

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR PLANNING THE ANNUAL
STRATEGIC PLAN UPDATING PROCESS

TUESDAY, JUNE 16, 2009

The meeting came to order at 10:00 a.m. in Conference Room H of 6130 Executive Boulevard, Rockville, Maryland, Thomas Insel, Chair, presiding.

PRESENT:

THOMAS R. INSEL, M.D., IACC Chair, National Institute of Mental Health

DELLA HANN, Ph.D., IACC Executive Secretary, Office of Autism Research Coordination, National Institute of Mental Health

ELLEN W. BLACKWELL, M.S.W., Center for Medicare and Medicaid Services

LEE GROSSMAN, Autism Society of America

LYN REDWOOD, R.N., M.S.N., Coalition for SafeMinds

CATHERINE RICE, Ph.D., Centers for Disease Control and Prevention (For Dr. Edwin Trevathan)

ALISON TEPPER SINGER, M.B.A., Autism Science Foundation

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PROCEEDINGS

10:01 a.m.

Dr. Insel: Good morning and welcome. This is the second meeting of the subcommittee of the IACC. This is the Subcommittee for Planning the Annual Strategic Plan Update and we are meeting in a somewhat different room today. So, there are a few people who I think will be coming a bit later because this is not a place that's very familiar to most of us.

Let's do a quick round of introductions so that those who are joining by webinar or on the phone will have an opportunity to know who's here.

I'm Tom Insel and I serve as the Chair of the IACC and happy to convene this meeting as well.

To my left?

Mr. Grossman: Lee Grossman, President and CEO of the Autism Society of America and also the dad of a young man with

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autism.

Dr. Rice: Hi, I'm Cathy Rice, a Behavioral Scientist with the National Center on Birth Defects and Developmental Disabilities at the CDC. I'm sitting in for Dr. Ed Trevathan today.

Ms. Blackwell: Ellen Blackwell, Centers for Medicare and Medicaid Services. I'm also the parent of a young adult with autism.

Ms. Tepper Singer: I'm Alison Singer. I am the President of the Autism Science Foundation. I'm the mother of a 12-year-old daughter with autism and I also have an older brother with autism.

Dr. Hann: And I'm Della Hann and I serve as the Designated Federal Official for this Committee of the Interagency Autism Coordinating Committee.

Dr. Insel: We have a couple of people who are running late and will join us soon. Lyn Redwood from SafeMinds and Story

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Landis who's the Director of the NINDS are both expected and Stephen Shore apparently is not going to make it today as far as we know.

Dr. Hann: He may be joining us by phone in and out.

Dr. Insel: Okay. First order of business is I'd like you to look at the minutes of the March 17th meeting and let us know if there are any changes, edits, additions or other comments about the minutes.

If there are no suggestions, can we have a motion to accept them?

Mr. Grossman: Move.

Dr. Insel: Second?

Dr. Rice: Second.

Dr. Insel: In favor?

(Ayes.)

Dr. Insel: Okay. Looks like unanimous to have the minutes accepted and we can move on to the rest of the agenda.

The first part of this is really a follow up of what we went through last time

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which was around the portfolio of analysis. Remember what we talked about last time and what's reflected in the minutes is the need to capture what was currently being done from both public and private agencies involved with autism research. You gave us a list of who you wanted to hear from in terms of what their investments were and we have, we being the Office of Autism Research Coordination, has done a lot of work in the meantime to both contact the agencies and then to take their responses and put them into a form that we hope will be useful to you.

I'm going to have Della take us through the slide sets on this because there's quite a bit of detail and actually I think much of this meeting is going to be wading through some of this information which I think you'll find very interesting. It's the first time -- I believe the first time we've had this compilation of the entire landscape of autism research funding.

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So, Della, why don't you start and if your voice gives out, I'll take over, but I'm going to have you take us through the slide set that has the portfolio analysis.

Dr. Hann: Okay. Thank you. Yes, I'm recovering from a cold. So, we'll see how well I can hang in there this morning.

Just as a reminder from our last meeting, you all had suggested that what would be very helpful in thinking through potential updates to the strategic plan was to get a sense of what the research landscape was showing right now in terms of the various portfolios and at our last meeting, we identified 19 Federal and private funders for ASD research.

We approached those funders in terms of the amount of money that they were currently spending in terms of ASD research and then also asked each of them to really do quite a bit of work for us in some cases. Which was to look at their current portfolio

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in terms of the objectives and questions in the IACC Strategic Plan and to codify their portfolio accordingly to that.

We got a very good response. As you can see from this slide, it says that we received 15 responses. Of those 11, actually provided data and four actually reported back to us that they really didn't have anything in terms of autism research going on at that particular moment.

Next slide. This is the slide that shows the actual funders that were approached. These were the groups that were approved not only by this subcommittee, but also by the full IACC in terms of approaching them for the information.

I wanted to point out two of the private funders. The Doug Flutie Foundation, I actually had some interaction with them. They weren't sure if what they do fell into research and I wanted -- I told them after going back and forth with them a little bit

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that I would bring that back to you all to make the determination as to whether or not you felt that it was -- would fall. They have not yet sent any data because they just weren't certain.

Essentially, what they responded to me was that if you consider the family service grants which is what they provide as a means of supporting research, then that would be an example. But, they said that they do supporting services research. They give examples of supporting services that we have funded including family grants which are used for therapy, education, caregiving, recreation, emergency medical funds and providing funds to organizations to purchase occupational therapy equipment.

So, I put that up for you all to consider whether you believe that that should be included in this canvas for autism research and I'm seeing two heads saying nay.

Dr. Rice: Just a follow-up

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question. So, do they provide any kind of evaluation component whatsoever in terms of --

Dr. Hann: They did not indicate that to me.

Dr. Rice: Yes, I would say if there's no evaluation component, then I wouldn't consider it research.

Mr. Grossman: They've funded a couple of our chapters who have put in grants directly to them and I'm trying to remember the specifics around them.

They were what I would classify as research oriented, but again, I don't know if they collected the data from it at all.

Dr. Hann: Right. I mean they were very charming and willing to participate.

I don't want to project them in any other way, but they just felt uneasy in terms of the request that was being made. That they actually had the kind of information that you all were seeking.

So, I will take them from this

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discussion that we'll -- I'll communicate back and say thank you very much. We appreciate it, but it sounds like your instincts were correct.

Dr. Insel: Great.

Dr. Hann: Okay. The other one I wanted to point out before we move -- sorry. If you could go back to the previous slide. Thank you.

Is the last one up there which is the Simons Foundation. We are currently still working with the Simons Foundation to acquire their data. So, they had a lot going on and were unable to respond in time for this meeting, but they are going to be providing information.

Dr. Insel: On that, Della, do we even have any data from them at all about what the total number would be or anything that we could put in place?

Dr. Hann: No, we still have no specific information from them.

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Dr. Insel: Okay. That's going to be important to include. That's -- they're a major player in this landscape.

Ms. Tepper Singer: They publish an annual report that had a good amount of data. Maybe we can start there so that we have at least a ballpark figure.

Dr. Hann: We anticipate that they're going to be getting back to us probably within the next week or so with their full coding essentially of their research portfolio.

Dr. Insel: So, maybe what we can do is when that comes in that could be distributed electronically.

Dr. Hann: Um-hum.

Dr. Insel: And make sure that the subcommittee knows.

Dr. Hann: Um-hum.

Dr. Insel: That really is a gap here. Looking at this full list, they're probably going to rank second or third in the

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full list of funders. So.

Dr. Hann: Um-hum. Um-hum. And we can do that. We can update much of the information that you'll be talking about today. We can update once we get the Simons information.

Okay. Next slide. So, the next slide is of the organizations that came back to us with data and provides a top-level sort of summary of what we received and we rank ordered them in terms of the funding by the organization and so, the lead organization is National Institutes of Health followed by Autism Speaks and Centers for Disease Control and Prevention and then the other agencies and organizations line up thereafter.

We also on this slide the number of projects that they reported to us as well as our calculation of the average funding per project. Okay. That did not come from them.

That came from our office just taking the total number of projects and dividing it into

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the total.

Dr. Insel: I have a question about this. SAMHSA was one of the agencies that was contacted and they also are represented on the IACC. Do they not have any support for any kind of research at all? Even though --

Dr. Hann: That's what they communicated -- that's what they communicated back to us. That they were one of the four organizations that said that they didn't really have anything that fit the request.

Ms. Blackwell: Can I -- I'm sorry. I think it's similar to what happened with CMS. We only have a very limited number of activities that go straight to autism. But, SAMHSA has other research, of course, that could impact people with autism. So, maybe that's the bucket that they decided to use though.

Dr. Insel: AHRQ didn't -- it says it did not respond.

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Dr. Hann: Yes, did not respond.

Dr. Insel: I was curious about that as well. What happened with AHRQ? With all of the interest right now and comparative effectiveness research and there being the site for some of this, was it that they couldn't identify any or they weren't -- there wasn't anybody home or what was the issue?

Dr. Hann: There was no response and we sent multiple requests to everyone and there was never a response from AHRQ.

Dr. Insel: Okay.

