U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR PLANNING THE ANNUAL STRATEGIC PLAN UPDATING PROCESS TELECONFERENCE

THURSDAY, OCTOBER 15, 2009

The teleconference was held at 2:00 p.m., Thomas Insel 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, and Designated Federal Official

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

LEE GROSSMAN, Autism Society

JENNIFER G. JOHNSON, Ed.D., Administration for Children and Families

STORY C. LANDIS, Ph.D., National Institute of Neurological Disorders and Stroke

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

PRESENT (continued):

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

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

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PROCEEDINGS

2:00 p.m.

Dr. Insel: Thanks very much. This is Tom Insel and welcome to the phone call for the Subcommittee for Planning the Annual Strategic Plan Update. This is, I think, the third such meeting for the Subcommittee following up on the session that we had two weeks ago. Let's do a quick round of introductions for those on the phone know who is attending. We have Tom Insel, Della Hann, Susan Daniels is out with the flu, and we have the staff from the Office of Autism Research Coordination here at NIMH with us as well. Who else is with us on the phone? Story Landis, Alison Singer, Lee Grossman, Ellen Blackwell, Cathy Rice, Lyn Redwood. Okay, that's everyone…thanks very much everyone for joining. Story, you said you wanted to start.

Dr. Landis: I've seen that some thoughts I jotted down during the recent Interagency Autism Coordinating Committee

meeting have been posted on Katie Wright's blog. I'm really sorry that my personal reflections during the meeting have been taken out of context and are being interpreted by the community in ways that I would never intend. As a responsible and committed member of the IACC, I really apologize for the upset that this has caused and concerns it has raised. Thanks.

Dr. Insel: Okay, thank you. A range of issues that we need to take care of here and the first one is to go through the minutes of the last couple of meetings which you should have with you. They were sent out electronically in the last few days which are the minutes from June 16th and the minutes from August 5th. If you could take a look and let us know if there are any corrections or changes recommended.

Ms. Redwood: I haven't had a chance to read over those yet. Is there any way they could be deferred for approval?

Dr. Insel: We could come back to them at the end of this meeting but I'm not sure that we'll have another meeting before we report out to the IACC which is on the 23rd and it would be really helpful to have everybody's agreement to accept the minutes or to correct them if they need correcting before the 23rd so is there a way you could look through them while we're meeting now and get back to this. I may have to leave early today but Della can make sure we do that towards the end and revisit them. Besides Lyn's issue is there any other question or comments about the minutes for those of you that have looked at them? Okay, so Della we'll come back to that. Let me quickly tell you what we're about here because we have a lot of work to do. Essentially we're required to update the Strategic Plan annually and annually in this case means by January 26th of 2010. Understanding that the Plan is still in its first year and what we're talking about is

making modest revisions or tweaks to what we have we want to make sure that we've accomplished a few things – one is to deal with the deferred items from last year; second is to make sure that we incorporate ideas from the Workshop that we think the IACC should hear about; and the third would be anything else even if it's something that didn't come up at the Workshop but those that the Subcommittee feel deserves some attention. Our task is to come up with a presentation for the 23rd that will be about two hours long in the afternoon in which we could go through those three items for the six objectives of the Plan and to find a way to convey that information rather quickly, doing our best to explain what it is we heard in the Scientific Workshop and distill that down into a set of recommendations for updating the Plan. Some of this will actually involve line edits for changes in the Plan. I know at least in the panel that I was in and I heard this from some

of the other panels there were concerns about wording in the original Plan and not just in the section of the objectives but in other parts of the Plan and certainly for strategic objectives 5 and 6. I think there was an interest in doing some significant rewriting of what was in that Plan, so we need help from you as a Subcommittee to think about the best way to convey that information to the IACC. Obviously, our role here is to make some proposals to them and try to give them the best sense of what we've been hearing and what we've been talking about, but it's going to be up to the IACC to vote on this and between October 23rd and the end of January we don't have, at this point, a meeting scheduled. We have a chance to take this to them next week and the next time we come back will be when we actually want to be able to complete whatever revisions are in place. I think you said the January meeting is on the 29th so if need be we could try to bring the Committee together

earlier to make the 26th deadline or we can decide if that will be acceptable. The issue is getting them this information within a two hour presentation next Friday in a way that they can understand what it is we recommend and make sure that they have a chance to weigh in on it. What we thought we would do here is go through panel by panel and listen to the liaison people from each group and I assume each group will have about 10 minutes or at the most 15 with some discussion to be able to put in front of the IACC what they are recommending for changes. Is that workable for the group? Any concerns before we start on this?

Dr. Landis: Tom, there is a little bit of time between now and the 23rd for us to be able for each of the panels to kind of hone in on what we want to recommend?

Dr. Insel: Ideally, if we could today come up with an agreement within this Subcommittee, it's possible that we would be

able to share that with the IACC before the meeting so that they could already have an idea of what the revisions would be and then we are pretty far ahead of the curve. We have a fair chunk of the IACC on this phone call so this is a chance to get pretty far down the road. I think if we could get most of that done today in the next hour it would give us a chance to give them a heads up before the meeting.

Dr. Rice: I guess I'm trying to wrap my head around – are you saying to take everything that was discussed in the meeting and then boil it down to say what are the reasonable things to recommend from that?

Dr. Insel: I think at this point I would go forward with the actual wording and use this group to come up with a recommendation to the IACC about what we would suggest for the revision of the update of the Plan. Maybe there would be nothing recommended and we accept it as it was in

January but I don't think it would be helpful if we go back to the IACC to do what it is they asked us to do and that is the recommendation for the updates. At this point we really want to be able to take what we've heard and come up with our best ideas about what would improve the Plan as written. Again speaking for Panel 4 we actually found that there were significant typos – there were things that needed to be rewritten. There were a couple of sentences that made no sense and I think it was just in the rush to get this done in January. That's not controversial but it would be improving the Plan. Any other thoughts about how we can proceed in the next hour? I take it that part of Panel 1 is going to be late joining us.

