

Roundtable Discussion with Presenters
Facilitator: Ellen Fox, M.D.

DR. WILLARD: We'll now open it up to a roundtable discussion, and I'm going to turn it over to Ellen Fox, who is going to be leading this part of the session.

DR. FOX: Thank you. I'd like to add my thanks to the three panelists. You've certainly given us a lot to think about and talk about, so let's begin the conversation.

Yes, Kevin.

DR. FITZGERALD: I'd like just to throw something out to all three. Thank you, too, for your presentations. I'd like to start with Professor Duster, first of all because it's so rare that somebody uses go as a metaphor. So I'd like to build on that a little bit and draw it out just a little further, because even after you have chosen the first few moves that you're going to make to sort of set the pattern that you want to pursue, then comes in this constant tension between continuing to make the bold broad move or having to consolidate at some point to either attack or defend a smaller territory.

I'm wondering would that decision, though not normally done in the game, be better made in this case by committee or community than by an individual or, say, a small group? So to use what we've heard before, if we were to follow a sort of community engagement model as a first step, take the issues that you have raised, all of you, and put it in that particular context, what would you see would be the advantages or disadvantages to addressing those issues within that community engagement model?

DR. DUSTER: Well, as you heard in the previous session, community engagement is a very foggy and vague idea. What's the relevant community for African Americans? So what would be the community engagement around prostate cancer? Well, you might say, given the fact that you're talking about males, you've got a cut right away. You're going to talk about black males age 40 to 70. That's going to be the relevant community.

I mean, I do think it's possible for some of these kinds of things to be understood situationally and empirically. I don't think one can come at this necessarily with a kind of didactic axiomatic system where you say, okay, we're going to have the community -- who is the community? -- be determined by the kind of research. So that's my first answer to the question. I don't think community engagement is the answer. It's the beginning of a probe, a wedge, an entry into the relevance of the research, and then the question is, well, is the community sufficiently informed to pursue?

This is an old horse. People will say things like does the community know enough, the community of 40- to 70-year-old black males? A huge variation here. One of the things again is I'm drawing upon my experience in the ELSI working group. We had this discussion earlier in this session, but just to sort of crystallize it here again, one version was you educate people because they don't know genetics, and I thought Joan Scott was quite good about that. You educate people about the issues. You don't teach them Mendelian genetics. You teach them about the issues in genetics.

So what would you begin to tell people about a prostate cancer study? Unless you begin with what I thought was powerful evidence about the possible migratory features, the way in which the environment is playing a huge role, nutrition is playing a huge role. If you simply start looking at

genes and environment, you're going to bring the community into a kind of a fog, and the scientists could say, well, we have good data indicating that prostate cancer is allelic frequency X, Y and Z. And what is the community going to say?

I mean, I think that the frame here is vital, and I'm not sure a community engagement is going to get us very far. But I'll let Pilar and Henry Greely respond if they want to.

DR. GREELY: I'm not sure this is community engagement exactly that I'm going to respond to your question with, and the only times I've tried to play go, the computer has crushed me on the simplest setting.

But I do think that there is a role in the creation of appropriate informed consent protocols and methods for preliminary discussions with communities and other research subjects, other potential research participants, to try to make sure that they understand the full meaning of what you're saying, and part of that is in a sense community consultation or community discussion to make sure that when you say these could be used by other researchers, that they understand how far that means; or if you say you won't have any control over subsequent uses, that they understand with some specific examples of what kinds of subsequent uses those might be.

So I guess I see it both as a possibility for discussing some of these consent issues with communities but also using that as a way to hone your consent process to make sure subsequently, when you put the consent process into play, that the people undergoing it truly, as best as you can guarantee, which of course is certainly less than 100 percent, but truly understand what you're telling them.

DR. DUSTER: Just a quick response. It occurs to me that maybe a better way of thinking about this is that maybe the community engagement that's relevant are those who live around toxic waste dumps, not blacks.

DR. OSSORIO: That was what I was going to say, actually, that I think Troy's comments really went to the question of exactly who are you going to engage, right? And I was a little concerned when I saw the kind of background paper that people were conceptualizing this project in kind of an old model and not thinking about the possibilities of gathering a lot of environmental information, gathering a lot of exposure information and how that actually cross-cuts a lot of these kind of simple-minded notions of race and genetic causation of disease.

So I agree with Troy, that when you think about whom to engage, I think it would be a failure if the engagements were just sort of done along the lines of racially organized communities.

