dawson: No, I think you have

characterized it well. I think the important points to underscore are that we don't really want to get too deep in the weeds in terms of very specific findings or even very specific individual studies that perhaps need to be funded. But rather, really it is the 30,000 foot look at what have we learned and what do we need still as we move forward.

I think the most sort of challenging thing just from an informational point of view is going to be trying to get as much information about what has been funded and what hasn't been funded. Because if there is a gap and there is already now a lot of funds that have been devoted to that but those studies haven't come to fruition yet, you know, we should identify that as a gap but yet now that gap is being filled.

There are reports and the program officers are able to let folks know what has been funded, the new NIH Center of Excellence grants are a good example of a huge infusion

of money that is going to start to fill some gaps. So we need to have a way of accessing that information.

It may be a little trickier too when we think about the private funding. So you will want to check in with Dennis and me about what has been funded when you have identified a gap so that you can note that as well.

Dr. Insel: And then one additional thought about this. This was the conversation we had at the IACC meeting and I think it was Lyn who stressed that we don't only want to look at funding but we want to look at information. What do we actually know beyond just what we have funded?

Because it is the ultimate deliverable is the data, the answers. And so we try to capture that as well as possible. That may be a very short list of findings.

Other questions or thoughts about this process?

Dr. Boyle: Tom and Geri, this is Coleen. I want to be very explicit here. So I am looking at the 2011 report, pages 8 and 9 on the hard copy. So for the first question, what do we know and what do we need sections. Do you see us adding on to that from an update or do you see us rewriting those sections?

Dr. Insel: Coleen, can you go to the next pages, 10 and 11?

Dr. Boyle: Yes.

Dr. Insel: And it says 2011 addendum to question one.

Dr. Boyle: Yes, yes, yes.

Dr. Insel: So that is the model.

Dr. Boyle: Okay.

Dr. Insel: And it is --

Dr. Boyle: So that is the update section.

Dr. Insel: Yes, that is the update that we did last year.

Dr. Boyle: Perfect. Yes.

Dr. Insel: And it gives you a pretty -- I mean those are done with a pretty good feel for the right level.

Dr. Boyle: Okay.

Dr. Insel: Walter?

Dr. Boyle: So pages 8 and 9 say, unless we feel like there is some things that we know now that we didn't know a year ago, perhaps, and then it is really we are focusing on the addendum part on question one.

Dr. Insel: Yes. So you will definitely want to go to the original. And then I think each group will want to look at that addendum and say okay, this is where we were in 2011 and now where are we as we get to the end of 2012.

And I should point out that 2011 addendum was done really early in the year. So it is really looking at 2010 reports for the most part.

Dr. Boyle: Yes, almost 18 months, right?

Dr. Insel: Walter?

Dr. Koroshetz: Well I was just thinking that in terms of that that 2011 addendum in terms of what is new, I think one step would be to look at that and see if things there should be moved up to what do we know and then rewrite 2012 events.

Dr. Insel: Yes, so we certainly want to start there to get a sense of what changed since the original write-up.

Ms. Redwood: Tom, this is Lyn. I had a question as well regarding looking back over the Portfolio Analysis. We have three reports so far but we don't have cumulative funding. And it is very difficult to go through each of those reports and look at each of the questions individually and then ask to tally up the number of studies and how much has been funded. Is there any way that we could get someone from OARC to provide for us a cumulative funding document based on those three reports?

Dr. Insel: Lyn, I don't think that is going to happen in this time frame. It is just -- and I am not sure in terms of we could go back to the points you made before. I would be less focused on funding and more focused on information or value of information. I am a little worried that we will assume that because something has been funded that it has been done or that that is sufficient. And I think it is going to be more important to talk about what actually has come out of investments made, rather than just track investments.

But I am open to other ideas about this.

Ms. Redwood: Well there were some that I looked at, Tom, that they were funded one year but like for the next two years, there was no funding at all. And we got those yellow light, red light, green light measures and I think those need to be updated because they are just for that specific year.

So I feel like if we are going to identify a gap we really need to know. You know, we may have had a bunch of funding for one year but it still doesn't hit the benchmarks that we identify when we develop those smart objectives.

Dr. Insel: Oh, okay. I'm following you now. I see what you are asking. So maybe on those individual items there is something like on a particular area where you are trying to get a better handle on what actually has been done. If it isn't clear from any of the electronic tools that we have got, we can help you out. We can help the subcommittee out with trying to figure out what that information might be. But I'm not sure that the subcommittee will be able to much better, that OARC can do much more than what you already have access to. think you have just about everything we have in terms of the tools to look at the portfolio. So we will work with you, especially around these

kinds of questions. And the more specific they are, the easier it will be for OARC to tackle them.

Ms.

Redwood: Tom, also back to Coleen's question, I am still a little unclear whether or not say for page 10 the 2011 addendum, would that 2011 addendum stay in place or will that now be replaced by the 2012 addendum? Like for example, the 2011 addendum talks about the new numbers out from the ADDM network but we since that time have even newer numbers. So not to be redundant, we will be replacing those 2011 addendums.

Dr. Koroshetz: I mean I would propose trying to move the 2011 materials into the main sections of what do we know, what do we need and then do a 2012 addendum that is completely new. That would be my thought.

Ms. Redwood: I think that sounds good.

Dr. Dawson: Yes, although let me
just -- I mean I don't have a strong point of

view on this. But you know, it might make things, kind of looking back historically on the documents, since we did do this nice update in 2011 and then you can see what happened 18 months later, that sense of kind of longitudinal look is going to be lost and you will just see, you know, you won't know whether those advances came in 2011 or they were just general advances there from the beginning and now here is where we are in 2012.

I don't know, I am just always for more historical information in context.

Maybe it is because I am a developmental psychologist. But so I sort of advocate for just saying here is the 2011 update. Now let's see where we are in 2012.

Dr. Insel: And then I guess,

Geri, one possibility is that we look to 2013

to really collapse all of this.

Dr. Dawson: Yes. Yes, I think that collapsing is sort of a start over point

because it would be interesting to see when you go back to this report that in 2011 here was the report on the CDC numbers and a year later, here is what it is saying. And I don't think you will capture that in the same way if you just integrate it all.

Dr. Insel: What do other people think about that?

Dr. Boyle: I like the historical perspective. But then again, so the '12 report, then Geri, you would see just -- you would see having both the '11 and the '12 addendum to it?

Dr. Dawson: I would, yes. Yes, because I think that is the actual exercise that we are doing. We are not -- we are actually trying, I think, looking back over the last 18 months and saying what has happened since we wrote this before, which was in 2011. And now where are the gaps.

And it will also help us to see just a little bit about the pace.

Dr. Boyle: Exactly, yes.

Dr. Dawson: Like for instance, if a lot of things happened in the last 18 months, that is encouraging. If not much has happened, or maybe in some areas it has and in some areas it hasn't, and that will be, I think, informative.

Dr. Boyle: We can try it with that frame.

Dr. Koroshetz: What would you plan to do with the next session, which is what gap areas have emerged since last year? Would you keep the historical 2011 and then add a 2012?

Dr. Dawson: Well I think what you would be saying is one is that this gap remains. Right? Nothing has happened in the last 18 months that has addressed this gap and it is an ongoing need. But chances are, new gaps have emerged because if the scientists moved forward, that tends to push the field in new directions in terms of kind of next steps

and what needs to come next.

You know, I don't feel strongly about this. I just wanted people to consider the information they would be losing by integrating it.

Dr. Koroshetz: You are not keeping the 2011 gap areas. You are just rewriting that section, the 2012 and discarding the 2011 gap areas or are you keeping that for historical purposes as well?

Dr. Dawson: Well, what does the committee think?

Dr. Boyle: I think we have to have been doing it to see about that last section.

