

## **Discussion of Ethical Implications**

### **of Genomic Data-Sharing**

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[PowerPoint Presentation.]

DR. ROYAL: Thank you, Steve. I don't know why I'm so fortunate to be thrust into this so early, but I'm going to talk a bit about the ethical implications of genomic data-sharing.

I am [also] going to lead a discussion of where we think SACGHS should go on this topic, what do we think we should do, and the issues in terms of genomic data sharing that have come out of large-scale sharing of genomic data, not the least of which is the NIH requiring that research funded by the NIH and conducted by the NIH, genomic from that research, GWAS studies, should be entered and submitted to DBGAP to allow for sharing and usage, and ultimately for additional information, as much as we can find out about health and disease.

The goal, of course, has been to develop methodologies to improve health, public health.

So the collection and broad sharing of individual genomic data. Later on, we will also talk about data

related to groups, not just individuals, when de-identified. The issue of de-identification, as we know, has raised a lot of issues.

We talk about de-identification, but research papers have come out, one last year from TJAN and another earlier this year, showing that it is actually possible to identify individuals from aggregate data. So that raised concerns about data being out in the open and available to researchers broadly.

The implications for consent, privacy, discrimination, those are some of the issues raised, and we could think about this in terms of the stakeholders that could be involved in this, the researchers, the physicians, patients, communities at large, industry.

So the issues span a broad spectrum in terms of what we might think about. Some of the questions that have been raised have to do with consent or traditional ways of thinking about consent, individual consent, consent where we actually know what is going to happen and we put that in the consent form, but with sharing data, we have no idea, in some cases, of what kinds of studies will be done, who is going to have access to data.

So the issues of consent and how do we deal with new ways of thinking about consent.

Genomics has really brought about a change in thinking about the lines between research and clinical care and that line is becoming increasingly blurred. We already see cases where genomic data, outcomes data actually, can be used to help us think about the clinical validity of genetic tests. That could be considered research, genomic GWAS studies that produce information that could be clinically relevant to participants, and communicating that information back.

So the lines between research and clinical care is an issue that this kind of research raises.

There is also concern about whole-genome sequencing being a unique identifier that can be linked with data that might be obtained or stored in other contexts. And then, this also raises issues of privacy protection.

So these are some of the issues that we think about or that the issue of sharing data, genomic data raises.

In terms of what SACGHS has done, I'm going to

talk about meetings that I never attended, and so my information certainly is coming from those who were at those meetings. In December, SACGHS identified this area, the ethical implications of genomic data-sharing, as one that it would place as a priority area for consideration, and here we are trying to figure out what specifically we are going to do in this arena.

At the meeting in March, there were briefings on the IOM Report on Privacy, the HIPAA Rule, and then from the Secretary's Advisory Committee on Heritable Disorders and thinking about informed consent.

At the end of that session, there were suggestions that SACGHS should coordinate their efforts with the Office of Civil Rights, and they have been very much involved in GINA, which, GINA, of course, we think about in terms of privacy protection. That office was represented yesterday.

The Secretary's Advisory Commission, SACHRP, their work on informed consent could really help inform our efforts here. The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, they recently released a report with recommendations on dried blood spots

for newborn screening and issues of consent, issues of access are things that that report raises in the recommendations there.

The HIT and David Blumenthal were here at our last meeting. [David's] groups, the Policy Committee and the Standards Committee, are also entities that we have been talking with about this issue. The HIT is involved in the meeting next week, on electronic health information, that I'll be attending as well.

One area that seems really ripe for collaboration is another collaborative effort that SACGHS has been exploring. In September, ASPE awarded a one year contract to the Lewin Group. Is Sandy here? No? Okay. Sandy is the one, the primary contact there.

The goal of that contract is to develop a report and that report would be informed by review of the literature as well as interviews with experts on the issue of genomic data sharing and that contract is designed to provide input to SACGHS but also our work. Our thinking is that our work would also inform that of the Lewin Group and we'll talk more about that project and how SACGHS might inform or be informed by the efforts of the Lewin Group.

And in order to complement some of what that group is doing, one of the things that we're proposing is a session at next year's meeting to explore models of genomic data sharing. So today, we're going to try to come to some decisions about what the Committee will do with regard to ethical implications of genomic data sharing.