DR. FOX: Next I have Julio, Muin, Joseph, then Jim.

DR. LICINIO: I'd like to thank the panelists for a really wonderful series of discussions. I have two considerations that I'd like to bring particularly to Pilar. If the other people want to talk, I think that's also fine. And I really appreciate all the comments about how there may be many confounding factors in the environment or social factors that may not lead to a clear association between a specific genetic allele and a disease, but let's say that that association is found. Then how do you handle this in the concept of informing people?

The two scenarios I'd like to ask you about are these. One is that most likely, almost certainly what you're going to find is a percentage risk that's attributable to that allele. So how do you tell somebody that they have a percentage risk for something? For example, if they have a 90 percent

risk of having a fatal disease for which there is a curative treatment, there is not much to think about. But what about if they have a 50 percent risk for a disease that there is no clear-cut treatment? You go around telling people they have a 1 percent risk of having this. What does it mean? Where is the cutoff and who determines that cutoff? Over what timespan? So that's kind of one line of questions.

The other is that I was in a very thought-provoking panel at the Kennedy School of Government on genetics and the law, which is exactly your area. The thing that is apparently a very hot topic now, and I don't think it's been dealt with very much here, is the issue of the genetic testing by proxy. It's basically obtaining genetic information about somebody without testing that person, but by testing a relative.

Just as an illustrative example, the BTK killer was apprehended because of a match between the DNA found in one of his victims and the DNA of his daughter, who did not give consent for DNA testing relating to any type of criminal investigation. Her DNA happened to be in a database.

So what about this issue applied to this project? This could be very farfetched and removed, but let's say if a member of the project goes missing and then a body is found, do you use the DNA that you have from the project to identify that person? Or what if the person is in the Empire State Building, there is a new terrorist attack, that building collapsed, you have a charred body and you know that the person potentially was in the study, and you want to check?

Then if you check, let's say, and it's not the person, but there is a kinship match and the search continues and it's found that the person's DNA is actually in a crime scene. So you know that the crime was committed by a sibling of that person.

Where do you stop? It sounds almost cruel, let's say, if a member of the study goes missing and a body is found, and it's natural to try to do the thing, but if you don't do it, I think it's problematic, since you have the DNA stored. If you do it, usually things unpredictable do happen, and if something like this happens, it can put the credibility of the study at large at risk.

So how can we address these two issues?

DR. OSSORIO: Well, the issue of finding alleles for which it looks valid and you have the statistics to say there is a 5 percent probability that if you have this allele, you'll develop X outcome, first of all, that would definitely not fall into the category of information probably that anybody would think it's obligatory to report that back.

So you would be in a range of permissibility and perhaps fairly low if you're talking about a range that is trying to be attentive to the seriousness of the condition and the importance of this information in managing somebody's medical care. Knowing that you have an allele that puts you at just a slightly increased risk for a common complex disease probably is not going to be the kind of thing that you'd put very high on your priority list for reporting back information.

Some people have said, well, you should report back anything that's clinically relevant. I think it would be incredibly difficult to do a study where you involve 500,000 or 1 million people and have that kind of regime where you're reporting back anything that's medically relevant. The economic burden of doing that would be so high, just for one thing.

So, number one, I think there's a range of permissibility, and some of these things that have only a slight predictive value would be the things that you'd put in the category of not reporting back.

How you make that decision, you know, there are a lot of different ways to make it. One of my suggestions is that that is the kind of decision that you might make, at least in part, in some kind of community engagement, and I think, for instance, the reproductive, things that have sort of carrier status, reproductive relevance, I suspect that if we did engagements, we would find out that for a lot of people that is very important information and that if we can give it to them, they would like to get it from us and that they would give that a much higher priority. If we say that there's going to be a limited set of things that we will report back and we have some choices to make, participants can help us make those choices.

Also, we can give participants a range of choices. Some people won't want any of it back and certainly wouldn't want back things that don't really affect clinical management or something like that.

But I agree. There are lots of choices like that that will have to be made.

Also, something I didn't talk about, is that there will still be unexpected things that come up. For instance, if you're a researcher doing follow-on research and you don't have the linking information, which will probably apply to a lot of people, and you find something that it turns out is very significant and wasn't really anticipated by you when you started the project, and you didn't go back and get additional informed consent, and now you feel, oh, gosh, it does fall into that category of things that we've said should be reported back, those are the unusual situations that should go back to the IRB to develop a process for contacting a person and doing that. So there will always be some adjustments that you have to make on the fly.