Dr. Insel: Other thoughts? The easy thing would be to leave the plan as is and add on. I think once you start to change what is there, you are complicating a lot of issues going forward.

So one possibility would be to start with that assumption and then see what

we have got once we have documents and then decide how to manage the 2011 language, whether it needs to be integrated or whether it can just stand alone and we can add to it.

Dr. Dawson: Yes, I think another point, too, to think about is that if we integrate, then each group has actually two writing tasks, not just one. So that is another consideration.

Dr. Boyle: It is easiest to do a whole new addendum for '12.

Dr. Insel: Which is what we did last time.

Dr. Boyle: Yes.

Dr. Insel: Can I ask the people on the phone, who was involved with doing the update last time for the ones that are in there in the 2011 report?

Dr. Boyle: Well I know I was involved in the first section, in the seventh section.

Dr. Dawson: Yes, I was involved in a number of them.

Dr. Insel: Okay.

Dr. Dawson: And I know you were involved because we worked closely together.

Ms. Singer: And this is Alison.

I was on Section 2 and Section 7.

Dr. Insel: Oh, okay.

Ms. Redwood: And I was on Section 3 and also the introduction.

Dr. Insel: Right, I remember that.

Dr. Dawson: Yes, and I worked on the introduction, too. I think Lyn, you and I did both the same ones.

Dr. Insel: And Geri, didn't you do Section 4? I think you worked on the interventions, right?

Dr. Dawson: Yes, treatment and introduction I think was mine, too.

Dr. Insel: Okay.

Ms. Redwood: And I think that was mine as well.

Dr. Dawson: Yes.

Dr. Insel: All right. So this is a little bit like deja vu for some of you who have been here before.

Okay, any other issues around the process?

So what we will want to do is go through some of the specifics about who and when and a little bit more about how this will get done.

So the deliverables that we have, we were thinking we have the meeting on October 30th, which is really the key point where external experts will come sit with us. We will have some breakout groups and we will really hammer this out. But we wanted to go into that meeting with pretty good drafts that will be done ahead of time so that the meeting is really meant to finalize the drafts, rather than to start working on them.

So the plan would be to have the groups get together and begin and actually get

pretty far down the road here by the 22nd of October. So at least a week ahead of the October 30th meeting and to do this through phone calls and emails so that each of the five questions that this subcommittee is responsible for will have a pretty good working draft by the 22nd that will be sent to OARC and then could be distributed so that everybody has a chance to look at this before the 30th. Does that sound workable?

Mr. Britton: Tom, I have a question.

Dr. Insel: Yes.

Mr. Britton: This is Noah. So does this mean the in-person meeting will only be the 30th? Because initially it was considered the 29th and 30th and I haven't heard anything since.

Dr. Insel: Yes, there is a meeting on the 29th but that is the other subcommittee.

Mr. Britton: Okay, so we wouldn't

be in attendance?

Dr. Insel: You know, these are open to full committee. So if you want to sit in, you are welcome.

Mr. Britton: Okay. All right, I understand. Thank you.

Dr. Insel: And I think it would be great if anybody is planning to do that and wants to come early. We should try to do some kind of an event on the 29th in the evening so we can spend some time outside of the meeting chatting about other things and also maybe we can get Susan to bring her baby and that will be some sign of progress as well.

And then the plan would be to use the 30th to kind of kick the tires on each of these chapters, and of course the 29th for the other two chapters that we won't be talking about with this subcommittee.

So by the end of October, we will have something, we will have a pretty good plan, a pretty good draft. We will have some

time thereafter to take whatever feedback has come out of those meetings and to finalize these so that we can have something ready to go certainly by the end of the calendar year.

Any questions about that schedule?

Dr. Boyle: Tom, this is Coleen again. The thoughts about what would be presented by the subcommittee at the October 30th meeting, that would be helpful.

Dr. Insel: I'm sorry, I didn't hear the final part of your question, Coleen.

Dr. Boyle: Sure. So we will be presenting our thoughts about the update to the experts at the Strategic Planning
Workshop on October 30th?

Dr. Insel: So the concept here would be that after today, once we have finalized the working groups, the five groups that will have work on the five chapters, that people would start by next week contacting the experts and beginning a series of phone calls to actually do the draft.

Dr. Boyle: Those three experts that have been identified.

Dr. Insel: Yes, and along with your two colleagues from the subcommittee.

Dr. Boyle: Okay.

would --

Dr. Insel: So the six of you

Dr. Boyle: This would be a team here.

Dr. Insel: You got it.

Dr. Boyle: Okay.

Dr. Insel: Although usually there is one person who ends up doing a lot of the initial work.

Dr. Boyle: The work, yes.

Dr. Insel: But what we will do is get that all going and so by the 22nd, --

Dr. Boyle: Okay.

Dr. Insel: -- so in about six weeks, we would like to have you send us the results of that, which will be, would really be a draft. And then that is what the group

will present -- Dr. Boyle: Okay.

 $$\operatorname{Dr.\ Insel:}$$ -- in the in-person meeting on the 30th --

Dr. Boyle: Got it.

Dr. Insel: -- to get feedback from the rest of the subcommittee.

Dr. Boyle: Got it.

Dr. Insel: So as you will see in a moment, even though we have had to break the subcommittee into these five working groups, everybody will be involved from the subcommittee in seeing what each of the updates looks like and there will still be plenty of time for feedback.

Dr. Dawson: Tom, this is Geri. I don't think we discussed this or maybe we did and it just didn't cement in my brain. Are we also, as part of this process, going to be updating the research opportunities and short-term objectives?

Dr. Insel: No, the idea was to

really focus at this point because we have to have this done in three months.

Dr. Dawson: Okay, so there will be no revising of objectives?

Dr. Insel: No. We are going to come back. That will be the project in '13.

Dr. Dawson: Okay.

Dr. Insel: We can start on that in January but I think for now to meet the statute requirement, we want to get something that is a true update with some outside input by the end of December.

Dr. Dawson: Okay because that was part of the process last time.

Dr. Insel: Yes, I know.

Dr. Dawson: It is good to make it clear that that is not an expectation.

Dr. Insel: You know, my thought about that is that if we do a really good job here on the gaps, it will make it very easy then to revise the objectives. And some of them would be great if we could actually say

mission accomplished, although maybe that is not the right term anymore, but have that for the 2013 plan and then new objectives to add into it. Dr. Dawson: Yes. Okay, thank you.

Ms. Weiblinger: This is Gemma, if I could just interject for a second. In terms of when you communicate with each other, we at OARC would be happy to help you set up phone calls, things of that nature. And also it would be important that if you conduct business via email, that you copy us on the email. And I think you have all of our email addresses.

Dr. Boyle: Maybe just for clarification for everybody you could just send that out in a general email?

Ms. Weiblinger: We will do that.

Dr. Boyle: Excellent. Thank you so much.

Dr. Insel: We will follow up this

meeting with that kind of detail.

Dr. Boyle: Great.

Dr. Insel: Any questions then about the task in front of us? Walter, go ahead.

Dr. Koroshetz: I'm still confused about what we are doing with last year's gap paragraph. Are we rewriting that?

Dr. Insel: No.

Dr. Koroshetz: Are we going to do an addendum?

Dr. Insel: We are going to do an addendum. So we are basically re-doing what we did last year but it is an update. It is revising both sections. What do we know? What do we need, based on science that has come out since then.

And it does cover, it really is a little more than 18 months because this was done early on.

Dr. Koroshetz: So what stays here? So what is in here stays and we just

change it. It will be what gap areas have emerged since 2010 and then we are going to write another, what gap areas have emerged since 2011?

Dr. Insel: Right. Is that workable? Okay.

Ms. Redwood: And Tom, I assume you want the research opportunities to also stay the same. We won't be making any amendments to that section of the plan.