One of the things we're proposing is to form a steering group, a steering group of three to five, three to six people and ex-officios, as appropriate, to explore models of genomic data sharing, and we plan to discuss that at the February meeting. That's the thinking, that we would explore models of genomic data sharing.

We talk about genomic data sharing and the Lewin Group will be doing a lit review and they will be doing interviews, but we thought it might be helpful to see what is going on out there in terms of genomic data sharing before we can really be qualified to talk about where it might go.

We're thinking of this session for the February meeting and then also to provide input to the Lewin Group and these are the things we're proposing. So there are a number of questions for discussion and I'm going to go

through these questions and then sort of come back. Just to give you an idea of what the questions are, I'm going to go through them and then we'll come back to discuss them to see what we think we might do.

So we want to first talk about whether we should organize such a session at the February meeting to look at genomic data sharing. Should we form this steering committee? Are there other things that we should do with regard to this topic, in addition to or in lieu of having a session? What should the session focus on in terms of models of data sharing? Should we focus on academic models? Should we focus on industry? Where should we place our emphasis in terms of looking at models of data sharing?

Should we focus on clinical data versus data from research? Types of diseases, rare diseases versus common diseases? Should we focus on specific elements of these data sharing agreements? We probably need to look at them to see what the common elements might be first before we even think about what we might focus on. Should we look at particular populations?

At the last meeting, I understand there was a

discussion about vulnerable populations, and we'll talk more about that and even what the definition of vulnerable populations is and where we might focus there, if we think we should.

Are there any drawbacks to organizing such a session, and what should come out of this session?

So I'm going to go back to our discussion questions and ask whether folks think we should organize such a session. Is Greg Downing around? Greg, would you come join us at the table?

DR. TEUTSCH: Actually, Kevin, why don't you join us, as well? Kevin had been spearheading this effort up until his recent departure from our group.

DR. FITZGERALD: Just when I thought I was out.

DR. ROYAL: You'll never be out, Kevin, never.

DR. TEUTSCH: He'll never leave this group.

DR. ROYAL: Yes. So these three questions on this slide will actually determine what we do next. They will determine whether we even need to answer the other questions. The first question is: Should we organize a session on models of genomic data-sharing.

Let me go to the last one: Are there things,

other things, that people think we should do as opposed to doing a session, or in addition to doing a session.

So the question about a session at February's meeting, where we explore models of genomic data-sharing, of course, needing to do some background work leading up to that meeting so that we can actually have these models to discuss.

DR. TEUTSCH: Greg, we know you've been giving this a lot of thought. Do you want to share some of your ideas about what this could be and how it could contribute to the departmental efforts?

MR. DOWNING: I would be happy to, Steve. First of all, thank you again for all of the hard work that this committee has been doing, and in particular to Charmaine, who we've had a couple calls with to share information, and I have been working very closely with Sandy Howard in the procurement of the study that's going on.

I think, as the initiative for that has taken shape, that there are some commonalities around a variety of things that we see happening, broadly speaking, around the elements of clinical genomics. So I think there is an opportunity here.

I have learned my lessons well when coming before this group: be careful what you ask for. There is no mandate here by any means, I want to be clear about that, but it seems as though one of the higher-level cultural things we're seeing going on, [and] what we think are good things for innovation and long-term benefits for healthcare, is a lot more collaboration amongst institutions and collaborators, not necessarily as a consequence of any particular funding initiative, but just as the basis of trying to get work done that requires larger populations than one can collect in their own institutions.

So I think, obviously, the ethical aspects of this has lots of hard questions associated with it. I think one of the things that we've been looking at is some of the new partnerships that are emerging across the organizations, and what are the models for addressing the consent issues, the data-sharing issues, the publication issues, and so forth.

Obviously, this builds on a lot of the work that your committee and others have done with GWAS-related studies, but we see that as just the one step forward here,

that there will be other areas where these comprehensive databases are evolving. The relation of that data to other kinds of data brings enormous power and influence, if you will, to many aspects of not just biology but to health and society.

