

NIH Proposed Policy on Genome Wide Association Studies (GWAS)
Susan Shurin, M.D

DR. TUCKSON: We're now really pleased to move to our update on NIH proposed policy on genome-wide association studies, GWAS. Susan Shurin, who is the Deputy Director of the National Heart, Lung, and Blood Institute, is now with us, and we appreciate it.

Let me just remind you that this is an important policy proposal from the NIH on whole genome association research. NIH wants the committee to be aware of the proposal, which is generally referred to as the GWAS proposal. We wanted to hear more about it because it raises some of the same policy issues as the topic that we have spent most of today discussing. NIH has GWAS as a high priority because such research will lead to greater understanding of the common genetic factors that influence health and disease and possibly to better ways of predicting and preventing disease. This type of research is also important for the development of personalized medicine.

God, am I good at filling time.

The GWAS proposal has some important components aimed at facilitating the sharing of genome and clinical information that will be generated by the research, including the creation of a central database at NIH to house the data. We cannot get away from data and databases and all kinds of stuff here.

Such a proposal clearly raises important policy questions, including some that we've identified in our large population studies report. NIH is currently seeking public comments on the proposal, and the agency is working hard to broaden public awareness of it.

Susan is a prime mover in the development of the proposal, and so she's going to sort of chat with us about it.

Susan also, as you get into the presentation, would you sort of, again, help us to understand from early on are you doing this for information for us, or is there something that you want us to listen acutely for?

DR. SHURIN: I'm going to start out with that. First of all, it's information, but the other issue is that we're in the middle of a public commentary period right now, and we are actually very eager to hear people's input and advice and suggestions. I wanted to give you an overview of what it is that we're doing and why it is that we're doing it and how we see these extremely complex issues because we're trying to balance a number of different issues in terms of potential benefits and risks to numerous groups, and there are not easy solutions. So it's going to be a matter of figuring out how to make things really work.

My name is Susan Shurin. I'm the Deputy Director of the National Heart, Lung, and Blood Institute. My background is in pediatric hematology/oncology. I spent 30 years on the faculty at Case Western Reserve. I ran a laboratory. I've been heavily involved in clinical research of multiple types. So my background actually is not from the standpoint of NIH administration, but from having been out in the trenches doing this kind of work and spanning a period of time of tremendous advances in pediatric hematology and oncology. The landscape is radically different now from what it was some 30 years ago when I entered the field.

So I can't promise you that the slides will be readable, but I think I can probably interpret them for you.

First of all, I don't want you to spend a lot of time learning about GWAS. We haven't come up with a better name for it. We think maybe when we're done with the public commentary period, we'll have a contest to name these things.

What we're talking about is a group of studies in which we're looking at scans across the entire genome. We're getting 375,000 to 500,000 single nucleotide polymorphisms, which are then linked to the phenotype which is in the person from whom it came. So we've got both control groups and patient groups. The idea is to help us better understand the etiology and background of diseases which often have a genetic component but may also have environmental components, may have behavioral components, may have lots of different components, and to try to sort some of these things out and to be able to come up with better ways of predicting risk, of implementing preemptive therapies and preventing the development or progression of disease, and developing new diagnostics and therapeutics.

So one of the big issues that we look at from the standpoint of the NIH is that the NIH really represents the public -- our job is the stewardship of the public investment in the biomedical research arena. We're really trying ultimately to improve the public health. If we're going to steward these resources well, we want to get the maximum benefit as we're making progress.

We have, for a very long time, encouraged the wide sharing of data. We've encouraged people to put papers on the Web in forms which are widely accessible to not only investigators but to the public. The work that we share we're eager to have widely available to people.

One of the things that we're encountering right now is -- and it's always been true that there's been a bit of an information glut. The information glut is now of a different order of magnitude from what it's ever been before. Basically we're doing studies now. I'm sure many of you have seen what these chips look like, and you've got thousands and hundreds of thousands of pieces of information. We are now generating far more data than any investigator or any single group of investigators will ever be able to analyze.

Many of the studies that we're doing that we're supporting are very resource-intensive. First of all, they cost a lot of money. But it really is more than that they cost money. Many of these studies are unique studies that are done on very limited groups of patients. The ability to get really well-defined phenotype data and to link it to the genotypic information, to compare it with people who are not affected with similar sorts of diseases is very limited, and you don't want to be particularly doing this multiple times if we're really going to benefit these subjects who are participating in our research. We want to make sure that that investment is maximized so that rather than having the same study over and over and over again, we'd rather have the data where people could use it and analyze it in a number of different ways to be able to come up with new beneficial interventions, both diagnostics and therapeutics.

