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SUBCOMMITTEE FOR
BASIC AND TRANSLATIONAL RESEARCH

STRATEGIC PLAN QUESTION 7 PLANNING GROUP

CONFERENCE CALL

FRIDAY, OCTOBER 12, 2012

The External Planning Group convened via teleconference, Donna M. Kimbark, Ph.D., *Chair*, presiding.

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PROCEEDINGS:

Operator: Good morning, and thank you all for standing by. All participants will be able to listen only throughout the duration of today's conference call. Today's call is being recorded. If anyone has any objections, you may disconnect at this time.

And now I will turn the call over to your first speaker for today, Ms. Gemma Weiblinger. Ma’am you may begin.

Ms. Gemma Weiblinger: Thank you. Hello, everyone. My name is Gemma Weiblinger, as the operator said, and I am temporarily acting as the designated Federal official for Dr. Susan Daniels, who is currently out on maternity leave.

Welcome to our conference call to discuss the update for Question Number 7 of the Interagency Autism Coordinating Committee Strategic Plan of 2011: What other infrastructure and surveillance needs must be met?

I will now turn the call over to Dr. Donna Kimbark, who will lead the discussion. Dr. Kimbark?

Dr. Donna Kimbark: Hi. Thank you. Thank you very much.

So over the past week or so, we have gotten some updates from everyone. And I wanted to know if you wanted to go over the – each one of these individually or if you would like to go over – what Sarah Rhodes sent out to us. She compiled everything for us, and we could go over that and see if there are any comments or revisions to what people have put together so far.

Anyone have any thoughts about that?

Dr. Catherine Rice: Donna, this is Cathy. Could you just tell us for this call, what are we hoping to accomplish in these two hours? Is it agreeing on the text or the general content for the workshop? What are we trying to –

Dr. Kimbark: I'm not even sure about the workshop yet. I haven't heard a lot about the

workshop at this point. What I thought that we would do is look at what everyone has put together and see if we have actually captured what we wanted to capture or if there is anything else that we think that needs to be added at this point. And then I would believe that during the workshop, we would put the final touches on it, kind of polish it up.

Dr. Rice: Great.

Dr. Kimbark: All right. So I thought that it would be nice if we could go – I hope everybody had a chance to read what everyone had sent out. I really like that Sarah had compiled everything together. What I wanted to know is whether – you know, should we go over it? We could go over each part of the questions again, if that's what people wanted to do, and look at what we added, or we could just look at what we have added. How do people feel about that?

Dr. Thomas Insel: Donna, this is Tom. I think what might be most useful is to just treat this, the piece that Sarah sent out, as

a first draft.

Dr. Kimbark: Right.

Dr. Insel: And just walk through it. If you go back to the original Question 7, there are these, oh, maybe five categories: –

Dr. Kimbark: Right.

Dr. Insel: – data sharing, biobanking, surveillance, communication dissemination, workforce development. And I think our charge would be ultimately to identify in each of those categories where the major – and I really want to underline "major" – developments since January 2011. And so the final text should be actually relatively brief unless, there is something that is huge that needs to be included here as a major update, remembering that we will probably be doing a much bigger overhaul in 2013.

Dr. Kimbark: Right.

Dr. Insel: But between now and the end of the month, what we're really looking at is taking everything that has come in and trying to consolidate it down, maybe think about the

right format. For instance, for biobanking, can we just use a table, instead of having to have a lot of text? I am just trying to find a way to capture the information so that somebody could look at this quickly and say, "Okay. This is what is new, and this is what remains to be done." And I would have a pretty high bar for what we would include as being new, because this really is meant to be a fairly brief and very focused update.

Dr. Kimbark: I would agree. What I would suggest we do is we go through like we did the last time, section by section, starting with "Data Sharing" and going through each one of them and possibly have each person that worked on it take a look at what they have presented to us – for instance, "Data Sharing" is first, and then you put together a nice summary of where a lot of the things are right now, especially what you are hoping to accomplish as far as harmonization is concerned, et cetera. So I would think that we could talk about that and see what you

could pare down a little bit and maybe get to the nuts and bolts of this section.

Dr. Geraldine Dawson: This is Geri. If I could just make a couple of quick comments? One is that the document that I am looking at starts with "Brain Tissue Banking."

Dr. Kimbark: Yes. That is "Brain Tissue Banking." And that was because of the fact that –

Dr. Dawson: I know. I was just wondering. You said it started with "Data Sharing." So I'm –

Dr. Kimbark: – that Sarah Rhodes compiled everything together and she didn't put it in a specific order – but I thought we could go through the order in which it is actually presented in the Strategic Plan.

Dr. Dawson: Oh, I see. Okay.

Dr. Kimbark: You just have to flip a couple of pages to page 6 in order to get to "Data Sharing."

Dr. Dawson: Okay. And then it does seem like that one of the things we might want to

do on this call but – you know, I made I am still not completely understanding the process – but it seems like that we would want to assign people these sections because I think people just submitted a lot of information just to get it all in one place. And now what needs to happen is pare it down and make it into, you know, a couple of brief paragraphs. And so it seems like we would want to assign people to take on different sections and come back and do that. Is that right?

Dr. Kimbark: I don't think that that – I mean, that could be – but I think that that is kind of a difficult thing to do because, I mean, for instance, what we did last time was we asked the experts in the areas to actually focus in on those specific areas within the Strategic Plan and within Question 7 and give us the information. So, for instance, Dan – and I am sorry to keep on using you as an example, but your name is right in front of me. Dan, did the data sharing specifically

talk a lot of NDAR, for instance. So to give his section to somebody else might not be fortuitous because of the fact that he is our expert in that area.

What I would like to discuss I – I would like to ask Dan – out of all of this, you know, what is your take-home message out of the – I think he's got three or four pages here of text and what is the take-home message so that we can pare it down to about one paragraph or, if you want, to some type of visual table or graph. I don't think this section lends itself well to that, though, but I would like to hear what he has to say about – a lot of what he has here, a lot of it, he has a lot of background that can be taken out. And he has – you know, what needs to be done. And I think that’s where it needs to be focused a lot about, specifically the existing – on page 7, about halfway down, he writes, "The existing data infrastructure should speed this process by allowing researchers to compare their data to similar

data collected by others. Federal and non-Federal funders should now take steps to encourage such experimental harmonization." I think that is one of the big take-home points of this whole text here for the data sharing.

So, Dan, could you come and say a little bit?

Mr. Dan Hall: Sure. You know, I probably wrote too much, but I guess it is good for the group to, you know, get a little context here.

You know, essentially we – you know – a lot has been invested in this infrastructure for data sharing. And we made significant progress in that a lot of data is now coming into this infrastructure or is expected to come into this infrastructure with our data-sharing regimen that we have instituted at the NIH, Simons Foundation, Autism Speaks. We are all emphasizing data sharing. And that data is coming in and becoming available.

The take-home is that this data – you know – we need to make best use of this data.

So we have done – you know – we have made a lot of progress by moving this data into the computational cloud. You know, we have dropped the barriers for access. And it is all harmonized to a degree but probably more than any other community to really offer a lot of opportunity to encourage investigators to use this resource.

The take-home message is, you know, to go back to the phrase "You can lead a horse to water." You know, how can we get the resource community to share, share faster, share better, and, you know, more often, as well as what we share?

You know, it is not just about all of this raw data to move it into this infrastructure. It needs to be harmonized and associated with results. And, really, the take-home messages were – some could say – the plea for help is these points down here, simplicity, timeliness, quality, and culture change that needs to happen to really best utilize this resource. There is tremendous

opportunity, but to do it effectively is the – are the take-home messages. And I think the IACC as a whole could assist in that endeavor.

Dr. Insel: Dan, looking through the document that we have that is now a couple of years old, the original – if you kind of go through this in succession – the original version of the Strategic Plan talked about the different databases that were out there. And then it got updated to say that in 2010, we formed the Autism Informatics Consortium that brought all of those pieces together. And it ends by saying we're now up to 10,000 participants in NDAR. I would think that - And then, in terms of what gaps have emerged, it talks about at that point the need for doing a little bit of a better job with the harmonization, with some of the things you just mentioned. But what I would love to see is something that is just consistent with each of those messages so that if somebody reads this, you can just follow it through,

and you'll see that in 2012 what we ended up with is saying that, now, having built on the AIC, the consortium, we have been able to do A, B, and C.

We're now up to X thousands. And in terms of the gaps that were identified – and it is really worth looking at specifically what we said 2 years ago, which was examples of gap areas identified include the need for improved options for data federation query, interfaces, and languages, genetic visualization tools, file, and data set management, data quality, and validation rules. And that goes on and on. Which of those have we actually knocked off? What can we cross off the list based on what we have done since January of 2011?

Mr. Hall: So, you know, we have combined all of these repositories. So we have federated with the AGRE repository, the ATN, IAN. And we have instituted a regimen, which – one of our goals was 90 percent of all newly funded projects. And it is a hard

number to hit. And we are close to that number. I wouldn't say we were at 90 percent, but everything coming in now has data-sharing expectation, at least at the NIH. So we have hit that goal.

We do have a composite harmonized data dictionary. So we have hit that goal.

Dr. Insel: So those are all great. So I think what you want – in bullets, you just want to say, "Look, this is what we said we were going to do. Have we done it or not? If we have done it, bingo – this is how we've done it." If we haven't done it, this is why not. This is what we'll do to make sure we get it done. This really is, you know, a Plan with milestones and deliverables. And we have said from the very beginning we want to be held accountable.

And you have got a great story to tell. So I would tell it. I think it gets lost with a lot of the background, which was good for us to read now, but I think for the revision, I would keep this very focused on saying

these were the things we said we were going to do and bing, bing, bing, bing. And then I would also put in the numbers. So if it has gone from 10,000 to 40,000, it is important to know we have got now any sort of metric that you can include that says, you know, this is what has been accomplished. And then if there is still more to be done, that goes into the gap saying, you know, we are still not there. What we're looking for is to go from 35,000 discrete data elements to 50,000 discrete data elements, but we have come from 5,000. So, you know, we've made real progress.