The second question of the non-medical uses of this kind of a database, I mean, part of this has to do with the data access policy and what kind of policy you have upfront. The idea that you would give out data to parties who have IRB approval on the face would rule out a lot of these non-medical uses or law enforcement uses, but if they wanted to subpoena or they wanted to get a court order to open up your database or get access to your data, in some cases they certainly might be able to do it. I don't know to what extent a certificate of confidentiality would really work in this kind of a case, but it might.

You know, what I wanted to say, though, was that what Kathleen said to you earlier on is very true. In those communities that are -- and you know this, right? -- disproportionately targeted for stops and arrests by the police, there is an incredible concern about law enforcement having access to these things.

Both Hank and I, and I think Troy as well, have been working at various times as part of a project at the Kennedy School where they're looking at law enforcement uses of genetics, and the things that the FBI wants to do with genetic testing, they're way out there. They would love to be able to get all kinds of genetic information from people.

It's interesting that there are provisions in the law to use law enforcement databases to do identifications in situations like another terrorist attack. Some state laws would perhaps protect a research database against being used for other purposes in many cases, but not all state laws would. So there certainly is a legal area where it would have to be a policy, some kind of policy, of the project and of the NIH or of HHS that would set those limits.

DR. LICINIO: But that would have to be set a priority.

DR. OSSORIO: Yes.

DR. LICINIO: And just to endorse what you said, in our community project in Los Angeles in the Hispanic community, the first issue that was raised was is this is going to be used for law enforcement? But because our collection is anonymized, so we completely don't know who it is, that issue is not applicable, but it is here.

The last comment is that if you really have this possibility that the sample could be court ordered, which was the case, actually, in the BTK example that I gave, should you put that in the consent form upfront that it's anonymous, but these records could be obtained by court order and we cannot stop this from happening?

MR. GREELY: You have to, I think. You've got to be honest and there's no way, even with a certificate of confidentiality, that you can necessarily guarantee that a court order won't be issued. The specific example that I think is most likely to breach a certificate of confidentiality is when a criminal defendant can make an argument that this information is crucial to his defense and he has a constitutional right to it, and the Constitution trumps a mere statute or regulation.

So if, for example, with a criminal defendant, there's other DNA found at the crime scene and he can show that it matches an anonymized sequence in this database, I think he has a very good argument that he has a constitutional right to get that identity regardless of whether or not there's a certificate of confidentiality.

In that case, you've got to tell people upfront we cannot promise you complete confidentiality, and here are some of the ways in which that confidentiality might be breached beyond our control.

DR. FOX: Thank you.

I have six people on my list. You're next, Muin.

DR. KHOURY: I'd like to thank the speakers this afternoon.

It may be the lateness of the hour or sort of my own fog here, but I'm looking a little bit for more clarity around a couple of areas, and I think Dr. Duster challenged my mind to think harder than usual around two areas. The first area is around representativeness and how you cut such a study by religion, group, ethnicity, et cetera. The other area is genes and environment. I'd like to throw back these things at you so that you can help me with more clarity.

As a primer to this, I'm a public health professional. I spend a lot -- actually, all my time and career collecting data on populations from a public health perspective.

Ideally, if you want a population sample that represents the whole U.S. population -- and assume we have 300 million people that live here -- and you want a 1 million person sample, you have a line listing and you pick every 300th person. You'll have a totally representative sample of the U.S. population, completely random. Then you can post-hoc study which group, which religion, whether they live in toxic dump sites, whether they live in rural or urban areas, whether they live in State X, State Y, or Z. That's sort of the completely random approach to public health research that we've used.

Unfortunately, because minority groups are minority groups, a complete random sample doesn't do us a service. So we've done a lot of tricks in public health to do what we call the stratified random sample. We go enrich the sampling scheme with sort of the minority groups.

But there is no limit to how much you can do that cutting. I mean, right now, we do it by race and ethnicity because of the health disparities around that area, but when you start doing it by state, by county -- you have 50 states, 3,000 counties, rural versus urban, zip codes, toxic dump sites, et cetera, migrant versus non-migrant -- you know, it gets a bit more complicated. So maybe you can help me with a bit more clarity.

