

NWX-OD IOD

**Moderator: Francis Collins
October 21, 2019
11:00 am CT**

Coordinator: ...for standing by. For today's call, all lines are going to be on listen-only. Today's conference is being recorded. If you have any objections, please disconnect. And, I will turn the call over to Dr. Collins. Thank you.

Francis Collins: Thank you, operator. And, good afternoon, good morning again. Now, I'll try to do it right. Very nice to be able to gather the members of the ACD -- the Advisory Committee to the Director -- for this special conference call which has as its main topic a discussion of the pair of reports about where we're going with the BRAIN initiative -- the BRAIN 2.0. And the BRAIN Neuroethics Subgroup report.

Which a lot of work has been done and many thanks to those who lead that effort. Many of whom are also listening to this conversation at the ACD has the chance to look at where we are and, frankly -- we hope -- decide that it's a good thing. And, we shall see how we go forward from this point.

Let me first -- and apologies for the cough -- see if I can find out which of our ACD members are on the phone so we can be sure we have a forum. We knew

a number of people weren't going to be able to be present, but I'm going to call their names anyway in case that changed.

Shelley Berger?

Shelley Berger: I'm here.

Francis Collins: You are, great. Roberta Diaz Brinton? Wendy Chapman? Anne Churchland?

Anne Churchland: Yes, I'm here.

Francis Collins: Francis Cuss?

Francis Cuss: Yes, I'm here.

Francis Collins: Rebekah Drezek?

Rebekah Drezek: I'm here.

Francis Collins: Mark Dybul? Jose Florez?

Jose Florez: I'm here.

Francis Collins: Geoff Ginsburg?

Geoffrey Ginsburg: I'm here.

Francis Collins: David Glazer?

David Glazer: I'm here.

Francis Collins: Linda Griffith? James Hildreth?

James Hildreth: I'm here, Francis.

Francis Collins: Kristina Johnson? Dina Katabi?

Dina Katabi: I'm here.

Francis Collins: Judith Kimble? Brendan Lee?

Brendan Lee: Present.

Francis Collins: Spero Manson? Jay Shendure? Roy Wilson? And, Barbara Wold?

Okay. That pretty much matches with what I expected except there are a couple of people on who we didn't know were going to join us, and that's great. And, I can confirm that we do have a quorum. So, I'm going to turn this over to Principal Deputy Director, Dr. Larry Tabak, who's going to walk you through how we're going to spend our time. So, Larry, it's all yours.

Lawrence Tabak: Okay. Thanks very much, Francis. And, good morning or good afternoon to all of you. We really appreciate you taking time to be with us today. So, there are two things that we need to do. The first, very short. The second, a little bit more time.

A few moments ago, literally, we received a public comment which as you know we are obligated to share with the ACD. The public comment has nothing to do with the remainder of the discussion today. It is about foreign influences. And so, after this meeting this public comment will be put on a

share file for your review. And, of course, NIH will work through in addressing some questions that have been posed in this public comment. But, I did want to make all of the ACD members aware of the fact that we have received this and it will be accessible shortly after the meeting today has been concluded.

The main purpose of our meeting today is to follow-up on the conversation that we had at the last in-person ACD meeting in June about the BRAIN 2.0 effort. And, in particular, the efforts of the two Working Groups that were focused on charting the next phase of this very important national initiative.

Now, as you probably recall, several of you asked to see a more integration - or more integrated version between the two reports. And, we in fact did work very, very hard at attempting to integrate the contents of the reports by interweaving related content while trying to maintain the fidelity of the recommendations in the associated context.

Having tried this, I have to report to this that merging of these documents proved to be extremely challenging. In part, because they were difficulties in resolving the variation and tone between the two reports. And, the report itself when merged became very unwieldy. It grew to over 400 pages including appendices, a sure sign that no one would probably ever read it. Which is not good.

Now, ultimately, NIH wanted to come back to you -- the Advisory Committee to the Director -- to make the case that submitting the reports as separate documents would make much more sense as a Working Group products. We know, however, the importance of integrating science and ethics in the BRAIN Initiative. And, of course, we intend to develop an implementation

strategy for moving forward within the agency after considering the reports in full if the group agrees with this path.