Mr. Hall: And so I think we hit those goals. As Alison pointed out in the last call, it's the use of this infrastructure.

Dr. Insel: So that's the gap.

Mr. Hall: That's the gap.

Dr. Insel: But even there, I think I understand this correctly. Just in the last month, the first manuscript has been published that is secondary data analysis of

NDAR data. Is that right?

Mr. Hall: Yes. We have had two publications: one using NDAR as a computational resource for – you know – and that was published. And yes, we do have this publication as well as, you know, a number of published studies, you know, cite NDAR as, you know, where the data is. So we do have that, but to me that's great, and we have got to start somewhere. But, you know, there's much more opportunity.

Dr. Insel: So I think that in terms of the gap areas and where we are still heading, maybe that is the way to word that is to say, well, there has been progress. The next big aspirational goal is to make this a source for information, a source for analysis, a source for new findings, not just a repository to put all findings into.

Mr. Hall: Yes, exactly.

Dr. Kimbark: And, just to add to that, what we talked about in the teleconference on the 20th of September was that, Dan, maybe

you could put a table together for the type of data included within NDAR and a table of participants, like a grant funding source in NDAR should be included in the report, that we actually wrote that, that we actually discussed both of those things.

Mr. Hall: Yes. And, I mean, I can certainly do that. You know, a lot of that is visible on the Website, but –

Dr. Kimbark: So you can just pull it from there, or you can write "Link" and say this is where you can find it.

Mr. Hall: Yes, yes. I think that's – because, I mean, it is all there. It is just –

Dr. Kimbark: One of the things that Tom was talking about was metrics. And, you know, to show some type of progress, it would be nice to be able to have that as well.

Mr. Hall: I mean, we could even – you know, to splash this up a little, is really our home page, you know, the – you know, with the pie charts of our home page pretty much

show the number of subjects, the imaging, genomic –

Dr. Insel: Oh, cool.

Mr. Hall: – and by phenotype.

Dr. Insel: That might be cute to put in here.

Dr. Kimbark: That would be nice.

Mr. Hall: So I would say, you know – and then people can actually see the progress in a year.

Dr. Insel: And I think at the end of the day, we want this to be something like a half-page or maybe not much more than that. Just the whole thing has to be 1,200 lines or something. And we have five areas to cover.

Mr. Hall: Okay.

Ms. Alison Singer: Well, I would just add that I think that we should include that NDAR won the NIH Director's Award this year.

Dr. Insel: That's cool.

Mr. Hall: Okay. They've gotten so many awards they don't really talk about it anymore.

Ms. Singer: Okay. The other thing I would point out is that – just as a general how we're approaching this – the way that a lot of the advocacy groups use the Strategic Plan is in print version; we hand it out to different people, particularly legislators and others. So when we put in links, I don't know how frequently people click on those links. So I think to put in the table with the funders and the content areas I think would be valuable, rather than put in other links.

Mr. Hall: Yes. I think we have some good things that, you know, I can work with the staff here on, trying to get it condensed and consolidated on, you know, how we're – you know, – I mean, a lot of this is just right there on the web. But I think if we stick that in as a graphic with a link under it, people might use that more.

Dr. Dawson: This is Geri. I have two comments. So in thinking about the gaps – and you just mentioned that, you know, it is

wonderful we have so many subjects in the database – and now the next step is to now, you know, have people utilize it. Would it be helpful, then, to actually articulate what would be the plan for making that happen? In other words, why are people, you know, not using it or haven't used it to date, you know, and what would actually facilitate the use of that data, you know, whether it is advertising or it is computational tools or computational support? I don't know. But it just seems like that, you know, if that is the next step, then perhaps articulating, well, what would make that happen might be worth, you know, a sentence or two.

Mr. Hall: Absolutely. I didn't do that. You know, I thought that might be the – for the IACC. But I can certainly add a couple.

Dr. Insel: Yes. I think into the gap area sort of –

Dr. Dawson: And then the only other thing I was going to say is that, you know, there are, of course, other mechanisms that

are in place for data sharing. And I am thinking about, too, how, of course, there have been data sets like the AGRE and the Autism Genome Project but also the Simons Simplex Collection and how people are now using that and how they have been used effectively.

So I know there is a section on biobanks, but those are really all about data sharing, all of those databases. And so I think it would be important just to highlight somewhere in one sentence the ongoing use of those and how perhaps they have actually resulted in some pretty phenomenal papers from last year.

Dr. Insel: Dan, you can work that in?

Mr. Hall: Yes. I add something in there that’s probably buried because I wrote too much. But I will try to draw that out.

Dr. Insel: Okay. And maybe you and I can work on this and just pare it down. And we'll make it very tight.

Just in terms of overall context, there

are I think 16 short- and long-term objectives for Question 7. And this is only really one of them. So we want to make sure that we address the original goal in 2010 to create mechanisms to specifically support the contribution of data for 90 percent of newly initiated projects to NDAR and link NDAR to other existing data resources by 2012. The most important thing is to respond to that very directly to the extent that we have done that, make that clear, and then fill it around that. I would keep this pretty brief just because there are so many other issues that we're going to put into the same update.

Mr. Hall: Got it.

Dr. Insel: Okay. Can we move on?

Dr. Kimbark: Our next section would be according to the plan would be biobanking. Roger is not here. And one of the things that we noted – And Geri, we had some stuff that has been pulled by Sarah into the biobanking section, so we could talk a little bit with you. And one of the things that we talked

about at the teleconference last time was that that there should be a figure or a table along with the pathway for the collection, which should include how many are available, the state and conditions, what are the needs for the future. I didn’t see a lot of that.

And, also, I think what I read didn't actually push any type of emergency response initiative to recover lost ground due to the freezer failure. I know I had read a little bit about it, but it didn't seem to be as urgent in what I read.

Geri, do you want to talk a little bit about what you put together?

Dr. Dawson: Yes, absolutely. So we had submitted several sections for this, beginning, you know, with brain tissue. And, you know, I think in terms of advances, what is new, there really has been some pretty exciting research that has been based on looking at pathway analysis, on gene expression data from brains, that I think it’s worth noting just because it underscores

the utility and the importance of this resource for future research. I think we want to capture that.

And also we want to capture that the Autism Tissue Program has worked hard to get their portal and information into NDAR and that that now has been successful and a completed task. And that's I think a real nice path forward for thinking about data sharing and making information more available. Also this year, there was a, you know, a clinical workgroup has been established to actually develop standards about how brain donor clinical documentation – which is not a minor issue at all – you know, what kinds of data are collected, you know, how do you conduct a diagnostic assessment on an individual who has passed away?

So that has I think been a really important step forward in terms of standardization of process. And it also represents a very nice collaboration across a

lot of different organizations, including, you know, NIH and Autism Speaks and so forth.

You know, in terms of gaps, yes, we did absolutely emphasize the freezer failure and how that has basically accentuated what has been an ongoing major gap and barrier to progress in the field. And then did emphasize, you know, the continuing need, of course, for outreach, for control brain, for very specific subtypes.

So I think all of that, you know, to the extent that it was not there before, should be reemphasized but also I think, you know, thinking forward about how to organize and collect the information that is done in terms of genotyping brains.

And, actually, there are some pretty interesting things going on at the Allen Brain Institute. And I don't know whether those are worth bringing in, but, you know, they're involved in, actually, you know, genotyping human brains with autism and other conditions and trying to build a database of

that. And, you know, this is a point where those data are now becoming available. And kind of thinking about how those data are going to be shared and combined across different efforts that are working on that is probably timely.

So that brings us to – let's see quickly. Let's see. The other one was genetics. And so, you know, I think that it is worth noting the papers that have come out in terms of [inaudible comment] sequencing, again underscoring, you know, the power of creating these biorepositories and perhaps highlighting how they pointed to targets for drug – for drug targets and for developing medicine.

Is it worth noting that this year the launch of the collaboration between Autism Speaks and the Beijing Genome Institute to sequence the whole genome sequencing on data from AGRE and the Autism Genome Project, which, by the way, will – the first of those data will probably be out by the time this

report gets published. So we want to kind of have that in place, and I think that they are actually going to really, really exciting.

And then, you know, thinking, then, as we start to generate – whole-genome sequence data – the big data problem that everyone is struggling with now I think, you know – that is what we are looking to in the future for autism, that we need to really think about how we warehouse and store the data, how do you actually serve the data sets to the broader scientific community. When you are talking about terabytes, you know, one terabyte per genome, how do you provide computational resources to be able to analyze and make use of the data as they become available? So that is I think a huge gap right now in terms of resources.

Mr. Hall: Just if I can comment on that, Geri? You know, we actually have received approval to move our genomic data into the Amazon Cloud. And we now have that data there, which does offer opportunity in that

area.

Dr. Dawson: Yes. So that kind of thing should be noted, but, you know, still there's a question of actually how you analyze these data and provide those computational resources for the investigators. In my understanding, you know, people are throwing these data up to the cloud temporarily to conduct these analyses. And then you pull them back off the cloud and so forth. So, anyway, these are not trivial tasks. And there's a lot of, of course, papers and so forth being written about how best to do this.

Dr. Insel: Geri, this is Tom. Just as a matter of process, what I would consider doing is recognizing that this is now an emerging gap. It is not something we thought about 4 years ago because, frankly, we just weren't so concerned about the big data problem then. But this is clearly something that does need to be addressed going forward. So I would add it on the gap side, saying

that the creation of these databases – or creation of these repositories has now created a new need that we have to address going forward. And, you know, exactly how that gets done, how it gets paid for, is something everybody is talking about and nobody has quite resolved.

