

NWX-NIH OD IMOD OFACP

**Moderator: Gretchen Wood
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Coordinator: Excuse me, this is the operator. Today's conference call is being recorded. If you have any objections, you may disconnect at this time.

Francis Collins: Well, thank you. Good morning, everyone. I want to welcome the members of the advisory committee to the Dir. for a conference call which was posted in the Federal Register.

And so there are other folks who have been notified about that and who are in listen only mode. This is Frances Collins, director of NIH. When we first find out who has been able to join as far as ACD members. (Frances Cuss), are you there?

Francis Cuss: I'm here.

Francis Collins: Mark Dybul

Mark Dybul: Yes, I'm here. Hello.

Francis Collins: Hey. Jose Flores

Jose Flores: I'm here.

Francis Collins: Geoff Ginsberg

Geoff Ginsberg: I'm here.

Francis Collins: David Glazer

David Glazer: I'm here.

Francis Collins: Linda Griffith

Linda Griffith: Here.

Francis Collins: James Hildreth.

James Hildreth: Present. Here.

Francis Collins: Brendan Lee.

Brendan Lee: Present.

Francis Collins: Jay Shendure.

Jay Shendure: Hello. Yes.

Francis Collins: Roy Wilson.

Roy Wilson: Yes, I'm here. Good morning.

Francis Collins: Good morning. We didn't expect three callers but let me check in case that changed. Anne Churchland.

Anne Churchland: Yes, I'm here.

Francis Collins: You are. Great. Richard Lifton

Richard Lifton: Good morning. I'm here.

Francis Collins: Oh, my goodness. And Spero Manson.

Spero Manson: I'm here as well.

Francis Collins: Wow, we've got everybody. That's fantastic. Well, thank you everybody, for getting on the phone for a half-hour call. We convened this to announce two new working groups of the ACD.

To tell you about those, since they will be now getting hard at work in the next little bit and we'll be reporting their findings to you at the December meeting and wanted to inform you, therefore, about the reasons for these working groups and what their general charges are going to be.

And let me go first to a working group on foreign influences. This is to address the threats that we have become increasingly aware of towards integrity of US biomedical research from undue foreign influence and including some breaches in peer review.

You might have heard something about this. I spoke about it yesterday morning at the Senate HELP committee hearing and also sent a letter the night

to over 10,000 institutions who are grantees or NIH applicants. Larry sent to you a copy of that letter yesterday. I hope you've seen it. I also emailed a link to the director's statement about this.

It is clear from information that we collect ourselves, but also from what we've been getting from law enforcement, particularly the FBI, that there are some foreign governments that have systematic programs to try to build their capacity in biomedical research and in some instances, to unduly influence and capitalize on research that we support.

Let me say the vast majority of foreign nationals make terrific contributions to American science and are hard-working and dedicated and certainly follow all the appropriate ethical standards.

But we are aware that there are exceptions and those are the reasons for this need to reach out to our grantee institutions and asked that we look carefully and try to identify such exceptions and make sure that they're not continuing to do harm to the American efforts.

Those kinds of exceptions include just not disclosing foreign support in a grant application, which you're required to do and which can, therefore, distort decision-making about how we spend our funds.

And that includes undisclosed shadow labs in other countries which can also be a source of considerable financial support but also potential for diversion of intellectual property. And we know of specific instances where that has happened.

Obviously, this kind of interaction and collaboration with foreign countries - and let me say it's China in particular that has drawn attention, but not probably the only case where this could happen.

Those kinds of collaborations are highly productive and welcome but they need to be fully disclosed and all the rules need to be followed in terms of how this intersects with such things as intellectual property.

We did remind the community, back on March 30, about the importance of disclosure to your own institution and then, therefore, to NIH at the time of the grant application or a progress report.

So it's not a new issue but we are aware that there are examples where identical applications have been submitted for funding to both the NIH and a foreign entity and both have gotten funded, but without disclosure to NIH.

And we are certainly aware of circumstances where IP has been transferred. There are instances, we hope we are also, where the peer review process has been affected.

One potential way is by individuals who were serving on study sessions, actually passing along to foreign governments, contents of grant applications that are supposed to be entirely confidential, applications that haven't even yet been reviewed, much less awarded, but which may contain information in them, particularly for things like technology development that would be of interest to other parties outside of the country.