Dr. Hann: Correct. Jennifer was going to try to join us today and she would be representing Panel 1 but she did indicate that she may be a few minutes late.

Dr. Insel: Why don't we start with

Panel 2 and who is going to walk us through the presentation from Panel 2?

Ms. Singer: I'll do it. In general Panel 2 felt that the content in Section 2 which focuses on "How Can I Understand What is Happening?" and looks at the underlying biology and pathways. Some concern was raised that no funds had yet been applied to two of the six objectives as outlined in Section 2 but we're hoping that some of the ARRA funding will go towards those objectives in Section 2. We had four action items that we wanted to recommend to be added to Section 2 – the first had to do with skin fibroblasts and leveraging that new technology to create stem cells and also we identified the need to develop standards and protocol around skin fibroblast work. Secondly, we identified a need to study non-verbal autism specifically and that there was a need to focus on individuals with cognitive disabilities in particular. Third, we identified the need to find studies

associated with genotypes with functional or social phenotypes including behavioral and medical phenotypes and we needed to better understand the difference between symptoms and behavior. The idea being that different subtypes might have underlying ideologies. And finally we identified the need to target the ideologies themselves possibly by pathway similarities and pathway differences in co-occurring conditions like autoimmune disorders including diabetes and rheumatoid arthritis. In general the panel and the discussion that took place afterwards there was a good sense that there was overall satisfaction with the content in Section 2. I also want to thank the members of Panel 2.

Dr. Insel: The way you described it sounds like these are items that would go into research opportunities or in some cases what we need. Would any of these become short term or long term objectives?

Ms. Singer: We had hoped that they

would all become short and long term objectives. One of the things that we identified that based on the information that we got looking how funding was applied to the Strategic Plan was that we were measuring the success of the Plan based on the short and long term objectives as opposed to research opportunities. We wanted to make sure that these got into the short and long term objectives so that a year from now we were measuring how well we did.

Dr. Insel: So if they were going to be objectives we also needed recommended budgets. Is that possible to do at this point from the discussion you had in the work group?

Dr. Rice: Would it be possible to send out to each of the panels the Word document that we could do a track change or modify and put specific language in.

Dr. Hann: We can do that. You can either do that as a functional work group or just you and Alison. The planning group needs

to figure out how to take all the information and put it into text so that's up to you if you want to involve your work group you could or you wouldn't have to. If someone is going to work with another chapter they should work with a liaison so everyone knows what's going on and there are seven different drafts.

Dr. Insel: I think the way to do this is to work with the liaisons. We don't want to start this process over again so I would recommend that the full IACC hear about it. What we're trying to drive towards is the actual text – the line edits that you would like to see in the document so that the IACC would be able to see what it would look like. You might have a strategic objective that might say short term over the next three years that might say repository for skin fibroblasts that can be induced pluripotent stem cells and then someone from Program will add in what budgetary requirement would be to do that.

Dr. Rice: What we're doing right now

reflects the work group's report and the best efforts to summarize that and then as an IACC member you have comments or new things or additional things that need to be added will be added in the next phase.

Dr. Insel: Right and that would be up to the full IACC. What we want right now is for you to distill whatever you heard from the Workshop and through the panel discussions that led up to that to come up with the actual text that you would recommend as a change to the document. That could include taking something that is in the document now and deleting it. What we need is an attempt to get final language that the group can look at.

Ms. Redwood: I guess I feel like I'm in sort of an awkward position because I'm the only Subcommittee member who was not on one of the panels so I'm just trying to have an opportunity to make input into what's presented to the IACC. I hear the suggestion is that I will have an opportunity at the full

committee meeting – is that correct?

Dr. Insel: Absolutely and I think if there's something that you know about that you think would be important for people to hear about as a member of this work group you could certainly bring it up today or separately leading up to the IACC meeting.

Dr. Hann: It sounds like the liaisons who worked for a particular chapter would be doing the text edits – it wouldn't be others commenting on chapters that they weren't involved with.

Dr. Insel: Alison and Cathy we're looking to you to provide the language. It sounds like essentially you're talking about four bullets if I hear you right.

Ms. Singer: Right, we had four additions and had nothing to delete.

Dr. Insel: What we need to know from you is where they will sit in this document – short term or long term. We'll take that forward to the meeting next Friday and if the

IACC in full feels that this is something that they want to include this in the update then we will get the budgetary requirements and anything else that would have to be done thereafter. That's the piece that could be done in November or December.

Ms. Blackwell: I have a question regarding the redrafts. When do they need to get to OARC in terms of getting ready for the upcoming meeting?

Dr. Hann: We would like them obviously as soon as we can but I don't expect them to appear tomorrow by any means. Since the meeting is held on Friday I think the other members of the Committee would appreciate it if they could get the information ahead of time so that they would be able to view it and then we would make copies to put in everyone's packets. Logistically speaking we would need to have everyone's into us no later than 10 a.m. on Wednesday morning.

Dr. Landis: Do all the edits need to be

copied and to whom do they need to be copied?

Dr. Hann: That needs to come back to OARC and copy the dialogue between the two of you to Susan or myself and I think that is it at this point.

Dr. Insel: Once that's collected this will go out to the full IACC so all of us will see it at that point.

Dr. Landis: If there have been significant changes in what we know is now the time to try to incorporate them?