Dr. Dawson: Right. So yes, I think it would be definitely worth at least having a sentence on it. It would be, you know, we would want to be thinking forward in that sense when you think about gaps in genetics.

And then in terms of pluripotent stem cells, you know, again, there have been some great papers that have come out. Some of those I think were noted in the earlier Strategic Plan, but, you know, there is some really enticing evidence that we might be able to use to not only look at neuron phenotype but also to study whether these phenotypes can be rescued through pharmacological intervention.

I think, you know, more work on the

utility of these for both understanding brain function as well as drug discovery, you know, is something that really needs to be emphasized.

I think in terms of gaps, there is still really limited access to patients, especially of specific phenotypes. And also you will need to continue to fund research that examines the utility of creating these cells, not just from skin tissue, which actually is an invasive procedure and is a barrier for collecting it on a lot of people. But, you know, what are some of the other innovative methods for collecting tissue that could become induced in pluripotent stem cells?

So whether it's the Tooth Fairy Project or people comparing what cells look like when they are derived from blood, as compared to skin and things like this. I think these are going to be really important issues down the road. And also the standardization of the techniques for inducing these cells and to become pluripotent stem cells, I think that

there are a lot of questions and issues around that.

And then yes. I guess consensus in the field around methodological standardization is, I would say, a gap that needs to be addressed. Again, these are not issues that only affect the autism field and are being grappled with, you know, across a lot of different areas, but I do think we should mention them because these are the kinds of questions that are on people's minds.

Dr. Insel: And this is this year's Nobel Prize as well.

Dr. Dawson: That's true. We wouldn't want to forget.

So, anyway, all of this is in the sections that we, you know, submitted. So it's there, and I think it is just a matter of someone, you know, condensing it and making sure to highlight those particular issues.

Dr. Insel: Is there a way we could create just a table for each of the

categories? So what you have talked about is brain tissue, IPS cells, DNA samples for exome/whole-genome sequencing? Are those the three major categories? Again, in the original Strategic Plan, we talked about blood spots – newborn blood spots – as one example of a tissue source that needed to be in a repository.

Could we – is there a way to actually get numbers for each of these things and to say where are we in 2012 in terms of how many DNA samples are available for analysis for both probands and controls or families and how many brain samples are available for analysis? Is that feasible, or do we not have access to the numbers?

Dr. Dawson: I think it would just need someone taking the time to go around and, you know, check with each one of the repositories and get an update and figuring that out.

I also forgot to mention something I think we want to think about. And I don't know. I think it will go in this. I think

that the last past of the document that has just sent out this morning or yesterday morning, maybe, that was on biorepositories that are connected to clinical samples that would participate in clinical trials.

So this year, you know, the creation of – I don't know if this is putting a lot to this or not – but Neuronex. I think we want to mention that and also that, again, the Autism Treatment Network, that the biospecimen collection that is funded through the NIMH has now been launched and underway. And four sites were added to that in the meantime.

And then another new effort this year that probably should be noted is the major EU-AIMS project. This is a project coming out of the Innovative Medicines Initiative in Europe. It is actually the largest project in autism ever, $55 million over 5 years. And a big part of that is establishing a very large biorepository. And, actually, Autism Speaks is one of the investigators on this project,

as well as we are supporting it. And they are making that biorepository, such that it is harmonized with AGRE, which, again, is harmonized with NDAR. So that is going to be another major biorepository down the road. So we probably want to include that. But that effort as well as the autism treatment effort are both trying to develop platforms for conducting clinical trials where there are biospecimens, so that people can look at whether particular subtypes based on genotyping are more responsive to certain treatments and questions like that, which I think is going to be absolutely critical.

And the gap, of course, is having these kinds of well-characterized patient populations for clinical trials that do have these biorepositories that are attached to them that can help us look at these individuals. Not only blood but also urine is important for certain kinds of analyses, such as looking at mitochondrial DNA and so forth.

Dr. Insel: So let me stop on that

particular point. Again, in terms of emerging scientific insights. We did not in the original Strategic Plan talk about the need to collect either urine or fecal samples, the latter being relevant to the microbiome.

Dr. Dawson: Right.

Dr. Insel: Is that something that we should now introduce as a gap, or is it still premature to think about that?

Dr. Dawson: I would add it. I would at least – yes, I would. And I think there actually are some emerging projects on that. I know we are funding one with fecal samples. And I believe that NIMH is, too, now, aren't they?

Dr. Insel: Yes. And there's been the work that has already gone on in the UK –

Dr. Dawson: Right.

Dr. Insel: – for many years now that has looked at differences in the microbiome, in this case looking at clostridia as being a predictor of autism. So maybe something – I mean, that is not something that were

thinking about, but, you know, in terms of again breakthroughs over the last 18 months, certainly the Microbiome Project has probably been one of the two or three most important breakthroughs in medicine. And maybe it is time to actually recognize that that is another place that might be very informative for autism going forward.

Dr. Dawson: And, you know, this is a little bit off topic in a way. I mean, it is not the big topic, but it gets down to this. But something you said has made me remember about the new very large database that is being put together in New York on brain imaging data. And I wonder if we should be mentioning that or not; I don't know. I know an area that there has been a lot of broader investment by NIH.

Dr. Insel: Yes. Yes. I was looking through. So it says in 2009, the call was for us to support – should also be “provide and develop an international Web-based digital brain atlas that will provide high-resolution

3D images and quantitative anatomical data from tissue of patients with ASD and controls across the lifespan, which can serve as an online resource of quantitative morphological studies by 2014 at a cost of $82 million.”

But, as you point out, I mean, some of that is already going on, and that might be another place to go. And, again, if we can get an actual number of images that are up there, that would be helpful to know.

So I am going to suggest we task Roger with coming up with creating a table that has the actual numbers so that, rather than having so much text, you could just see at a glance where we are in December or October of 2012. Is that okay?

Dr. Dawson: Well, since I didn't get tasked this, absolutely okay.

Dr. Insel: I think you have a lot to do, doing this as well. And I think he has already tracked down some of the numbers. They're just kind of embedded in –

Dr. Kimbark: I think they are embedded

in the text.

Dr. Insel: Yes.

Dr. Kimbark: A lot of it is embedded in the text. I actually just went through and have underlined some of it so that as we look at –

Dr. Insel: So we could turn –

Dr. Kimbark: There's 11 pages here just here on biobanking?

Dr. Insel: Yes.

Dr. Kimbark: We actually have to cut that down significantly.

Dr. Insel: Yes. So this is – I mean, we could take these several pages and turn it into half a page with a table and then some additional comments on projects underway. And then I think, as Geri has mentioned, you know, there are some new opportunities that have created, new gaps that we should also identify. So when is Roger back? Does anybody know?

Dr. Elizabeth Baden: I believe he's back on Monday. And just on his behalf, as you all

are looking through this section, are there any numbers that seem to be missing? This is Elizabeth. And I have been helping him try to reach out and connect to various places but I'm not sure if there are ones that we have maybe missed. So if you notice anything, or if you look through it after the call and come up with someone that we should contact to try to get numbers, if you could, please email me and/or Roger.

Dr. Dawson: Are we talking about –

Unidentified Participant: Elizabeth?

Dr. Dawson: – brains and DNA and blood and DNA?

Dr. Insel: Yes. Yes, and if we have fibroblasts, which we do have. We'll have the Rutgers fibroblast numbers. That is just one phone call. And I think that is available online. So it may not even require a phone call.

Dr. Dawson: One of the things you will notice in the section on pluripotent stem cells is right at the bottom, we have a list

of the people that we contacted. Those are the folks – at least in our – that are doing a lot of the work and that they would need to be contacted because a lot – not a lot but a number of universities are establishing their own – so, you know, Harvard, Johns Hopkins, [inaudible comment] Allen Brain Institute, CIRM in California, and Stanford – I think we would want to contact them if we are going to be trying to find out about stem cells.

And I think it would be remiss not to mention what is going on with Ricardo Dolmetsch going to the Allen Brain Institute and the Allen Brain Institute supporting what is going to be, you know, really a landmark effort in terms of these induced pluripotent stem cells in autism.

Dr. Insel: I agree. And certainly, you know, in terms of what has happened in the last 18 months, the Pasca paper, the Timothy syndrome paper, is really important as an exemplar. And, as you say, it is not only a matter of looking at what is different in

terms of the molecular pathways, but it is also being now used to screen for new therapeutics, which is very cool.

Dr. Dawson: Well, and I think you know it is pretty phenomenal that basically Paul Allen is funding this work, right? That is something we want to note in there. We would like to see more of that kind of philanthropy –

Dr. Insel: Yes.

Dr. Dawson: – and really reinforce that as something they could bring back to him and say, "Hey, look, you're now mentioned in the Strategic Plan." And it is phenomenal.

Dr. Insel: That's great. And one last thing to say about this before we move on is that in terms of the standardization that you had mentioned, Geri, about how to acquire and how to differentiate, how to redifferentiate, all of that, there is a very big effort going on at NIH in the Intramural Program. It is the National Stem Cell Initiative, which was created just to do that. And we have already

had several meetings around this.

And, you know, autism is not the main focus for any of the people who are doing this, but all of the work is highly relevant to what will make a difference in the autism community. So we can cite some of that. Obviously, it's mostly focused on Parkinson's and type I diabetes and other areas that are a little further along, but there is a lot happening around the technology itself. And all of that can be relevant. So we will figure out how to insert something like that that makes it clear that this is a broad effort, which autism will benefit from.

Dr. Kimbark: Okay. What we have is we have tasked Roger to do a table of essentially the numbers that are within these 11 pages. And I didn't actually capture how else we were going to work with this section. There was an awful lot of information here that I don't think is table – you know, will fit into a table very well. So is there a thought on how you would like to consolidate

some of this information into a paragraph? It's seven pages.

Dr. Dawson: So you are talking about the biobanking piece?