The other issue is around genes and environment. I think it should be obvious to everyone that a study like this, if it was only based on genes, it's not worth doing because using appropriately collected case/control studies, you can look at the genetic contributions of all diseases because genetic variants don't change. You measure them once and that's it. You don't need to do a cohort study.

I would say the major impetus for such a resource or a national project would be to look at genes in the context of environments, and we all know the complexity of measuring the environments, although we're making major progress in measuring toxic chemicals in the serum and the blood and the urine and all of these things. Some of it is tough, like measuring social environment.

This reminded me. You know, at some point you said that 80 percent of cancer is environmental. To me, it doesn't imply that the other 20 percent is genetic, because one famous epidemiologist many years ago said, "We can easily show that 100 percent of a disease is environmental and the same 100 percent is genetic as well," because all of it is due to gene/environment interaction.

So if there is anything to be gained by a resource like this, you'll have to get sort of the balanced view of measuring genes and measuring the environments, and doing the appropriate sampling scheme that would allow us to get the most pragmatic sample of the U.S. population to allow generalizability of results.

So given what I just said, maybe you can repackage what you said earlier and help me see how what you said can change my way of thinking, because I think there are some gems there that I would like to get at the table, and anybody else who wants to respond is welcome.

DR. DUSTER: No, I don't think I have any gems. I mean, I think the message that I want to deliver is that this early stage of framing of the project is so vital that we need around the table some understanding not just of the genes/environment, but how the genes/environment interaction is going to be reported out, how the data are going to be collected, and that can't be done by a group like this.

That's simply a cautionary tale, and what I was suggesting is that one way to think about it is the kind of work that Cooper does. You're talking about race and genetics, boy, that's already volatile. So let's talk about race in four or five different countries and see whether or not the rate of hypertension or prostate cancer or breast cancer among Groups A, B, and C changes.

That's a different kind of study than a national study. A national study in some ways I think reduces your capacity to tease out the genes/environment issue. I mean, that's an old argument and we shouldn't go down that road. You know, one should never say "genes and environment." It's always interactional, but we're going to just parcel that out.

DR. KHOURY: Pilar?

DR. OSSORIO: You know, when I try to think about this in great detail, like what would be the best sampling strategy, I just get myself really bamboozled. Part of it I think is that those questions would be easier to answer if there was some particular medical focus, so that understanding how to do the stratification, it might matter whether you want to first look more at cancers or first look more at heart disease. That might actually change the optimal way to do the stratification.

I'm now way outside my area of expertise, but I know that in discussions with NCI a few years back, one of the issues that came up was that different collections of tissues and information are better suited to answering particular questions. In that case, they were talking about there are reasons to go ahead and do new large studies, make new large collections.

Again, there are some choices to be made about how much this resource is going to be very broadly applicable and how much it might, if you focus towards a particular set of conditions, that might influence the stratification scheme that you would use.

You know, we had some discussions this morning about interdisciplinary work and so forth. In my own sort of discussions with people about how to develop a project that could really measure interaction better, I'm constantly struck by the fact that there are, for instance, out there data sets that are longitudinal that go back decades about air quality and certain pollutants in the air that go across the United States zip code by zip code that could be married to medical information and genetic data. There actually are a lot of environmental data sets already out there that it's worth trying to figure out what they are and how they've been collected because that might actually, if we really wanted to be serious about collecting environmental information, help guide some kinds of sampling schemes.

DR. FOX: Jim Evans?

DR. EVANS: This was a great panel. I learned a lot.

One of the things that's worthwhile being reminded of as a geneticist is that it is definitely true that most of the maladies that afflict us are more environmental than they are genetic, and I think that if we are going to look at genetic/environment interactions, we have to be as diligent in our methods for looking at environmental influences as we are about genetics.

My question is for Professor Greely. I think you pointed out something really important, which is that truly informed consent in this situation is impossible. In fact, there are those who would argue that truly informed consent is almost always neither, even in a clinical situation, and that what makes it work, what makes the interaction work, say, in a clinical situation or, perhaps in a more abstract sense, the research situation, is one of trust, that if there is trust between the practitioner and the patient or the researcher and the participant, then those issues are much easier to get around. I think that underscores everything we've been talking about about openness and having some degree of trust.

My question for you is it seemed like you were talking mostly in the issue of opting out. You know, what kind of control a participant has. In trying to decide those things upfront, isn't there a huge role if you can maintain contact, which you would have to do anyway? If you can continue to inform participants in aggregate about the research projects that are going on?