Dr. Hann: Yes, that would be great. From my perspective ideally the changes that you give us to get back out to the Committee would be to each of the sections in your chapter as well as the opportunities and the objectives. If there are changes to any of that and changes can be additions or deletions, you indicate that in the Word version that we are going to send to you in track changes so that we can see it.

Dr. Landis: Presumably those changes

would reflect advances that we all agreed on?

Dr. Insel: They should. Those were in the 2008 advances so if there's something that happened in 2009 we haven't actually submitted that one yet and that might be what would inform the revision today. Absolutely – this is a good chance to put all of that in and gives us a chance to tell the IACC about a breakthrough that maybe not everybody would have heard of. Anything else from Panel 2? We're expecting four bullets which can essentially be a small amount of text. Alison you're not planning to do any kind of rewrite.

Ms. Singer: I'll go through that in the conversation that took place at the Workshop and see if there is any kind of plan that disagrees with the outcome of the Workshop.

Dr. Insel: Were there any deferred items?

Ms. Singer: We looked at our differed items as a panel and we decided that they did not need to be included.

Dr. Insel: Okay, perfect, we can close the loop on those things. Is there anyone on the call yet from Panel 1? Okay, how about Panel 3 – who is going to take us through that?

Dr. Landis: I can start. I think the most important thing to bring to the IACC are the recommendations that came out of the group and were discussed at length about how to approach the issue of immune responses and sensitivity to vaccination. I think that was an item that was deferred in the first version of the plan but there was quite a lengthy discussion in our panel and also at the Workshop about the best way to approach that. I think there were specific things that we could do. Did you want to add anything to that?

Mr. Grossman: I just wanted to point out the gaps that were identified around heterogeneity. Our first gap was to take further account of heterogeneity across the

spectrum and then the second gap was to identify the factors. There's quite a bit of discussion around that. In our conference call it didn't seem as though there as much time devoted as at the actual Workshop. I'm still a little bit fuzzy on the recommendations that we had made regarding the vaccine issue other than working with the full IACC to address this issue.

Dr. Landis: Lee and I have not been communicating since the Workshop about how best to do the next step which is to make edits in the document. It's pretty clear that we need to be very thoughtful about how to make the recommendations on heterogeneity both on heterogenic causes and phenotyping needing to be incorporated. Now that he and I have a clear understanding we will be communicating a lot over the next couple of days.

Dr. Insel: What would help a lot is to get real language as you look at the Plan just to see where it can be improved and especially

if you feel there needs to be different objectives – again it could be deleting ones that are there or adding ones that are not. This is a great opportunity to do that.

Dr. Landis: I think the most important thing would be for us to look specifically at the previous objectives and determine whether or not changing the wording which is what you suggested or actually adding a new one would be the best way to go. I think the recent evidence that we heard about at the Workshop is that people with similar genotypes can end up with quite different phenotypes is something we need to add to the What Do We Know piece and then build on that in the opportunities.

Dr. Insel: Okay, anything else we should talk about from Panel 3? So, Story and Lee, you'll send something to OARC over the next few days?

Dr. Landis: We'll do our best. Lee I'm going away for a meeting but I'll take it with

me and we can work on the writing. I think it will be very helpful to have the original text to have what recommendations we would make or change.

Dr. Hann: After today's call I will send each of the liaisons their respective chapters in the Word version and what the charge is in terms of the changes and the due dates.

Mr. Grossman: Story, I'll be able to put some time into it in the morning so whenever we can connect we can do that.

Dr. Landis: I think we'll be able to do a fair amount of it by email if that's okay.

Mr. Grossman: That's fine. Tom, I hope I'm not speaking out of line here but I wouldn't mind some guidance or some impression that the Planning Committee may have in terms of what was discussed in our panel. I want to make sure we are reflective not only on what we saw on our panel but what others heard or were thinking about as far as our

presentation.

Dr. Insel: Let me open that up to the rest of the work group – any feedback for Lee and Story? It certainly was a very energized conversation at the Workshop.

Ms. Redwood: I would be glad to provide feedback but it would be easiest for me to put it in writing so if we have the Word document I will be glad to provide feedback if that would be helpful.

Ms. Blackwell: Lee, were you asking for feedback from the discussion in the meeting?

Mr. Grossman: After this phone call, anything we can get certainly would be helpful.

Ms. Singer: There were three things that I took away from the discussion of Panel 3. One, Story talked about a little bit about heterogeneity but the second one was really a lively discussion on how we need to focus on preventing the negative aspects of autism and focus on the debilitating portions and how

we're going to use research to reduce disability relative to autism. And finally I came away thinking that the panelists were in general in favor of maintaining the existing language and that there was really no new information presented that would recommend changing the recommendations on vaccine research and that there was nothing new to warrant such a change.

Ms. Blackwell: I think it's less about limiting disabilities than it is more about maximizing quality of life. I think that's more what your panel was aiming for, Lee.

Mr. Grossman: In all the notes and writing that I took that's exactly how I expressed it.

Dr. Johnson: This is Jennifer Johnson with ACF.

Dr. Insel: Welcome. We're working on Panel 3 but we will move back to Panel 1 in just a minute.

Ms. Redwood: Lee, I also think there

was not much focus on environmental factors and we did not have much expertise around the table with regard to toxicology. I think if we're going to look at some of these immune system abnormalities and findings that it would be interesting to try to link those to some of the environmental toxicants that we know cause immune abnormalities and we can look back at problems we see in our children and whether or not we can do some more sophisticated testing to be able to identify what environmental factors play a role in autism.