Now, in fact, there was already integration evident in the documents presented in June. One factor of the BNS report explored opportunities for neuroethics across each scientific priority area. Commentary on neuroethics considerations exist throughout the 2.0 Working Group document from the introduction with each priority area and extending into the organization of science and transformative projects.

So, at our last meeting -- if you recall -- it was general support to the BRAIN 2.0 Working Group report as written. And so, that report has not been changed. And, hopefully, after taking a look at this that is reflected by your review. There were, however, a few requests for clarifications within the BNS report. And as a result, this report has undergone several revisions to address the comments of the ACD which I'll address in a moment.

Before I begin, though, I would like to acknowledge the difficult task in front of the Neuroethics Working Group. Digging through ethical considerations associated with ongoing research, let alone forecasting what the future may look like, as you all know is an extremely daunting task. With that said, this is exactly what NIH was asking when we formed this group.

And, we recognize that in some areas forecasting the future may be speculative while this is not our present state of science. However, we must be aware of the future in order to proactively consider best paths forward. Our stakeholders are the American people and the diversity of views on these topics needs to be reflected in our own processes.

Thus, consensus is not only unlikely, but we are not looking for that. Rather, we are looking for a roadmap of issues that we should be aware of to ensure that we remain good stewards of the taxpayers investment in neuroscience. We laud the neuroscience community for their willingness to be proactive in working through these tough issues and demonstrate to the public just how seriously they take this responsibility.

Now, regarding the reports you have in front of you, there are a few revisions that I would like to highlight. And, again, we're referring now to the BNS report and some of the specific edits. In the previous report, text in the executive summary did not precisely match the report text regarding recommendations for a budget proposal for neuroethics research.

The executive summary and the body of the report now both clearly state that the NIH funding for neuroethics research would be increased over time with the aim of approaching -- and I emphasize the word "approaching" --5% of the overall BRAIN Initiative annual budget. Previously, it was indicated that 5% represented a floor and that has now been changed to approaching 5%.

There were some discretion about the animals in the research section. This section includes some changes to clarify the original content. Specifically, the context for the importance of animals in research is strengthened. No recommendations for changes to the policy or regulation in the current research environment are made. The language continues to stress the importance of vigilance moving forward to ensure that policies keep pace with research. And, the stakeholders list now specifically include veterinarians, people who work with animal models, and climatologists.

There was some discretion around the transformative projects section. And, in particular, the consciousness project. No revisions were made to this section

as it as intended to be a bold proposal. Now, reasonable scientists can agree to disagree. NIH can take these projects under environment - under advisement as it considers if and how to integrate these approaches into the funding portfolio.

So, now, I will just let you know that the co-chairs of both working groups on the call - they are not going to be repeating their reports because you heard them at the June meeting. But, if members of the ACD have any specific questions, of course they would be happy to answer your questions. So, at this point, I would like to open it up for discussion by the members of the ACD. I can't see your hands raised so just jump in and we'll try and maintain some semblance of order.

Anne Churchland: I had some comments I'd like to make, but that's perhaps a different moment.
Is this questions only?

Lawrence Tabak: Yes. Let's start with questions by the ACD members for clarification. And then, after that we can proceed to any comments that people would like to make.

Anne Churchland: Okay.

Lawrence Tabak: Thank you.

David Glazer: This is David. I'll start with a very simple question. On the changes to the animal section, I'm looking at the redlines and I'm not seeing any changes. What section should I be looking at?

Lawrence Tabak: We'll get you the specific...

David Glazer: Because I just did a search for animal and didn't see anything that looked like it matched your summary.

Lyric Jorgenson: Chapter 4.

Lawrence Tabak: Chapter 4 and... Okay. Hang on one second, we're just scrolling through the text.

Lyric Jorgenson: Yes. So, if you're looking at the Word document and you move it into review and the "all changes shown" instead of the simple markup of the original - you have the one with the redline? Or, are you looking at the original?

David Glazer: Yes. I'm looking at the redlines.

Lyric Jorgenson: So, it's Chapter 4 Page 52.

David Glazer: Okay.