Dr. Insel: Right. Yes, I think we want to keep this simple for now. And again, we can revisit all of this in January but to get this done I think we really want to provide the update on the science and again emphasize the places where the science has not yet addressed what was in the plan.

Ms. Redwood: Even though there may not be something published, it may be a good idea, since we will have the experts there, to sort of get their suggestions for research opportunities and then we would have

that information going into 2013.

Yes, I think we should try to find some way to capture that. And I think that -- I mean I could imagine that we write up the gaps or what do we need section in such a way that it would be that we need to do this because this is a new opportunity to really shed light on autism. So I think it may happen anyway. But I think it is a really good point that if we are going to all this trouble to bring in 15 additional people here, we ought to get as much information as we can and find a way to capture that.

Dr. Dawson: Yes, I was going to say the same thing. Lyn, I think that in the second section where the gaps, particularly the unfunded gaps and what do we need, I think you can, in prose, capture the concept of research opportunity and directions of research and where it needs to head and so forth, without getting down into the sort of

explicit bulleting of very specific research opportunities.

So I mean I think it should be captured there in general terms and so you will be able to kind of utilize the information that emerges from the discussions with experts.

Dr. Insel: Anything else before we move on to talk about the who? We have talked about the what and the when.

Okay, so let's go through the names. And this is still a work in progress. We didn't want to wait to invite experts because we are talking about a meeting that is only at the end of October. This is already getting into September. These are busy folks, as all of us are, and we need to get this on people's calendars.

So thanks very much to all of you for sending in your nominations. Some of these were easy because most of the committee endorsed the same people. And so we have gone

ahead whenever that was very clear and invited them. Unfortunately, many of the people that you most wanted were not able to come because of prior commitments. But we have got some of the names, some of the slots were filled and we still have some opportunities to add a few others.

So on question one about when should I be concerned, Cathy Lord and Ami Klin have signed on, so we have them in the list. You had also asked for Karen Pierce, so those were the top three nominees but Karen is not able to do this because she is going to be very busy writing grants that are due at the beginning of November, so she declined.

So we have one additional spot to fill here. There is a long list of names but no one who got a huge number that is more than one or two votes from the committee. So I would just throw this open to the group. If there is somebody who you think would be a really good balance to Cathy and Ami, that is

somebody who would I think complement it would represent a different perspective.

That would be a good person to add in as an external expert.

Mr. Robison: Well who are the choices then that each got one vote?

Dr. Insel: Well there is a long list. I should point out that many of them ended up in other categories. In fact, some are coming in other categories. So for instance, Craig Newschaffer got two votes but Craig is going to be working with us on question number three. So we could ask him to do double duty but that might be asking a little too much.

I will go through some of the names and there may be others that will, as I read these and as you look at the ones up here will come to mind. Deborah Fein, Fred Volkmar, Eric Courchesne. Actually I should say Eric also is unable to come. We have invited him for another question, so he is off

the list. John Constantino, Yvette Janvier, Sally Rogers was on the original list but she also can't make it. She has got a conflict.

And then there is another group of about 10 or 12. I could read through the names but that gives you some feeling. Is there anybody that somebody wants to nominate that you think will be a good compliment to Cathy and Ami?

Dr. Batra: Would you mind reading the other 12 that were nominated?

Dr. Insel: Okay, let me go
through the -- I'll read through the whole
list. And again other than Craig and Deborah
Fein, everybody basically has one vote.
Actually there is one other person. Fred
Volkmar had two votes from the subcommittee.

And then it is Steve Dager, Diane Chugani, Eric Courchesne who can't come, Wolf Dunaway, John Constantino, Bruce Waslick, Sally Rogers who can't come, Doreen Granpeesheh, Yvette Janvier, Celine Saulnier,

Tony Charman, Audrey Griesbach, and Peter Szatmari.

And since we are meeting as a subcommittee, if there is somebody else that somebody feels strongly about who you think would balance Cathy and Ami, then we can add them to the list.

Dr. Koroshetz: There is a very talented young neurologist, Shafali Jeste. I don't know if people know her. She has been working in kind of at an infant level trying to determine ways of identifying early cases. I think she is at UCLA. So I think it would be nice to have a clinical expert.

Dr. Insel: I think that is where Yvette's name came from as well, as a clinician.

Male participant: Tom?

Dr. Insel: Yes?

Dr. Batra: That is exactly -- I would have to second that in terms of I think having Cathy Lord and Ami Klin, they are just

top notch experts in terms of the science.

And I think we have to have someone who has a clinical background.

Dr. Boyle: What about Peter Szatmari?

Dr. Insel: Does he see a lot of kids?

Dr. Boyle: He does, yes. I mean, he fits that description.

Dr. Dawson: By the way, Cathy and Ami are both clinicians, --

Dr. Insel: Yes.

Dr. Dawson: -- very active clinicians and see kids almost daily. But not to say we shouldn't add another clinician but I just want to clarify that they are both licensed clinical psychologists who have diagnosed probably thousands of kids and still are very active running clinics and seeing kids; not only kids but also adults. And I know Cathy is working very hard on adult ADOS and things like that now.

Dr. Insel: Geri, would it be useful to have a neurologist amongst the three of them or is that not enough of a complement?

Dr. Dawson: Well actually, I would say a pediatrician.

Dr. Batra: So I was, you know, I had nominated Audrey Griesbach, who is a developmental and behavioral pediatrician in Los Angeles. And I have to tell you, I mean, she has been practicing for 30 years, trained at Children's Hospital. And because of the nature of what she does and being a pioneer in the community, sees people from infant to adulthood now. And her clinical experience and expertise I think would be a good complement to the other two experts that are on the committee.

Dr. Kau: Yes, I think that sounds great.

Dr. Choi: Two other developmental pediatricians might be Lenny Rappaport or Sue Swedo, if she is available.

Dr. Insel: Yes, Sue Swedo was invited and can't come. She was invited for another question.

Dr. Dawson: Another person is
Ricki Robinson, who is again a person who is
a developmental pediatrician who has spent
her career but I think the other two sound
fine, too.

But I do think the idea of having
-- or maybe even someone from the American
Academy of Pediatrics.

Dr. Boyle: How about -- I was going to say how about Susan Hyman? I mean she represents the academy and their subcommittee on autism.

Dr. Dawson: Right. Right.

Another one would be Dan Coury, who is a developmental pediatrician and the medical director for the Autism Treatment Network.

Ms. Redwood: I think that would be good, Geri, because one of the things which we are missing is looking at some of the

medical comorbidities.

Dr. Dawson: Yes and that is the focus there.

Ms. Redwood: Right because we have the developmental pediatricians but we really don't have a medical person that is addressing the medical issues.

Dr. Insel: Yes, I would agree. I think that complement that we are looking for is either someone who is a pediatrician or a neurologist who can fill in on the medical side.

Dr. Dawson: Well Dan would have a broad perspective of all of the different assessment tools that are being rolled out and he could broadly represent a lot of the work that is going on in that area, if you decided to.

Dr. Insel: These are great. So if we have Audrey Griesbach and Dan and there was another name also that was --

Dr. Dawson: Ricki Robinson.

Dr. Insel: Ricki Robinson. And we can do our homework -- sorry.

Ms. Singer: And also Susan Hyman I thought would be a good idea, if Dan can't do it, she could.

Dr. Insel: Okay, why don't we chase those down and we will fill in that third name based on this list. I am sure out of the four we can get somebody who would be able to fit the bill. Okay?

And then what we have done and there is no -- this is not set in stone but we have just taken the groups that you each volunteered for and there was no way that it matched up perfectly. So we tried to just assign people so that you get one of the questions that you were willing to do but if you want to switch this around, we certainly can help you do that in terms of the IACC, members of the IACC who work with these three experts.

So Alice, John, Coleen, are you

okay with this?

Dr. Boyle: I'm okay.