Mr. Grossman: Yes, they've been pretty busy lately. Not to defend them, but I thought at one of our Services Subcommittees in the initial IACC, one of the last meetings that we had there, that they had started a few projects around autism research. But, I'm not familiar with it. So, I'm meeting with them later this month and I'll ask them.

Dr. Insel: Good. Yes, I was going to flag this because it looks like there

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may not be much to discuss this year, but this would -- it would be a real mistake for AHRQ to be left off the map. In coming years, we definitely would want them to be involved with large scale efforts for clinical trials in autism and as we evolve best practices, they're going to be hugely important to have as part of this picture.

So, Lee, maybe what we could do is if you could be our bridge and we could get a contact at AHRQ.

It's interesting how it may be easier for someone who's not in government to make these bridges sometimes. Sometimes that's unfortunately the case, but we can follow-up afterwards and it's quite possible there isn't much for them to talk about yet.

But, we would want to make sure that they become part of this effort as we move forward. So, really important to keep them in the picture.

Mr. Grossman: I'm meeting with

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Carolyn.

Dr. Insel: Okay. Yes, so --

Mr. Grossman: And she's going to have --

Dr. Insel: Great. You know, she's generally very responsive. We've met with her on many other issues. Autism has not come up in the previous meetings, but I don't know that they have anybody assigned in this area. So, that would be a good place to start. All right.

Ms. Tepper Singer: Can I just clarify the time frame that the data represent? It says the most recent 12 months.

So, does that mean June 2008 to June 2009 or does that mean calendar year 2009? What --

Dr. Daniels: The most recent 12 months that they have available.

Dr. Hann: Yes, we purposed in the past. So, last year when we approached some of the funders for information, there was a lot of confusion on that point because

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different organizations start their calendar at different time points. So, the government, we have the fiscal calendar. So, it starts in September and many of the non-Federal do January by the calendar year and so, we allowed organizations to select their start point and choose the most recent 12 months for which they had data.

Ms. Redwood: I think at the last subcommittee meeting there was a discussion of including FDA. Was there a particular response from them or reason that they weren't included?

Dr. Hann: I don't think --

Ms. Redwood: Okay.

Dr. Hann: And it's like when the list was finally approved by the IACC, I don't believe the FDA was on that list.

Dr. Insel: The research is not something they do much of. So, there's some internal research, but it's pretty minimal. So, you know, there's a growing conversation

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about the composition of the IACC. They were on in the first phase up until 2006. That may be a discussion to have if the composition's going to change and bring them more into the picture.

They are certainly involved right now in approval of medications for a wide range of children and even in the past week, there was this discussion about medications for antipsychotics and when they're appropriate for children. So, autism was part of that conversation.

Dr. Hann: Okay. The next slide that we prepared is again sort of a high level, but we thought interesting take.

Essentially, the total amount of funds that were reported to us was approximately 179 million and out of that as you can see, the larger share is the Federal, but the private actually is significant in terms of nearly 35 million in the private sphere versus the 144 million from the

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Federal.

Ms. Tepper Singer: How does this compare to other disorders or diseases at the NIMH?

Dr. Insel: Oh, it's -- so, for NIMH -- well, remember. The Federal is not NIMH. It's many different agencies. We're a component of that, but if -- just a reference point, there's really only one major private funding agency for research on mental illness and that's NARSAD and well, there are a couple. Because now, the Stanley Foundation is doing this as well.

But, their total budget is going to run probably under \$5 million of support per year in total. Somewhere in that range. Maybe it's a little bit higher on good years.

This year is not a good year and we're spending about a billion. So, just -- and that's on all disorders, but it gives you just a picture.

The other point about this will be

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for us, I think, very interesting to see what 2009 looks like. This is such a difficult year for private funding and so, part of our interest in having this now is as the baseline to map within autism to see what happens over this period.

Mr. Grossman: With mental health funding, would you consider any of the industry pharmaceuticals as part of the private funding?

Dr. Insel: We don't have a good map of that. So, I couldn't tell you. Certainly, pharma -- you know, overall the pharma R&D budget's about double the NIH budget or has been traditionally. That's kind of the figure that we usually use. Is about -- the NIH's budget's roughly \$30 billion and the pharma budget is, with bio together, about 50 to 60 billion. In that range.

But, we can't really capture those numbers in terms of specific disease investments from pharma. So, don't have any

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way to compare that.

No question though that pharma does support research in the academic sector and so, some part of what the academic sector, particularly those who do clinical trials, part of what they rely on will be the pharma support, but I can't give you what those numbers are.

Dr. Hann: So, the next slide. What we're going to try to do is sort of progressively go deeper into the data with each slide.

So, this is -- again, based on the codings that we receive from the organizations who responded, this is how it lined up in terms of the strategic plan question. So, this is divided across the six areas and then you'll see there's a seventh area which is other.

So, if a funding organization felt that the work that they were currently supporting didn't fit one of the six areas of

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the strategic plan, it went into an other category.

So, roughly 15 percent of the total is going towards the first question. When should I be concerned?

Nineteen percent on how can I understand what is happening?

Thirty-four percent on what caused this to happen and how can this be prevented?

Twenty-four percent with regard to treatments and interventions.

Boy, are my slides -- here about 1 percent in terms of where can I turn for help and about 3 percent on what does the future hold and roughly 4 percent was falling into that other category that I just previously mentioned.

Ms. Tepper Singer: Can you give us an example of a project that fell into other?

Dr. Hann: Certainly. Actually, you have it. If you go through the tabs in

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your notebook, you'll see they're divided up by question and the last tab is other and that provides a listing of the projects that the people who again responded to this indicated as falling in other.

Dr. Insel: There's a lot of data here.

Ms. Tepper Singer: I'm just questioning for comparative purposes whether having looked at the data that some groups self-selected as other, whether you think that if other groups had looked at this same data they might have put it into one of the six categories.

Dr. Hann: Coding data is always in the eye of the beholder in many cases.

If you're just asking for my own personal opinion, I would say yes, that some of these would have fallen into some of the six questions. Yes.

For example, there is at the bottom of the first -- bottom of page 76 of

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80, a psychometric evaluation of behavior problems inventory. I would have thought would have gone with question one, but the people responding didn't feel as though it fit.

Dr. Insel: But, even if you did include that, this is only about 4 percent of the total. So, it's not going to change the numbers hugely.

The other thing to remember is this still doesn't include the Simons data which could shift.

Lyn, before you came in, just to back up for a moment, so, we're going through the portfolio analysis of the private -- of what we've been able to capture and we have a pretty good collection, but the Simons data isn't in this group. That's still coming in and still being integrated. Everything else that we had looked for is now included. So.

Ms. Redwood: Della, I'm wondering if just for consistency since we're collecting

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data from so many different other entities if somebody on the staff here might be responsible for deciding which category so it's more consistent and we don't have so many variables in terms of deciding the categories that they fit into. Would that be feasible or is that too labor intensive?

Dr. Hann: I think that's all up to the committee to determine. Again, what we understood our charge was to get the codings from the organizations and present that.

How you all want to use that data and if you want it subsequently coded in other means, that's your decision to do, but we didn't feel comfortable moving forward and taking that kind of a step.

Ms. Redwood: I think Alison brings up a good point. That there may be some as you say, you know, the category's in the eye of the beholder. So, you know, maybe we should look back through these or maybe staff could just look over and if you think

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they're relatively correct, then let's go with it. But, if not, then maybe we should re-look at it again when we receive the assignments data.

Ms. Tepper Singer: I think at least the other. I don't know if we need to go through all the data, but I'm looking at some of these in other and I -- I mean they could -- I think they would be more illustrative if they were in the categories with other studies that were similar to them.

Dr. Insel: Does the next slide help in answering this question?

Dr. Hann: So, again, taking it now -- the data a little bit further, we though it would be useful to not only talk about again using the codings that we received from the organizations in terms of the questions, but then how they relate. How they relate to the strategic objectives in the reports? Now only does it relate to a question, but does it actually seem to hit one

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of the major objectives that was developed by the IACC?

We also asked that of the people who were doing the coding to do that. So, again, this is based on their opinion of how it rated.

But, as you can see from looking at the bar charts, for question one and question two, the proportion that's going to the strategic objectives that are listed in the IACC plan is around \$10 million. However, when we get to questions three and four, a larger proportion of what's being reported to us, they are also seeing us falling into the strategic objectives of the plan and in the next slides, we're going to go into that a little bit more in detail. Just so you know, that's what's coming up.

Dr. Insel: So, what does that mean? I mean how -- so, that -- I mean for the people who actually did the coding and who worked on this, does that mean that they said

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this really does respond to the question?

Dr. Hann: Yes.

Dr. Insel: But, it doesn't -- it's not aligned with any of the specific things that the IACC said that they wanted to accomplish?

Dr. Hann: That's correct.

Because remember, the questions themselves can be quite broad and then IACC decided on some rather specific questions and research protocols in some cases that they really wanted to see accomplished and so, that's where this breakdown falls. That people did feel, for example, for question one, that the work that they were supporting was relative to diagnostics. However, in terms of the very specific studies that the plan was calling for in terms of the diagnostic work, only a portion was hitting those very specific studies.

So, actually, why don't we flip ahead to the next slide. I think --

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Ms. Tepper Singer: Can I just ask a question about this slide?