Dr. Kimbark: Oh, yes, the whole biobanking issue, from brain tissue all the way through, you know, what you were talking about with the genetics and the pluripotent stem cells as well as going into – I flipped over to the clinical trials network that you talked about at the end there.

Dr. Insel: So that is a separate topic.

Dr. Dawson: For Roger –

Dr. Kimbark: It is a separate topic?

Dr. Insel: Yes.

Dr. Kimbark: You want to keep that separate? Because it wasn’t – it doesn't fit into any of the other sections.

Dr. Dawson: I was going to say perhaps – you know, poor Roger not being on this call – but perhaps it would make sense since he is putting that table together for him also to draft a paragraph. And he could send it to

me, and I could respond because the alternative is I could certainly try to draft a paragraph, then. It seems like we might get a disconnect then somehow, or we would be duplicating because it would be two people working on the same sections. But I am happy to do whatever people feel will be –

Dr. Kimbark: We'll have Roger put together the table and draft the paragraph and then send to you – can he send both of those to you?

Dr. Dawson: Absolutely. And then I will review it. And then we can send it around to everyone.

Dr. Insel: I like that idea. And, again, just for context, there are 16 short-term and long-term objectives. This only deals with one again, the D in the original list from 2009, but we could also ask Roger to include a comment about N, which is enhance networks of clinical research sites offering clinical care in real-world settings that can collect and coordinate these materials, because we

have done that. And I think, as you mentioned, Geri, that would probably be worth a couple of sentences in the same update so it is clear that we are responding to both.

Dr. Dawson: Yes. Progress is always good.

Dr. Insel: Yes, yes. So I don't see any other items that deal with the whole biobanking issue. But I just want to make sure that we are responding to all of the things that we committed to do in the last 3 years. And this looks like it only addresses 2 of those 16. Should we move on?

Dr. Kimbark: Yes. I was just looking at that. Just as a quick followup for the clinical trials network, where are we going to put that, then?

Dr. Insel: Well, I think we have to – unless we create a separate section – I would put it into this piece because it what it says specifically is that we will use the networks of clinical research sites to develop this, these kinds of biorepositories

in a standardized way. I do think we have done that between Autism Speaks and NIMH through the ATN. Is that fair to say, Geri, or –

Dr. Dawson: I think we have taken a major step forward. And it is eight sides collecting some family. So it's not I think as robust as we want to see it down the road. And I do think, you know, we should be thinking about, you know, how is this going to happen for, you know, subpopulations that we know are going to emerge. You know, I don't think we're there, but I think we have made a step forward that is significant, and we should be able to capture that.

Dr. Insel: Actually, this exercise becomes useful when you realize we have done that, but I am not sure we are getting fibroblasts from all of these people or doing all of the things that we might do. So we are thinking about this.

Dr. Dawson: Exactly. And we are getting urine. We are getting whole-blood DNA. And,

you know, but – yes. But they are not having –

Dr. Insel: Yes. So there may be opportunities to do even – to take what we're doing now and take it up a notch. So that's good. Okay.

We are going to run out of time unless we move along here.

Dr. Kimbark: I guess the next one, then, is surveillance. Cathy and Geri?

Dr. Rice: Okay. This is Cathy. I will start and appreciate all the work that the Autism Speaks team did. So in terms of what it is, there was – can you guys hear me? There was a lot of paper shuffling.

Dr. Kimbark: I can hear you fine.

Dr. Rice: Oh, okay. All right. I'm hearing a lot of background.

We have updated prevalence estimates in the U.S., continuing to document increases, significant increases, over time, both in the ADDM network and in national surveys. We also have the study in South Korea indicating, at

least in that population, when doing a general-population screen, prevalence is even higher and certainly raising concerns about the need to look at general-population screening, in addition to at-risk screening.

So in terms of this section, some of the 'what is new' is included in the gaps –if things have not come to fruition via publication or reports. So there have been some advances in terms of studies in the U.S. looking at direct screening. CDC has funded a study in Florida State – which I realized that I left off of here, about doing direct screening in pediatric offices as well as the Autism Speaks-funded supplement to the ADDM Network to do direct screening in one ADDM site in South Carolina.

Other advances are certainly better understandings in the disparities in identification and that some of the gaps that are closing but still exist among certain racial and ethnic groups are contributing to the prevalence increases but certainly not

fully explaining it, and we need to continue to understand and track over time how that is changing both for service provision, as well as full potential etiologic understanding.

Last year CDC and Autism Speaks co-hosted a workshop, where we brought together a range of expertise and stakeholders in the community to look at important advances that we could make using U.S.-based data. Many excellent recommendations came from that workshop. So that is available. And some of those have been acted on. And we have had some specific publications coming out looking at the changes in diagnostic processes as well as some risk factors, like limited effect of certain perinatal risk factors changing in terms of effect on prevalence.

Certainly we have a better understanding of some of the disparities, as I mentioned. And another example of the sort of action that has come out since last time is the followup from the National Survey of – actually, that should be Children With

Special Health Care Needs – led to a followup survey of families, who reported that their child once had autism but no longer meets criteria for autism to further examine what is different between those children that were reported to still have the diagnosis and those that were reported to no longer have the diagnosis. So those are some of the advances.

And then in terms of gaps, we certainly are still in the midst of a changing situation with prevalence. We will need to continue to monitor using the same essential methods. However, they can also be continued to be supplemented.

There are projects - six projects – underway looking at prevalence among younger children, as well as incorporating direct screening and case confirmation. As I mentioned – into one ADDM site. We certainly need to be able to continue to look at variation in prevalence. And one project, joint project, across multiple agencies is

looking at prevalence of Somali children in Minneapolis. But in terms of a gap, we need to be able to further evaluate variation in prevalence in additional areas, as well as looking at research across different countries, cultures, and regions.

Another huge issue is the change in diagnostic criteria and how that will affect prevalence estimates. And efforts are underway to be able to look at, at least within the ADDM network, prevalence estimates in the current and the future criteria. That is underway and not yet fully supported. So also following up on many of the recommendations from the workshop, in terms of looking at very specific hypothesis-driven analysis of identification and the risk factors that could be contributing to ASD prevalence increases, as well as further understanding what is happening in terms of underserved populations and gaps and identification and barriers to services.

So those were the primary points that we

made. A few things that –

Dr. Kimbark: Do you think, Cathy, that it would be possible to take some of this – I think a lot of this might lend itself to a table or a figure. Do you think? For instance some of the statistics that you are quoting here, do you think there is any way that we could consolidate it into a table?

Dr. Rice: Potentially. If people have an idea of what that would be and then kind of a summary of multiple different strengths – I'm not exactly seeing how all of this could be –

Dr. Kimbark: Yes.

Dr. Rice: – put into a table, but if someone has a suggestion, I am happy to do that.

Dr. Kimbark: Yes. Because there is a lot here, and there is a lot of information and a lot of numbers that are quoted, but I am not exactly sure how to do this. I mean, I don't have expertise in this area. So I am not exactly sure how you would confine this into a table, but there is a lot of information

that maybe we could collapse somehow.

Dr. Rice: Yes. I mean, one way would be to look at all of the prevalence studies that have come out in this period and put that into a table, but that would really just get at one aspect of what we're talking about here. So I don't know. Do folks have ideas about how to make this more visual?

Dr. Dawson: It almost seems better as a paragraph just because there are so many diverse streams of information that you are trying to integrate, but, again, you know, there might be a creative way to do it.

Dr. Insel: Yes. I don't see how to do this much differently than what you have sent in. I think what you sent is good and tight. And this is the one area where there has been some really important information to convey in terms of new findings. So I think you want to lay that out very clearly. And you have done that.

The one comment I would have, Cathy, in thinking about this is, again, when you go

back to the original document, in terms of objectives, the language is a little different than where we are now in thinking about this. It is not too different, but if there is a way to write this up in a way that it is clear we are responding to the original goals. And so goal number – Objective G was "to develop a Web-based tool that provides population estimates of ASD prevalence for states based on the most recent prevalence range and average identified by the network by 2012." I don't know that we have done that, but, you know, I just want to be mindful these are the things we said we were going to do: "supplement existing ADDM Network sites to use population-based surveillance data," – exactly what you have described, but "to conduct at least five hypothesis-driven analyses evaluating factors and may contribute to changes." So, to the extent that there is a hypothesis-driven piece in the Autism Speaks' ADDM supplement, that would be really important to know.

And then the last one, L, which was revised in 2011, “expand the number of ADDM sites in order to conduct surveillance in children and adults, conduct complementary direct screening to inform completeness of ongoing surveillance, and expand efforts to include subtypes by 2015.”

So, anyway, as you write this up, I just – you know, the goal eventually is it, is all going to sit in one document? And people should be able to cross-reference from what we said we were going to do to what we have actually done as of 2012. And it's not that we have to have accomplished everything, but we want to make it clear that we did the Strategic Plan to focus us and to drive us in the particular direction. And so what we are trying to do with the update is to show the progress on each of those goals.

So I would just suggest – and maybe, Donna, we want to think about this in the way we organize the whole thing, that as we report out each of these sections, we

actually identify or even restate the original objective that this is tied to so it becomes transparent how we are responding to the original objectives.

Dr. Kimbark: Yes. I think that that is an excellent way to go about it. That way we can show progress and then [unintelligible] forward for what needs to be done in the future.

Dr. Rice: I think that is very helpful guidance across all of the questions. And we can certainly go back and tie it more directly to those objectives.

One thing that I was thinking about while we were talking about while we were talking about the biospecimens - where is the right place for the ACE Network that was recently funded, led by Reichenberg at Mount Sinai, linking both records and biospecimens across seven different countries. That can go, in some ways, in multiple places, but I think we might want to capture it somewhere.

Dr. Insel: Yes.