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Do you think that's a viable kind of solution to much of that problem to allow people to give very generally consent initially, which I think we all agree at some level is necessary for such studies, but then to opt out if they see that, okay, there's a project planned that raises problems in my mind, et cetera? Would that be a way of addressing it?

MR. GREELY: It would be a way and it would be a way that's better than the current system. I don't think it would be the way I would most recommend.

First, I do think we should talk about this initial interaction of the research participant as more, in this context, permission than consent. It's useful to use a different word to separate it entirely from the concept of informed consent, which, though it can never be done perfectly, can almost always be done better than it can be in the context of one of these multi-use, multi-decadal resources.

The idea of maintaining communication is I think an excellent one, and trying to inform the subjects, the participants, of what things might be done with their DNA and their data is a useful one, and I think that will help you with sort of intermediate ones, intermediate issues where you wouldn't really think that anybody is going to be all that concerned about it, but it turns out you've got four research participants who really are quite troubled by research into pancreatitis. You had no reason to suspect that was the case, but by golly, they are and they read about it in the newsletter, and so they objected. The newsletter told them if you object to any of this, please let us know, et cetera.

My problem with it is if you get into ones that are more clearly controversial, where people are more likely to object, the difficulties of maintaining real contact with people are so great and in recontacting people six months later, you lose a large chunk of people. A year later, you lose a bigger chunk of people. Then -- and here I'm speaking from anecdotal, personal, empirical experience -- the odds that any piece of mail is going to get into the trash can without being read are fairly high in most households, I think.

So if it's something that you've got reason to believe a significant chunk of your population really might be concerned about, I don't think the information plus opt out is sufficient, because some of the people won't get the information or won't read it, won't realize it, won't take the opportunity to opt out, and if you later tell them, hey, we told you about it and you had an opportunity, they're still going to feel misused.

DR. FOX: I think we have time for the last three I have on my list.

Cindy?

MS. BERRY: Muin was actually getting at what I was thinking about and articulated it far better than I. I would like to make one more point for clarification for lay people like myself.

It's directed to Dr. Duster. Am I correct in assuming that the dangers that you are speaking of are not so much in the fact of collecting data and including a representative sample of individuals throughout the country -- I mean, we always hear at our meetings that it's important to include women and it's important to include different racial groups and have a good mix because it does nobody any good if we just have a bunch of 20- to 40-year-old white males. What good is that? We have to have everybody represented.

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But that the real danger is really more in the interpretation of the data once it's been collected and the types of studies that are embarked upon using that data? Because I don't know that just having a lot of different people from urban areas and rural areas and different racial groups in and of itself is problematic. It's more what people do with it and the jump-to-conclusion type of results.

Am I correct in assuming that or are you saying that at the very beginning --

DR. DUSTER: Both. Both things are true. I think how it's reported out is vitally important. How one interprets these data on, let's say, prostate cancer and race, that's the reporting out problem.

But having shaped the study and framed it in terms of these categories is itself the problem of go. That is, once you've said we're going to separate people based upon race and then come at them with an understanding of different allelic frequency patterns, there's a tendency to believe that those frequency patterns are in that racial group, whether they are or not. You see?

Now, one could say empirically that that will be sorted out. Over the next 30, 40 years, we'll find out.

But in the interim, there tends to be a reporting out which says -- let's take the example I used earlier. Blacks actually may have a different kind of allelic frequency than whites who have prostate cancer, but we don't know if there's functional outcome. We just know that that's the pattern. In the interim, the reporting out is going to sound like it must be genetic.

MS. BERRY: But isn't the problem more in the prostate cancer study or the person who is trying to reach those conclusions as opposed to just the fact of getting people to participate in the large population study?

DR. DUSTER: Well, if we leave and go to the caste system, I think it becomes clear. Right? You'd say, oh, why would you think that people from different castes would have different genetic makeups? Well, because they married each other for over 3,000 years. That's why you might think that, but would you think that therefore that had an impact on their prostate cancer rate?

That is, having set it up to collect data by caste, you've already prefigured the capacity to report out certain things. That's why the two are related. It's not just collecting data. It's collecting data by certain social categories, and societies being stratified, it's inevitable that the allelic frequencies are going to reflect that as well. So the danger is going to be genetic interpretation of stratification.