I think it would also be very useful for this committee to see a chart like this that was exclusive to the Federal spending in that this committee really only has jurisdiction over the Federal spending. To see how the Federal spend aligns with the strategic plan.

Dr. Insel: Yes, how difficult would it be to just divide something like this up so you'd have a bar for -- so, we'd know how much is private --

Dr. Hann: Yes, we could do that.

Dr. Insel: -- and how much is public?

Dr. Hann: That's quite doable.

Dr. Insel: Okay.

Dr. Hann: Don't have it today, but it is doable. Okay.

Dr. Rice: One more follow-up. It seems -- maybe the next slide will answer

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this, but it seems kind of like the red is like the other. In that looking through some of them, they may be able to address some of the objectives. So, maybe something we'd consider is having personnel go through and trying to evaluate not every single objective, but those that are either in the red, not tied to a specific objective and the other category to see if they really do fit.

Dr. Hann: So, I'm -- okay. I understood part of what you said.

So, in terms of -- in your book, the tab that's labeled other, those are other other. Right? They don't pertain -- according to the people who provided the data, they do not pertain to a question nor to a strategic objective and what I heard earlier was the committee suggesting that they were comfortable in having staff go through that collection of, what is it, like 60 grants or something like that.

Ms. Wagner: Can I make a comment?

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Dr. Hann: Um-hum.

Ms. Wagner: Okay. I think it's important to remember that the --

Dr. Hann: Ann, you need to come to a microphone.

Ms. Wagner: As someone who did a lot of this coding, it's important to remember that this is what 2008 data? The strategic plan came after and the objectives were designed to be gaps. So, we didn't -- those were things we didn't think there was a lot going to already. So, just to remember that.

So, we're hoping, you know, obviously, more -- will be more -- so, they're very specific which is why a lot of things didn't fall into there. So.

Dr. Insel: But, I think the message, if I'm hearing this right, is that at least the other category, the ones that are at the very last tab, you would like some quality control on that. So that some of that might actually end up in another bucket in one of

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the six questions and actually just glancing at the titles and the comments, it does look like some of them are relevant.

Dr. Hann: I think there will still be a handful that don't fall.

Dr. Insel: Great. And you might expect that. That it would be actually very healthy to have people doing the things that we hadn't thought about yet.

Dr. Hann: All right.

Dr. Insel: So.

Dr. Hann: But, in terms -- going back to the bar chart, the section that's in red was codified by an organization as being relevant to the question. It's just that they didn't think it was hitting the nail on the head with regard to the specific objectives.

So, they do believe it's part of that question. That domain of that question.

Dr. Insel: And, again, a quality control question for those doing the coding. Was there a problem with people double dipping

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or anything like that? Can we assume that if they've assigned this to question two they didn't also assign the same project to question four?

Ms. Wagner: Right. You could only assign one question.

Dr. Insel: Thank you.

Dr. Hann: We asked and I do believe people complied with that. That they only assigned it to one.

So, the next set of slides then goes into further detail for each of the questions. To get a sense again for those areas that were coded as being relevant to one of the strategic objectives, we actually found out which one they thought it was relevant to and so, that's what we have here are the dollars that are affiliated in your detailed information in your books. It provides very specifically what projects fell into that area, but it was a little too much detail to try to put on a slide.

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Dr. Insel: Della, this may be hard for people who are joining us by webinar to see because this gets down to very small type and a lot of detail.

What's the plan for making this public? These slides.

Dr. Hann: They are -- after today, after our discussions today, they'll be posted and available.

Dr. Daniels: But, they need to request them.

Dr. Hann: We still don't have that?

Dr. Daniels: We can't post things on the web.

Dr. Hann: Okay. So, they'll need to be requested. We're having some 508 compliance issues with our website. So, in order for people to get them, they will have to make a request. We can't post them.

Dr. Insel: Request to whom?

Dr. Daniels: IACC public.

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Dr. Hann: To the IACC public information.

Dr. Insel: Okay. Thank you.

Dr. Hann: Okay. So, we can go through each of the questions if you'd like. I believe it sort of -- I know this was a great deal of information to go through. We tried our best to find ways to present it to you in ways that were -- would be helpful.

I think it's interesting, for example, if we go to the next slide which is how can I understand what is happening. You will see that there are several questions for which the funding organizations did not think that they had any currently active projects and again, as Ann Wagner pointed out earlier, at least for the Federal agencies, most of us were using our 2008 fiscal data which was done essentially prior to the issuance of the plan.

Question three which is what caused this to happen and can this be prevented, there was a fair number of projects

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that were lining up with various objectives that were indicated by the IACC. Particularly the last two have a fair amount of funds in them.

Ms. Redwood: Della, maybe you answered this before I arrived, but when you have projects that are funded over several years, say some of the centers, how is that broken out? Did you just do it for one year?

Dr. Hann: Yes.

Ms. Redwood: Okay.

Dr. Hann: Um-hum and we requested that similar level from the organizations that we approached. So, while an organization would say well, I'm going to give eventually.

Over the next four years, we'll be giving \$4 million dollars. We say no, no, how much did you do in the last 12 months?

Question four, move ahead, which treatments and interventions will help? Again, there is activity for each area. The last receiving right now the smallest amount

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of funding and the most significant amounts of funding going to 4.5.

Ms. Redwood: Della.

Dr. Hann: Um-hum.

Ms. Redwood: Another one and you may already have done this. Let's say, for example, we've got this one where we're wanting to spent, let me find a larger number, say 75,000 over five years or something and so far, we've only spent let's say three.

Dr. Hann: Um-hum.

Ms. Redwood: Can we break it out in terms of what our shortfalls are to see overtime with each year of these plans and what we're funding how close we are to meeting those goals? Does that make sense?

Dr. Hann: I think I understand.

Dr. Insel: Yes, I think you will next year. So, this is all pre-strategic plan and actually, I would have to say that if -- on some of these what's really striking to me is we may be already spending what we had

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planned to do with the strategic plan which makes me think that we should have had these numbers ahead of time. Because that really was to try to move the field in new directions, but it seems to me that what you really want to do with this is establish this as a baseline. Because this was 2008 and then the plan became active beginning of 2009 and then we'll want to go back next year to see how did the plan shift the way we're funding and it'll get really interesting in the year or so after that as projects are actually getting funded because it takes us about a year to move the money.

But, you're right. I think the real beauty of this would be to be able to identify the mismatch. You know, a place where we said we should be spending -- this is going to cost us 75 million and we've only allocated 5 million to something that the committee thought was really important.

That's what you want this for and

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that's really -- that's why this subcommittee is trying to do the portfolio analysis. It's to modify the plan so that then you go back to the IACC and say hey, guys, we're not getting what we said we needed in this area. Let's take it up a notch for this next revision.

Dr. Hann: So, that one, 4.5, the IACC had recommended that 75 million be devoted over a five-year span. So, that would be roughly 25 million -- 15, excuse me, a year and we have half of that for the first year.

Ms. Redwood: Areas where we're lacking already. A lot of areas we might already be ahead of schedule with regard to -- to accomplish -- even though we didn't know at the time that's what we wanted to do, we were already doing it.

Dr. Insel: 4.3 is interesting for instance. So, that was the place where we said we wanted to spend 16 million over five years, but last year, we spent 8 million. We, collectively, the whole community in one year.

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So, that -- you know, in terms of your next set of investments, it might tell you maybe that's a place that we don't need to pour a lot more into. We now ought to be looking at some of these other items.

Ms. Tepper Singer: That's also where it would be interesting to see the breakdown of the Federal spending versus the private spending.

Dr. Hann: The details for each of these is in your notebooks and it indicates who provided the -- say who the funder was as well as which question and which strategic objective it lines up with.

So, those details are -- obviously, it's way too much to go into today, but this is essentially for you to study and to look at in terms of providing that information.

Yes, it's there.

And then turning to question five, where can I turn for services, again, we have

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two of the objectives for which organizations don't believe they have anything specifically addressing those objectives. That would be 5.2 and 5.3.

And then turning finally to question 6, there are areas where the funders were not thinking that their portfolios addressed the strategic objectives, 6.2, 6.4, 6.6 and 6.7.

Dr. Insel: This is helpful. Is this what you wanted as a committee? Is this the right grain size, the right kind of information?

Ms. Redwood: I think this is wonderful and I want to applaud the staff for all the hard work they put in to getting this data. I think the other thing that we talked about doing that I don't know if we'll be able to do right now is also to look at the research once it's funded and it starts coming back in to see if it really met the mark with what we wanted it to do. Was it good data?

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Was it publishable? You know, somehow categorize that data as to whether or not it was able to really make a significant contribution to our level of knowledge about autism.

That's going to be the hard part.

To be able to classify. What do you use to really be able to evaluate?

Ms. Blackwell: I agree with Lyn.

This was a tremendous amount of work and all our staff did a really good job putting this together in a short period of time in a very comprehensive way. So, thanks to all of you.

Dr. Insel: As a funder, I really love seeing this because it's the first time -- really the first time I've been able to see all of these sources arrayed in one place. So, I'm assuming that with these Excel files you could sort by investigator and find out for investigator X whether she's supported by Autism Speaks and Simons when that data are in here as well as NIH and see whether she's

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being supported to do precisely the same things or whether there -- you know, whether there was an opportunity for coordination there that we didn't really take advantage of.