Dr. Rice: Other findings or gaps that anybody –

Dr. Dawson: Just a comment on that last one. So the linking of those has been done. You know, was that done last year or the year before? Because the new – is to now have $12 million of funds to actually build on that infrastructure, right?

Dr. Rice: Right.

Dr. Dawson: So the iCARE Project has been ongoing for a while. It's a project that Autism Speaks funded. And they based it on the infrastructure that was built that pulled together those and some initial findings that have already been published out of that infrastructure. Then the really, I think, neat thing – and that we might want to highlight – is now that is actually being used as an ACE Network to study environmental risk factors. And I think our community would like to see that highlighted somewhere. I think it’s a really good point.

Dr. Insel: Yes. I guess I have two

thoughts about that. I think it is great to show that there has been progress, but when we talked about this as a Committee, just to remind you, what we wanted to do with the update was not so much to talk about the progress as funding but progress as findings and what is it that we have actually discovered that is hard data that means we don't have to do it again. And that is a real sign of progress. I guess it is progress to say that we have got a new network, but I just want to avoid making a statement about the new grant as a sign of progress because the goal here is not to spend money but to actually get a job done. And we want to always keep that in the forefront.

Dr. Dawson: I guess I was just responding to – it sounded like there was an objective that had to do with trying to understand how risk factors might influence prevalence. And so, actually, you know, some data have been reported already out of that infrastructure. But I don't know whether we

just point back to the section of the Plan that has to do with ‘why did this happen,’ right, but point out the infrastructure was built to allow those discoveries to be made because there actually have been quite a bit that has been out.

Dr. Insel: Yes. Okay. So that is a great point. And since this is about infrastructure, that is a good way to put it.

The only other thing I had, I think, in answer to your question, Cathy, I think you have got, from my perspective, the main papers, which are the CDC report, the Kim report, and the Brugha paper.

One thing I guess I would say in terms of gaps, which has been an issue from the very beginning of the field, has been the relative absence of clusters. And I thought that was good that you talked about the Minneapolis potential cluster there, which could be very, very helpful. So I think it is good to put that in as a gap, because it's the something that has become more evident in

the last couple of years.

And, of course, the extent to which there are other clusters is going to be a very important future area to look at.

Dr. Rice: Okay. Anything else?

Dr. Dawson: The only thing I wonder – and this is probably too much, you know, given that we are trying to really make this concise, but I just want to at least get it on the table, which is whether we have said enough about *DSM*-5, given that that is such an important issue.

One thing is that there really have been some pretty major papers that have been published in the last year, right? And so just to even reflect that there have been multiple – you know, I don't know how many – papers now. There's at least probably been a dozen and some of them major papers trying to look at the impact, most of which have suggested that this will allow for better specificity and probably adequate sensitivity. But I think that something in

there that really reflects, you know, in terms of objectives, the need to actually look at how the *DSM-5* works, you know, prospectively haven't really been done, you know, except for the small field trial. And we have that one study that Autism Speaks is sending one of the ADDM Networks, but, you know, I think it is a pretty important issue, particularly thinking about it relative to ethnicity, you know, gender. There is literally no information on adults yet in terms of – there is nothing published. And I think the adults on the Committee will point that out because I hear about it frequently myself. So I just wonder whether we needed to beef it up a little bit.

Dr. Rice: Yeah, that sounds reasonable to cite a couple of the key studies and then talk a little bit more about the need for evaluation prospectively.

Dr. Insel: A question about that. Elizabeth, is that question going to fall in Question 1?

Dr. Baden: Yes. I do know that that the group that is working on Question 1 does plan to spend quite a bit of time working with that. And they also have Cathy Lord as one of their experts. And they have asked her to try to address that. Certainly any overlap could be worked out at a later point, but just so that you are aware that it will be addressed by other chapters.

Dr. Dawson: It may not be necessary. Maybe we want to again talk about the infrastructure needed to do that and then point backward to the –

Dr. Insel: Yes. That is a hugely important point. It has probably gotten more coverage than almost anything else here. And it's something that has emerged in the last 18 months as a bigger issue. So I agree that we need to at least reference it.

Dr. Rice: Focusing on the infrastructure piece of it, that part of our ability to evaluate it quickly, is dependent on existing data sources that also had to build on

projects that already exist and to supplement them in a way that allows us to look prospectively as well. So I think we can think about how to beef this up a tiny bit in an infrastructure-type way.

Dr. Dawson: In that regard, Cathy, does one of the objectives – I should have this open, but does it say anything about trying to build a better infrastructure for looking at prevalence in adults?

Dr. Rice: It is very broad in terms of expanding the number of ADDM sites to conduct ASD surveillance in children and adults – conducting complementary screening and expand efforts to include autism subtypes. So that will certainly fill a gap in terms of looking at prevalence.

Dr. Dawson: You might be able to say something to the effect that – you know, to address questions about how the *DSM-5* would impact prevalence in adults as well as other questions that pertain to adults and surveillance that, you know, it is going to

be necessary to build that infrastructure.

Dr. Rice: Okay.

Dr. Baden: This is Elizabeth. There is an objective in Question 6, which more specifically addresses adults. And it does say, "Develop a method to identify adults across the ASD spectrum who may not be diagnosed or are misdiagnosed to support service linkage, better understand prevalence, and track outcomes, with consideration of ethical issues." So it is within the Plan, just in a different chapter.

Dr. Insel: And we have good reason to believe that the update for Questions 5 and 6 will be at least 300 pages long. So I'm sure there will be plenty of information in there based on long, long discussions about those two questions already. So, okay.

Dr. Kimbark: I think that we can move on, then. We are pretty clear that this section is fairly tight, that we are going to try to tie it to the objectives. Is that so?

Dr. Rice: Yes.

Dr. Kimbark: And, Cathy, could you take the lead on that?

Dr. Rice: Sure.

Dr. Insel: But, you know, just one last comment about this. Cathy, what I really liked about your write-up is – and I think we should use this as a model – that you have kept a very high bar for those papers that you cite. You could probably have cited another 50 papers in the general area of surveillance and prevalence, but I think it is really important as we do this update that it doesn't have to be comprehensive, but it does have to be – it has to capture what are really major contributions. And I feel like you have done just that. So we may want to actually use this.

This is a comment to Elizabeth and to Gemma because I noticed in some of the other sections there will be a huge number of references, most of which are not really contributing anything substantially new or different. So we want to keep the update, as

being just that – something that is really significant, that is a new insight or an absolutely new piece of information that will change everything that we do from here on. And I think this is a good example. Okay.

Sorry about that. Moving on.

Dr. Kimbark: Moving on to information and communication. Alison and Dan put together some stuff that is useful. I mean, it is very concise. It is very, you know, to the point. So I am not exactly sure we have to talk too much about it. Alison?

Ms. Singer: Well, I put this together based on a conversation we had on the last conference call. I tried to stick to the format of the previous update. One thing I noticed that I wanted to point out is that, even though communicating research and disseminating research is one of the overarching goals listed under Question 7, at the top of Question 7, there are actually no objectives that specifically relate to dissemination. So that is just something to

keep in mind when we do the larger Plan revision.

Dr. Kimbark: Actually, Alison, when I was looking at the list of the objectives and I went through and I found one that said – that I put in here, I mean, when I was shifting them around – and it was "Begin development of a Web-based toolbox to assist researchers in effectively and responsibly disseminating their findings to the community, including people with ASD, their families, and health practitioners," This was in the 2011 Strategic Plan.

Ms. Singer: Which objective is that?

Dr. Kimbark: I don't know exactly where it is in the –

Ms. Singer: Oh here. I see it. It's Objective “E”.

Dr. Kimbark: What I did was I took all of the ones that we had here and I put them into a spreadsheet in each one of the categories. So it's from the 2011, it's from 2011, I thought. And then –

Dr. Insel: 2010

Ms. Singer: Yeah. I see it. It's Objective “E”. We haven't made a toolbox. So –

Dr. Insel: Yes. Well, you know it's – that was the point that –

Ms. Singer: – [inaudible comment] capture here is that the conversation we had, which is that while there are a large number of publications, we need to stop thinking in terms of measuring the number of publications as the sole output measure. And we need to start thinking about outcome measures that are focused on value for real people and how people's lives are improving, which is harder to measure because you can't count it. But it's something to keep in mind.

In the second paragraph, that one is tied to Objective C with regard to family participation. I've been trying to get – I've been trying to solve for X in line 2, the number – the percentage of families who participate in research. We had that number

back in 2005. Paul Law cited that number. Back then, he said about 5 percent of families with autism were participating versus 90 percent of families who participated in trials for pediatric cancer. He said he does not have that for 2012. So we may just want to say that it is a lower number or just revise that in some way.

And then in the third paragraph, we talked on the call about concerns that had been raised by the autism community, particularly around issues of surveillance, but I would almost expand this at this point to say with regard to federally funded projects I think is a particular concern because people feel like that's their tax dollars at work.

So, similar to the concern about the communication about surveillances, there is also a lot of confusion about the ACE projects and how those were selected and why certain projects were selected. So I might suggest we revise this paragraph to change

the word "surveillance" to "federally funded projects" and talk both about surveillance and the ACE awards.

Dr. Rice: I think also we could add about the outcomes of specific research studies. We hear about them primarily in the press. And is there a way to disseminate that information, which I think in some ways some of the – I don't know if this actually meets the need – but the *Summary of Advances* may be something to note that that is one effort that has been a positive change in terms of putting out some of the key research findings as well as, you know, maybe some of the work of the non-Federal organizations as well, like ASF and Autism Speaks, that try to translate science. I think it is helpful to mention those activities as well as a positive movement.

Ms. Singer: Okay.

Mr. Hall: You know, the section that I put in there, I think, you know, that was just discussed recently on Objective E, is

that, you know, we do have a facility now that links publications with the data supporting those results. And I think this was a huge breakthrough that is just ripe for the field to begin to use, so that, you know, these findings can be corroborated or critiqued immediately. And so that's the tool. That's a tool in this toolbox, which is Objective E.