MS. BERRY: But just to play devil's advocate, is there something wrong inherently, are you saying, with including all of these different groups and factors? For example, race, gender, ethnicity, all of those things? To me, it just seems that the danger is in what you do with that and the conclusions you reach.

DR. DUSTER: I think that's right. I agree with you completely. It's in the conclusions and the reporting out.

What I was pointing out was something at the very outset of the study, which is why I went to the caste system to make the case. It becomes clear in the caste system that there's a real danger if

you begin to do genetic studies in that system, people will say you're recreating the very taxonomy we thought we got rid of in 1949. That is, you give a kind of reality to the allelic frequencies, which are going to be there. I mean, if Brahmans have been marrying each other for 3,000 years, there are going to be certain patterns there. But what do you do with it when it comes to health outcomes?

DR. OSSORIO: If I could just add a little bit to that, I think one thing is to be really clear about what your notion of representation is and why it's important. I frankly think that part of the reason it's important to have broad representation with respect to race and gender and so forth is not necessarily to achieve a particular scientific goal, but because this is a huge project potentially in which millions and millions and millions of federal dollars will be spent and those categories are politically important, and there are disparities of all kinds, including health disparities, that map on to those categories, and that participation is a political way of saying to people you are important, you matter, your needs matter.

It might perfectly well be that if you did a study with, say, only white people looking at the ones who lived right near toxic waste dumps and the ones who lived out in pristine wherever, you might find a gene/environment interaction that's absolutely generalizable to anybody who has a particular set of alleles and a particular set of exposures over their lifetime. It might be perfectly generalizable to all those people who weren't included or many of them. It might be a very important one.

Even if that were true, I still think that it's very important to have representation in the political sense, and then there are also scientific reasons to have people with different exposures and different life experiences and of sort of the greatest amount of genetic variation that you can. To the extent that you're using things like race and ethnicity to try and expand the amount of variation that you've got in there to study, there is a scientific justification for that.

But part of what happens is that we sort of collapse every reason for inclusion into some kind of notion that's very deep in our culture that races are genetically distinct groups of people and when you see differences between races or ethnic groups, in some cases, there's a genetic cause, and we don't get much beyond that.

I think this project or some project of this sort has the opportunity to break down some of these kind of simpleminded ideas, but part of that is thinking what kinds of data would you collect about people. Not just are we going to go rural, urban, whatever, but what other kinds of information are you going to collect about them that will help you understand the gene/environment interactions so that you're not just left at the end with analyzing your data based on race and gender?

DR. FOX: We have only three minutes left in our scheduled session, so if I can ask folks to keep your questions and answers brief.

Debra?

DR. LEONARD: Actually, I realize that we're going to be having a general discussion about this, and my question is more relevant to the SACGHS members than the panel. So I'll hold.

DR. FOX: Michael Carome?

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DR. CAROME: Hi. Mike Carome from the Office of Human Research Protections. Some of the comments I've heard seem to presume that the research studies that are going to be used and this database that's going to be created are all going to have IRB review, and I presume that's based on the assumption that the regulations are going to require such review.

I think it's important to note that some guidance has come out of our office involving use of coded private information or coded biologic specimens actually can be done in a way in which the recipient of those specimens and the data can't readily ascertain the identity of the individuals to whom that data and specimens pertain, and therefore, under the regulations, that research doesn't involve human subjects, and therefore that research doesn't necessarily need any further IRB review or any more informed consent process or exchange of information with the subjects.

I just think the group needs to be clear about that. It doesn't mean you couldn't impose some ethical review -- call it IRB review or some other review -- for any uses of it, and that's probably a reasonable ethical consideration, but it may not be based upon a regulatory requirement. I just wondered if the group had any reaction to our guidance on this topic and whether they find it to be problematic, given the type of research being proposed.

MR. GREELY: I would hope that such a resource would include as a condition, contractual or otherwise, for the use of its data IRB or IRB-like review. I would also hope that IRBs, though recognizing that it might not technically be human subjects research and might not technically be something that they're required to review, would be willing to review it.

The broader question about your guidance I do find is a much longer story than we have time for, but I'll just say I do find it somewhat problematic, particularly because of the limitations on confidentiality and anonymity that I talked about earlier.

DR. FOX: Thanks to all the panelists, and that ends our roundtable discussion.

DR. WILLARD: Thank you, Ellen, and thank you all three of the panelists and, by extension, the whole day's worth of speakers. It's been tremendously educational for all of us and we appreciate your contributions and your being here.