So, I can't think of any other time when we have an opportunity to do this. Where we can see it all in one place. So, I think it's really terrific.

Dr. Hann: Well, that basically is -- the last slide that we have is really -- it's just the other and we didn't try to do anything with it at this moment in time except to let you and those folks who are attending vis-a-vis the webinar know that it was roughly \$7 million that was in the other kind of categories and based off of what you've said today, we will go back through those -- that category to see if staff think that it could be lined up at least with the questions.

It may not line up with any of the specific objectives, but I think it could line up with some of the questions and we can do

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that as well as we'll be receiving the Simons data and that will change the landscape yet again in terms of their information and we can provide you that information as we get it electronically. That would probably be the easiest thing to do.

Dr. Insel: I have a thought about this which I hadn't considered before, but seeing this for the first time in this format makes me wonder whether we should really create a database that's ongoing.

So, the plan now is that you'll hit up each of these agencies or we will hit them up once a year and ask for the same data and they'll download it in some way, but in a sense, since we're collecting it ultimately into this public format anyhow, would it make sense to just have an ongoing database that would try to pull all this together. Maybe NDAR could do this and NDAR since it's so interested in providing the kind of infrastructure for all of autism research,

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should they be charged with trying to maintain a database that would allow anyone who wanted to know what science is going on or what clinical trials might be happening to search it and find out where to go or who to talk to?

Dr. Rice: I think that would be a very helpful tool particularly for collaboration. People that are interested in working or not duplicating what other people are doing in terms of getting collaboration going across research organizations as well as for our tracking purposes here and doing objectives. I think it could do a lot to help the science in general.

Dr. Insel: That might be something to take back to the IACC. It's not going to be our call, but we were hoping that NDAR would come to the next meeting in July and -- someone from NDAR. Maybe we could raise that with them.

I had just gotten a note about this from someone else asking what NIH does to

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-- like ClinicalTrials.gov which does provide the electronic home for all registered clinical trials and they're required to register whether they're pharma trials or publicly funded trials.

The problem is if you look at that in the case of depression, there are 2700 entries and no one would know how to sort through that. So, it may be that for autism we could do this in a way that would make it much more usable and actually provide some value beyond what we were looking for which was a way of just monitoring the implementation of the strategic plan and helping us to revise it.

So, if you're interested, I think that might be something that we could bring to the full committee at the next meeting.

Anything else on the portfolio analysis?

Okay. Thanks, team. Great effort. Huge amount of detail and as you

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said, this would be available by request to the AHRQ website. The IACC website. Sorry.

The next item on the agenda, we're a little bit ahead of schedule here is the request for information, the RFI and there we need some help from you about what you want in it and the timeline for getting it done.

Dr. Hann: So, just as a process, our remembrance of that discussion, when last we met, there was discussion and as well as discussion at the May 4th IACC meeting about the use of an RFI potentially to inform the strategic planning process, the updating of the strategic plan and what we had talked about, again my memory, is that what would be helpful potentially is to launch some sort of request for information and have that information available for the scientific workshops in the fall.

That was one option. I'm not saying that there was a decision on that, but that that was one of the options.

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Alternatively, the RFI could come out at any other point in time in order to update this committee since this committee is charged with providing the updates to the plan.

So, but, if we wish to do an RFI and if we do wish it to inform the scientific workshops, we have to do that rather expeditiously and get it out the door so that we have the information available for the workshops that will likely be the very end of September.

Dr. Insel: Questions about the timeline? So, that means that we've got to get serious today to decide what's in the RFI. Right?

Dr. Rice: The first question is is the RFI for revising the objectives or evaluating the progress? I think that's our first question to decide on and it seems like evaluating progress is to soon given that so many things aren't reflected in here. So, is it sufficient to just do an RFI focused on

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evaluating the objectives? That seems what's reasonable to me.

Ms. Tepper Singer: I think we already did an RFI evaluating the objective. So, after the plan came out, we did an evaluation.

Ms. Redwood: The only thing with that, Alison, is that the public never had an opportunity to comment on the final plan and what was voted and accepted on by IACC.

So, yes, we did solicit public input, but there's not been any opportunity for public input on the plan as it was approved and sent to the Secretary. So, I think that would be good to have.

Mr. Grossman: When we issue this RFI, I just want to kind of get an idea from the staff on where you stand in terms of what you think you can handle. Because we don't want to put out an RFI that's just going to totally overwhelm you and so, I mean can we make it as broad as possible because I -- I

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would like to get comment on the current plan, but also get comment on how we're going to move forward. Do you see that as feasible?

Dr. Hann: Well, I think many things can be feasible. I think from staff -- from my perspective, what is easiest to deal with is if RFIs can be broken into specific issues.

Mr. Grossman: Okay.

Dr. Hann: And asking public comment on those issue. When we asked for public comments in the past, it was incredibly broad and that made the task then of trying to take that information and distilling it into something that could be usable much more difficult.

So, I would just ask that the committee consider and think about what are the burning issues that you really want to gain, you know, information about. Knowing even if you ask something specific people can go off track and come in with other things. I

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realize that, but it does make it -- it makes it more streamlined in terms of being able to provide useful information back to the committee.

Otherwise, you will end up with however many comments we get and the committee here will need to read them all. Because if they're not somehow broken into some discrete issues, there's nothing that the staff will be able to do with it.

Dr. Insel: I think the question is what do we want to know? What do we want to ask?

I remember from the last IACC meeting there wasn't enthusiasm for a townhall meeting at this point and where we ended up -- because we had a set of options. We ended up saying we'd do an RFI and do some workshops and that's what's on there.

The workshops would be late September/early October. With the idea that perhaps next year, they would be integrated

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into IMFAR or they'd be done a long with a national meeting of some sort.

So, this year may be a kind of odd schedule, but I think the discussion we had last time that both this subcommittee and a little bit in the IACC was that it would be worth getting some additional public input before we moved to a revision in -- which will be late this calendar year for the final January submission.

Ms. Tepper Singer: Will you have data on stimulus funding by the end of September?

Dr. Insel: We'll have data on -- by the end of September, yes, we will know what we have funded from the autism RFA because it will be out by September 30. That is the fiscal year ends September 30th. So, our plan would be to have funding decisions for the -- there are two things. Actually, there's several things, but for the grand opportunity grants and the challenge grants,

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we will probably not know about who's finally going to get funded until end of August or early to mid-September.

Dr. Hann: Even that --

Dr. Insel: It's going to be tight.

Dr. Hann: -- even that will be tight because we still have -- and I realize all the institutes are doing expedited council reviews, but everything will have to go through council as well.

Dr. Insel: Right.

Dr. Hann: Before it can be announced.

Dr. Insel: So, we have a -- we'll have a council meeting to handled some of this, but that's going to be the last piece.

The earlier piece will be the autism RFA which will go to the NIMH council and that is on a faster timeline. So, that we're hoping we would have probably by the end of August. So, it's going to be tight, but

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we'll be able to -- we'll certainly have everything by September 30th at 5:00.

Now, on the RFI, what do you -- how do you want to constrain it? What's the question?

Dr. Rice: Well, it seems -- from the workshops last time, it was helpful to have the information of what people thought was important, but here if it could be more targeted of -- you know, basically, I would say rather than commenting on the plan is approve -- combining that together and commenting on the plan as approved with the -- what are the gaps here?

So, the main question to the public would be here is the plan. What do you see as missing in this plan? Do you have any additional objectives to recommend by category?

And then that would be helpful I think to the workshops to have that information.

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Ms. Redwood: I think we also -- and I agree, Cathy, that that's the most important thing, but also to see if there might be any shifting in priorities or funding from what we have in the plan as well.

Mr. Grossman: It says here that sometime in November we're going to do the update. Is that realistic and how long do you think that the update will take?

I would support that we give comment on -- through the RFI on what we've done so far, but I just kind of want to have a realistic idea if that's going to be used for the update, what the timeline is for that. Because it seems like it might be kind of tight if we're going to do that update in November and that's the planning for it.

I mean I believe it's doable, but it's going to be tight.

Dr. Hann: Well, just to clarify from again what I was thinking which is -- may not be accurate, but the RFI would inform the

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workshops and together the workshops, the RFI would then inform the updating. So, it's sort of a trickle through approach.

Ms. Tepper Singer: So, maybe we need to talk about the workshops first and then figure out what data we need for them, for the RFI.

Dr. Insel: Yes, this is an odd conversation to be having when we're kind of at the very beginning of the plan. There's not really much to point to that we want -- that we're going to be altering because we haven't even implemented yet or we will be over the course of the next few months.

Nevertheless, I mean there were some things and they're in the notebook. There were some items deferred. There were some things we said we would come back to in the sort frame of -- because we wanted to get this on the Secretary's desk at the end of January.

So, there are a few things that

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are already there in front of us that will require some attention and should be part of whatever we deal with at the workshops.

Dr. Hann: One suggestion from the May 4th IACC meeting when this was discussed was a suggestion to focus the workshops and possibly the RFI as well on those issues which are in your notebooks that were deferred.