So it seemed appropriate to us. We don't have specific questions or a destination that one would want to necessarily arrive at, but it seemed as though this body might be interested in questions like that.

The other elements that I think Charmaine's [report] brought out is that this committee has engaged many other advisory committees in their discussions around health IT and newborn screening.

I think, one thing, in my observations over the years, is that the communication has gotten better across different advisory committees and the coordination elements. So I think there is an opportunity here, and we don't want to influence the Committee's bias, in one direction or another, toward any particular outcome.

The other thing I want to share is that, from the perspective of looking at data and technology overall, there is a great deal of interest in the aspects of how

technology supports the movement of data, and the applicability of data to solve problems. There are many efforts in the government, right now, to enhance and mobilize data from a variety of different sources. All of our agencies are feeling that.

From the standpoint of being able to support this kind of information being used in a variety of different facets of human life, having not only the technological and scientific means to share that information but having the public policy perspectives prepared, or at least be thought of as that mobilization of data takes more shape, that we are not so much ahead of the game but at least trying to catch up faster. I don't know if that makes any sense.

I'm guessing that most of you are starting to feel the imprints of Facebook and MySpace and Twitter, and all of these technologies. It's really only a matter of time when the capabilities of that hit other elements of data sharing.

So principally, I think we are interested in models that portray the thoughtfulness that the people who developed the foundations for collections of data [demonstrate] about themselves. Obviously, we use

Framingham as a reference. The President spoke about that in his NIH remarks earlier this year, that that is really a badge of honor in many ways, and finding the respectful ways in which new technology [can be utilized], and ways to disseminate and use information, that we respect the aspects and take the time and have the policies in place to do that.

I think Charmaine has thought about these issues over the years, and I think we were delighted when she stepped up and shared her interest. So again, I want to emphasize, no mandate for any particular outcome of this, other than a careful examination of what these new capabilities [are] and the power this information provides.

So I would be happy to answer any specific questions and, Steve, I hope that helps provide some clarity.

DR. TEUTSCH: Yes, it does. We'll open it for discussion in a minute, Greg. Appreciate those thoughts.

Kevin, did you want to give -- I know you've given a lot of thought to this, and then we'll open it up for some general discussion.

DR. FITZGERALD: Well, thank you, Steve.

Actually, I did give a lot of thought to this and whoever came up with this idea, this silly idea should have been thrown off the Committee and never invited back. Thank you. No.

Actually, we have given a lot of thought to this idea and, in fact, Greg's being a little humble here, as always. He helped us put together at Georgetown a meeting looking at the consequences for genomic research in some of this database sharing with vulnerable populations, in particular indigenous communities, because we thought this would be an interesting group to engage, obviously groups that have been marginalized for some time, particularly in the healthcare arena, but also groups that are of interest to genomic researchers, due to their somewhat isolated genomic characteristics.

So I think there is a lot to be learned here, and I think, as one could pursue this, you could actually see this as sort of a microcosm for some much broader issues.

What are the goods and the goals that are desired coming out of this research at all, period, across the board? This gives you at least some leverage to break that open a little bit more because you have to ask people what

it is they expect and desire if they do engage in this sort of thing.

So I just see this as another opportunity for SACGHS to again continue to explore this area that is your mandate, genetics, health, and society, and how the research is going to continue to sort of ramp up the importance of these issues and make them very much a part of everyone's lives.

DR. TEUTSCH: Thanks, Kevin. All right. Why don't we open this up for discussion? I will harken back to our messages that I mentioned from Francis Collins to be forward-looking, anticipate issues going forward, and figure out how we can move these fields constructively forward. So think about that and let's open it up.

Charmaine, do you want to coordinate this discussion?

DR. ROYAL: Sure. I can do that. Go ahead, Sylvia.

MS. AU: I totally support this as an activity of SACGHS, especially since I won't have to be on the task force. But, I mean, with the other committee, one of the things that, of course, is a big concern with us is newborn

screening and retention of residual blood spots and data and so this obviously is something that's really important to the states because we all do newborn screening.

DR. ROYAL: Marc.

DR. WILLIAMS: I would also support pursuing this and to bring Sylvia back in on it. The other thing that I think is interesting that isn't represented in your very nice presentation are the issues relating to the direct-to-consumer aspects of data collection.

