

**PMI Cohort Program Advisory Panel Teleconference
December 17, 2015**

Operator: Welcome and thank you for standing by. For the duration of today's conference, all participants will be in a listen only mode. I'd like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Dr. Josie Briggs. Thank you. You may begin.

Josie Briggs: So, I want to give a very warm welcome to the very first meeting of the PMI Cohort Program Advisory Panel. By the way, for the terminology used by our conference, you are speakers not participants. This is a public call, and as many of things we do here at the NIH, it is open to the public to listen in at this stage, and not to speak. We have a lot to accomplish in the short time, and before we quickly get to Dr. Collins, I'd like to ask our executive secretary Gwynne Jenkins to take roll.

Gwynne Jenkins: Okay thanks Josie.

Gwynne Jenkins: Rob Califf?

Gwynne Jenkins: Lon Cardin?

Lon Cardin: Yep, here.

Gwynne Jenkins: Alta Charo?

Gwynne Jenkins: Tony Coles?

Gwynne Jenkins: Rory Collins?

Rory Collins: I'm here.

Gwynne Jenkins: Karen DeSalvo?

Karen DeSalvo: Present.

Gwynne Jenkins: Eric Dishman?

Gwynne Jenkins: Mike Gaziano?

Mike Gaziano: Here.

Gwynne Jenkins: Alejandra Gepp?

Gwynne Jenkins: Sachin Kheterpal?

Sachin Kheterpal: Present.

Gwynne Jenkins: Marie Lynn Miranda?

Marie Lynn Miranda: Here.

Gwynne Jenkins: Bray Patrick-Lake?

Bray Patrick-Lake: Here.

Gwynne Jenkins: Dara Richardson-Heron?

Gwynne Jenkins: Greg Simon?

Greg Simon: Here.

Gwynne Jenkins: Sharon Terry?

Sharon Terry: Here.

Gwynne Jenkins: David Williams?

Gwynne Jenkins: And in the room, Francis Collins?

Francis Collins: Yep, here.

Gwynne Jenkins: Josie Briggs?

Josie Briggs: Yes.

Gwynne Jenkins: Kathy Hudson?

Kathy Hudson: Yep.

Gwynne Jenkins: And I'm Gwynne Jenkins. Okay, that's it. Thank you Josie.

Josie Briggs: So, I'm really delighted to have this finally happening, and really appreciative to all of you for your time. By the way the bios of everyone are available online. So we're not going to waste time with introductions, but we are scheduling as you all know a face-to-face meeting now set for January 15th and going into the 16th which is Saturday and at that point, we'll all hopefully get to know each other's faces as well as voices. But anyway, thanks so much, and now I will turn this over to Dr. Collins.

Francis Collins: Well, thanks Josie and again let me say to Josie thank you for the role you're playing as Interim Director and chair of the panel. This PMI Initiative aiming to enroll a million or more Americans in an unprecedented cohort is really quite a major task, and Josie has been ably leading that effort since she agreed with a little bit of arm twisting to take this on while we undergo a national search for a permanent director. But I want to say particularly thank you to all of you on the advisory panel.

There is a lot to do here, and it's going to be fantastically interesting. But we really need your help to make it happen, and we will be asking for that help. In setting together the roster for this panel we included a number of you who served on the working group of my advisory committee to the director who delivered on September 17th the design plan for the PMI Cohort. Of course that is the plan that we have now used as our starting point for an implementation effort, which is what we really need your help with to be sure we're getting it right.

But we have other members who are part of this panel who were not part of that working group. So, welcome to you all, and we will try to quickly get everybody up to speed. The goal for this panel and I'll go through the specific goals in a moment are to provide external oversight and expert advice on division, scientific goals and operations of the PMI Cohort Program of the National Institutes of Health. You have been sent the charter and it goes into some more detail about what the charges are here.

The panel is charged with evaluating and providing recommendations regarding the cohort program activities. Importantly, findings and recommendations of this panel that you have joined will report to the NIH Council of Councils for further consideration. We need to anchor you in a FACA Committee that's government speak for a chartered committee and in this case, the Council of

Councils is that committee which will use the panel's findings and recommendations to pass those along as final recommendations to the PMI Cohort Program Director at the moment that's Josie and to the NIH Director at the moment that's me.