One of tabs indicates I believe it's called deferred topics and this is the tabulation of -- during those several meetings when we were going through the plan, issues that were brought up, but that people for one reason or another felt that that was not the time.

So, for example, and again for the -- to assist those who are on the webinar, under when should I be concerned, there were three questions that were deferred. One having -- one dealing with research opportunities. Proposing outcome studies that evaluate the impact of early diagnosis on long

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term quality of life and possibly even moving that to a different section. Another on active screening and prevalent studies and a long-term objective on effectively disseminating at least one valid and efficient diagnostic instrument that is briefer, less time intensive in general clinical practice.

So, those were examples of things that were discussed during the creation and final editing of the plan, but were deferred and there are examples similar to that for each of the six questions.

Ms. Redwood: I think those are great. Della, I also think that it would be interesting to solicit feedback from the people who we select to participate in the workshops in terms of what do they think is the most promising opportunity to pursue.

I know in the past it seems like there's a great finding that comes out, but then it just sort of sits and it doesn't really get followed up upon with regard to

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funding.

So, I'd sort of like to hear from the researchers similar to what we did when we at our last meeting decided what research this past year was the most important to see how we could follow up on that, too. I think that would be something I'd like to hear more about from the researchers.

Dr. Hann: So, if we're going -- it sounds like folks want to discuss the workshops in order to help sort of map this all out. In thinking of the workshops and thinking about what the workshops accomplished, a tremendous amount of work, in the last set of workshops that were held by the committee, it seemed based off the discussions that there were some basically elements that people wanted to have discussed.

One would be portfolio analysis. The information from the portfolio analysis would contribute to that discussion.

That we would want to get

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information from funders on anything that's new. Because again particularly for the Federal folks, this is a year old -- these data are a year old and so there are new initiatives. For example, the funding through the Recovery Act that you all were just speaking about would be an example of that.

Then the scientific presentations and Lyn, I think you just mentioned that you would really like to hear from the research community what they think are the promising areas to pursue and another aspect which was built in, but I think again based off of discussions and listening to the committee and the value of having the public be part of the process is to think about a way to involve public stakeholders in this process and there's a variety of ways in which that can be done.

Again, though, we come back to what are the questions, what are the issues that we want to focus the workshops on and

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then getting into more of the details about the invitees.

In terms of looking at calendars, we've done a preliminary look and it appears that those dates, September 30th and October 1st, would be very workable from a logistical point of view here as well as giving us some time to make invitations to people. Since people's calendars fill up so quickly, we didn't feel to eager of moving that any -- to early in September as a result of that.

But, again, all of them for discussion for you to consider.

Ms. Blackwell: Can we structure the workshops according to the questions in the strategic plan? I mean I know we did it differently last time, but it seems to make more sense in this next iteration.

Dr. Insel: Sure. We can do it anyway you want. You know, I think what we're really asking is what do you -- I mean it's our responsibility to figure out how to revise

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this plan or to make recommendations for the revisions and what will be most helpful for you in getting the input you need. Both public input, scientific input, input about current funding. All of these things.

I'm hoping that once we add the Simons data we'll have the portfolio analysis pretty much locked down. So, you'll have a -- you know, then you'll really be able to say okay, this is what we're now doing and we can update that it says here with -- like we just this last week announced the early initiative which is a joint effort between NIH and Autism Speaks which is, you know, a fairly large effort that we can add in that wasn't captured in this portfolio analysis.

But, what would be helpful to you?

As Lyn mentioned, you know, are there -- you know, would it be good to hear about recent important findings that could inform a new objective? You know, was there something from IMFAR, for instance, that we should bring into

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the conversation so that we've got -- even if it isn't yet published. If it's something that is so substantial and potentially transformative rather than waiting another year before we wrap it into the plan, this is a chance to say hey, maybe we need to make an investment or we need to recommend an investment in this new area or this new opportunity.

So, if that's what you want, then we just need to give some thought as to how to capture that for this workshop and how to structure it. Certainly, we could have it around the six questions, but I don't think we want -- last time what we did is we did one day per topic and we had four topics and I don't think anybody wants to spend six days at this process at this point. So, we probably want to make it a much more compact review of each of the areas bringing forth those items that were deferred.

Because I think from everything

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I'm hearing at this meeting, that probably needs to be at the top of the list since these were things that the committee said we would get back to in sort order and already, you know, the months are piling up.

Lee.

Mr. Grossman: Yes, I'm having a hard time visualizing what this would look like. Will the people there be by invitation only? Is this going to be a big conference-style type of workshop? How do you think that this would best work?

And I know you're throwing it over to the committee, but I'm having a hard time really getting my head around how to make this most efficient.

Dr. Insel: Well, you know, we talked about this a little bit last time and we had the same discussion. Because we couldn't quite figure out, you know, it's so early in the process, how much time we wanted to spend on something. It's kind of like, you

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know, we're in the first inning and we want to review the game already. So, it's a little hard to know.

I will throw it back to the group.

I mean we could do whatever you think will be most helpful. This is really -- it's entirely to help us do our job. So, if you think that one day bringing in a group of people in a kind of scientific presentation format would be helpful, we can do that. Really whatever it is you think will give us what we need.

I think that -- Della, I think you've captured the core elements pretty well of what we've been hearing about. What people want in this and I would probably add to that the deferred items that you've already put into the package.

So, the question now is how to do this. What's their best format and I'd love to hear ideas from the subcommittee about how you want to see this structured.

Cathy.

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Dr. Rice: Well, I really like the idea of structuring it based on the existing questions, but I think we also need one level that says is there a question that we've missed. So, some sort of evaluation of the questions which could be brief. A question put to all of the workshop members basically.

But, so back to the simpler part, structuring it according to the questions and then to me, it seems like there are two main questions which is are there objectives in the current plan which no longer need to be a priority and hopefully that can be decided based on this background information, based on the portfolio analysis, the research findings, public input and then are there objectives which need to be added which can include evaluation of the public input, latest research findings and the deferred items.

So, I don't know if there's -- if we can at least agree on that there are two main questions to answer or if people have

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other ideas about that.

Ms. Tepper Singer: I think there's a third question and I think that is looking at the data that we received today and having identified the areas of the plan where there is zero or minimal funding, are there opportunities to invest in those areas? Is there good science that's ready to be funded in the areas where there are currently zeros that are already in the plan?

Dr. Rice: So, if they're in the plan. So, I guess what I'm not sure is what the role is in terms of the funding piece of it and saying okay, can we set a priority? Is that what you mean? Like let's put that up to the top. So, within each question, there's multiple objectives, but because nothing's been funded there, we're going to reorder it and say this is now priority one. Objective one is now the priority to seek out funding. Like --

Ms. Tepper Singer: I think that

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would be a secondary step. I think before we could answer that question we would need to know and maybe this is the question for the scientific workshops. Are there good studies ready to be funded in those areas or does more preliminary work need to be done so that we're ready to fund in the areas that we've already identified as priorities?

Dr. Rice: More like -- potentially refining the objective to say look it's either ready to go and this just hasn't been put forward or maybe it is saying this objective maybe isn't quite right. That maybe there's some background information.

Ms. Tepper Singer: I think that if the committee and the full IACC have said that these are priority areas and these are objectives, then we need to understand why is there no science being done there and what can we do to stimulate science in the areas that the committee has already determined to be priorities.

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Ms. Redwood: Or maybe, and this is what I mentioned earlier, to look at gaps, changes in direction with regard to priorities. Maybe there was something we thought was a priority before and it really sort of ended up not to be as high of a priority or when we looked at these initiatives, half of it's already funded in one year. So, changes with regard to priorities and also changes in funding levels.

If something, you know, had, what, a million and we wanted 75 million, then we really need to push in that area.

I'd also want to add that I think it would be really great to increase the cross talk between the scientific community, the clinical community and the stakeholders because we've got a lot of really smart parents. We've got a lot of smart clinicians.

So, I'd like to see these workshops opened up a little bit more to encompass a broader perspective than just the funders.

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Dr. Insel: I really like that idea and so, that's -- in terms of the format for the workshops, if -- rather than having this built around a set of scientific presentations and leaving it at that, if we could use these really as a kind of forum to bring those three groups together and to be thinking about how do we optimize what we've got here.

I'm a little concerned about making big changes in the plan before we have a chance to actually see where things go and while I agree with you that if something -- if we have an objective that's already being funded, it looks like maybe we don't need that objective.

There are some cases in which we put objectives into the plan because we thought they were so important not because they were complete gaps in the portfolio, but because these are things that just still really needed to get done and the fact that we

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were already invested in them was just a recognition that either Autism Speaks or one of the groups or maybe NIH recognized that that needed to be done without the strategic plan.

So, I wouldn't want us to say well, because that's being funded, we don't need to fund it anymore. Because sometimes those are the things that we're really making progress on and you don't want to -- you know, first rule here is do no harm.

But, having the portfolio analysis as a piece of this where at least the group -- those three groups that you mentioned, Lyn, and we'd have to think about who can represent them and how to do this right, but having a group look at this just as they would a business plan. It's really kind of a -- I think an unprecedented way of approaching this where you have -- we've laid out what it is we think needs to be accomplished. We can then give them what is being done.