For the purposes of our blog that I'm inflicting on all of you, look through the User Agreement of one of the direct-to-consumer companies. I think there's some very interesting things there relating to how they're choosing to use this data and Jim had mentioned yesterday about this new research model, again which I think is still an open question as to whether or not this really represents a new and innovative way to do research or whether this is not really going to point out.

But I would certainly increase the scope to include that, as well, since there's probably less in the way of any sort of -- I'm not using oversight in the very specific federal term here, but there's much less scrutiny

of that, I think, than many of the other things that were referenced.

DR. ROYAL: Thank you, Marc. Very good point.

MR. DOWNING: I think there's some ways in which the work of this may have practical applications for some of the work that government agencies do, and I would like to share one experience that we had not long ago with a publication that provoked some interesting remarks that I heard about from -- it was a Friday afternoon in the early part of the summer and who the heck is really actually even reading anything, and all of a sudden I started getting e-mails from all over the place about particular reaction to a publication that I'm sure no one had read but just saw the title of it, and it really related to the genetic findings associated with certain patterns of human behavior associated with substance abuse.

And the notion of being able to relate the sort of behavioral elements and patterns and genomic characteristics together by assimilating information from a variety of different sources that actually did address a salient biological issue really provoked a lot of -- particularly from folks that didn't have backgrounds in

biology, were trying to understand, well, what were the messages coming out of this.

So the thing that really struck us after a series of dialogues that I was trying to understand what is the real root cause of the anxiety of all of this, and it was the notion that the information wasn't being placed in a context that broader communities could understand the meaning of that.

So there were elements that came up about the implications that this would have for people actually seeking help because of these genetic findings were leading to some conclusions that would probably isolate certain populations and so forth.

And as we had a lot of phone calls about this with a variety of people across the department, and it really became obvious to us that we didn't have the informational resources that help put into context the meaning of population-based studies and associations and how, if this work is going to go forward, we have to do a better almost preemptory kind of stage-setting for why we're asking the question, aside from just getting the answers and knowing more knowledge, and the implications of

that.

And one of the things we've been working on with our public affairs groups across the department on trying to set the stage for what does it mean when you're being able to take these large genomic databases and isolate factors, whether it's in diabetes or depression, that these things have real meaning to people and yet the context of what those research projects means by being able to take these large population datasets often have implications that we're not able to explain very easily.

So there's a communication side to this that I think the work that you can do from the policy and the science side might inform the public communications apparatus around the department that helps do a better job around that.

So we would like to use technology in new ways to help explain these research findings so that when you're just getting a publication out there, there's other kinds of technologies or videos or podcasts or things that provides a social construct for what are the implications of the research thing.

So your committee doesn't have to go that far,

but I'm just trying to lay a stage for how other parts of the work that goes on here could be used and consumed by other pieces of the department.

DR. ROYAL: Thanks, Greg. That issue cuts across populations, but when we think about vulnerable populations, that's a major issue in terms of how the data is going to be used, who's going to have access, what kinds of questions are they going to be asking, and that has some implications for whether not just the participants who are the folks who are in these cohorts but the researchers and their willingness to open up their data for sharing.

What I found in some of the groups that I've been involved with, cohorts of African American patients or participants, and it's the researchers that are -- who knows what the consumers, what the people think. The studies haven't been done yet for some of these to see what the participants actually feel about their data being shared, but the researchers of these studies or some of those that have contacted me about them being required to share their data and not wanting to do that because of the group that they're studying.

So those issues are really very, very salient to

the issue of vulnerable populations but also other populations, as well.

DR. AMOS: I just want to get a little bit better idea of this, sort of your vision for the scope of this effort from the standpoint of will it include some of the more practical things.

Greg and I have talked about some of the sort of nuts and bolts of how you actually share data and how you actually -- some of the IT tools that have to be developed to ensure the interoperability of all these systems, and I just want to get an idea about if you're thinking about tackling that, as well.

DR. ROYAL: I didn't think of it specifically. This forum is for us to explore what the scope might be, and if the Committee thinks that that is an area that we need to look into, then we probably will explore it.