So specifically, just to enumerate a little bit more clearly what we're going to ask you to do. You consider the overall vision and direction of the PMI cohort program. You will be asked to weigh in on concept clearance for new initiatives to be established under this program. You may recognize that as something that councils generally do at NIH. So, in many ways although you are reporting through the Council of Councils a lot of what you're doing will be very council-like yourself.

You will be asked to review preliminary funding plan proposals. Obviously a critical part of the cohort plan is how we're going to spend the money, and after grants come in and get reviewed, funding plans will be drafted up, and you will be asked to help us make those decisions correctly. You will also be asked to do an ongoing assessment of the current projects and programs supported by the PMI Cohort, and to be sure that those are being coordinated and integrated with activities of individual NIH institutes and centers and we'll obviously help by providing information, and access about appropriate data about that.

Not right now, but between years five and six this panel is charged to provide an intensive examination of the progress to ensure the vision has shown continued adaptation to what undoubtedly will be a rapidly evolving landscape of research. And as necessary to help you with all of this with approval of the chair of the panel which again at the moment is Josie and will become the new PMI Cohort permanent director once that person is identified you may call upon special consultants.

You may assemble ad hoc work groups. You can convene conferences, workshops and other activities. We want you to feel empowered to gather information from every kind of expertise that you need. So, I thought I would say a little bit more about this Council of Councils, because that's not necessarily a body that everybody's familiar with, and since you are reporting through them you might want to know a little bit more about them.

So, this is a group of about 30 members selected from NIH institutes and Centers Advisory Councils. So these are all people who are on an advisory council, but who get an additional job of serving on the Council of Councils. And we try to choose those representatives so that they have broad expertise across many different areas of our research portfolio. And that includes lay representation as well as a member of the NIH Council of Public Representatives. This was established under the Reform Act of 2006.

So it is a chartered permanent council, and it advises me on matters related to policies and activities of the part of NIH we call DPCPSI; the Division of Program Coordination, Planning, and Strategic Initiatives. Frankly, one of their main tasks has been advising about the common fund, the common fund decisions have to go through them, and they've been very helpful in that space. The PMI is actually as an initiative has a budget which is being carried through this same portal as the common fund although we do not consider the PMI as a common fund project in the traditional sense.

But because the funding does flow through the same offices in DPCPSI it is natural for the Council of Councils to be the parent body of your panel. So that's just a little bit of background. Let me now say something about what we are hoping you might be able to do and maybe give you a sense of what this commitment adds up to. We will be asking you for a lot. We're going to be

bothering you, but I think you'll like it, because you'll find it I think truly inspiring what we're trying to do here in the number of tasks that are in front of you are going to be really interesting.

We have already begun implementation of the recommendations that were put forward on September 17th. There are six funding opportunities on the street including four more traditional kinds of RFAs -- except they're not really traditional and two solicitations that are in a different mechanism we call other transaction authority. So six funding opportunities. Many of you are very familiar with these. Some of you have actually been involved probably in putting together potential applications. I'll come to that in a minute in terms of conflict of interest. We are also engaged in a search for a new director. We will want help from you on that as we narrow down the candidates.

Josie Briggs: Most of them are on the search committee.

Francis Collins: And a couple of them are probably on the phone right now. And there is also an RFI that is out there on the street about physical evaluation and biospecimen collection for the direct volunteers. How should we carry that function out, and once we get responses to that we'll want to discuss those with you. The first area that will actually have reviews done are these two other transaction award opportunities, because those move very swiftly.

A fairly short timeline for response, and a very quick review, and we will need your help on those as soon as January.

And likewise if we are successful with this director search we may very well have somebody for you to meet hopefully early in 2016 who will need your support, provision and other aspects of crafting the cohort. So it's going to be a wild ride. We'll be riding there with you, and I think when you consider the impact that this cohort could have across the whole landscape of research that

all of you care deeply about with full participation by the individuals who are going to sign up for this.

Remember these are participants. They're not patients. They're not subjects -- certainly not subjects. They're participants. They're our partners, and we're happy that some of them are represented on this panel in larger numbers than is usually the case for review groups of this because we want to be held accountable that what we're doing here is responsive to what the participants want, and not just what researchers want. Let me say a word about conflict of interests.