Dr. Insel: Alison, can I follow up with you about the question of participation? So Objective “C” is "Develop and have available to the community means by which to merge or link databases that allow for tracking the involvement of people in ASD research." How could we do that? Is there something? Maybe, Dan, you would have a better sense of this. Is there something that we could do now that would allow us to track this and to say the numbers have gone from X in 2007 to Y in 2010 to Z in 2012? I don't know exactly how it is done for the child cancer trials, but how would we do it? Is there something we have

available?

Ms. Singer: Is it possible to count the number of GUIDs and then to determine the number of people who have participated in more than one trial and to start to track that over time?

Mr. Hall: Yes. I mean, yes. I mean, it is kind of a difficult number to arrive to. I think with IAN, which is a self-reported repository on – you know, there are 40,000 subjects there. And we could use that almost as a cohort on – you know, to see how many of those individuals are participating in studies elsewhere. So, you know, you could extrapolate to that number, but I don't know if I would trust it entirely.

Dr. Insel: Does a “GUID” identify a person with an ASD diagnosis or would a “GUID” be given to a control?

Mr. Hall: Yes and to a parent. But, I mean, we have done this categorization of individuals within our system, of course. So you can tease out the probands.

Dr. Insel: And you can assume that anybody who has a GUID, who is listed as a proband is involved in research?

Mr. Hall: Yes.

Dr. Insel: Okay. And that number just generally? Do you want to take a guesstimate of what that would look like?

Mr. Hall: I don't want to take a guesstimate, but, you know, I could give it some thought and see if we could, you know, get an idea of what a number could be, or you could do it at a more macrolevel, taking the CDC prevalence numbers to how many subjects we have, unique subjects we have in research for the data. We could extrapolate it that way.

If you really want this number, I mean, it's going to have – you know, Cathy is probably cringing with that kind of thought, but – it wouldn't have a lot of scientific merit, but it would give us a ballpark figure.

Dr. Insel: What “C” calls for is that we

develop a method to do this so that we can track. And I know that the Cystic Fibrosis Foundation does this very well. The pediatric oncology community does this well. Interesting, actually, the adult oncology community does it terribly. So, you know, it's not like everybody has figured out how to do this extremely easily. It works best on rare disorders, where we have a pretty good sense of what the total population is. And we try to get as many people, as many families, involved as possible.

I think we can actually do this for Fragile X and Rett pretty quickly, but I don't know that we can do it for ASD.

Mr. Hall: Now, I mean, one – you know, if this was something – you know, what you could do is if we assign GUIDs, I think there has been a discussion on this at the – you know, for the prevalence studies and all of those individuals. If we could assign GUIDs there, then we would – you know, we would know what the denominator is with the

numerator would be all of our GUIDs. So I think that is probably the most accurate way, but there are a number of consent issues related to that.

Dr. Insel: Geri, does Autism Speaks think about this law?

Dr. Dawson: We do within specific efforts. So obviously for, you know, things like AGRE, our HRSA grant, we have ongoing numbers of, you know, the people that are participating in trials. You know, that is such – there are so many different places one would have to look and search through. I wonder whether it might be better to just take one source, maybe IAN or one of the other sources, NDAR, and just look at kind of rate of change over time and say, you know, "as evidenced by this example."

One can see that, you know, over time, there has been this kind of increase, you know, in participation. I mean, clearly with the huge explosion – I have an editorial coming out on just the explosion, in the

number of publications. And, you know, it is based on the NIH report that really shows that the increase in the number of publications over time since the year 2000 – so that would imply that there must be people, more people, participating.

So I don't know whether more of a general trend and maybe even talking about a little bit about the report would be better than all the effort to really try to nail down at this point, you know, before – you know, in a month.

Dr. Insel: Is there a cool figure from your editorial that shows the growth in publications up through 2011 or 2012?

Dr. Dawson: Well, actually, in that piece, I am pretty much capturing aspects of the NIH report on publications, but you would like to –

Dr. Insel: Okay. So we have done it.

Dr. Dawson: – which I think is the best analysis out there right now. And then I talk about other things, but that I thought was a

beautiful analysis.

Dr. Insel: Should we include that in here?

Dr. Dawson: I think if you want to talk about changes in participation and research, it is one way of capturing changes that have occurred. It is just an idea.

Dr. Insel: Okay. Okay.

Dr. Dawson: But it really is – what is the name of that report? I am sure you guys know. It's the most recent one that you did like –

Dr. Baden: Yes. It's the IACC/OARC publications analysis.

Dr. Dawson: Yes. I think that is a beautiful piece of work. And it's amazing to see what has happened. And so that might be one way of just capturing it.

Dr. Insel: Okay.

Dr. Dawson: But that is, I think – it's still – and maybe one thing to really emphasize is that most of these studies are still mostly Caucasian, you know, higher

economic and just do not reflect the diversity. We were just talking about this with respect to the ATN. How do we increase the diversity of people who will, you know, participate in a buyer repository? And so maybe that is something to highlight.

Dr. Insel: Okay. And, again, you are going back to Alison's point. If we cite this, it is in response to C and E as the short- and long-term objectives, but we want to clarify that the end game is not publications but to create something of real value to people other than grantees.

So let's think about how to show that. It is kind of an odd thing here because, as Alison was saying, we want to do this update on information and communications, but it is not clear that that is specifically linked to the goals in the way that we are talking about it here. In a way, it is kind of an emerging gap or an emerging need.

Dr. Kimbark: And so as far as – I think we understand how to link some of this to

objectives. I am still not 100 percent buying in on percentages of children participating with autism in trials. Personally, I mean, I think it is better to leave off data that you can't really validate. It's kind of fuzzy science, rather than hard science, because you will get called on the carpet for it, and you are going to have to stand up to those numbers. And unless these numbers are really hardcore numbers, I don't think that we should include them.

Ms. Singer: And then, what would you include against Objective “C”?

Dr. Kimbark: I think it was Geri said something about talking about the changes, looking at the differential. The participation over a period of time has increased or decreased accordingly. We would have to put that in respect to how many children are being diagnosed now that is a higher percentage. You would have to put that in respect to that, but I don't think we should put just percentage of families of

children with autism per se. I think we should talk about the change over a period of time because that we can actually – I think what Geri had said – Geri, was that you that said that?

Dr. Dawson: Well, I think we were talking about publication rate. And so unless it's the same group of people that's participating in one state –

Dr. Kimbark: Yes. That wouldn't hit that. I am not sure. I just don't feel comfortable with putting numbers in that we have no way to – you know, we have no way to solidify them or back them up. I'm not even sure that 90 percent who participate in childhood cancer trials is really a good number either because you have to talk about different childhood cancers, you know, and standard of care in childhood cancer – leukemia, for instance. You get 80 or 90 percent remission rate. So you're not going to take your child and put them in a cancer trial, instead of going into a standard of

care, but some of the brain cancers are completely different. So I am not exactly sure that these numbers will actually tell you anything.

Dr. Rice: I think at this point maybe describing the data sources and the change in terms of numbers that we have in those data sources – so whether it is NDAR or IAN or any large repositories that allow us to track participation in terms of those numbers and change over time – seems reasonable.

And then I think the issue in terms of diversity and representativeness of the population is also very important. And potentially a way would be to look at each – the makeup of those data, specific data, repositories in comparison to general-population statistics about distribution by race, ethnicity, gender, SES factors. That's a little bit in some ways a stretch, too, with the assumption that the autism population ultimately will reflect the general population in terms of those factors,

but it will give us some idea in terms of the makeup of the subjects that we have.

Dr. Insel: Yes. The problem is we don't have a denominator, right? So we don't know what the full number would be, but we could at least show the increase since 2010 in GUIDs and the increase in people who are registered with IAN and other places. So that would be one way of describing it, not ideal for tracking the involvement in terms of percentage of the population, but at least it gives you a sense that there are more people who are getting involved.

Dr. Rice: Right. So, then, the denominator becomes for each of those data sources – it's not based on total percentage –

MS. Singer: Right.

Dr. Rice: – participating, the distribution of characteristics among those who do participate, so, you know, with the denominator being the number of people with a GUID. And then we're looking at what's the

distribution by race, ethnicity, gender, socioeconomic factors.

Dr. Kimbark: That to me – do we think that we could put that into some kind of table then?

Dr. Rice: That goes back to is that really something that we could do within a month, or is it really thinking through, is that an appropriate method and maybe right now just sticking to the number and then for the next iteration, determining if that disparity analysis needs to be done?

Dr. Kimbark: That's actually a good idea.

Dr. Insel: I have a thought about this. I am not sure how we got to this point, but the heading of "Information and Communication Dissemination," which I agree is really important, doesn't really match with what we have got already in the objectives. I am wondering if, in terms of an update, whether this heading ought to be a little more tightly linked to the objectives we have,

particularly C and E, and then maybe even a couple of others. And then we think about the issue of dissemination of information and the communication strategy as being something to do for the 2013 Plan.

But Alison, I am just going to put that out there because I really need your input and thoughts about it.

Ms. Singer: Well, I mean, if we are going to go by what is in the current Plan, then that would probably be the way to go because, somehow or another, we missed it.

Dr. Insel: Yes, I agree. I'm not sure how we missed it.

Ms. Singer: I don’t know how we missed it but we did.

Dr. Insel: Yes. And it's become a bigger problem, not a smaller problem, as time has gone on. Let me just look at the issues we were just talking about the *DSM*-5, where communication has been a huge issue. So I wonder if we should just focus this more narrowly on what we have got already and then

kind of bookmark the idea of a dissemination issue and bring that up again in 2013.

Ms. Singer: Okay. I mean, I think it makes sense, given how we decided to set up the process for the revision. It makes sense to do it that way.