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We can update this because if -- if we're doing the meeting at the end of September, we will have the information. If it's September 30th -- well, if it's October 1st, we will have information.

Dr. Hann: We won't have all of it.

Dr. Insel: But, we'll have -- certainly, we'll have the large piece which is the -- the big RFA for autism. That will be very clear.

So, we can add that into this picture to know what might be still missing in the investment portfolio and then hear from people about what are the things that still -- we haven't even captured yet in terms of new objectives.

So, talk to us about what you think would be the most useful format. If we bring those three groups together and we can work with you -- we can work with the whole IACC to get the right representatives from

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each group.

If we have six objectives -- at one point at the last meeting, somebody said well, maybe we should just make this one or two of the objectives rather than trying to handle all six. Although, we have deferred items in all six. So, probably will want to find a way to address each of them to some extent.

But, how do we do this in a one or two-day period? We could -- do you want to do two hours per objectives or what do you think would be the best?

Ms. Tepper Singer: I think rather than siloing them into the six different objectives, one thing we have to think about is separating implementation of the plan and updating of the plan.

I know that the law requires us to update the plan, but to your point earlier, we really haven't had very much time to implement the plan and I think one thing we need to

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really think about is now that we have all of this data that indicates where there are holes in what the IACC said were priorities, how are we going to stimulate science and scientific investment so that we are funding the priorities that have already been -- that have already gone through the process and then in addition, look at whether we need to amend or add new priorities?

So, I would like to see some of the time spent looking at some of the areas in the current plan that have little or no funding based on what we need as opposed to -- and I also agree with you. I don't think we should take out objectives that are currently funded. That's just an area to say that's great. Now we can take some of those funds and move them to areas that are at zero.

Dr. Insel: So, Alison, best way to do that? So, let's just kind of imagine what the agenda will look like.

So, let's say that we do commit to

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having this as a day and a half or a two-day workshop, how would you get at those things? What would be the best approach?

Mr. Grossman: Well, one of the ways that I look at this and how we do this when we put together workshops and conferences is put together like framing questions and in looking at this just quickly and this is just being thrown out for discussion purposes, we could have three framing questions here.

One being what have we done and since we are going to issue an RFI, what we've now heard and the third one, what needs to now happen? And I think that that would encompass just about everything that you brought up, Alison.

And so, once we have the framing questions, we can kind of formulate -- I think that that would create a momentum throughout a two-day process where people would feel engaged in a process of engagement addressing all three of these issues and then moving it

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forward. I think it would keep their attention for three days.

I think that throughout this we could have a diverse group of people that would be presenting as well and even like have general sessions broken up into plenary sessions. The general sessions would address the three framed questions and use the plenary sessions to really get into some details with other speakers.

Just throwing that out for what it's worth.

Ms. Tepper Singer: I would just add to Lyn's point, it would be nice to have the public input throughout the day as opposed to the way we've done it in the past which is saving it all for the end of the day.

Ms. Redwood: And also have the public at the table.

Dr. Insel: Well, what if we -- let me up the ante a little bit for you. What if we've created six groups of three people

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each minimum, so, one from each of your stakeholder groups and we got to them well before September 30th and gave them -- we created this sometime earlier in the month and had them work together to create a presentation that would be collective. Kind of the aggregate view of those three perspectives on each of the questions.

There would be then at least 18 people who would be participating. Since you have six questions, you could choose the people based on their expertise around each of these items and then provide for them a kind of format. So, they'd go through these, but also give us some input about what we might have missed or new opportunities or things to watch.

Would that be a workable way to do it? But, it would require -- I think what we don't want is for everybody to show up and spend a day and a half trying to figure out what they're suppose to do. It might be much

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more efficient if we could get them to do a lot of their homework ahead of time and then use this out as a chance to -- use this as a chance to report out what their conversation had been and also, get input from the rest of the group in that case.

Dr. Hann: So, in terms of that model, it sounds like there would be -- to build off of Lee's questions and maybe just tweak them a little bit.

Based off of what Lyn and Alison have said, too, would be to ask those three people to review the data for their chapter, the portfolio analysis information, any new information that the funders may have in terms of what might be going on as well as any information that came in from the RFI that's relevant to that issue and to take all of that and think about from their perspective as a clinician, as an active researcher, as a parent or at least a public stakeholder in the process, what are the gaps, what are the

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opportunities and what are the priorities.

The bases from their perspectives and they wouldn't necessarily have to come to consensus by any means. They could have different ideas that they would share then with the larger group about all of that and they would each have -- be able to do that.

Dr. Insel: So, to do that though, we'd have to provide them with this whole book.

Dr. Hann: Um-hum. Yes.

Dr. Insel: Everything that this subcommittee's been looking at.

Dr. Hann: And more.

Dr. Insel: Right. Because the devil's in the details here and I think where we've had problems in the past is we've asked people to give us suggestions about what needs to be done without really letting them know what is being done.

So, it's very hard for anybody to come to the table and try to do that unless

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they've got this in their hands.

Dr. Hann: And we would. We would provide. So, what I'm envisioning is, again, let's just break this down.

So, for question one which is primarily the diagnostic kinds of issues, that there again from what I've heard from you describing, there would be three individuals who would have knowledge, expertise, compassion, whatever for that topic. Have a valid interest in that topic and they would be given the information in the portfolio analysis that's relevant.

They could have it all, but I think what they're going to look at is question one. They would also be given the deferred items from question one. If we do an RFI, if there's information that comes in that's relevant to question one, they would given that information as well and asked to in their judgment in terms of all of that and from their own perspectives and backgrounds to

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think about the plan and the gaps, the opportunities and the priorities for the plan.

That's a lot of homework for those individuals. So, you also may want to think of a buddy system for that process. Just an idea to throw out there.

So, if you have identified three people for that, that a member of the subcommittee also be willing to work with that group to assist them in going through all of that information because that's a lot of work.

Dr. Insel: We happen to have six members of a subcommittee. So, how convenient.

Ms. Redwood: Della, we may want to also consider having some people at large and I'm thinking about adults with autism and -- and --

Dr. Hann: Well, those may be some of the stakeholders to be involved in potentially some of the questions.

Dr. Insel: Okay. Other thoughts

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about this?

Dr. Rice: Just a question. So, how would that background information be different from what we would be expecting the whole workshop group to understand? Because we would expect that when they come together and present this that we would want the workshop members to also have all of that same information.

Dr. Hann: People I think just -- I guess what I was thinking is all of the information would be available to everybody, but similar to a peer review meeting, you end up focusing then on the things that you are assigned. If you have the time and energy to look at additional items, you will, but you don't have to feel like you have to take it on.

Dr. Insel: And I think the other difference is we'd want this group also to say what's new. So, you know, you'd pick somebody at least for your scientific expert somebody

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who's very close to the cutting edge of that area, that question. So, that there may be something that wasn't here.

So, if we've got a sort of basic format for the workshop, what about the RFI? How do you want the RFI to inform this? Do we need an RFI?

Mr. Grossman: Well, I'm going to go back to the workshop just so again I can visualize. So, we have these six sessions with these three people reporting out.

How will we engage the public more in that? For the other people that are attending the workshop, what opportunities are we going to provide them to give input into what they heard from the three presenters?

Ms. Redwood: I don't know if this would work or not, Lee, but if whoever we identify as that public person for that particular question, could we funnel? If we could go out with an RFI asking for input on the plan, funnel those specific responses to

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that part of the plan to that public person and somehow have that public person be somewhat of a representative for the broader community with regard to that question. Do you think that would be too much to ask? Yes.

Mr. Grossman: Yes, I think it's a lot to ask, but when I say about getting comment, I mean there's going to be not only public members there, but there's going to be other funders. There's going to be clinicians, researchers and we need to hear from everybody and I guess what I'm trying to figure out is how we're going to get that.

Dr. Hann: Oh, I see. Well, let me see if I can be helpful for that.

So, a way to think about it is you have your group of three, provide their information. Then you also have an open discussion period after that for -- and but, this is your -- I mean I'm just throwing this out. You could have an open discussion period for the other presenter. Because remember

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you've got these other five groups of threes that are going to be there to react to and will have also shifted through information. So, they're coming in at a little bit different vantage point than other people.

And I'm assuming, maybe my assumption's wrong, these meetings would be open as well to whomever to attend and that there could also be opportunities for not only the fellow presenters to have a discussion, but then having it open for general discussion as well and to capture those ideas.

We haven't quite worked through our -- I mean we can certainly webcast and so forth the meeting, but I think in terms of doing live interaction with the people remotely, it will be a challenge, but it's certainly something that we could consider as well. At least to get their information in. Whether there can actually be a discussion essentially, but at least to get their thoughts. Those could also be brought to the

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table as well.

Ms. Redwood: It would be -- also at the end of the entire workshop dedicate a few hours or so to summarizing all of this --

Dr. Hann: Sure.

Ms. Redwood: -- and bringing it together and --

Dr. Hann: Well, what might be very useful is at that moment at the end is for you all to provide some comment, synthesis, et cetera at the end of the day. Because remember, each of you will be a buddy to one of those groups and then be there as -- you know, throughout the period of time as well.