Dr. Landis: One of the topics that we actually did discuss ahead of time was trying to be open to the notion of a broader search for environmental factors and we may not have the most bang for our buck but we continue to focus on some of the factors that come up again and again. I would also discuss the fact that NINDS has a very broad epidemiological study in Norway where we look

at mothers before they even get pregnant and there's an extraordinary repertoire of biological examples that are already coming out of that study so I think there will be wonderful human material linking exposure and outcome that will be able to build on in the next couple of years.

Ms. Redwood: My only comment would be that it would be important to look at that in the U.S. as well because the environmental factors in Norway may be completely different. I think it is difficult to draw parallel to other countries and what we're exposed to here in the U.S.

Dr. Landis: I absolutely agree, Lyn – I was thinking that we've kind of got an experiment going with the Norway sample and it could guide how we would do directed studies in this country.

Ms. Blackwell: I was just looking over this section of the Plan and it looks like it could use updating so you and Lee might want

to take a look at this section, Story.

Dr. Landis: I absolutely agree and that's why I asked Tom how much attention we should pay to the "What Do We Know" piece.

Dr. Insel: The other thing that hasn't come up that I heard was some concern about the imbalance between support for genetic research versus environmental research and the issues around funding studies and that hasn't been a large focus and then after the panel presentation was a question about how much regularity to put in the recommendation and I think what I heard from some people is that they didn't think the recommendation should be changed and potential vaccine factors might be something that someone would want to be put in there. Some felt there was a need to clarify this because it was an area that needed to be verified and it's not that different from where we were a year ago but we once again heard much about that debate.

Ms. Redwood: I think there are

recommendations that have come out of NVAC for specific vaccine-related research but the only problem is they have no money so I think including those in the Plan as Story recommended would be helpful.

Dr. Rice: One more thing to add that I heard was also in terms of some of the objectives that do talk about environmental factors being a little more specific and maybe not about the specific factors but about the outcomes and how is the outcome of autism different from other outcomes that may be related to autoimmune disorders -- so thinking of terms of distinguishing the outcome.

Dr. Insel: Cathy, is that something you could work into the language because I think that's a great point that did come up in the discussion.

Dr. Rice: Yeah I guess I would just send that back to Lee and Story in terms of when they're thinking of tweaking some of the objectives.

Dr. Insel: That's a great point.

Mr. Grossman: That is a great point and I don't recall any amount of energy associated with that and I don't think environmental health has been addressed adequately in autism and across all disabilities so if we could find a way to jump start that I think we'll have an immediate benefit in autism as well as other conditions and certainly in potential immune deficiencies.

Dr. Insel: Is there anything else we can provide to Lee and Story that would be useful?

Dr. Landis: If Cathy could just go over that issue briefly I wanted to jot some notes down or just even repeat the sentence.

Dr. Rice: When we're talking about environmental factors basically we're looking at controlled group and comparison group issues but that we consider the overlap of health outcomes both in terms of comorbidities in terms of other conditions that might be

affected by the same environmental factors. I'm speaking very broadly because we have so far that we need to go in terms of disentangling what they are but saying this particular factor exposure and focusing on the outcome of being particular autism symptoms that overlaps conditions or we're talking about the whole package of the syndrome of autism and how might that play into separate conditions. The example that came up was autoimmune disorders. In terms of some children are those overlapping autism and autoimmune disorders? That's sort of a broad not very clear take of what I remember in the discussion.

Ms. Redwood: The other thing would be if we could focus on a mechanistic based biomarker that we could use to be able to better assess some of the environmental toxicants and pollutants. If we could use some animal models or cellular models to develop some mechanistic based biomarkers

which we heard over and over again throughout the Workshop I think that would help us to better be able to assess environmental toxicants and what type of symptom profile they may present with.

Dr. Insel: Anything else for Panel 3? If not let's move on to Panel 1. So Jennifer and Yvette – if you could quickly take us through what you're thinking about in terms of Panel 1 and changes you want to make to the text or to the objectives or to anything else. We could try to give you some feedback if that would be helpful.

Dr. Johnson: Yvette and I worked on what was in the 2009 Strategic Plan and then the recommendation coming out from the Panel and we concluded that there weren't significant changes per se. They weren't saying to take the Strategic Plan in another direction for this particular question but really the need to focus it more. The original Plan has some rather broad

objectives, both short term and long term, and, again, what this Panel did was make recommendations that focused that a little bit more. I think we were both pretty comfortable with what the recommendations were and that they covered a broad array of areas and that there weren't any gaps in what was really being recommended from the Panel. We also concluded that the emphasis for this question or that the age span would be covered under this area where originally it was conceptualized that in the earlier childhood you could diagnose a child the better their outcomes would be and in the long term the reality is that there's people across the age span that are being diagnosed with autism spectrum or maybe the need to have a reassessment or new issues are emerging for them. That was a change from this Panel for this area to really focus across the lifespan and not just in early childhood. Yvette, do you have anything that you want to add?

Dr. Janvier: Also the group seemed to want to kind of up the ante a little bit with the aspirational goal and I remember very vividly Story telling me how boring I was when we came up with the original aspirational goal so we were looking to change the wording of that and it states that children with ASD will be identified through reliable methods during a preclinical stage before ASD behavioral characteristics are present and people who have ASD will be detected at the point when ASD characteristics are observable across the lifespan. That would address what Jennifer alluded to that we had Paula Durbin-Westby from Self Advocates very actively participating with our group and kind of changed the focus a bit and we also had Geri Dawson talking about some of the work that's going on with prenatal markers and markers in infancy.

Dr. Insel: I think I have the text that you worked on but I don't know if that's been

shared with others.

Dr. Hann: Jennifer I believe you sent it to everybody on the Subcommittee, correct?