I am just scratching my head, saying, how did we miss this?

Dr. Baden: Alison, this is Elizabeth. And if you look at the very beginning of Chapter 7, there are four guiding questions.

Ms. Singer: (inaudible comment)

Dr. Baden: And one of them is, yes, how can we ensure that findings are communicated to the public in a responsible and timely manner?

Dr. Insel: We just follow it up.

Dr. Baden: But there is not an objective in Question 7 that addresses it, even though it talks about it in the text. But there is an objective in Question 5 that talks about testing for methods to improve dissemination, implementation, and sustainability of

evidence-based intervention services and supports. So that is kind of where it is currently within the Plan.

Dr. Kimbark: Essentially what you have is you have – Question 5 is talking about services; whereas, Question 7 should be able to disseminate information that is more research-based information for the community.

Dr. Insel: Yes. And we actually say all that in the preamble. So the whole section about what do we know and what do we need has this whole part on communication and dissemination, which is why it ended up here. It is just we never followed up with objectives that were tied to that. And we even say that. And we even say that, we say there is a need to build the system for rapid replication, although that is an objective, which we, I don't think, have done. “Additional attention needs to be paid to improving the communication channels,” there are a whole bunch of things that we mentioned as a need. We don't actually have that as one

of the 16 objectives.

Dr. Kimbark: So, I mean, I think we still have a gap there, then.

Dr. Insel: Um-huh.

Dr. Kimbark: So, as far as what we talked – we have got to move on because we have one more section, and we have to talk a little bit about the objectives. As far as – this is concerning in all of what we talked about as percentages and tracking changes and registration and such and NDAR and IAN and so on. Dan, could you help put that together with Alison?

Ms. Singer: I'll take another shot at rewriting this based on the conversation. If you can get me the numbers, Dan, that would be helpful, but I am happy to do the writing.

Mr. Hall: Yep.

Dr. Kimbark: Okay.

Dr. Insel: Okay. Good.

Mr. Hall: And let me show you that capability that we have. I think that might play into some of this to – associate data

with publications.

Ms. Singer: Yes. No. I'll put that in.

Dr. Kimbark: The last part, the last part is research workforce development. And, Alison, you're on the –

Ms. Singer: Yes. So this relates specifically to Objective “K”, which, for those of you who don't have it in front of you, Objective “K” says, "To encourage programs and funding mechanisms that expand the research workforce, enhance interdisciplinary research training, and recruit early-career scientists into the ASD field."

So the data we really need here, we need the number of trainees that NIH supported in the last year. We reported that data on the 2010 update. So I am making the assumption that it is available. Is there someone who can provide that number? I guess it is the number of K awards?

Dr. Insel: I think we can do that, Elizabeth. That should be straightforward to

get that from program.

Dr. Baden: Yes. I think we should be able to track that down.

Dr. Insel: And what we want to do, just to be clear, Alison, the best way to do this would be the “K” awards that were supported in 2011 and 2012, right?

Ms. Singer: Okay. Right.

Dr. Kimbark: Can I just ask a question as far as this is concerned? Do we want to talk about a change in the number of trainees as well as does anybody think about the idea of how much money is per trainee as well? Just to look at, you know, when you think about inflation and how much it costs and so on or no?

Dr. Insel: I would be more interested in the number of people, rather than the number of dollars. I think the key here is to build the capacity. But, in addition to K awards, we may want to look at the T-32's, training programs, and then, to the extent possible, to divide that between graduate students and

postdoctoral fellows. And I would also add, you know, not only what NIH is doing but what is being supported privately, so the Autism Science Foundation early-investigator awards – things like that, that are new and help to build capacity.

Dr. Dawson: Yes. I was just going to suggest the same thing. This is Geri. You know, if we're going to be listing numbers, it would be nice to list – I think that would be an easy number to actually get is how many I don't know if we want to do – 2011 is fine.

We also launched a new postdoctoral fellowship program in translational research over the last year, which has been really nice and successful I think. And then we have data which I don't think is fascinating for our fellows. You know, how many of those – was this the first time that they came into autism research? And what percentage now planned to stay?

Dr. Insel: That's great.

Dr. Dawson: And I think that those are –

it is pretty powerful to see how these fellowships, you know, can influence bringing people into the field. So, anyway –

Ms. Singer: I think this is going to work out perfectly, Geri, because we have that data for our grantees as well. So if you can send that, if you can send me the numbers for your 2011 and 2012, Weatherstones, whatever pre- and postdoc awards you have, and then that outcome data, I will put that into a table.

Dr. Dawson: Okay. So you want '11 and '12?

Ms. Singer: Yes. We're supposed to just cover '11 and '12, right?

Dr. Dawson: Okay.

Ms. Singer: – because we didn't do a – is that right?

Dr. Insel: Yes. And let's see. What would be – if we are interested in looking at a delta, is the base year 2009 or when we first – the original plan was 2009. So that would have been 2008 data. I'm just trying to

if there's any – because the actual wording of Objective “K” is to expand the research workforce and enhance research training and recruit early-career scientists. So since it says expand, it means they want to show some change over what you were doing. I assume that for Autism Science Foundation and Autism Speaks, the 2009 or 2008 numbers would be zero, right?

Ms. Singer: Yes. So that will be a nice delta.

Dr. Insel: Okay. Good.

Ms. Singer: And I don't know if that would be fair – because Autism Speaks didn't have the Weatherstones and we didn't exist. Maybe we can show –

Dr. Dawson: We started the Weatherstone –

Ms. Singer: each year for the data, so we can show the curve. It doesn't look like zero –

Dr. Insel: And maybe we'll see what we can get from NIH and –

Ms. Singer: Okay.

Dr. Insel: I wonder if there – is there a training program through HRSA as well?

Dr. Dawson: I am trying to – you know, there is a lot of training that the Autism Treatment Network does through their HRSA grant. And I think we can give you that training data as well, but I would have to look. You know, I don't know if it is really like a fellowships, though. So if we want to specifically stick to fellowships, then, you know, I think we will start mixing apples and oranges. We have to be careful.

Dr. Rice: Yes. I think HRSA does have several traineeships, but they are more focused on service provisions.

Dr. Dawson: Yes. When you get into USED, you know, there are a lot of fellowships that are relevant, you know, even through some of the other professional organizations and societies. Society for Developmental Behavioral Pediatrics has one. So I think if we just say, for example, and do three, it

will probably be pretty reflective of what is going on. But, you know, again, it just depends on how much effort you want to put in being comprehensive.

Ms. Singer: Well, maybe we have to do it in two stages. Maybe for the purpose of the update, we do three, and then as we move to do the larger Plan, we write, we have more time. We will be able to collect the data.

Dr. Insel: I like that idea. I think we can actually say up front "While not comprehensive, this is a spot-check on some of the programs just to give a sense of the responsiveness to K." And, by the way, the goal for Objective K was by 2013. So we can actually even note that, that we're on the way to doing that.

Ms. Singer: Okay. And then in the second paragraph, actually, the end of the first paragraph, I put in something to reflect the conversation we had on the last call, which was a mechanism to hit that period between postdoc and assistant professorship and

early-career award. That's a point at which we are losing researchers.

In the second paragraph, I focused on ARRA money and the loss of ARRA funding, which basically means that, even if there is an unchanged NIH budget appropriation – which is not at all certain – but even with an unchanged appropriation, autism research will actually experience a real decline in economic terms versus 2010 levels and the risk that that really puts us in with regard to positions that have been funded using ARRA money and the potential loss of those scientists.

Ms. Singer: One thing that I actually am noticing that I did not put in here is the – I want to put the dollar amount in. I just put in the percentage, but I will add in the hard dollar amount because it is substantial.

Dr. Kimbark: Yes.

Dr. Dawson: And this is the dollar amount for?

Ms. Singer: ARRA.

Dr. Dawson: Oh, for ARRA.

Dr. Kimbark: I think that IACC has published this before, right?

Ms. Singer: What?

Dr. Kimbark: I think that I have actually seen the total funding amount in some of the IACC documents before.

Ms. Singer: Yes. I can get that data. I mean, that is right in the Portfolio Analysis. Susan does a great job every year the last two years of separating which was ARRA money and which was not.

Dr. Kimbark: Right.

Ms. Singer: But the point here is really that in terms of – you know, dollars are fungible. So whether you got your money under ARRA or whether you got your money from the regular NIH appropriation in the scientific community doesn't really make a difference except for the fact that now we're going to experience this real economic loss of funding, and how is that going to be felt?

Dr. Kimbark: Okay. So is there any other

discussion on the workforce development? Anyone want to make any more comments on the actual objectives for long term?

Dr. Insel: So I have a general question. And maybe we should have talked about this at the very beginning, but we have focused our update on what was done before, which was taking these five areas that we just talked about – data sharing, biobanking, surveillance, information dissemination, and research workforce development – but that doesn't map perfectly, as we just said, onto the 16 objectives.

And there are objectives, which we haven't talked about at all, like the last one, "Provide resources to centers or facilities that develop promising vertebrate and invertebrate model systems."

One from 2010, "Support 10 'Promising Practices' papers that describes innovative and successful services and supports being implemented in communities." There's just a whole bunch of them that we're not talking

about, even the state of the states, which was supposed to be completed and which I don't think we've referred to in the previous update. Or have we? Elizabeth?

Dr. Baden: The Services group will address that.

Dr. Insel: They'll do that? Okay. So maybe you could help us on this, on the ones that we haven't talked about here, of which there are six, five or six. Is somebody else going to hit those, or do we need to deal with them in some way? I am just thinking of how do we become responsive to all of the things that we said we were going to do?

Dr. Baden: So, to my knowledge, I know that the Services group will address the state of the states, but other than that – the Services Research and Policy Subcommittee, I should say. Other than that, I don't know of any that are being addressed by another group.

Dr. Insel: Hmm. Okay.