And obviously that is an inappropriate use of a study session, members access to confidentiality. There are also a few instances, and yet we hope they are rare, all attempts to influence priority scores in study sessions by individuals

who are supported by the same foreign government, and we are obviously troubled to hear of any such influence of that sort.

So given all of this, and the fact that NIH has a very significant interest in making sure that the integrity of everything we do is absolutely unassailable, but also the fact that our grants do not go to scientists. They go to institutions.

Now we felt it was appropriate to draw attention to this, to actually build a stronger relationship with institutions to be sure that we're working together to find solutions.

But also to be sure we are working to emphasize how important the contribution has been, is now and will be of foreign nationals to our biomedical research enterprise.

So to help us with that, we thought it would be very valuable to have a working group of the ACD particularly populated by leaders and institutions that we send a lot of our grant money to.

And so we have set up, as of yesterday or the day before, a working group that will look at this issue. Let me tell you how that's going to work. It will be co-chaired by Roy Wilson, who's on the phone, president of Wayne State, and by Larry Tabak, who often gets the opportunity to co-chair one of the working groups when we have a thorny issue, and this is one of those.

We have also invited, as part of the working group, because as you know, we can reach out to experts in this space and asked them to be part of the working group and then obviously report back to the full ACD, but we have a wonderful lineup of academic leaders.

Jeff Balsler, who's the president and CEO of Vanderbilt, Ana Mari Cauce, who's the president of the University of Washington, Michael Drake, the president of Ohio State University, Sam Stanley, president of Stony Brook University, Maria Zuber, vice chancellor for research at MIT and Wallace Loh president for the University of Maryland.

All of them have agreed to take part in this and that information has been shared as of yesterday as part of the Senate hearing because Chairman Lamar Alexander, who has been quite concerned about this issue, and also enhance previous life at the university president wanted to be sure that we have a mechanism in place to work closely with our university colleagues to address the issue.

I must say, he seemed very happy when he heard about the roster of the working group members that are going to take part here in what we want to do. We are asking this working group to move swiftly and in what might be called a sprint to pull together recommendations for us and how we can work best with our grantee institutions as part of that long tradition of partnerships.

And also how we can be sure to recognize the honorable participation by foreign nationals the vast majority of the things that go on in the American scientific enterprise.

So we have given a charge to the working group as of the day before yesterday to identify the best approaches to approach this, make sure that all sources of research support and affiliations are being accurately reported to the institutions and then to NIH, to propose the best approaches that facilitate appropriate collaboration that still safeguards intellectual property.

And proposed steps that NIH might take a look at anyways that the peer review process might be affected and then to be able to identify those and act accordingly.

And we've asked this working group to work intensively on this and be prepared to make some recommendations to you, the ACD, at the December 13 and 14 meeting.

So that is one of the two working groups we want to tell you about. I will stop here and see if Roy and Larry want to make comments about this and then to hear what your questions are. So, Roy, any comments?

Roy Wilson: Just very shortly, you know, certainly you've covered it very nicely, Francis, as you usually do. I just wanted to just emphasize that there are a number of university presidents on this committee and this is arguably the busiest time of the year for us as new students, the board.

But, I think all of us agreed to serve on this committee because we think it is such an important topic. It was just an issue of identifying the bad players and coming up with some sort of recommendations that would address those negative behaviors, I think this would be very - relatively straightforward.

But, as all of you know that on these working groups, very few things on these working groups are that straightforward. And I think what complicates this particular issue is, as Francis already mentioned, the overwhelming majority of students and faculty from other countries including China who are involved with funded biomedical researcher, not only playing by the rules, but they're contributing greatly to the advance of scientific knowledge to our benefit.

And so, we have to make sure that whatever recommendations become up with, that we take special care not to stigmatize these colleagues and also not to disincentivize the scientists from continuing to, you know, enrich the scientific environment in our university.

So, we are committed to working hard to get this done and we know what the timeline is and we'll - I look forward to reporting to you on the December ACD meeting.

Francis Collins: Thanks, Roy. Larry, comments?

Larry Tabak: No, I think it's been covered well. Thank you.

Francis Collins: Questions from the ACD?

Geoff Ginsberg: Francis, this is Geoff Ginsberg.

Francis Collins: Yes.

Geoff Ginsberg: I'm wondering if the issue of cyber security as it pertains to this issue is in the remit of this committee. And if not, if it's being handled somewhere else. In other words, the ability to hack a server with valuable grant information or intellectual property related issues seems to be an important issue to me.