Dr. Insel: Yes, so, I really like that idea. So, this -- in some ways, you could think of this as the convening body, this subcommittee and if we do have each of you take a role, then you would be responsible for the summary at the end and you're actually the group that will be bringing this forward

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to the IACC back on the timeline at a subsequent meeting. So, that's going to be a very important piece.

That doesn't give what you're asking for which is the -- you know, another public input period, but we could build that into the schedule.

Mr. Grossman: Well, I think the public input would be somehow incorporated in each one of those six presentations. That's how I was looking at it and I'm just trying to logistically put my mind around it.

So, we're looking at like two days of 8:30 to 4:30 and essentially with breaks and lunch and et cetera, it gives you about two hours per session. Is that enough time or an hour and half per session enough time to do the three-person panel, have the response by the rest of the panelists and then have the input?

Ms. Tepper Singer: Yes.

Mr. Grossman: Okay. I mean --

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Dr. Hann: I think -- I mean I think it is. I think it's quite -- because again if people through your buddy system working with your folks, they're all primed. They're ready to go. They've got their 20 minutes essentially to -- or less to speak. We will have any written materials that they wish to provide in terms of slides, et cetera ahead of time.

So, I think, you know, obviously it'll take a lot of work. I mean it's not going to be -- I think it'll take a lot of preparation, but I also think it could be incredibly informative and helpful.

Dr. Insel: And again, I think for us, you know, it's always the hardest thing when you do it the first time, but we're going to do this every year in some format. So, we want to create a precedent kind of -- really a framework for which we can rebuild and revisit this plan every year to see how it might be changed.

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So, this may not be perfect the first year, but at least, it'll get this thing started and we can see how to tweak it for the subsequent meetings.

Ms. Redwood: Be flexible. If this doesn't work, we'll change it next year.

Dr. Insel: Sure. Absolutely. Yes.

Dr. Hann: So, one of my staff just came up and asked. We talked about three areas of specialization. So, clinicians, researchers, public stakeholders. They were wondering if you also wanted to consider funders as a potential fourth category or just to have the information from the funders.

Dr. Rice: I'd say just to have the information. There's too much stake.

Dr. Insel: Sound like we're back to three. I don't see a lot of enthusiasm for that.

Dr. Hann: Wanted to bring it to you.

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Dr. Insel: Okay. Is there another group that does need to be brought in or -- okay.

So, talk to us about the RFI. If this is what the workshop looks like, what do you want to make sure these 18 people as well as the six that we have here know before the workshop in terms of RFI input?

Lyn.

Ms. Redwood: I'm just wondering, Tom, if we need two RFIs this year or one. I guess that's sort of the question. If we want an RFI prior to this workshop and then do we want another one at the end of the year before we move the whole plan forward?

Dr. Insel: Can we go back to the timeline? There.

Ms. Redwood: Where is it on there?

Dr. Insel: Yes, the -- oops, the RFI is beginning of -- end of July, beginning of August. It's the bottom in blue second

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box.

Dr. Hann: And actually, if we wanted to contribute to the workshops, we'd have to get it out in July.

Dr. Insel: Yes, it would -- we will. Just technically, it would have to be before the end of -- it would really be probably --

Dr. Hann: Yes. Yes.

Dr. Insel: -- mid-July at the latest.

Dr. Hann: Yes.

Dr. Insel: So, we're talking a month from now that we'd have to put it out there.

I just don't see how we can do a second one knowing that we have to -- we have to bring something to the full committee in October for the October meeting. I just don't know if there will be time to get more input and do another iteration of this.

Of course, we're going to do it

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again next year. So, it's not like this is the final change. The whole idea is to modify this every year.

Ms. Redwood: So, then I guess it would be most logical to have the RFI follow what we want each of these groups to address.

Dr. Insel: Yes, it sounds like we've got a set of questions for the groups already.

Della, is there an impediment to using those for the RFI? In the same way, you've kind of map out for us already what the presentations would look like for the group for the workshop.

Dr. Hann: So, just -- that would look like an RFI going out requesting information on the following six topic areas and we would do a brief description of the six domains of the plan referring them to the full plan by all means. They can look at that and to ask for public comment on what folks consider to be gaps, opportunities and

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priorities for the specific -- for each of the six sections. Is that -- I believe that's doable.

Dr. Insel: So, talk to us, Della.

Let's -- we've got -- so, this is now mid-June. We want to have this thing published and out by mid-July. What needs to happen between now and then to get something out that this subcommittee be comfortable with and be useful for the workshops?

Dr. Hann: We keep the RFI like I just explained it. We can, I think, pretty realistically be able to get that out by middle of July.

Generally, you want an RFI to be on the street for a minimum of 30 days. We would have to -- in order for it to feed into the scientific workshops, it would have to be close to the end of August. Absolutely. In order to give us time to take the information and feed it back out to whomever is involved, you know, to provide sufficient time for

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people.

Dr. Insel: Even more. I would say mid-August if we want to be able to turn it around. We want to give the workshop presenters at least a couple of weeks or more with that information so they can --

Dr. Hann: Well, we could fast track the development of the RFI. I think we can probably do that relatively quickly.

Ms. Tepper Singer: Is there any data on response rates to RFI based on the time of year in which you put them out? Because it seems to me that an RFI at the end of July and early August is not going to really get the number of people that we would really want to participate.

Dr. Hann: It's been my -- I've now participated in three or four RFIs for different topics and I will be very honest. An RFI draws based on the topic and it really doesn't seem to have much to do with the time of the year. If people are interested, they

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will comment and they will comment in the period of time that you suggested.

So, I don't know for those of you who followed, but NIH recently had an RFI out with regard to proposed stem cell guidelines for research. They received over 45,000 comments in less than 30 days.

Dr. Insel: Okay. So, given that, yes, so we will fast track this. We'll get something out by mid-July. Hopefully have it back 30 days later and be able to provide that as the basis for which these six groups of three will -- it will be one of the things that they can use for planning their presentation at the end of September.

Dr. Hann: So, what I would like to do if you all agree -- I mean I think the IACC has already sort of said yes, it's fine to do an RFI on this topic. Go forth and do so.

So, we can draft what the RFI will look like share with you the draft. We'll

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need to turn it around very quickly though in order to be able to get it through the system.

It usually -- it's about a five to seven-day window for clearances purposes internally to an RFI on the street. Even once you have it done, it has to go through a number of checkpoints.

So, we will try to move that forward as fast as possible and get that to you probably giving you maybe at most three days to take a look. It's short. RFIs, we try to keep them short. The whole idea is to keep it clear. Right. Because you want people to understand what it is you're asking for. So, if you take a look at it and you don't understand it, that's the kind of feedback. Also, if we forgot something, but I think we've hit the high points here. So.

And so, we'll get that on the street as rapidly as possible and put it out for 30 days from the time that we're able to post.

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Dr. Insel: So, okay. So, that's a little bit of follow-up homework for the subcommittee.

Dr. Hann: There's another one.

Dr. Insel: All right.

Dr. Hann: The other piece of homework, we will also draft the ideas that you just described today for the workshops just to make sure, you know, we're all on the same page kind of thing and I think it would be very important to start thinking of nominating people to be your buddies for your various chapters and for you each to sign up for one of the chapters as well.

Dr. Rice: I'll volunteer for three.

Ms. Blackwell: Don't we have more subcommittees members? I mean Story's not here today. Stephen's not here. Only those two? Okay.

So, some of us might have double buddies.

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Dr. Hann: You could have double.

Ms. Blackwell: Double buddies.

Okay.

Dr. Insel: Well, we could draft a few people from the full committee if necessary. Yes. I'm sure there would be people willing to do that. So, and there will be from some of the offices. Like the Office of Disabilities, there will be a new member on this committee who we could get involved as well.

Dr. Rice: I would say maybe questions three and four, it's good to have two buddies because of the size of the portfolio and information that will need to be reviewed.

Dr. Insel: Yes, great idea. Maybe for some of these we can -- clearly, there's -- it's not balanced in terms of number of objectives and the number of projects to be reviewed. So.

Dr. Hann: Well -- and actually,

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too, in that regard and it's your decisions whether you want to combine five and six.

Dr. Rice: For the five, six and other.

Dr. Hann: Well, the other one's I can try to disperse. So, I don't think we have to worry too much about the other, but chapters five and six, there are some similarities in terms of what that work is talking about and so forth and those portfolios are also small. So, it might be worthwhile to think about combining those.

Dr. Insel: Plus the expertise is probably --

Dr. Hann: Similar.

Dr. Insel: -- yes, similar enough that you could have the same people doing that.

Dr. Rice: Plus logistically that then gives you time at the end of day two for the summary.

Dr. Insel: Um-hum.

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Ms. Blackwell: Would it be worthwhile to talk about the workshops inviting the full IACC to participate and not just the subcommittee? I mean yes, that's what I think.

Dr. Hann: Yes, absolutely. It's just I'm thinking we got to get the nominations soon for the people to participate because we have to extend the invitations. So, I'm more than happy to share it with the full IACC, but I -- waiting until July 15th to get that information, I think is risky logistically.

Ms. Tepper Singer: Maybe we can do that by e-mail to the full committee so we don't have to wait until July.