Dr. Johnson: I did – I just replied to the email that you sent out.

Dr. Insel: For the short term objectives you were going from two bullets to thirteen and I remember when we did the original bullets we spent a lot of time thinking about the verbs because we wanted to have something that was accountable. The question would be whether we got that and if it is something that we know when we've done it. I guess I would want to feedback that you think through because essentially there are eleven more than we had when we started.

Dr. Johnson: Some of it had to do with the folks that were on our Panel and their personal research. For example, there's one here about broadband developmental screening and that could be under existing tools but that comes directly out of Debbie Fein's work.

Also we have on developmental trajectories and this comes out of Catherine Lord's recent work.

Dr. Insel: I think we have to be really careful not to turn the Strategic Plan into an entitlement for research communities that have had a chance to write it. Without implicating any individual I just want us to take this to a different level and they may have very good reasons for their recommendations but our job is going to be to take this to a level where it's not quite specified and you certainly don't want to put out a Plan that then becomes the rationale for a specific individual who had some role here and getting funded later. I would just recommend that you look at this very carefully to make sure we're keeping this at the 30,000 foot level and that it doesn't target any individual's research as being something necessarily that we have to support.

Dr. Johnson: I think you could certainly look across those 13 objectives and

find themes within those and that could be easily done to better group them and make them more summative and global in nature.

Dr. Insel: Maybe some of that could be shown parenthetically but I'd feel better if we could keep the objectives down to something a little more manageable.

Dr. Johnson: We also had discussions that you could have the greatest screening tools in the world but if it's not being utilized or implemented it is a problem. Getting the people to use the tools is a challenge. Also we got into a discussion about co-occurring medical conditions that really was not at all in the original concept and biological signatures that overlapped with other Panels which is Panel 2 and even the lifespan identification – that to me was addressed more in the other panels so we sort of picked up some overlaps.

Dr. Insel: The Subcommittee can help with that to the extent that there may be some

redundancy. The biomarker issue comes up several times in different parts of the Plan so we do want to think about how to specify that. I would encourage you just to be a little more specific so that it's clear that it isn't the same thing that comes up later.

Dr. Hann: Jennifer and Yvette – at the very beginning of today's call we talked about liaisons and their tasks and essentially between now and Wednesday morning and you've already taken a step towards that in terms of the document being prepared and circulated but for the two of you, you will receive chapter 1 in a Word format and we're asking that you provide text edits through Word so that you're showing those areas that need to be deleted. We can then provide that back to the committee and that would become the focus of your short presentation at the full committee meeting about what is being recommended for changes in terms of Chapter 1. I'll be sending out that email right after the conclusion of today's

meeting but I just wanted you all to be aware of what the next phases were.

Dr. Insel: Anything else for Panel 1?

Dr. Johnson: I guess I would be curious about people's reactions to some of the recommendations. Are there any thoughts on the aspirational goals?

Ms. Blackwell: I would certainly suggest that we take a lifespan in perspective and diagnosis. Panel 5 acknowledged one item in a new short term objective which was to develop a method to identify adults across the spectrum who may not be diagnosed or are misdiagnosed because we thought that Panel 1 would be dealing with diagnosis itself including adults. So I think that's a great direction to head in. Lee, do you have any comments on that?

Mr. Grossman: No I agree with what you're saying there Ellen.

Ms. Singer: I think if we're going to go ahead with the change and I know we haven't

talked about Panel 5 yet, but to change Panel 5 to read “What to Achieve for Adults.” I think we have to single out adults because they are being underrepresented or we have to take a lifespan issue throughout the entire Strategic Plan. I think if we’re doing both of those things it’s not going to give enough emphasis to the needs of adults. I think we have to choose one or the other.

Dr. Insel: Alison what do you think about the wording in this aspirational goal?

Ms. Singer: I would like to better look at it and I would like to come back to this after we make the changes that we want to make to section 6 and see how we’re going to incorporate that wording in there and then maybe we can come back and revisit some of the lifespan questions.

Dr. Janvier: I agree with Alison with regard to the original concept being applied to adults and I also felt that Panel 1 was really focusing on early identification so

that we wouldn't have people at 4 years old being identified.

Dr. Insel: This is an opportunity when you present this to the IACC to provide that. I don't think we have to provide them with a finished document but what we have to do is give them a draft of what we're recommending but we can also share the complexity of any of these things so they can get a sense of what the whole discussion was about.

Ms. Redwood: I agree with Yvette and Alison and I would like to see a lifespan perspective throughout the document.

Dr. Insel: Okay, Panel 4 – Stephen, are you on the phone? I'll go ahead and get started because I know it will take more time to do 5 and 6. We had a terrific go through of Panel 4 and I think the first thing that happened was recognition that there were just some things left out in the interventions discussions and there was almost nothing in the original Plan on interventions for adults

nor was there anything on interventions for non-verbal people on the spectrum. The discussion started by really focusing on those as two areas of opportunities and particularly around new technologies that could be developed for non-verbal people with ASD and we heard about an opportunity to provide some of the research that's really needed around devices and technologies for everything from communication social skills and cognitive mediation and support. The other big opportunity that came up in the discussion was comparative effectiveness which really wasn't so much in the discussion in 2008 but has become a much bigger issue in 2009 with health care reform on the agenda and the need for trials to look at why they used treatment and compare active treatments. Also the need for doing trials on administrative data and registries which can be used in this comparative effectiveness agenda and it was pointed out that there's quite a bit of new