Dr. Kau: Yes, I'm okay as well.

Mr. Robison: Yes, I'm okay.

Dr. Insel: And can we ask one of you to volunteer to take the lead on this question?

Mr. Robison: I would agree to do that.

Dr. Insel: Thank you. That's great.

Dr. Boyle: And John, I am happy to help you however.

Dr. Kau: Same here. Count me in.

Dr. Insel: Super, okay. So, moving on to question two. I think here as well -- I think we may have a third person, we are not sure. So again, we had great nominations, lots of people on the list.

Unfortunately, again, some of the people who got the most votes, like Judy Van de Water and Eric Courchesne, are not able to participate.

But other people who got a lot of votes -- actually Sue Swedo was also in that category. So all of them got several votes from you guys.

But two people who did quite a few, David Amaral and Kevin Pelphrey, have signed on. And there is one person who we thought would be a good addition who got, again, multiple votes from the committee:

Carlos Pardo, who we have invited and we haven't heard back from him yet. Carlos is a neurologist at Hopkins who has been a real pioneer on the inflammatory and neural immune aspects of autism. And it seemed like he would provide a pretty good complement to Pelphrey and Amaral.

Dr. Koroshetz: Can't you get Dan Geschwind on that?

Dr. Insel: Yes, Dan is very interested in helping but he can't. He is not available on the 30th. He offered to call in but we thought it was important for people to

be present.

I can again read off the many names that are on here, if you would like.

Dr. Boyle: Yes, that would be helpful.

Dr. Insel: Okay but, again, since Carlos has been invited, if he is able to do it, and I suspect because he is local that it will work out, we will have a full group.

So just going down the list in terms of the number of votes, and again we are talking about two or one from here on.

Martha Herbert, Craig Powell, George

Anderson, Mustafa Sahin, Allan Jones, Joe

Piven, Lilia Iakoucheva, Pat Levitt, Isaac

Pessah -- and I should point out that Isaac

is coming already for another question, so he will be part of the group -- Morton

Gernsbacher, Laurent Mottron, Tony Attwood,

Valerie Hu, and Gene Blatt.

Again, thanks for -- this is a really good and diverse list. But I think,

unless Carlos can't do it, we won't have to go back to the well on this one.

Dr. Batra: By when we will know, Tom, whether Carlos has accepted or not?

Dr. Insel: I'm a little surprised that we haven't heard from him already, but I would say if we haven't heard by the end of the day today I will call him, although the phone number we have wasn't that helpful. If anybody knows him well and is willing -- Walter, do you know him or work with him at all?

Dr. Koroshetz: I could find him.

Dr. Insel: Yes, I mean, it would be great if somebody could reach out to him personally. If that is not an option and we don't hear from him I would say by -- I mean, it is possible that he is away that is why he is not getting his emails. So I'd give him until Monday. But if we haven't heard by Monday or Tuesday we will go back to the well here. Okay?

Dr. Dawson: We should probably define or at least choose the next, you know, who would be the runner up if Carlos doesn't say yes.

Dr. Insel: Yes, so looking at this for the biology, who would you say is a complement to Amaral and Pelphrey? We want to capture space that they may not know as well. Although, Amaral probably knows everything about everything in autism. I'm not sure there is a lot of parts of autism that he doesn't know pretty well. But if there is --

Dr. Koroshetz: Well, the other guys they have these niches. I mean, Sahin is really a smart guy, mostly on --

Dr. Dawson: Yes, the nice thing about Mustafa is that his expertise is broad. So he has expertise ranging from genetics to neuroimaging, to actual development of therapeutics and running some clinical trials and doing a neuropsych assessment as outcome measures.

And then he also is a practicing neurologist.

Dr. Insel: Yes, he was somebody who was not involved previously who would be good to pull into the IACC. He is doing some of the most original work in TSC these days.

Pat Levitt was another name that somebody from the subcommittee suggested who is also very broad and who would work well with Pelphrey and Amaral, I think.

Ms. Redwood: Also Martha Herbert,
Tom, is a neurologist and has done a lot of
research on neuroimaging and I think she
would be a nice addition, too, to that group.

Dr. Insel: Okay, so we have got three backups if we --

Dr. Choi: Tom, can you hear me?

Dr. Insel: Sorry, you are breaking up so it is hard to understand.

Dr. Choi: Sorry. How about that?

Dr. Insel: That's better.

Dr. Choi: Okay. In terms of

complement, I mean, Pelphrey and Amaral are both on the macro, neuroanatomical and behavioral side. Optimally, what we need of course is genetic work.

Dr. Insel: So we will get to that on the next one which is the risk factors, we will have some of the genetic crew.

Dr. Choi: Okay.

Dr. Insel: So I think we will cover that.

Dr. Choi: Very good.

Dr. Insel: And that is maybe the other reason to think about someone like Sahin or Levitt who could cover that as well.

All right, so we will have some backups. And then here, again, Alison, Dennis and Walter, are you okay with serving on this? And can we get -- Dennis, is it okay with you?

Dr. Choi: Sure.

Dr. Insel: And Alison?

Ms. Singer: Yes, I am happy to.

Dr. Insel: Okay, I just got a thumbs up from Walter, so he's onboard. Can we get one of you to take the lead here in terms of just making sure that all the work gets done and we get there on time?

Walter is putting his hand up. Is that okay with you guys?

Dr. Choi: Sure.

Dr. Insel: Okay?

Ms. Singer: I'm happy to help in any way I can.

Dr. Insel: Super.

Let's move on to question three, risk factors. And here we do have a full slate of three people who I think are actually fairly different in looking at the issues of what caused this to happen and can it be prevented. So Isaac Pessah, Matt State, Craig Newschaffer. And the three members of the committee are shown below.

Any heartburn about the three external experts?

Dr. Birnbaum: Tom, this is just Linda. Cindy is actually not a member of the committee, although she will be the one who represents me doing this.

Dr. Insel: Okay. Okay, so we will have both of you listed under the members.

Dr. Birnbaum: Or just put -- you can just put Cindy in parenthesis for Linda Birnbaum or something like that.

Dr. Insel: Done. And then what about on the external expert side for Pessah, State, and Newschaffer? Are we okay as a subcommittee? Are they going to give us the bandwidth we need?

Geri, okay with you?

Dr. Dawson: Oh, yes. No, I think it is a strong group.

Dr. Insel: Great. So we are all really excited to do this.

And then under the IACC members, Lyn, Matt, and Linda/Cindy. Okay with that?

Dr. Carey: Tom, this is Matt.

I'm good with that.

Ms. Redwood: And so am I.

Dr. Birnbaum: And so am I.

Dr. Insel: Okay and then can I get a volunteer for who will lead the charge?

Ms. Redwood: I'd be glad to help,

Tom.

Dr. Insel: Thank you, Lyn.

Let's move on to number four, the treatment one. And here again, we are short one person. We have gone through a number who can't do it. I will -- we have Connie Kasari and Lin Sikich, who are, I think are quite different in terms of what they would bring.

You also voted for Sarah Spence, who is not available. Tris Smith, who is also I believe not available. Is that right? There is a question about Tris but the question also is whether she was really complementary to the two we have or whether she just represented and overlapped with who

we have.

Sally Rogers, who is not able to come on the 30th, and that takes us down to a long list of people who got a single vote. I can read through that list and then if there is others that you want to consider. This is a very long list.

So let me run through this for you very quickly. Every one of these people got only a single vote. Brian King, Ricardo Dolmetsch, Steve Dager, Nancy Minshew, Margaret Bauman, Paul Wang, Rebecca Landa, Michelle Dawson, Matthew Lerner, Suma Jacob, Alvaro Pascual-Leone, Matthew Goodwin, Marcel Just, Jill James, David Berger, Antonio Hardan, Cheryl Klaiman, Tony Charman, Erna Blanche, Michelle Garcia Winner, Audrey Griesbach, who we talked about already, Sam Odom, and Phillip Strain.