Dr. Dawson: Now, what about the Lewin

study?

Dr. Kimbark: Right.

Dr. Insel: Is that going to be covered someplace?

Ms. Singer: Not that I know of.

Dr. Dawson: A lot of services that are being documented and studied, right?

Dr. Insel: Right.

Dr. Dawson: And then there's also – I know we're funding some studies that piggyback on a very large services database that Lisa Croen oversees the mental health. And now we have added autism measures to that. And so I know that we're getting into a whole new area, but, you know, there actually has been some progress in this area.

Dr. Insel: So that would be in response to "M", the "Promising Practices" papers?

Dr. Dawson: I'm sorry. I thought you said that one of the objectives was to do surveys of services available?

Dr. Insel: Yes. Well, that is the state of the states assessment, which I gather –

Dr. Dawson: There is no other – that was specific to states. So –

Dr. Insel: Yeah.

Dr. Dawson: Okay. I'm sorry.

Dr. Insel: Yes. I'm just looking through the list. I mean, some of the things we have covered perfectly, but there are others.

Ms. Singer: Yes.

Dr. Insel: I am not sure we’re actually going to be addressing it exactly as we have described it.

Ms. Singer: Yes, not at all. The interesting thing to note is that we didn't address them in the 2010 update either in many cases.

Dr. Insel: Well, you know, this is up to us. I don't think we have to have 16 paragraphs for the 16 objectives, but I am really just putting it out there to get your feedback about whether – you know, we may want to stay at a higher level and just cover just the way that we had done it before, which is to talk about the five general

areas.

Dr. Kimbark: Well, one of the things we did talk about, we discussed today, was how those areas link up to some of these objectives. And, of course, they didn't link up to all. I think you said that there were six that were kind of hanging out there.

So I would suggest that as people are revising their sections, that they take a look at the objectives and make sure that wherever they can, they address an objective within their paragraph, even if it is only just a line or two.

And when we figure out which objectives are not answered, then we can see if there is anything that is met out there, that we could place them in another section or if it is one that hasn't been filled yet. Do you think all of the objectives have been filled and answered?

Dr. Insel: My guess is that there is progress on every one of them. I am just not sure that they fit neatly into the five

categories that we have got. The one that I am particularly struggling with is the vertebrate and invertebrate model systems, which –

Dr. Kimbark: I tried to put them into research workflow development. I didn't know where to put it, I mean, but it seems to me that it would be some type of – it could either be under genetics or that type of – talking about that type of thing because you could imagine I'm doing a genetic study, for instance, in whatever, one model system or another might fit into that section. Ort could fit into our research development. So what do you want to develop in that area?

I mean, what was the original reason why this objective was added to the Strategic Plan? Unfortunately, I don't have that historical knowledge, but why was it placed in the Plan in the first place?

Dr. Dawson: I am just going to throw out a suggestion about that vertebrate/invertebrate. Perhaps under

biobanking or we could even say biological – biobanking and biological resources for, you know, discovery research or something, but perhaps we could have a section that kind of relates back to that, the vertebrate/invertebrate. I know that in terms of the development of rat models, there has been some really significant progress that has been made over the last year. And also that is another area that the Allen Brain Institute is now taking on, is to consider, you know, a rat – but, anyway, I think that there is a new model now that is being developed that is going to be pretty important for the field. And we might want to capture that.

Ms. Singer: So maybe we add another section that addresses the objectives that have not been addressed and just one or two sentences for each.

Dr. Dawson: Well, you know, the other possibility would just be for someone to take the [inaudible comment] look at the

objectives, see if they have been addressed; if they are, make sure that they are tagged. So at the end of a sentence that is relevant, you could just have in parentheses "relevant to Objective 1" or just "Objective 1" or something so that there is always a reference. And then if there are ones that are left out, perhaps we could try to reference if there is another section to mention that.

So then you really do have sort of a cataloging: "Okay. These have been addressed. These have not."

Dr. Kimbark: I think that we need to do that prior to deciding how to deal with the ones that we were not addressing because we really need to know if there is any chance that some of these ones that we think are, you know, not addressed at this point, that we are addressing them, but we – you know – I know I am not making a lot of sense right now. But I really think that we have to kind of take an accounting of what we have

addressed before we can say what we haven't addressed.

Do you think that everyone, as they're working on their paragraphs, could send to me which objectives that they are addressing? And then I could compile them and send out to everybody what we are missing?

Dr. Rice: Sure.

Ms. Singer: Maybe we can do that on the phone right now.

Dr. Insel: Yes. I think we have already – we have probably covered it.

Dr. Kimbark: I mean, I don't have a lot of time because I have to leave my office in a little bit, but if we can go through it right now, I could do that.

Dr. Insel: So, Donna, I think we can send you – this is easy enough to send you the letters that link to the five topics. What I would suggest we do is if we don't have all 16 objectives covered, we add a section at the end of the gaps and say, going forward, "These are the objectives that are

going to need fresh attention or some new focus because they haven't received sufficient progress in the last 2 years" – something like that.

Dr. Kimbark: Yes.

Dr. Insel: I don't think we will be able to stretch. I mean, some of these things probably aren't going to fit perfectly into the five themes that we have got.

Dr. Kimbark: I think someone mentioned that some of the ones that we have here might be partially addressed in one of the other groups.

Dr. Insel: Yes. And that's another way of capturing that. And we can say that in a final paragraph for the update.

Dr. Kimbark: Okay.

Ms. Singer: I hate to add more administrative work, but I think that we should – just from a procedural standpoint, this is going to have to need to be one of these Committees that, at the end of this, goes through all of the updates and smoothes

it so that there's not – like, for example, I know that there is going to be a section on biobanking and brain tissue banking in Section 2.

Dr. Insel: Yes, we did that last year through OARC to make it one voice.

Ms. Singer: Okay.

Dr. Insel: That's why we wanted to get this pretty much in shape at the end of our –

Ms. Singer: As long as it's part of the work plan, then that's fine.

Dr. Insel: Yes. And then we use November to kind of clean it up –

Ms. Singer: Okay.

Dr. Insel: – so that we can get it submitted in December.

Dr. Kimbark: Okay. So we're running out of time both in our conference call here and to try to get this all put together in October. So I'd like to know when people think that they can get the revisions done and – put together their information and their data. When is the soonest you can do

it?

Let's start with the – let’s backtrack. When do you want to have a teleconference to discuss our progress, because I would like to have at least one more teleconference before we get together on the 30th. So I think we should at least have that teleconference to figure out what we're missing and so that we can polish things up at the workshop. So when would you like to have that teleconference? About what time? You don't have to commit to a time and day right now, but give me, you know, a ballpark time.

Dr. Insel: Well, let's see. What we had said originally is we wanted the drafts in by the 22nd.

Dr. Kimbark: Right.

Dr. Insel: And so what we have got is an early draft. I wonder if we can do this without even doing another teleconference given the feedback we have got here – if people because there will still be an opportunity to work on this on the 30th. So

all we really want by the 22nd is a working draft, meaning, you know, better than what we have got in front of us, and at that point, you know, have tables and grab that into a document. But I wonder if we can do that even without another teleconference and just get – we can circulate something to the group between now and the 22nd as we get responses in.

Dr. Kimbark: I think that is fine. If people feel confident enough that they can do that, that is fine. But I would still like to see everyone being able to circulate and – do you want to – Tom, I am not exactly sure how this works. So do you want those drafts to circulate amongst our small group here by sometime next week? And then we can submit them all in by the 22nd, or do we say that everybody sends their drafts in by the 22nd and we're good to go? I'm not exactly sure how this actually works.

Dr. Insel: Yes. Why don't we shoot them around over the next week? So we have got a

couple of weeks – well, not quite. We have got 10 days.

Dr. Baden: Ten days.

Dr. Insel: Ten days to work on this. So if we can get something, the next version, circulated next week just to get comments back from people. And then we'll get – and, again, what we're sending in on the 22nd is not going to be perfect. It's a working draft so that we'll give the group something to work on the 30th.

Dr. Baden: Right.

Dr. Kimbark: Tom, who are we sending the draft due on the 22nd? Where does that go?

Dr. Baden: This is Elizabeth. And if you could send it to me and Gemma Weiblinger?

Dr. Kimbark: Okay. So let's say that we will give people a couple of days to work on it and that we are hoping to start seeing the first draft sometime on Tuesday and Wednesday of next week. So that will give us a little bit time to discuss back and forth comments. And then if everybody could send your draft

to me and copy Elizabeth and Gemma on the 22nd, I think that would work. All right?

Dr. Insel: Okay. Great.

Dr. Kimbark: Okay. So I think that will be it, then. Do we have any idea about the 30th, when this is going to happen, what time, where it is going to happen, anything like that yet?

Dr. Baden: Yes. This is Elizabeth. The workshop will be from 9:00 in the morning until 5:30 in the evening. And it is going to be at the Omni Shoreham Hotel in Washington, D.C.

Ms. Weiblinger: It is a 2-day workshop. This is Gemma. On the 29th, the other Subcommittee will be meeting, and everybody is welcome to come to both days if they have the time and the interest.

Dr. Insel: Has a notice gone out to the IACC?

Ms. Singer: Yes, I got it.

Dr. Insel: Okay. Good.

Dr. Kimbark: I haven't actually gotten

any information as far as time, place, or anything like that.

Dr. Baden: Okay. I will follow up, Donna, and make sure you get that.

Dr. Kimbark: All right. Thank you. Okay. So that will be good. Okay. That is all for today unless anyone has anything that they want to still discuss. Okay. So I will try to get what notes out probably by the end of the day. Unfortunately, I have to leave to take my son to the doctor. So I am going to be out for part of the day. So I won't be able to write these up immediately. Okay.

Dr. Insel: Thanks so much.

(Whereupon, the Question 7 Planning Group conference call was concluded.)