I really want it to be open for discussion about how the Committee moves forward because there are other organizations and agencies looking at this issue, the broad issue of data sharing, and what is it that SACGHS can bring that could add to that that will complement and supplement that rather than duplicate it, necessarily.

DR. TEUTSCH: Mike, we're of course on record, as you know, and having met with David Blumenthal last time, we sent notes to the Secretary, really talking about the importance of getting those standards in place so that this kind of work can proceed.

I think it is something we can talk about, whether we need to do more going forward, but we've at least made some statements in that regard.

DR. AMOS: I just want to make sure, if you think you need our help, that we get the right people involved.

DR. ROYAL: Gwen.

MS. DARIEN: This may be a little bit of a detail, but one of the things that we talked about a little bit when I came on the Committee was being the only advocate/consumer representative on this committee, and I think this would be an incredible opportunity to bring in some more of the health advocacy voices.

Sylvia knows because she went to Sarah Lawrence, but I've been doing work with their Health Advocacy Program, and there are a lot of people that are dealing with issues like this. I mean, I know from the tissue-banking and the tissue-collection issue point of view

where, at least the advocates I work with who are cancer advocates and patients, come down on this.

So I think that is a way of bringing other voices into this, which could make it very rich.

DR. McGRATH: Thanks. I would like to also support the formation of a group like this. It is sort of circular. The very first report that I was involved in when I came was the large population study, and it addressed a lot of these issues.

One of the comments that came from the interviews and public comments, and from the experts, was a concern, an underlying concern that those sorts of studies are really the best use of limited resources for addressing population health.

So if this group is formed, it is dealing with the downstream of that, the data that emerges from large studies. I don't know how you integrate that, but it seems like that question hasn't gone away in our country, that is, this is the best way to really improve the health of the greatest numbers of people.

So when we talk about communicating results to consumers and talking to researchers about that, there

might be a way to continue to realize that that is still a public priority, to make sure that the questions asked are the appropriate questions; not just the doable studies, but the important studies.

DR. ROYAL: Doug.

MR. OLSEN: Yes. I just wanted to say, because of the nature of the way VA provides services and the fact that we have an enduring population, we have a lot of plans to do these kinds of studies. We're doing a lot of gearing up for large data collection and improving the capabilities for data sharing. So we have a real interest in this area, and a real interest in the ethics of the informed consent and how to do these things right.

DR. ROYAL: Greg.

MR. DOWNING: I forgot to mention earlier, one of the important contributions that I took away from the workshop that Kevin coordinated was the different models of community consultation.

I don't know if Jennie Weiss is here or not, but we went looking for literature on this and struck out in terms of finding, what are effective models for engaging communities on an ongoing basis for the uses of that

information. We learned a lot from our experiences in going to Framingham, and want to thank a number of you who helped us do that in the past.

The different communities have different needs, we found, and I just think this is more of a social-science issue kind of thing: how do you find out what the communities' needs and information needs are, and how they play roles. There isn't one common model that we found.

Many studies are now international in nature; so, how do you take into consideration the various cultural perspectives on ownership and asking. Through the Native American population here, we've learned a lot, but there are various other models that we've been seeing.

Kevin, I don't know if you want to comment on that, too, but that was one of the rich points that I took away.

DR. FITZGERALD: I agree completely. I think that was what came out of our gathering, but also, the fact, I think it's important for us to acknowledge, that there are other nations and places in the world that are ahead of us in this game, that have been looking at these issues, that have been pulling together some methodologies

and some models. Canada and Mexico, in fact, have been doing a lot of work in this area.

So we don't have to reinvent the wheel, in some regards. There is a lot that we can tap into, and then I think [we can] use that richness to help us move forward. So I think there are ways in which this could move quickly.

DR. ROYAL: Just to piggyback on that, I think you said it's social science, Greg, but I think it's all part of this. I think we do need to look at the perspectives of various stakeholders and the patients. Participants are a critical group.

So I think the social science needs to be combined with the biomedical research. It's all part of who we are. I think it's absolutely important.

MS. LLOYD-PURYEAR: Good morning. I'm the executive secretary of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, and we would be glad to work with this committee on this issue.