Lyric Jorgenson: ((Crosstalk)) looks significant changes. But, over the next subsequent pages as well.

Lawrence Tabak: David, are you in that same place?

David Glazer: I'm looking for it -- I'm trying. Chapter 4. All right, thank you. I don't want to take everyone's time. I will look for it offline so you can keep going.

Lawrence Tabak: Thanks. Let us know if you have a problem. We'll try to get it to you. Okay. Other questions, please.

Geoffrey Ginsburg: So, Larry, this is Geoff Ginsburg. I just want to clarify that what you're effectively proposing is that the ACD would accept the fact that there would be two guiding documents for BRAIN 2.0 and that there'll be some work ahead of us and ensure that they are followed as the plan goes forward. ((Crosstalk)).

Lawrence Tabak: So, a friendly amendment to your comment, Geoff, which is spot-on. A friendly amendment being that the work will be taken on by NIH. And, of course, given the magnitude and importance of the BRAIN Initiative, you know, we will periodically report back to the ACD. But, now it will be on the staff here to work this forward.

Francis Collins: Yes, Geoff. You're correct. The proposal is to accept these two reports as freestanding and not to try to pursue a formal integration of them as we found that to be difficult and not ultimately satisfactory.

Geoffrey Ginsburg: Thank you.

Lawrence Tabak: Yes, thank you Geoff. Any additional questions?

Brendan Lee: This is Brendan. I did review it and I think the changes are reasonable. I would like to hear from the co-chairs on the neuroethics group to just - in their perspective what they felt was the most substantive change to the document.

Lawrence Tabak: Okay. Could one or both co-chairs from the neuroethics report answer that question, please? And, that would be if they are able to do that.

Man 1: ((Crosstalk)).

Man 2: We're on.

Lawrence Tabak: Thank you.

Jeffrey Kahn: This is Jeff Kahn, and I'm happy to really just reiterate what you heard in the introduction. So, we heard the comments when we were with you all in person in June and we corrected what was an inconsistency in the recommendation related to the funding. So, you heard about that and that was made consistent in this draft.

We also heard that the comments did not sufficiently recognize the importance of certain stakeholder groups. And so, those have now been articulated as you heard Larry spell out. And, I think the rest were really just clarifying editorial kinds of changes. But, the substantive changes were really in response to the comments of the ACD when we met with you all in person. And, really those two big areas were the main points.

Brenden Lee: Thank you.

Lawrence Tabak: Thank you. Any additional questions by members of the ACD? Okay. Now, let's then turn to any comments that members of the ACD would like to make. And, I believe it was Anne who initially said she had some comments. So, Anne, could you please proceed.

Anne Churchland: Yes. I'd just like to make a couple of comments. First, I think the decision to keep the two documents separate was really the right one. I think each report will stand on its own as a document that the NIH director can consider when laying out plans for the future of the BRAIN Initiative. I've read the revised BNS report and I appreciated the changes that the authors made.

Like Larry Tabak mentioned a moment ago, the author suggested if the field is based with novel animal welfare considerations that conversations about how to handle those should include diverse stakeholder groups, veterinarians, researchers working with animal models, climatologist, et cetera. I thought that was an important change.

In other new text, the reported knowledge that research with nonhuman primates is likely to be necessary to translate knowledge gained with other species to applications in humans. And, also, to acquire near new knowledge on specific aspects of brain functions that are particularly advanced in non-human primates, such as face recognition and so on.

I also appreciate that the text about the budget was corrected -- so that's good. I still maintain that the report would have been stronger without the inclusion of the transformative project at the end. I also thought there were some missed opportunities in terms of preventing brain organoids in a more balanced way. And, I say that especially because of glioblastoma -- the potential of organoids for making advances that can lead to treatments of glioblastoma is really in earnest.

Still, I appreciated that the authors explicitly elected not to use the terms humanoids in the report. And, I think that was the right call. So, I really want to move forward with this. And, I do recommend that the ACD should accept these reports and that NIH director should read them really thoughtfully. The BRAIN Initiative has been an enormous success so far and the ongoing potential of the initiative to generate even more technologies and discoveries is truly monumental.