Larry Tabak: So, Geoff, this is Larry Tabak. Certainly we will touch upon this but I will say that, when the case is that we are aware of, this has not been the approach used.

We have extremely sophisticated approaches to maintaining security on the most sensitive materials. It's only when humans acted appropriately that we have detected significant breaches.

But that said, we all appreciate that there is no such thing as a completely invulnerable system today. So it will be touched upon. But given the timeline, I'm not sure that it will be a major topic of discussion.

Francis Collins: Yes, there's this new term we're hearing called a nontraditional collector of information. And that's really what our concern is, nontraditional collectors who are, themselves, part of the scientific community but who are engaged in diversion of information that is not proper.

But it doesn't involve cyber security. It's information that they, quite rightly, would have access to but are not treating appropriately in terms of where it should go.

Geoff Ginsberg: Thank you.

Francis Collins: Other questions? If not, let me go on to the second working group because I know we only have a half an hour. This I think will be more fun and more upbeat and it's a really exciting time for the ACD, I think, to get engaged in this through the formation of a working group on artificial intelligence.

We had a very seminal meeting here in July which was something that was put together over some time as we saw more and more examples where artificial intelligence and machine learning are becoming central to various things that are going on in biomedicine, all the way from very basic science investigations, to clinical applications.

And yet, I think it's fair to say that we have not really done much more than scratch the surface of where that may take us over the course of time. And it would be a very appropriate moment, therefore, for NIH to consider what additional roles should we be playing in encouraging these kinds of approaches.

We're all excited about the data and we are producing massive amounts of big data. We all say that this ought to be a great opportunity for insight to emerge for various things such as machine learning or deep learning approaches.

But are we actually positioned to make that happen, both in terms of training, in terms of recruiting experts that know a lot of what's going on in this field in terms of other kinds of applications and getting them to work on medical problems.

We, at NIH, generate hundreds of terabytes of data. Just pick the Pub Med program as one example. We have repositories that have vast amounts of genomic information and now, more and more, electronic health records coming on board, images, new programs like All of Us which has just hit 100,000 enrollee mark yesterday, on the way to 1 million.

Generating various types of data all of which is going to be incredibly useful as a source of information that won't be as useful as it could be if we don't have our act together here in terms of how to integrate concepts of artificial intelligence into biomedical and clinical research.

So, we want to build a community around this effort and we need expert advice on how NIH can maximize our impact. We did have this meeting on July 23. It was fascinating.

We brought a number of folks that we support who were already applying these kinds of approaches to various basic or clinical problems. Craig Mundie, who is with the Quantum computing group at Microsoft, and prior to that was sort of chief advisor to Bill Gates about how to position themselves in the AI field, came and blew us all away with predictions about where this is all going and what we should be doing to try to capitalize on that.

So, it just seemed like a great moment to use the mechanism of a working group which allows us to basically sign on anybody who has expertise in this space, is willing to put some time into it and many of whom will probably not be from academia but maybe from private sector, and give us advice about where we need to go.

So, the decision then was made that the ACD is a great venue for this. That means we need a working group. We have so far managed to convince David Glazer that he would be willing to serve as cochair. I hope he's not going to disagree with me right now.

And once again, Larry Tabak, in his role as the interim associate director for data science, will be the co-chair along with David. We have not yet identified the ideal roster of participants, although we have some names that are floating around.

And one of the things we would love to hear from all of the ACD members, not necessarily now, but any emails that you want to send to me and Larry afterwards, if you have the greatest idea about who would be appropriate to consider for this, that would be terrific.

And so let me stop there and see if David or Larry want to make a comment about our intentions here. David?

David Glazer: Not a lot to add, Francis. Just to second your - the enthusiasm and the general statement of we are - have come a long way towards solving the problem of generating the raw data and now we have an opportunity to apply new tools to find new insights.

So, I agree it's an exciting time and the right time to take a principled approach to how can we use artificial intelligence to take the next step.

Francis Collins: Larry?

Larry Tabak: No, I think this will be both informative and enjoyable for the ACD to wrap their arms around. Certainly I'm not knowledgeable about this in any way but, you know, I'm just fascinated by what can be done as experts have slowly been trying to teach me about this.