We are aware that those will arise. We wanted to have people on this panel with the greatest expertise, but that also meant that these were people who might very well be engaged in putting together applications for some of the opportunities that are coming forward as part of this. We are used to that kind of situation. We know how to manage that. If it comes to pass that a particular discussion of an RFA or some other competition is happening in the panel and you are involved in one of the applicants -- applications, you will be recused and asked to leave the room, and not take part in that conversation.

We will be very important therefore that everybody on this panel is comfortable with full disclosure, and if there are areas where you believe that there could be a real, or imagined, or at least a concern about conflict of interest. Please be sure to raise that so that we don't get surprised later on by any concerns. And this can be handled by your addressing any of these questions or possible conflicts with our very able executive secretary Gwynne Jenkins who you heard from a minute ago calling out roll and you're going to be very well served to have somebody as the executive secretary of this group with her experience, and knowledge of the field, and incredible work ethic.

Some of us have been really fortunate to be working with Gwynne for many months now, and she will be a wonderful asset to all of your work. So those are the things I wanted to put in front of you by way of a charge, and a description of the charter, and a little bit of context, but let me stop and see if there are questions from panel members.

Greg Simon: This is Greg Simon. So I assume this also means that we all must askew all of those royal titles that we're being offered by foreign monarchies for the duration of our service.

((Laughter))

Francis Collins: Oh yes, you know about the analogous clause of the Constitution -- I can tell. Yeah.

Kathy Hudson: Actually, Francis it does not apply to working group members.

Francis Collins: Oh, that's right. You're not on a FACA committee. So, okay. Go ahead and take all the royalty things as long as they don't represent some other kind of conflict of interest.

Greg Simon: So the crown and scepter I can keep?

((Laughter))

Gwynne Jenkins: That's right.

((Laughter))

Francis Collins: Yeah.

Francis Collins: Other questions?

Gwynne Jenkins: While you're thinking about your questions, this is Gwynne Jenkins. I'm just going to can ask has anyone else joined the call since I took roll? Okay, thank you.

Operator: Excuse me. This is the operator. The people joining with the participant passcode are in listen-only mode, and are not able to respond.

Gwynne Jenkins: Yes - no. I was just wondering about the speaker code.

Operator: Yes. Thank you.

Gwynne Jenkins: Thank you.

Operator: Okay.

Francis Collins: Oh good. Everybody is I guess shell-shocked or something. Did you know you were getting into this? Well, I hope -- I hope you did, because I called many of you to ask you to take part in this, and you got other invitations from other people here. Seriously, we don't want to in any way to take advantage of your skills, and we will try to limit what we ask you about to those things to where we really need serious, high level advice.

There will be quite a bit of that. I think this group will find over the course of the next few months that you get to know each other pretty well, and that you have the opportunity to have the whole become greater than the sum of the parts. Because you have a remarkable variety of expertise, and a really remarkable level of experience represented in this group. So, while we are going to be a little bit in your inbox, and on your phone, and occasionally bringing you together, I think you will find this to be a pretty interesting experience.

Josie Briggs: Now some of the decisions that we have ahead I think are going to be incredibly interesting, and I'm really delighted to have the input and advice of such a

knowledgeable group of people. And I'm also very grateful to Gwynne Jenkins who will be the exec sec and you'll get to know her name well, because most of the communications will come through her. I think you do know that we have an open meeting. That part of it will be a re-discussion of some of the key elements from the Advisory Committee to the director so that all members of the group are equally informed about all of the deliberations that have gone on to date.

That is scheduled for Friday, January 15th. The following Saturday we've also asked you to block half of the day, and at that point we anticipate moving into closed sessions. We may have funding plans ready for you to discuss in any case we have many items of planning where your input and advice will be helpful. So if any questions have occurred to you given five more minutes to think there is still time for questions or thoughts.

((Crosstalk))

((Laughter))

Josie Briggs: Yes, go ahead.

Sharon Terry: Oh, this is Sharon Terry, and partly just want to say something, because I know it's horrible just talking to a vacuum for you guys.

((Laughter))

Josie Briggs: Well thank you Sharon.