money that's being put aside just for that. So in the interventions arena people saw that as an opportunity that we didn't have when we did the original Plan. In another way of an opportunity it was recognized when we did the original Plan that we were beginning to see some molecularly based treatments such as Fragile X. A lot of that has just happened in the last 4 to 6 months and people thought that we should reflect some place in the Plan that this is happening and this is a very exciting new area that ought to be identified as a new opportunity. The group looked at the recommendations and thought that the language wasn't efficient. They just didn't like the way that the bullets were laid out because they confused several issues. They confused the need for biomarkers with the need for studies across the lifespan and studies in various groups. They recommended consolidating the bullets and we actually did a text edit in a way that essentially pulls

the need for clinical trials across several different groups and age spans and to make that essentially one bullet. They wanted to incorporate the need for biomarkers in each of those studies so at the end we would have some idea about who was responding and how to predict who would respond to which intervention. They felt that could be done up front rather than separate that out as separate bullets and then those kinds of measures be incorporated into all of the RCT's. They also felt the outcome measures ought to be identified and they wanted to make sure they were quality of life and functional outcome measures added to all of the RCT's including those in children but specifically for adults. I think those were the major points. There was some discussion about creating sort of more powerful language around heterogeneity so that was clearly an area that was focused on but a lot of what we heard was actually very similar to what was brought up

on other panels – the lifespan approach and the need to include adults in these studies and the need to focus on the heterogeneity piece. The only thing I would add here was an emphasis on personalized medicine and personalized information using biomarkers to predict response. In terms of actual objectives besides the rewriting of those first few objectives to make them a little bit clearer we'll send you this text so you can see what it looks like and also putting in an RCT proposal for adults on the spectrum. There really weren't any other specific objectives. What I've just told you is what Steven and I cooked up together so I think that probably reflects as best I can both the panel's discussion and the emails that Steven and I sent back and forth. Any questions or comments about that? We actually did the text edits as a group because there was a pretty good consensus about what needed to happen in interventions so we really did try to go back

and work with the original language. There was one deferred issue with us which the group really didn't want to deal with – it was something around seizure control and they thought that was too specific a level so they wanted to keep it more general.

Ms. Singer: There was also some discussion during that panel about possibly using the treatment studies to elucidate information about mechanism of action and the need to learn from response or lack of response to interventions. Maybe that's something that can go into the "What Do We Need."

Dr. Insel: Great point and it was something we talked about on the panel but came up in the discussion so that would be a good thing to add into the text. In a way it is sort of related to the personalized medicine part of it. It's interesting when you realize that a lot of things like comparative effectiveness and this

personalized medicine approach was just not so much on the table 18 months ago so we'll look at the text for that as well. Anything else for Panel 4?

Dr. Johnson: One of the questions that came up in our panel was the relationship between the diagnostic evaluation and the intervention itself. It possibly could fit in other panels so I don't know if that came up in your panel or if it's worth introducing it or discussing it further.

Dr. Insel: I guess the way we talked about it mostly was in terms of heterogeneity but I should have clarified because the term biomarker was broadened to be more than just biological samples – it could also be clinical history or family history factors or a whole series of what we call moderators. We didn't actually talk about trying to draw lines between diagnostic subtypes and specific interventions – it was more thinking about interventions kind of at an individual level

or that's why we call it personalized. What about Panel 5?

Ms. Blackwell: Our panel had both question 5 and question 6. I believe that the slides that we presented are actually track changed versions of what's presently in the Strategic Plan so Della I can provide you with the document but I think the slides already have the track changes in them. We actually did work with a Word document when we were working on both Chapter 5 and Chapter 6 and made recommendations in the slides for research opportunities, changes. We had some small edits in Chapter 5 for the aspirational goal, we clarified some of the research opportunities and we added several research opportunities. We felt that Chapter 5 was not as well developed as some of the other chapters so we fattened it up a little bit. We did the same with the short term objectives – one is already in process and we certainly didn't want to make too many changes to

objectives that were already in the Plan other than clarify so we clarified the two short term objectives in Chapter 5, we added a few short term objectives, and we again clarified the long term objectives that are presently in the Plan. Also we did have some contributions as far as perhaps augmenting "What Do We Know" and "What Do We Need" so I'd be happy to try to integrate those suggestions into the text that are in the present Strategic Plan.

Dr. Hann: While we were talking I was told by my staff up here that we do have your marked up Word version so I will send that back to you and you can add or delete whatever you need to do.

Ms. Blackwell: The one thing we did not submit were text changes so I think it would be worth going back to take my group's ideas and integrate some of the larger principals into that text. As far as Chapter 6 I don't know what to say Alison – we had discussion about what this chapter was and I think it

came up at the end of the Scientific Workshop that when we read this chapter the way that it is I think Peter Gerhardt alluded to the fact that most of it is directed at adults and the group felt that it was also very important to acknowledge the need of transitioning youth. That is one reason why I suggested clarifying this chapter and I would like to say that another thing we talked about and you alluded to the fact that this chapter might just be a catch-all for some things that didn't fit elsewhere but I'd like to propose an infrastructure section in the Plan for the ideas and objectives that don't fit anywhere – for example the database objectives – I've seen other Strategic Plans that do that and I think that would clarify some issues surrounding the data collection in What Does the Future Hold that might make the Plan fit together a little bit more neatly. The group felt rather strongly after all the materials came in both from the Town Hall and the

Services Subcommittee RFI and the RFI on the Strategic Plan that there was a general consensus that adults in transitioning youth especially because they are generally served through different service systems than the child in adolescent population have a special focus so that was our recommendation and we clarified the title of the chapter and also expanded the aspirational goal somewhat, clarified the present research opportunities and the short and long term objectives that are in the Plan. We felt that this chapter had the short straw the last time so the group added additional short term objectives and also some additional long term objectives that were consistent with other parts of the Plan.