Dr. Dawson: I was just going to say there are sort of two ways, I'm sure there is more, but at least two ways that we could

think about filling a gap here in terms of breadth of topics. One way would be to invite someone like Paul Wang who has that really deep more molecular view of what is going on in the world of medicines development. Another though would be to think about more of a lifespan and the need for someone to represent interventions for older kids, especially after that report that came out two weeks ago that showed we had five studies on vocational interventions for young adults.

But in any case, so someone in that area, you know, I mean one person comes to mind is someone like Jeff Wood who is doing a lot on cognitive behavioral interventions for adolescents and young adults, both higher and lower functioning individuals. So anyway, those are just a couple of thoughts.

Mr. Britton: Tom, can you tell me who the two that have been selected are? I'm not ashamed to admit I don't know who these people are.

Dr. Insel: Yes, I'm going to ask Geri, who knows them probably.

Mr. Britton: Sure.

Dr. Insel: It occurs to me if we were starting from scratch, the first person to nominate would have been Geri Dawson.

Dr. Dawson: Well anyway, so
Connie Kasari is a psychologist. She is at
UCLA. She does a broad range of early
behavioral research ranging from
interventions for very young children. She
has been doing these targeted interventions
where she focuses on a pivotal skill like
joint attention and does very specific
interventions both for parents and for
therapists.

But in addition, she has more recently been moving into the school aged and is very interested in how you export and test interventions in the context of schools and particularly how to adapt those for ethnic minorities and other under-served populations. And then most recently she -- actually

building on an Autism Speaks grant received an NIH ACE Network award, which is going to be developing interventions for children who are non-verbal and developing and testing.

So that is a pretty exciting unmet need. So working with kids who have not developed language and how we can adapt some of the interventions to help promote language development. So she has a very nice kind of diversity of background.

Lin Sikich is a child psychiatrist here at the University of North Carolina in Chapel Hill and has participated in a wide range of pharmacological clinical trials, including the large, the Citalogram study as part of one of the -- I think that was STAART.

More recently she received a grant, she is heading up a network, an ACE Network grant studying oxytocin in young children with autism, utilizing the DNA methylation measures as biomarkers of response to change and using some very interesting kind

of early efficacy biomarkers as well.

Dr. Batra: This is Anshu Batra.

Those two are wonderful. What a great complement.

I would really vote for someone who again, someone who has some background in the sensory motor system, the neural sensory motor system and that is why I had nominated Erna Blanche who is at USC a Ph.D. in occupational therapy.

And you know, I just find that of the interventional plans, as I am assessing children and diagnosing that the OT and the speech and behavioral components are key in my training and planning.

Dr. Batra: I think that might be a good way to round out a group of experts because then you have got somebody who you know, they are the cognitive, and those kinds of things, and then you have got the pharmacology, and then you have got sort of the OT kind of stuff, too. It is like you are

developing a treatment team. Now if we get our experts, that would be representative of each member of the treatment team.

Dr. Boyle: This is Coleen. I also thought the point that I think Geri made or someone else about the lifespan approach is a really good suggestion. So trying to get someone who has some expertise in that area might be very helpful.

Mr. Britton: Yes, thank you,

Coleen. This is Noah. I want to second

that. It does sound like it is very heavily

weighted towards young and non-verbal

children at this point and I really don't

want to leave out people like myself in terms

of who is represented by these experts.

So somebody who has experience with adolescents and someone who has experience with more verbal autistics, which is why I nominated Matt Lerner, who Geri you know and would be someone that I would look to just in general for support on this as I would

write in terms of his work.

Dr. Dawson: Yes, and let me just tell you about Jeff Wood so you can consider him along with the others.

Mr. Britton: Sure. Okay.

Dr. Dawson: So Jeff is also at UCLA and he really has spearheaded the adaptation of cognitive behavioral intervention to autism. He has run a number of randomized clinical trials now showing its efficacy and now is moving into adapting those cognitive behavioral interventions to address core symptoms. But he has also, I have worked with him on a number of projects. He is a roll up your sleeves, really gets engaged and does a lot of work kind of guy, too.

Mr. Britton: What particular symptoms is he working on?

Dr. Dawson: In the work where he is adapting it to address core symptoms?

Mr. Britton: Yes.

Dr. Dawson: So friendships and

feeling comfortable in social environments, peer relationships, --

Mr. Britton: Okay.

Dr. Dawson: -- conversational skills.

Mr. Britton: Okay.

Dr. Dawson: Things like that.

Mr. Britton: All right.

Dr. Insel: Geri, is there somebody with new technologies or taking a completely different approach for adolescents or adults to work on these kinds of things?

Anybody come to mind who you think could add that element?

Dr. Dawson: Well I know that Jeff actually is using some new technologies in his outcome measures but the other area that I know there is some beginning work in is things like work on developing programs, develop social networks on the internet, and kind of the use of the internet to build in both a therapeutic and kind of a social networking

context for higher functioning individuals.

Dr. Insel: Would Jeff be able to

Dr. Dawson: Yes, he would definitely be aware of that literature.

Dr. Insel: Yes, I think we need people who have the bandwidth to be able to cover these, even if they haven't done it themselves, they would know.

Dr. Dawson: Right but there hasn't been a lot published in that area, just to let you know. I mean it is a very new area and it would have to be identified as a gap.

And I'm trying to think. Does anyone else know about anyone using technology? I am trying to think of --

Mr. Robison: Well, I nominated Matthew Goodwin who used to be at the MIT Media Lab and now he is at BU. He was leading our Autism Speaks technology challenge at IMFAR the last two years.

Dr. Dawson: Right.

Mr. Robison: He'd be an excellent guy.

Dr. Dawson: Yes, and I think Matt is great, too. The only thing I would say about him is I don't think he has ever done a treatment study. So I think he is more focused on assessment, physiological assessments that can help us understand the biology and phenomenology of autism and arousal and things like that.

Mr. Robison: While, I think that is true, I do think that he is a guy with a totally fresh new and comes from a different perspective.

Dr. Dawson: That's true. It is a good point.

Mr. Robison: And we need to bring other disciplines in here.

Dr. Dawson: Yes.

Dr. Batra: That is why I really strongly would recommend bringing someone again who would really have round out this

group in terms of interventions, in terms of the core components of a program.

And again, in my experience, I
think Connie and Lin would be great
complements and adding someone like -someone who has that sensory, motor neuro
component who can give us an expertise on
what is out there, what intervention programs
are helpful for not only the little ones but
also the older ones.

Dr. Insel: It looks like we might need four people instead of three on this particular question.

Dr. Batra: Actually Tom, I think that is a terrific idea. That is what I meant before.

Dr. Boyle: And this Coleen. So one thought that just came to me when we were talking about technology and autism is Gregory Abowd, I think I am saying his name correctly, at Georgia Tech. He is just a real pioneer in this area. So if we do have four people, he

would be just a great person to bring in.

Mr. Robison: You know another person, I didn't nominate here before but we have Katharina Boser, who actually does therapy and is based I think outside of Baltimore. And she worked with Matthew on the technology committees for Autism Speaks for a few years.

Dr. Dawson: Yes, she is very strong.

Mr. Robison: And she has clinical and technology experience.

Dr. Dawson: Yes, that's true.

Dr. Koroshetz: And that would be good for question one, when should I be concerned, using technology that makes very early assessments.

Ms. Redwood: Hey, Tom and Geri, this is Lyn. When I look at this question four, treatments and interventions and the external experts that we have, they seem to be behavioral and cognitive. And I'm concerned

that we really don't have anyone here under treatments that are adjusting the medical comorbidities. And I think that is a huge overlooked area.