And I think we will all, you know, learn together, you know, at some level. And I look forward to at least getting this going. Francis alluded to the fact that I'm doing this one with my interim ADDS hat on.

My hope - my real hope is that we are able to recruit a chief scientific data strategist really soon and then that I would turn this role over to him or her the data they arrive in the new home.

But I'll certainly look forward to working with David, you know, just to get things up and running.

Francis Collins: So, any questions about this proposed working group which we hope to get initiated pretty soon? Again, would love to have any ideas from ACD sent by email about ideal numbers for it.

Anne Churchland: So, we should send those directly to you? This is Anne Churchland.

Larry Tabak: Send it to me, Anne – Larry Tabak.

Anne Churchland: Okay. Thanks.

Geoff Ginsberg: Francis, this is Geoff again. I just want to see where the boundary conditions are for this working group. Like, are you also thinking that there should be some policy agenda for this or the end-users involved or is this more strictly, you know, an AI ML community?

Francis Collins: I think the main charge is to identify what NIH to be doing to nurture and encourage the development and application of artificial intelligence, machine learning, deep learning to problems of biomedical significance.

That might very well involve some consideration about what policies need to be considered to make sure that this happens. But, mostly I think we're trying to figure out how do we nurture a research community that's still sort of nascent to take full advantage of what's coming? Is that fair, Larry?

Larry Tabak: Yes, I think that's right. I think - so there are a number of groups across government that are wrestling with various policy issues, Carrie - you know, who is expert in policy domain, may want to comment about this.

But I would - my own feeling is this group should focus more about how we enable the science, how we attract people with this unique expertise to biomedical research, how we train more people in biomedical research in these disciplines so that at least we are not in the Tower of Babel and are able to, you know, crosstalk. But, you know, specifically policy procurement.

Carrie Wolinetz: Yes. I will just say that there is a lot of interest in those across the government both at sort of the broad federal level, you know, through OSTP, for example, as well as at the HHS level.

That's a lot of the policy discussions, you know, really strategic planning and coordination are occurring around at those levels. And I think ultimately will trickle-down to the agencies. But this is much more focused on the science itself.

Mark Dybul: So, can I just ask on that - this is Mark Dybul - I mean, those conversations involving scientists and science ethicists related to science because I think there's some concern about you could wind up with a lot of nonscientific views of what's going on from a policy ethical level?

So, you know, that's not happening, you might, Francis and Larry, consider having a group of scientific ethicists looking at some of these issues, too, to feed into those policy conversations.

Francis Collins: Yes, that's a good point, Mark. Certainly we are optimistic of the arrival of a White House science advisor, director of OSTP, whose confirmation hearing was yesterday, that being Kelvin Droegemeier, they help a bit with this in terms of providing a real framework for the White House's interest in artificial intelligence to become more scientific.

There has been a working group - we've had a representative to that from NIGMS who's sort of - this Susan Gregurick, who's been keeping us informed about what's going on. But I think if Kelvin gets confirmed quickly, that may help quite a bit.

Anne Churchland: It also could be - this is Anne Churchland again - it also could be feasible to try to recruit people for the new working group that have sort of a mind towards ethical issues.

I think a lot of people that work in a higher where of the big ethical implications and are enthusiastic about thinking them through. I organized and an AI neuroscience meeting at NYU a few months ago and one of the breakout sessions was an ethics one, and it was the most popular one that was attended.

So I think, if that topic is considered one that the working group could keep on the back burner, I think it would be very feasible.

Francis Collins: That's very helpful, Anne, and if you have specific suggestions based on what you know in these particular interactions you've had, please pass them on if you've got a great idea of the perfect people to do this.

Anne Churchland: Yes, I will.

Francis Collins: Thank you. Any other comments? We only have a few more minutes, but if people want to raise issues, please do. Well, hearing none, thank you very much, everybody, for making ourselves available.

Again, this was not a decision call. It was an information call but we wanted to be sure you were updated on what we're planning here. And there will be much more to talk about all of this together in December 13 and 14.

I hope that's on your schedule because it's great to have everybody here in person for the day and a half that we ask you to come to Bethesda for. This will be a very busy meeting.

We have three working groups that will be reporting at that point and others that will be giving interim statements about where they are. I think it would be pretty interesting.

So with that, again, thank you everybody. Thanks to those who called in, in listen only mode, to hear this. We will consider ourselves adjourned.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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