Ms. Singer: I agree with what you're saying Ellen although I don't recall that was the intention of question 6 when we wrote it. I think it makes sense in light of the feedback that we've gotten from all of the public input and the Town Hall and the panels

but just from a very practical standpoint when we're doing this exercise next year and we're looking at studies that are attached to various objectives in the Plan if we have a lifespan theme throughout the Plan and then we have a specific section of the Plan that only focuses on adults we're going to come up with the issue of where are we going to put studies that focus on adults. Are they going to be tracked in the various lifespan questions or are they going to be tracked specifically in the adult section? I also agree with your suggestion of having an infrastructure section. I think you correctly pointed out that in section 6 right now half of the short term objectives and a third of the long term objectives are focused on the future but are not focused on the infrastructure. I also think there were a lot of general themes that came up over the course of the two days of the Scientific Workshop that have no place to go with an existing infrastructure that could go

into a section that was marked infrastructure or other. Some of these themes could include the need to expand the work force to encourage more scientists and providers that enter the field and we talked about the need to speed the research on some, and we talked about the ethics and risk communication, and we talked about needing to possibly have a meeting or a workshop to try to reach some sort of consensus on more symptoms to target on treatment studies, and we talked about the need to focus on replication studies so I think there are a lot of things that could go into an infrastructure section.

Dr. Rice: I agree with your summary Alison and another thing that I don't think we had a good place to put it and it's sort of a core to understanding the issues are the prevalence studies that currently are represented in the current Plan. I don't know if that should be put into infrastructure or we need to think about where to put it but it

really didn't have a home.

Mr. Grossman: Let me make a case for having this section on adults. We support any of the research and services that would involve lifespan but I'm not sure where vocational services, residential services, employment, long term issues, aging, etcetera would fit and it might become lost if we try to deal with it in the lifespan issue. I think the fact that we haven't addressed adult issues well enough result in the fact that we've lumped it into lifespan. The greatest costs in autism are in adult services and it's been a group that's been entirely underserved. In the system that is in place their failures create a perfect storm of the crisis we have in adult services now and I feel strongly that we need to have a specific emphasis on adults otherwise it's going to get lost again and we're not going to solve the issues that we're dealing with.

Dr. Hann: Any other comments for Ellen

with regard to Chapter 6? First of all Tom had to leave because he had to go catch a plane so I'll be summing it up and closing out this call. So it sounds as though from the discussion that we just had there is a consensus from this Subcommittee that there is an additional chapter – I'll call it Chapter 7 for lack of better words – that talks about infrastructure needs to support autism research.

Ms. Blackwell: I wasn't actually sure if it was a chapter or if it was a piece of the Plan. Does anyone else have thoughts about that?

Dr. Johnson: One of the things that has come to mind is whether there are certain criteria or guiding principles that need to be reflected throughout all panels and whether some of these things like expanding the lifespan. I question whether it needs to be a separate section or just principles that are conveyed throughout all of the Plan.

Dr. Hann: It's interesting that you mention that because the introductory chapter of the current Plan does include sections that relate to principles and cross-cutting themes in the current version. The themes that are included in there are heterogeneity, prevention, early detection, the lifespan perspective, and then there's one on data sharing, another on resources which looks like it's mostly focused on repositories, public private partnerships and community engagement in ASD research. So that's currently in the introductory section of the Plan.

Ms. Singer: The reason I felt it needed to be a separate section is because of the way we are tracking our progress of the Strategic Plan. Right now we are looking at studies that are funded against only the short and long term objectives so if we're going to continue with that metric for next year then really everything that we've identified as a priority needs to be stated in a short or long

term objective so that we can measure our progress. On the other hand the other choice would be in addition to tracking the short and long term objectives as part of our success metric is going to be how well we're doing across the overarching themes which we didn't do this year but we can decide as a group that we want to do next year but I think if we've identified as a Workshop group these are priorities we have to somehow get them into the Plan in a way in which we can measure our progress against them and not just say because they don't fall in one of the six questions we're not going to track our progress. I think we need to do one or the other of those two things.

Ms. Blackwell: I agree with Alison – I think they do need to be treated in a way that whether they are a chapter or a section or whatever we decide in a manner that we are able to track them going forward and attach monetary funding to them and the way we have

other items planned. I just don't know if that's a chapter or a section or what it is.

Dr. Landis: It's always very hard to know where to put those infrastructure kinds of things but I do agree that it would be good to be able to track activities and successes.

Dr. Johnson: I also agree that it would be good to track progress and I understand that obviously having specific items to track makes that easier but I guess the question I have is whether some of these things need to be embedded into the research that would be conducted. There needs to be some sort of these notions across the panels themselves. That was why I am wondering if they need to be embedded in guiding principles or if that makes it harder to track.

Dr. Landis: You may not want to have lifespan tracked in each of the different panels. Maybe that's a topic for the meeting of the IACC to try to figure out and maybe people could work up two different proposals

with the implicit directive that no matter what happens we need to track it.

Ms. Blackwell: Della is that something that OARC can work on before the meeting next week?

Dr. Hann: I know in today's call we walked through a number of themes and we would want to confirm what the themes are and I think also what we might also want to do is to look at the existing cross-cutting themes to see whether or not those were already there because I think a couple of them were and what I'm hearing as the models is we have a current model where we have cross-cutting themes sitting in the first chapter and what I'm hearing is if that's a possibility we would need to find some metrics or some way of measuring progress with them if they stay there. Alternatively they could be moved and have a separate chapter where objectives would need to be developed to address these various themes so they would have dates, they would

have dollars, etc. Is that the two models? We can draft up what we heard to be the themes, shoot that back to you all to make sure that we capture what were the themes and we could certainly say that these would be the two models and open it up for discussion during the discussion of the Plan if that's the way the Committee would like to proceed. Okay, that's what we'll do. Just to circle back on a couple of things – Alison you had at one point expressed an interest in potentially going back to the new aspirational goal for Panel 1 based on the discussion that we just had about Chapters 5 and 6. Do you wish to revisit that?