When we look at our plan, based on some of the work out of the Autism Treatment Network, it shows that 65 percent of individuals with ASD have sleep disturbances. We have a high rate of seizures, 60 percent with gastrointestinal problems and we really don't have anybody that are addressing those type of medical comorbidities, which I think has been really overlooked kind of treatment.

Dr. Boyle: Yes, I agree with Lyn on that.

Dr. Dawson: That is a good point.

So a person that comes to mind there would

be Beth Malow. And although her focus is

primarily on sleep, she is a child

neurologist and she did a lot of work in the

area of epilepsy clinically and knows that

literature very well.

So anyway, she is very aware of what is going on in the GI area just because she is part of the Autism Treatment Network.

Dr. Insel: Geri, is there someone in the ATN that kind of oversees the entire project?

Dr. Dawson: That is Dan Coury.

Dr. Insel: Oh, okay.

Dr. Dawson: Yes, so Dan and then of course we could invite Jim Perrin, right?

I mean, he runs the Clinical Coordinating

Center for the ATN and he is a pediatrician.

So Jim Perrin is the other person that has that, --

Dr. Boyle: Yes, that's a good idea.

Dr. Dawson: -- a broad view. He also is probably going to be the President of the American Academy of Pediatrics. He is very up on what is going on in the AAP.

Dr. Boyle: Yes, I like the idea of Jim because he could bring in a lot of

resources there, too.

Ms. Rewood: And those medical problems affect the infants, children, and adults. So I think it does bring in that lifespan perspective, too.

Dr. Dawson: By the way, Matt

Lerner, you know, I do know of him and he has
written some nice blogs for us and things.

But I am looking up he is an assistant
professor at UVA and he does work on program
design development of clinical interventions
for children and adolescents. He is
interested in improving quality of life
measures, peer relations. So those are some
of his areas.

Mr. Britton: Yes, he covers older children and has done a lot of work on social stuff but he has a really wide breadth of knowledge in terms of all intervention research and that is why I nominated him.

Actually, Jeff Wood sounds fine to me, Geri, as a third, if anyone else is okay

with that. Because I do really want somebody who covers older and more verbal autistics.

Dr. Dawson: All right so we have really talked about three areas. One is the medical comorbidity, the other is the kind of use of technology, and the third is older and higher functioning individuals and developing programs or lifespan programs.

Dr. Boyle: I mean this is such an important and complex area, I think we need to support it well with the experts.

Dr. Choi: Geri, one way of picking up those names and adding even a fourth, if we decide to look at the industry side of things, is to go with your earlier suggestion of Paul Wang.

Dr. Dawson: Yes, Paul Wang.

Dr. Batra: Well and also again I think a lot of the individuals who have autism also have underlying sensory motor dysfunction and I would really like to see someone who has that expertise on the expert panel who can

give us some guidance on that.

Dr. Insel: Would that be true of any of the people that we have talked about, Anshu? Is there anybody that you have heard on this list? I'm trying to find somebody who can --

Dr. Batra: I know him very well and I think he is terrific for giving us some insight into again some of the cognitive behavioral pieces, social pieces. The other folks that Geri, you mentioned --

Dr. Koroshetz: I'm sorry. Who is that you are mentioning?

Dr. Batra: Jeff Wood at UCLA.

Dr. Insel: Okay.

Dr. Koroshetz: Okay.

Dr. Batra: So he would address some of the, you know again, the cognitive behavioral components and social components and some of the comorbidity issues in terms of anxiety and such. He has some research studies going on.

Dr. Dawson: Yes, I forgot to mention that, that he also has done --

Dr. Batra: -- anxiety, which is nice. But again, no one that I have heard so far really addresses that lower level. And I really strongly urge the committee to consider someone who can shed some light because that is really, you know, again, as I hear parents, as I have read, as I -- you know, the resonating of sort of the frustration that I heard at our last meeting was just about looking at research that is in those areas, a little bit outside the box, quote unquote.

And so I think we have got -- you know and Connie and Lin I think are terrific, as I mentioned in terms of complementing those components but I think we have to look at -- I would like the committee to consider someone who can help us look at some of the lower level sort of sensory motor neural systems to help but then build and allow some of the higher cognitive functioning to then be

developed.

Dr. Insel: And that would be, I mean, you are thinking about that very much in terms of treatment intervention, not so much around mechanisms or diagnosis. Right?

Dr. Batra: I think that is really what I feel would be sort of a newer, fresher approach, which we haven't been looking at.

And so again, Geri, do you know anyone who would fit that bill?

Dr. Dawson: Well the people that are coming to mind are, you know, there are people that are really studying from a little different angle. So Stewart Mostofsky is a person who does a lot of very elegant work on understanding motor systems and sensory input in motor learning.

And then the other person is Jana

Iverson who is doing some really cool work on

infant siblings and the development of their

motor systems, also using some really

innovative technology.

Now I would say Matthew Goodwin is also interested in sort of sensory motor issues. Right? So he might kind of cover that technology and sensory motor perspective. So at least that is one person that can do two things. You know, Matt has written about that topic and thinks about it. You know, how the sensory systems work and how it affects motor output and things like that. That is an area of interest for him.

Dr. Koroshetz: Geri, has it gotten to treatment already? I mean, --

Dr. Dawson: Pardon?

Dr. Koroshetz: Has it translated to treatment?

Dr. Dawson: You know, --

Dr. Koroshetz: Or are we talking 20 or 30 years from now or not?

Dr. Dawson: Right.

Dr. Koroshetz: I mean, because you want -- for this one I think you really want things that are either pretty close to

going into to patients or things that have been early tested. I think you run the risk of going too far to the basic biology, if you just get people who are just sensory experts but haven't really gotten the field to the point where it could be used for treatment.

Now if you had a treatment that was based on sensory inputs and control of sensory inputs, that would be the best.

Dr. Dawson: Well we do have a -I am on PubMed right now. There was an
article by the American Academy of Pediatrics
last year written on sensory integration in
children with developmental and behavioral
disorders by a guy named Zimmer. But I am
trying to look for someone that we all would
know.

You know it is not, I think it is not well --

Dr. Batra: Geri but there really is not a lot of research that has been done in that area. And so I think that between

collectively all of us, I think that it would be someone who probably is not a household name. And you know, I think we have to sort of agree on someone who might be able to -- who is doing some nice innovative work, who can shed some light in this area.

Dr. Insel: So it is funny, I thought of Matt Goodwin as the person to do this. He is probably not the first name that comes to mind but I think if he were charged with reviewing this area and helping us to know what is there, he can probably be a twofer.

Dr. Dawson: Yes, I think that might be the best solution because there are such diverse needs and he really would cover two of them.

Dr. Insel: I wonder if we, on this particular question -- it is so broad.

Maybe we just need a longer list. So if we were to include someone who could address the medical comorbidities, I think we have to do

that. It is in the plan and I am not sure that Connie and Lin themselves would know that literature as well as somebody who had been in part of the ATN.

Dr. Dawson: Yes, I agree.

Dr. Insel: Somebody who could cover well we are just talking about the sensory motor issues and if Matt could do that in new technologies, that would give us that coverage. And then as several people have said, the need to bring in other kinds of interventions for older subjects and it sounds like Jeff Wood is a good person along with -- either Jeff or Matthew Lerner to fit in.

So would the committee be comfortable with us expanding this to six names, instead of three? I just feel like we really do want to get the best information and it is a broad area.

Dr. Birnbaum: It sounds like an awful lot. I mean I think going from three to four would make sense but there is a very

short time window that this really has to be accomplished in.

Dr. Dawson: Well if you added someone like Beth Malow, someone like Jeff Wood and someone like Matthew Goodwin, so that would be five. Right, so we are only going two more than our typical --

Dr. Insel: Right.

Dr. Dawson: -- then I think we would have it covered.