Sharon Terry: Yes, thank you for the opportunity. This is pretty clear. I mean one of the obvious questions is, how much time and effort will this take? I think all of us who have said yes and I can see the caliber of my colleagues know that this will take a lot of time and effort, and it's a worthy cause. So we look forward

to it, and look forward to the kinds of things that we may get into with each other.

Josie Briggs: Yes, as Francis said, we'll try to use your time well. We'll try to make the meeting agenda packed and informative, and --but also make sure there is plenty of time to let us to hear from you about some of the hard issues that we face. At present time, we're thinking in terms of three face-to-face meetings. Some of them timed closely to precede the Council of Councils. That may change, because we may have topics that come up where we think a day of having you either in Bethesda -- may be particularly helpful for some hard issues but that's approximately what we're thinking of is a three times a year, day and a half.

Any other comments? Sharon is also serving on the Director Search Committee. Sharon and I had a slightly confusing email exchange today, because she suddenly realized she was on two panels, and began asking about two meeting dates, but I think we are on track for really superb input and advice. So, I thank you all, and...

Marie Lynn Miranda: Can we - May I just add it. This is Marie Lynn Miranda. If it would be possible for us to lay out sooner rather than later when you -- when we might have these additional meetings, you know, by the time the meeting on January 15th was announced. There were really immovable things I think on some of our calendars.

Josie Briggs: Right, I apologize for that, and we will indeed at the time of the meeting in on January 15th we'll have a tentative agenda for the certainly the meetings of the rest of the calendar year, but it is a very valid point.

Francis Collins: Yeah --sorry about that Marie Lynn. We're trying to build a plane while we're flying it, because this is one of those where the President of the United States expects to see this enterprise get up and going before he walks out of the White House. So, we are doing things at an unprecedented rate of speed. Obviously, that sometimes compromises our ability to give people advance notice and that certainly happened with the January meeting and I'm sorry about that.

Marie Lynn Miranda: Well, far be it for me to, you know, to disappoint President Obama. Just going forward, if we could have a little more advanced notice on when the meetings would be, because I'd be delighted to build my calendar around those meetings. It's just, you know the more time we have, the easier it is to do that.

Francis Collins: Yes.

Josie Briggs: Thank you very much.

Francis Collins: Point well taken.

Greg Simon: This is Greg Simon with one other comment. One thing, you know, when you talk about the breadth of experience of this panel, it was interesting to me and I have to say my first, you know, thought after being asked was why would they be asking me to do this. And noticing that the expertise at least in the named panel members lies not so much in the area of genetics, but more in other areas which I think tells me something about where you think some of the big questions are.

Questions about understanding patient's experience, about how health systems work or don't, about how we deal with an avalanche of data, about environmental exposures. So it's interesting to me if that tells us something about the diversity of the questions that you think we'll be needing to deal with.

Francis Collins: Oh Greg, you are very perceptive. I think there has been a sense or maybe an assumption on the part of people about this program that this was just Human Genome Project 2.0. It is not. The goal here really is much broader than that. To try to capture information from patient reported outcomes, from access to electronic health records with all kinds of information there. With access to various technologies that can be used to monitor health and disease, wearable sensors and so on, and laboratory efforts which may include some genomics, but will include other things as well.

So yeah, it would be great for us all to sort of broaden the horizon here, and think about what you could do with a project of this sort not limited in any way to a particular window of opportunity but trying to embrace all of those windows.

Josie Briggs: And indeed some of our most immediate questions are how to successfully engage participants. So social science has become very relevant.

Francis Collins: Indeed.

Josie Briggs: Oh, I gather that there are Dara Richardson-Heron is just added to the call. I wanted to welcome you as well. Thanks for joining us.

Dara Richardson-Heron: You're more than welcome, and I've been on for --since about 5:20. So I heard the whole discussion. Thank you.

Francis Collins: Perfect. Thank you.

Josie Briggs: We appreciate your help and advice as well.

Dara Richardson-Heron: It's quite an honor to be on the panel. Thank you.

Josie Briggs: Any further questions or comments before we close? Okay, so I again thank all very much, and look forward to seeing you all again on January 15th and -- again -- my appreciation for your help and advice.

Francis Collins: Yep. Thanks everybody.

Dara Richardson-Heron: Okay, thank you.

((Crosstalk of participants saying good-bye and thank you))

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