I would also like to add that the Newborn Screening Committee and the Rare Disease Committee have already begun to grapple with many of these issues, funding projects and newborn screening around long-term follow-up

or effective follow-up, and looking at the communication issues in order for that process to take place. That includes engaging communities, and also looking at standards development to allow that information exchange.

So I would like to add that the issue of standards development needs to go hand in hand with this effort, because communication won't take place unless you have those standards to communicate. So it is a really important issue to think ahead prospectively about that.

DR. DALE: I'm David Dale. I just was going to comment briefly. For about 20 years, I have overseen an international registry of a relatively rare set of conditions, where we have built a pattern of cooperation. The hard part has been linking the biological and the clinical data, but that's the richness of the registry.

The challenge has been to deal with the continued evolution of the requirements regarding informed consent, particularly where we were on a path of discovery of genes that cause diseases, particularly in children, and the diversity of causes.

Our original request was highly simple, but over time, it was worthwhile to look at other genes. So the

flexibility to do that. I think it's also a framework or foundation for building understanding in a community of interested people about the value of genetic studies as it relates to long-term health.

So it's a model, actually, which could be expanded to consider more common conditions in larger populations. The key feature is linking the clinical data to whatever genetic or analytical data you might have that comes from a laboratory.

DR. ROYAL: Marc.

DR. WILLIAMS: I'm going to put Alan on the spot here, because I don't know if there has been an official announcement or not, but there has at least been some indication that NIH is going to be investing some additional monies into issues relating to the ethical allele of social issues.

I'm just curious as to whether or not this is ripe, then, for some input from a group like SACGHS or this consortium, or whatever, to help to direct some of the distribution of those funds.

MR. DOWNING: I'm not sure exactly what you're speaking of, but I don't think it would be a very good

precedent to have SACGHS directing funding. I think it's great for SACGHS to make suggestions to the Secretary, et cetera, et cetera, but I think it is the science that ought to direct the research, and therefore the funding.

Now, that said, of course the LC Program, for many years, has looked at the issues that get into this, and I think will continue to do so. I'm actually either not aware of, or I'm not hooking up the specific thing that you're thinking of.

DR. WILLIAMS: I don't have enough specific information about what exactly it is I'm talking about. I didn't mean to imply that we would direct funding, but it seemed like if there is some overall sense of the direction that a number of different groups would want to go, that that would at least be of some interest.

MR. DOWNING: Yes. I mean, I think it would go back and forth. I would think that, obviously, it has very much been part of what I think the chairman has been talking about, that this would be informed by the research that has already been done, et cetera, et cetera, but I clearly do think whatever came out from such a group, which I think is a very good idea, would help inform NIH and

others, particularly NIH, about future areas to explore more. Absolutely.

DR. ROYAL: We'll go to Mike.

DR. CAROME: I just wanted to make two comments and mention one area SACHRP is working on in this area.

Charmaine, you mentioned the issue, one of the important issues is the blurring between clinical practice and research, and you see this topic as being important in that area.

I'll just note that that certainly has been an ethical concern and issue, dating back three decades when the Belmont Report was issued by the National Commission on Human Research, and it's an issue our office struggles with frequently when we're trying to separate out what was research and what wasn't research.

It's unclear to me, at this point, why this area of genetics further blurs that line in a way that's different. And if that's true, it would help us to be better informed about why that is. That might be a topic the group could address. And if so, what should be done about it, if it's making the line more blurry.

The other thing, we have had longstanding policy

positions regarding de-identified tissue or coded tissue samples, and have described circumstances in which that doesn't involve human subject research. One question of interest to us is whether these new technologies and advancements would cause us to rethink those positions and, if that's the case, any advice from this group could be beneficial to our office.

Lastly, in terms of SACHRP, they are currently working on, as you mentioned, informed consent issues regarding biospecimens. Their thoughts on that are broad, looking at research in general.

So they are not specifically focused on genetic research. They are focusing on, in general, any research uses of biospecimens: when is informed consent needed; when specimens exist that have been banked, either for clinical reasons or research reasons; when can you continue to use those, given the consenting that was done. Those are the issues that they are currently looking at.