Dr. Batra: Geri, how do you spell Matthew Goodwin?

Dr. Dawson: G-O-O-D-W-I-N, Goodwin.

Ms. Redwood: Geri, who is from ATN?

Dr. Dawson: Beth Malow.

Ms. Redwood: Beth Malow? Okay.

Did somebody also mention Antonio Hardan?

Was that one of the names that you read off the list?

Dr. Insel: Yes, it was.

Ms. Redwood: Because I think his recent research with N-Acetylcysteine is very amazing, too, in terms of working with repetitive behaviors and those types of novel interventions I think, I would hope that Beth would be able to bring that to the table, too.

Dr. Insel: Right. So this reminds me that part of what we can do as members of the subcommittee is to make sure that we have got the coverage we need. So if there are areas like that, we should bring them -- or studies like, then we want to make sure to get into the discussion we can bring them to the meeting. I'm not sure we have to have the person who did the study there.

Ms. Redwood: Right. I agree.

Dr. Insel: One would hope that one of the three or four or maybe even five people who are coming to the table would be able to comment on those. If not, then we will have to do some extra homework.

Dr. Koroshetz: I know Beth Malow

is very good, a very broad and good person on a team.

Dr. Dawson: Right and she is also a parent of a child with autism. So she brings that perspective in.

Dr. Insel: Linda, could you live with five people as external experts here instead of three?

Dr. Birnbaum: Yes, sure I can. I am just a little bit of a pragmatist.

Dr. Insel: Sure. Well we would have some work to do to actually figure out who would be able to attend. We have had, as you can hear, about a 50 percent hit rate in our invitations.

So Geri and I can work on this and try to make sure that we cover these areas.

I think we have gotten a very clear sense from the committee about what areas you want to make sure are in the mix at the end of the day.

Dr. Farchione: And it would be

interesting to have most of the work done even before October 30th. Then I'm not sure that having extra people is going to somehow impede progress in any way.

Dr. Insel: Right. You are really talking about one more person on the phone call.

Dr. Farchione: Right.

Dr. Insel: Of the people who are in the group from the committee, so Noah, Tiffany and Anshu, does one of you want to take the lead here?

Dr. Batra: I will.

Mr. Britton: Oh, okay. Who just spoke?

Dr. Farchione: I think that was Anshu, right?

Dr. Batra: Yes.

Mr. Britton: Anshu, do you want to split this in half?

Dr. Batra: Sure, absolutely.

Mr. Britton: Okay, that sounds

good. We can talk about this later.

Dr. Insel: We can also let you arm wrestle but it is hard to do over the phone.

Mr. Britton: I put my money on Anshu.

(Laughter.)

Dr. Insel: We will work with you to get this done. So thanks.

Mr. Britton: Okay.

Dr. Insel: Let's move on to the final category. Again, we have got, I think we have got three people already signed up; Roger Little, Cathy Rice, and Dan Hall. This is on the infrastructure piece.

Roger Little is taking the lead in the biobank for autism. He is here at NIMH and has pulled the community together around trying to get buy-in for a repository.

Cathy Rice I think you all know from CDC is involved with epidemiology of autism and Dan Hall who has been part of the

NDAR effort and has worked closely with OARC as well as NIMH.

And then you can see the three members, Donna Kimbark, Geri Dawson, and myself. And let me see if there are questions -- actually I just noticed these three got the highest votes so we just ended up with a pretty good match from what you recommended and who was available.

Dr. Kimbark: Well this is Donna.

I don't have any questions regarding the external experts. I do have one question regarding how we are supposed to put this together. After reading through it, I noticed that several of the questions and the gaps overlap. For instance, postmortem tissues overlapped in several different questions. How do we handle that?

Dr. Insel: I wouldn't -- I mean I think at this point let's do it question by question. We will come back at the end of the day when we put all this together with some

support from OARC to make sure that the language is consistent, that there aren't redundant areas, that it all fits together as a single document.

But at this point, we just want to stay at the level of the individual questions.

Dr. Kimbark: Okay. Okay, that's good to know. Thank you.

Ms. Singer: That issue actually came up last year, particularly with the tissue. And so I ended up last year working on section two and then also section seven, so that we could make sure that we weren't redundant. And I would be happy to do that again if you think that would be helpful.

Dr. Kimbark: It would be helpful to me. I would like to have some type of cross-communication between the different groups. So that would be great.

Dr. Insel: So this is one of the places when Gemma said at the beginning she wanted to make sure that OARC was on all of

the communications between you, it is partly for this reason. So the staff here can provide some cross-reference as well. They will know what is going on with each of the questions.

Ms. Singer: Okay.

Dr. Dawson: But Alison, did you say you are also volunteering to be on this working group?

Ms. Singer: I mean, there are already three people and I am already doing one but I am happy to play that role and work on making sure that there is not redundancy because I recall we did have that issue last year as well. If Gemma has a plan in place for trying to make sure there is no redundancy, then I am good with that.

If you guys think you need another person on this, I am also happy to help there too, whatever you decide.

Dr. Insel: One of the reasons why we were suggesting that we hold pretty closely

to the 2011 update is that we kind of went through that last time we did this to try to make sure that there wasn't a lot of redundancy. Alison, I remember we had all these conversations then about where things should live. So it is a bit sorted out. It may still come up again, all over again in some of the same areas. But I think if we follow the structure we have now, we are in pretty good hands.

On this one, does somebody want to take the lead between Donna, Geri, and me?

Dr. Kimbark: Well I could try. This is Donna.

Dr. Insel: We will give you lots of help.

Dr. Kimbark: Okay, that would be good.

Dr. Dawson: I'm here to help.

Dr. Insel: So we wanted to provide you, kind of just in reference to the conversation we just had about what these also

look like. And as we have already said a couple of times in this phone call, if you look at the addendum that you all have from the 2011 plan, it is a pretty good guide to the level that these need to be. And we could probably make these comments a little bit longer because they cover a little bit more territory. And in fact, there has been a lot more science in these 18 months than in the previous 12.

But I think those -- what I recommend for each of your groups is to start with that and to build from that. And then we have listed for you what we think are the key questions, which we hope each group will address. I'm not going to read them out to you but if you look at them, let me see if anybody on the committee has additional questions about this.

Dr. Dawson: I do have a question.

So do you want each working group to

actually have headings that are these

specific

questions or do you want us to use the two big headings of what do we know and where are the gaps and then just make sure that within those paragraphs, we have addressed these questions?

Dr. Insel: Right, exactly. So the latter, just as we did last time.

Dr. Dawson: Okay, good.

Dr. Insel: So we have the two big headings. Geri is there -- go ahead.

Ms. Redwood: With regard to the needs of the community, I am just curious about recommendations for assessing that information. I know in the past we have gone out with RFIs.

And I was just curious what your suggestions were to address that need.

Dr. Insel: One of the ways to do
that will be through the subcommittee members
themselves because the subcommittee
represents a pretty diverse part of the
community. The other I would say that we can
use public comments that have come in. We
can use what

all of us know about the community. I am open to other suggestions.

I don't think we will have time to do an RFI and to get results back that will be useful by October 22nd.

But I could encourage any of you who are part of this process to reach out to people to get ideas, especially for information about findings that you think are going to be important, to make sure that we know about them and that they are part of this process.

Geri, anything else you would think about in terms of the needs of the community?

Dr. Dawson: Well one of the things that we did last year is we had a webbased -- and actually Linda we used, pulled exactly the same, even used the same software that you used when you developed the NIEHS strategic plan. But is a web-based mechanism where people have the opportunity to just

submit ideas. We asked where do you think the funding for research should be put. And this is all, you know, people out in the community, you know, we have got thousands of people participating.

And then people submit an idea.

And after an idea is submitted, then people participating can vote on them and you can see which ideas rise to the top.