These advances are really needed because brain diseases affect many, many people and we really need better treatments to help them. So, my hope is that

these documents in their new separate format will pave the way for the final five years of the BRAIN Initiative and I'm really looking forward to the discoveries that come as a result of that.

Lawrence Tabak: Okay, thank you. I'm not a betting man, but I think I heard a motion. And so, if I get a second then we can have discussions before calling the motion. So, do I have a second?

Francis Cuss: Second it. Second it.

Lawrence Tabak: Great, thank you. Is there additional discussion and/or comments from members of the ACD, please?

Brendan Lee: This is Brendan - sorry, go ahead.

Francis Cuss: I just wanted to support what Anne said. I think while it would have been great to have had an integrated document. I think the work that the two work groups have put into it I think reflect the complexity of the field. And, I think this the best way moving forward. So, I'm completely supportive.

Lawrence Tabak: Thank you. I believe I heard Jose.

Jose Florez: Yes. I just wanted to maybe clarify what is the plan forward for the integration of the two groups on the continued conversation exchange of opinion focused on this. Is there any, or?

Lawrence Tabak: Right. So, the two working groups will now having discharged their responsibilities and will go back to doing their science. And then, it will fall upon NIH staff to engage going forward with, you know, the sort of integrated holistic approach. And, as I mentioned earlier, because of the importance of

this initiative we will of course circle back to the ACD and let you know how we are proceeding in that manner.

Francis Collins: And, this is Francis. Just to remind you, the overall management of the BRAIN Initiative -- which involves a lot of senior scientists but particularly at NIH it's been led by Walter Koroshetz and Josh Gordon -- does include a neuroethics group within that BRAIN Initiative. They're not going away.

So, that enterprise will undoubtedly be able to try to take what I think are two really substantive thoughtful deeply useful reports and bring them forward in actions that we can now look forward to. Managed, as they should be at this point, by the overall leadership of the initiative.

Jose Florez: Okay.

Lawrence Tabak: Thank you. Any additional comments from the ACD members? Okay.

David Glazer: One - this is David. One comment that - lots of good context on this, but I think it would be useful going forward to be clear on where the ethics - the neuro - where neuroethics are different from ethics. And, it's kind of implied throughout, but there are parts of the report and recommendations that say, "Here are good bioethics practices. We should do them." And with others that say, "And, here's where it might be different. And, we should think about it."

And, I think that as we think about rolling things forward as the NIH work on that it'll be important to say where we - where the action is to reinforce existing best practices. And, where -- and I think this will be a much shorter list -- where the actual new practices that might be called for. And, I found that information in the report, but I found it kind of defuse throughout the report.

Lawrence Tabak: Yes. So, there are nodding heads around the table here at NIH. And, I suspect nodding heads on all the phone lines. Yes, indeed. It needs to be integrated in everything that we do. And, we will of course, you know, ensure that that happens going forward.

Other comments by anybody. All right. I think we can call the question then. Let's try this first with a voice vote rather than going through one by one. All those in favor, aye.

Group: Aye.

Lawrence Tabak: All those against, nay. Are there any abstentions? All right. Then we're going to record that this is a unanimous acceptance of the proposal. And, with that, I want to thank all of you for your effort which was really quite substantial. And, I want to thank the ACD members for joining us today to let us tidy this and move forward. And, we look forward to seeing you in December.

Francis Collins: In particular, thanks again because we're now setting you free. To all the members of the BRAIN 2.0 Working Group, you worked incredibly hard and produced a remarkably exciting set of proposal goals that we're now going to wrap our arms around. And, likewise, the BNS group who also worked under very tight timelines in difficult territories and did a wonderful job, I think, of putting forward things that we need to really think hard about.

So, you all are to be thanked. I know this got a little complicated in the last couple of months trying to figure out how to get this over the finish line. Consider yourselves of having crossed the finish line moments ago. And, you know, go have a drink. It was a great product in both instances. And, trust us

now to take your wise advice and push it forward into what we think is going to be a remarkable next five years of the BRAIN Initiative. So, thank you.

Lawrence Tabak: Thanks, everybody.

Brendan Lee: Thank you.

Anne Churchland: Thank you.

END