DR. ROYAL: Thank you, Mike. On the issue of blurring, we can move on, but we recognize that it is not a new issue but that there are questions about the sharing of data, data being available to everyone. There are new

questions that could be raised from data moving from the clinician who collected the data to whomever else.

So that's another area that we will talk about, whether we want to focus on research or clinical, or look at those lines.

In general, I am getting the sense that there is agreement that we should have a session on this in February, and the specifics. We talked about models of genomic data-sharing, which is one area that we will focus on, but we talk about so many others that there might be other things that we might want to incorporate into that meeting. We will talk about that later as we move to plan the meeting.

The formation of a steering committee, I don't know. Steve, do we take volunteers now?

DR. TEUTSCH: I agree with you, that I'm hearing that this is a subject of considerable interest. I didn't hear any dissention. So I think it would make sense that we get a small group together to help shape the meeting in February.

DR. ROYAL: Yes.

DR. TEUTSCH: Then we can decide where we're

going to go, after we have had a more complete discussion. It sounds to me like we are in the market for interested volunteers and/or appointees. So, Charmaine, I hope we can count on you to start, and we probably need to draft with Kevin because he can give you some assistance. He's sitting here, so he can't escape.

DR. ROYAL: Yes, he can't escape.

DR. TEUTSCH: We could use a few others who would like to work on it. It would initially be primarily about this committee. I see David, I see Sheila.

MS. WALCOFF: Although I really do want Sylvia to come with me.

DR. ROYAL: I do, too, actually.

MS. WALCOFF: I'm just kidding. I was really just kidding. She has done a lot of work.

DR. ROYAL: I'm not kidding.

[Laughter.]

MS. AU: As long as Kevin's on it.

DR. FITZGERALD: I'm already on it.

DR. TEUTSCH: So we've got Mike, Sylvia, Sheila, David, Kevin, and Charmaine. I think that's a great group to start with.

DR. ROYAL: I think so.

DR. TEUTSCH: And, Rochelle, I think we may call on you at some point if we need to, as we're making these different groups up.

Oh, Sandy. Sandy, don't go away. We've been talking about you. Sandy, I don't know, we had talked about the contract with Lewin that you've got in place. I know you haven't had the benefit of this whole conversation, but could you say something about the status? We understand the contract's let and the scope, and how you see it fitting in with this committee.

MS. HOWARD: All right.

DR. TEUTSCH: Thank you, as always, for your strong links with us and helping us move these things forward.

MS. HOWARD: ASPE is happy to work with you on this. We have a shared interest in a number of things, and I'm sure Greg has mentioned that. He and I are working together on some things related to genetics. We did award a contract to provide analytical support to the Committee, and [for] its work and guiding ASPE in its policy development, as well, to the Lewin Group, just a couple of

weeks ago.

We haven't kicked off the contract yet, but we will in a couple of weeks. As our guide to that, we used the white paper that the Committee put together -- was it last year, or earlier this year? -- and we structured it around the questions that were asked. We hope to find some answers or some examples of things that you could think about through literature review and expert panel interviews.

We will be in discussions with the people who have signed up to work on this from your subcommittee, and we hope it will be a fruitful interchange, because we want to produce something that is going to be useful to you.

DR. TEUTSCH: Yes. I mean, these have been extremely valuable to the Committee over the last few years.

Doug.

MR. OLSEN: I just wanted to volunteer because I think this is the one area that our office is most uniquely in a place to help.

DR. TEUTSCH: Terrific. Happy.

MS. LLOYD-PURYEAR: Steve, I would like to have

our involvement early, only because our next meeting is in January and I would like to be able to present this.

DR. TEUTSCH: Terrific. This is an obvious area where we need to work together. So that's terrific.

Okay. Charmaine, thank you so much. That's great. Thanks for moving it forward. Thanks to everybody, [to those that] have done a lot of the work in prep for all of this, over the last few years.

DR. ROYAL: We won't bother to go through that. We'll just leave the rest of the questions for the subcommittee at this time.

DR. TEUTSCH: Yes. I think, over the next couple of months, if you can sort through that, that would be great. I'm sure we will revisit those as we decide how the Committee wants to actually move forward after February.