Ms. Singer: No. I think a decision will have to be made by the broader IACC. I think all of the panelists interpret that Chapter 6 as being intended to focus on adults so I think it does make sense to strengthen it that way and to clarify it and I also think it makes sense that we need to focus on adults

and they've been underrepresented and they do have different and intense needs for services that have not been addressed. I think if we focus on that we then have to go back and make sure that the rest of the Plan is sifted with the fact that we've singled out adults in their own section.

Ms. Blackwell: I can say because my team had both question 5 and question 6 we did take that approach to question 5. When we understood that Chapter 6 or interpreted Chapter 6 the way we did we revised the question in Chapter 5 to make sure that they were consistent with that approach.

Ms. Singer: For example, if you have a whole chapter focused on adults then in section 1 I think you do have to focus on children. You have to call out the need to improve diagnostic criteria for children and individuals across the lifespan. Otherwise no other place will focus on children. When Question 6 was a lifespan question then

everyone was included in there. Now I think we just have to go back and make sure that maybe in the first iteration of the Plan we under emphasized adults but we need to correct that but we have to be sure that we now focus on the need for early detection and early intervention.

Ms. Blackwell: We actually did not try to adjust any of the diagnosis of adults in Chapter 6. We talked about diagnosis but we didn't talk about identification.

Dr. Hann: What I'm hearing from this discussion is a real need now for the Panel to do what needs to be done and to look at it in totality.

Ms. Singer: We've done this chapter by chapter and I just want to make sure that someone is going to read the entire Plan and the story is totally consistent.

Dr. Hann: Absolutely and that will be one of the next steps.

Ms. Blackwell: I have another question

– we have our meeting coming up next week and I thought I heard you say that each panel chair will have to make a presentation for the findings at the next full IACC meeting. Are you planning to provide us with some sort of templates to do that by PowerPoint or some other way or do you just want us to provide our input.

Dr. Hann: OARC will have to take that into consideration because we're going to be working with you obviously to get your line edits back and that will really be the jist of it. We want the IACC to actually see those line edits. To the extent that this is out in time for people to take a look at it, it may just be the liaison needs to just verbally describe as you did today essentially what the major issues are. Now having the text before you it will be easier to follow. As you will remember what we did before with the Plan when we worked on it last winter we were able to show that on the screen so people in the

audience could follow along as well.

Ms. Blackwell: I'm sending a big shout out to my group for doing the track changes.

Dr. Hann: The other follow back item that I had was to come back to the minutes for the Subcommittee. Lyn – did you have any comments or suggestions with regards to the minutes?

Ms. Redwood: No, they look fine but the only thing on the call there may have been some mix up with whose voice was recommending who.

Dr. Hann: If you could tell us what page you are looking at and which ones.

Ms. Redwood: Can I email it to you because I would have to go back and open up the PDF again.

Ms. Blackwell: They don't have page numbers on them Della. The second one – August 5th I think is the one Lyn is referring to. If I count the pages – on page 4 on which treatments and interventions will help there's

actually a parens that wasn't meant to be left in here.

Dr Hann: Thank you. Lyn, if there was something that was attributed to you that is incorrect, let me know. And if you find any others if you could send them to us today that would be helpful.

Dr. Landis: I don't know what the plan will be for the next revision but if this is what we're going to do going forward if I and the members of my panel had a better grasp the ultimate thing would be to edit the current Plan we might have gone about it a little differently so really good lessons learned and it will be interesting to see how we choose to do this next year.

Dr. Hann: I think this was a work in progress in terms of trying to figure out how to do this.

Ms. Blackwell: I would just like to reiterate that our group – we really did a yeoman's job here – we had two questions and

the group recommended that the questions be split because it was a lot of work having two questions.

Dr. Landis: I don't mean to say that our panel didn't do a good job – we did a great job but it was more broad-reaching and not as focused on the specific task at hand. Lee and I will be working hard to rein in what our panel did and focus on revising the Plan.

Dr. Johnson: I agree and I think from the OARC perspective we would appreciate a little more generous timeline to be able to help the people for next year's process.

Ms. Blackwell: Maybe one of our lessons learned is that we need to be heard a little bit earlier because it was really intense – at least for our group – trying to get all of that rewritten. I think they did a great job but it was really intense. Christine and I asked a lot from our panel and yes, they came through, but it was intense.

Dr. Hann: I think that will be

something for the Subcommittee to take up as this revision the ink is at least capped but we'll probably need to have a Subcommittee meeting to have a discussion about lessons learned and how to map out next year.

Dr. Rice: I have to sign off now but thank you.

Dr. Hann: Thanks for joining us Cathy. Are there any other items as we've run through everything on the agenda actually with a few minutes to spare?

Dr. Johnson: Do we have an agenda for our meeting on the 23rd yet?

Dr. Hann: Yes we have a working agenda that we need to put the final touches on so we hope to get that out within the next day or two. It will probably go until about 3:30 or 4:00. My team is saying 5:00. We do have a very full agenda. The meeting will be held at the NIH campus so you will need to go through NIH security and may need to give yourself a little extra breathing room in the morning.

It will be a 9:00 start time. Any other comments or questions? Terrific – we are adjourned – thank you very much.