Dr. Insel: I'm sorry. I missed this. You want the full committee to join in this effort. Right? We could certainly send out a note explaining what it is we're planning to do and we'll report out on this July 15th as well so they can here more of the

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details.

I think before then though. I'm getting a sense of this tight timeline. We're going to need to know who's going to be part of each of these groups and that we can do by e-mail and come to some conclusion before -- maybe July 15th, we can actually show them the slide of how this is structured and who's going to be doing what for this workshop.

Dr. Hann: So, there's sort of two levels in terms of practicalities for this. One is for you all -- Lyn's already offered the question that she would like to work on. For you all to consider which of the questions you wish to work on and provide that information to me. I can look to see where the holes should there be holes.

Then also to be considering particularly for the question that you're going to be working on who you would like to see be those three people. Providing more than one name because some people may be out

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of the country or whatever and may not be able to -- or may not want to do this work because it's a fair amount of work.

So, I think in terms of nominating the individuals to do -- all of this information will be publicly available just like everything else that we do. So, but I would like to see us get going.

Ms. Blackwell: I know yesterday Susan was kind enough to provide me with a list of folks who participated last time. So, you might want to send that around to the group as well. I needed it for something else, but it was helpful for me to just look at it again.

Dr. Hann: We would do that.

Dr. Insel: Yes, I think that's a great idea. At least on the scientific expertise part, we -- I think we're fairly well distributed and maybe we had clinicians there as well from those meetings. So, we could take a look at that.

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It would be good to get some fresh perspectives as well.

So, but that would be a good place to start and where I think we may have the most difficulty is getting the list of clinicians that could serve on this because they're not people that we'd know at NIH and they don't -- they're not represented in quite the same way here, but all the more reason why we can put our heads together to come up with that. Terrific.

So, let me make this even more onerous and say that we would love to have this done over the next week if we can do it by e-mail and just get names -- potential names. We'll do the homework of actually doing the invitations and getting the arrangements made, but we need to get started now and really the end of September is not that far away. We need to get this on people's calendars.

Dr. Hann: So, what I can do to

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help facilitate that process is if not tomorrow then certainly the day after send you a note reminding you of the homework, giving you the rosters of the previous workshops participants and asking you to sign up for a question as well as for you to provide nominations of individuals that you would see for the different questions.

Dr. Insel: Anything else about RFI or the workshop?

Let's talk a little bit about when we want to all get together again and again looking at this timeline, how we're going to shepherd this thing along so that we're finished. Really, we'll have to be finished by November because we want to be able to deliver something to the IACC for the January meeting. So, when do you want to get together as a group? We don't necessarily have to meet in person if it's -- especially as we go along, I think our tasks become more and more well defined. We can do this by phone or

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tele-conference of something.

But, give us a sense of where you think you'll want the most input from your colleagues here. Do we want to get together before -- we want to have a phone call anyway before the workshops happen.

Ms. Redwood: Tom, our next meeting of the whole IACC, that's going to be the 15th and 16th or --

Dr. Insel: Just the 15th.

Ms. Redwood: Just the 15th.

Dr. Hann: Right.

Ms. Redwood: Okay.

Dr. Insel: Right. Yes, 15th of July.

Dr. Hann: Right. The 15th of July and then the following next full IACC meeting is October the 23rd and those are the only two that are scheduled for the remainder of this calendar year at this time.

We probably will be looking to potentially have something maybe. Although, I

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think it's going to get pushed to January.

Dr. Insel: So, I think it might be helpful for us to talk before the workshops for sure. So, by that time, you'll have a sense of what the issues have been with your buddies and how to refine the presentations.

As Lee said, we won't have much time for each of these. So, they'll have to be very structured and focused.

So, what about if we were to touch base in early September or second week of September, something like that?

Ms. Redwood: What's the RFI, Della? You were saying it would go out -- or give us some time frame because it might be nice to talk after we get the input back from the RFI.

Dr. Hann: I would say roughly -- for planning purposes I would be thinking that the RFI will come back in by mid-August.

I mean as we've done with the other RFIs, we'll put the information up.

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It'll be publicly available. But, any "sort of assembling" of it in terms of the different questions and so forth like that, bundling, I would give us at least a week or two to be able to do the bundling. So, we probably won't have the bundling done until the beginning of September.

Dr. Insel: Yes, so, that's why I was thinking to delay a little bit after we get that back.

So, why don't we think about first or second week of September? Either meeting as a group or doing it as a conference call with potentially a kind of webinar. We can work that out, but I think we're going to need to have a conversation before the workshops so that we're all on the same page. Ellen.

Ms. Blackwell: We do have a townhall meeting. Is it July 24th, Lee? So, that also might help in terms of informing this whole other process. I think it's good to have this information today to think about

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how we might be able to get additional comment when we go on the road in July.

Dr. Insel: Yes, that's mostly on the services end of things. Right?

Ms. Blackwell: It is, but that's questions five and six. So.

Dr. Insel: Right. And there may be something that comes up that's more research plan related. Fine.

Anything else that we need to put on the table for this meeting?

Dr. Hann: You may want to also consider if the workshops are going to be September 30th/October 1st if this subcommittee wants to have some sort of gathering prior to the October 23rd IACC meeting to discuss what you all heard, et cetera. Just something to think about because I know you all are very busy and to get something on the calendars. So.

Ms. Tepper Singer: I think it might also be useful to the six groups if we

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had a structuring document so that all of the presentations had a similar format.

Dr. Insel: Yes, we can provide template that everybody will follow. I think we're going to have to do that to get this done in a way that is most useful.

Della, in terms of the -- what did you say October 23rd? Is that the --

Dr. Hann: That's the next --

Dr. Insel: Yes. Is there a possibility that we would meet before the IACC meeting? That is we could take an hour or two on the same day or is that going to be a full-day meeting?

Dr. Hann: That'll probably be a full-day meeting.

Dr. Insel: Lyn.

Ms. Redwood: I'm just wondering if our -- there is really no set deadline to get this back to the Secretary for updates or is -- there's a January --

Dr. Insel: Yes, it says the

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annual. So, January 26th is kind of our deadline.

Ms. Redwood: I'm wondering if we're not going to need to add in a meeting like in December logistically. I don't know if we could get all this. I mean we're looking at a sort of short time frame because if we're having the meeting September 30th/October 1st, getting all the input to be able to turn that around and present it back to the IACC in a little under three weeks, I think that's a lot to do. If that's going to be our only time. If our plan is to present it then and vote and --

Ms. Tepper Singer: What if the committee met at the conclusion of the workshops? All of the data would be fresh in our mind and we would all be there.

Dr. Hann: We'll be tired.

Ms. Tepper Singer: We'll be tired. Yes.

Dr. Insel: So, maybe -- so, if

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we're combining five and six and picking up two hours there, right, that might be a possibility if we could pull things together at least in some form.

It always happens though that there's still -- like there is today. There's still a lot of kind of -- yes, there's the residual affect of things that you still need to pull together and need to be checked. So, there will still be a lot of work to do before the 24th, but there's no reason we couldn't get together as a small group at the very end of the workshops just to make sure we've captured the main things to report out to the IACC.

Dr. Hann: I hear exactly what you're saying and I think it's really important to keep things fresh in your head for these kinds of discussions, but I also think there's a percolation effect that's also very useful.

So, you may want to consider just

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a call amongst yourselves maybe two days after or something like that. Just to -- after things crystallize.

Ms. Redwood: What if we have the staff -- hate to dump this on you guys again, but to take the information from the workshop, what was discussed, put that in some format for us to have a call maybe two weeks later and review. Would that be helpful? And that would give the amount of time for that percolation process to happen and for staff to take in that information and summarize it for us in some way.

Dr. Hann: We can certainly try to be helpful in that regard in terms of what we heard to be the gaps, the opportunities and the priorities based off of the various discussions. I mean that's what we would focus it on are those three main questions and if there were additional things that you all heard that you would be bringing that to the table.

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Dr. Insel: But, what I think I'm hearing in this is that the group wants some opportunity before October 24th to talk together about what's going to go to the IACC and maybe even to review a presentation because it's suppose to summarize the RFI, the workshops, all the conversations we've had here and it really is the moment at which we can make revisions or recommend revisions, I should say, to the full group. So, there needs to be some time for us to do that.

I am concerned, Alison, that if we try to do that right after the workshops we won't get our best thoughts to the table.

Ms. Tepper Singer: We're all there.

Dr. Insel: So, if -- yes, but we -- why don't we think about convening some sort of a conference call or some other thing where there is a document that can people can review and it ideally would be a draft of what will be presented to the IACC and then a

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chance to tweak that in a way that everybody's really comfortable with and that you feel will reflect what we heard through the RFI, through the workshops and through the conversations we've had as a subcommittee. Okay.

We'll work that out. It'll probably be -- it'll have to be, you know, sometime in probably the second week of October to find the time. I particularly like Saturday mornings, but I understand that it's not ideal for everybody. So.

Anything else before we adjourn? We got this done very quickly.

The fact that Dr. Landis isn't here shouldn't be taken as any indication of her role.

Unless there are any other questions or comments, we're adjourned. Thank you very much.

(Whereupon, the meeting was adjourned at 11:53 a.m.)

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