And I have summarized that in a letter to the community and it is pretty interesting. And I thought it was very informative, at least for our organization about what people view as really important areas for us to be funding. So I could provide that to people as a simple letter I have written that I could circulate.

Ms. Redwood: That would be great.

How long ago was that, Geri? Was that in
the last year?

Dr. Dawson: Yes, yes. I think it was, I want to say June. It was definitely in

the last six months or so, six to eight months.

Ms. Redwood: That would be very helpful.

Dr. Insel: Let's make that part of the process so we can make sure that each of the groups get that. Other ideas?

Ms. Redwood: I have another question about how much overlap, if we are reaching out to each of our three experts and the IACC committee members in each of these bucket questions, when we actually come together on the 30th, it would be great if we had all these people together.

You mentioned breakout sessions but I think there is such a diverse expertise here, I hope we do have time at that meeting for a lot of good, frank, open discussions.

Dr. Insel: You know, one of the things that was clear is that even though we broke this into five categories, a lot of the people were nominated for multiple categories.

Ms. Redwood: Right.

Dr. Insel: So some of these, I think Craig Newschaffer could be helpful on three or four. Actually, several of these people could be extremely helpful across the board.

And we have a lot of expertise in the subcommittee itself and so I think that is great. We want to make sure that the October 30th meeting is very interactive and we have lots of time for feedback.

What I think will be best, a little bit like we did today, if we come into the meeting with a lot of materials to work off of, rather than trying to start a process then. So what we are trying to do here is move all of this along so that we use the 30th to essentially confirm the work that has already been done and to update it or to refine it, rather than to be starting over at that point.

So if you could think about it

that way, most of the heavy lifting will happen between now and the 22nd of October and then we will really look to a very good conversation between the entire subcommittee and all of the experts on the 30th to see how to make this document the best it can be.

Is that okay? I mean does that make sense to people as a way forward?

Dr. Koroshetz: Yes.

Dr. Insel: Okay. Other questions or comments? I added in this one paper that came out last night in *Science* not because the details in this paper are so essential for you to see but this is, for one thing, it is way up to date. So this is really not even 24 hours old in terms of its public view. But it was an attempt to do just what we have been talking about, to look at what is known about the biology of autism and how can we see what is really there and what still needs to be done. And it is about two pages, something like that. We can send it out to the people

who are interested. But it is a pretty good example of the kind of evidence I think we will be looking for in this process in each of these areas so we can get a pretty good handle on the most up-to-date summary.

Dr. Kimbark: This is Donna. Is it possible for you just to send that out to just everyone on the committee, rather than just onesies, twosies of people that might be interested?

Dr. Insel: I would be happy to.

Dr. Dawson: By the way, I just wanted to double confirm because I was kind of aware that this article was coming out and I was looking for it and yesterday I sort of downloaded the September 7th issue of Nature -- or Science and I didn't see there. So was it then updated last night?

Dr. Insel: I know that the embargo lifted yesterday. So we will find out --

Dr. Dawson: Okay.

Dr. Insel: -- before we distribute it. We will make sure that we are not breaking an embargo.

Dr. Dawson: Yes, and it may have been that it went online at midnight last night but the September 7th issue that came out yesterday in the afternoon didn't have it.

Dr. Insel: Okay. I know that we received with an embargo 2:00 p.m. on the 6th.

Dr. Dawson: Okay, that's good. So it is probably there.

Dr. Insel: But I will double check to make sure we haven't violated any AAAS embargo. I don't think so.

But if we can send it, we will share it with everybody. And I am sure -- it is interesting actually since Matt State is going to be one of our external experts, we didn't know that this was coming out at the time he was invited but it is a good match.

Okay, anything else that anybody on the subcommittee wants to bring up or any

other issues we should talk about before we get together next, which will be on the 30th of October? We will send you the details of that, including the actual venue. We don't have that. We are still working on finding a place.

Dr. Kimbark: I have a question.

This is Donna again. I just wanted to know, and I know this sounds like a strange question but is there a possibility instead of just getting PDFs or hard copies of the information in the strategic plan from the last year, is there a possibility of actually getting the actual working Word document?

Dr. Koroshetz: Oh, that would be helpful.

Dr. Insel: Let me check. We will find out if that is doable.

Ms. Redwood: Tom, this is Lyn. I have a question. As committee members, we fill out very extensive disclosures --

Dr. Insel: Yes.

Ms. Redwood: -- in regard to conflict or potential conflict. How will that be handled with these external consultants?

Dr. Insel: Yes, they don't become

-- they are not special government employees
so they don't have to fill those out. Some
of these people may be special government
employees for other assignments. So if they
are on an NIH council, for instance, they
will have already gone through that. But as
members of a subcommittee like this, they
don't.

But if you have concerns about any individual and if you are particularly concerned about a conflict of interest issue, let us know about that and if it is an area that we want to make sure it doesn't become a vulnerability for the committee.

Ms. Redwood: Well, there's a lot of the experts that I don't really know. But my concern is take someone like Matthew State, who I don't know at all but obviously he is

doing genetic research and that means that he is probably NIH-funded. I just want to make sure that we don't have someone making recommendations that are geared toward projects that they apply for and get funding. So that is what I am throwing out there just to see how we would --

Dr. Batra: That's a very good point.

Dr. Dawson: You know what? I guess what I would say, Lyn, I mean I think it is a very valid point but I also think that it is, you know what we could kind of create some of those scenarios and conflicts for even people on the committee now, but I think that the important point is to give very strong instructions to people when they come in that they are supposed to sort of leave their own personal hat at the door and think broadly and I think people try to do that. But I think also because the committee has five or six people, hopefully there will be a lot of

voices represented. And maybe if we start to see someone is really overbearing and trying to pitch a point of view, we could bring it up or talk to Tom or something.

But I don't know how we can get around that because you can think about any of the folks who are experts. They are all funded. That is why they are an expert. And so I don't know how we would get around it.

Ms. Redwood: Well what if they, as part of their introduction, sort of shared with the committee what projects they are actively working on now? I don't know. I'm just throwing that out there because I know there are several people I don't know and I am not familiar with what they are doing, what their research is currently.

Dr. Insel: It is always been a problem that people are experts on the things that they really believe in and are committed in and those are the things they are likely to emphasize whenever you ask them about what is

the most important area to pursue, people generally will talk about what they do and not something that they haven't done.

question is that that really falls to us as a subcommittee and then ultimately to the full IACC. That is why this process is that we use the input of the external advisors but it is really our responsibility at the end of the day and we are the ones that will be held accountable for what ends up in the document.

any of those concerns, we will have to wrestle with them post-October 30th and there will be plenty of time to do that. That is why we left some space between October 30th and when the document becomes final. And remember, it has to actually go to the entire IACC, not just the subcommittee.

So all we do is propose a set of recommendations for these two sections. The other subcommittee will do the same thing for

questions five and six and then all of us collectively will look at entire document and we will have to decide if there is something in there that looks like it is biased in some fashion or is not representative of what we want from the document.

Any other thoughts or questions?

Hearing none, I think we are going to be able to adjourn early. I want to thank all of you for getting so actively involved in this process. I think we had full attendance at this meeting and almost everybody has been very responsive to our request for nominations of advisors, which has been great.

So we will be working with you now going forward to develop these working groups on each of the questions.

And now keep October 22nd in mind as the due date for the next thing we are going to need, which is a draft of a document for each of the questions.

As always, if you have questions

in the meantime, you can contact me, contact Gemma, contact anybody from the OARC staff.

You will hear from us a little later with more of the details about what we need to do going forward for next steps.

Geri, thanks for co-chairing.

Dr. Dawson: It was my pleasure.

Dr. Insel: Okay, bye-bye

everybody. Thanks again.

(Whereupon, the above-entitled matter adjourned at 11:48 a.m.)