It's very important that the participants in our trials have their privacy protected. So that's a huge issue. What we're talking about largely is maximizing the benefit to the public health, the investment that we're making in the support of research, trying to ensure that the privacy and safety of the participants in these studies are protected.

And there's a huge intellectual property issue. I heard a little bit of this discussion before because one of the things that's happened is that if we're going to come up with new therapeutics, if they're going to be developed, people have to be able to protect their intellectual property or they won't actually develop things. On the other hand, if things are patented at too early a stage, they may tie up data which then won't actually be available for publication.

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So what happened really at about the beginning of 2006 is that as we're looking at our research grant portfolios, what we're finding is that we are receiving an exponentially increasing number and double exponentially increasing cost of applications to do genome-wide association studies on persons, in our instance, with heart, lung, and blood disorders.

Dr. Nabel, who is the Director of NHLBI, and Dr. Collins at Genome were discussing a number of these things, and we felt that it was going to be important that we develop some policies that would enable us to ensure that investigators share their data very widely, as long as that's consistent with the consent that's provided by the subjects.

So we started a discussion between our two institutes. NHLBI put out a request for information from our investigator community, and they gave us some idea of what they thought. And using that information, we started developing a policy and had a discussion with the other institutes and center directors saying, we're going to be doing this, would you like to opt in. It rapidly progressed to the point where everybody said it's not a good idea for us to have different policies across the NIH. It's confusing to the investigator community. It's confusing to the participants in studies. We really need to try to develop some kind of coherent policy.

Now, you understand this represents now millions and millions and millions of dollars in research applications.

We are at NHLBI doing genome-wide association studies on a number of the cohorts of patients. We followed some for many decades. The Framingham Study, for instance, we're doing genome-wide association studies on. This started in 1948 and now includes three generations of subjects.

One of the things that I want to be sure that you understand is that wide sharing of these data is already taking place and has been taking place for a very substantial period of time. What we are looking at doing is to try to develop a coherent approach to this, to try to change the culture in the investigator community so that instead of having a totally proprietary sense of their data, they're willing to sort of put it out there and let other people look at it in order to maximize the benefit.

It also becomes clear that if we're really going to be able to provide optimal protection for privacy, for intellectual property issues, to standardize the phenotyping information that we're getting, to standardize the oversight to really protect folks, it's very helpful to have a single portal of entry. Now, we may have different ways in which you get in there. There may be different standards that apply to how you access data depending upon what's in those data. But we'd like to develop something that's reasonably coherent. So that's actually what we've been working on.

It's very easy for you to find a lot of this genome-wide association data available right now. The CGEMS project at the NCI which looks at prostate and breast cancer has just posted a vast amount of genome-wide association data. Among other things, if you go in and try to manipulate that, you'll see that you actually do need to know what you're doing if you're going to make any sense out of it. It's not like it sort of sits there and says, this is me. It really doesn't. On the other hand, we are talking about genetic data, so it is intrinsically potentially identifiable.

So our guiding principle is that the greatest public benefit will be realized if the data are available under policies and procedures that are consistent with the informed consents that are provided by the participants in a timely manner to the largest number of investigators. So this is what we're trying to accomplish.

There was a wonderful cartoon in the New Yorker a couple of months ago which had a couple of cave men sitting in their cave and they're sitting there over their fire, and they're saying, I don't get it. Here we are. We get lots of exercise. We breathe fresh air. We eat this high-roughage, healthy diet. He says, how come we're all dying in our mid-30's?

(Laughter.)

DR. SHURIN: So this is the issue. If we're going to make advances, we better learn to do something with this.

So we've broken it down into a number of elements. The first is data management, how do the data get into something that we're going to be sharing, how does it get out. Publication issues and intellectual property issues.

One of the things that happened, as we were having this conversation, is it became increasingly clear that it would be difficult to have either the kind of coherence that we felt we needed, particularly for such things as the extent to which the genomic data are curated and the extent to which the phenotypic data are defined, unless we had a common repository for all of this. If we're having a common repository for all of this, we need to have it done in such a way that we can ensure that there's a longstanding commitment to it.

So our proposal is that the repository be at the National Library of Medicine, at the National Center for Bioinformatics, the NCBI. So the idea is that it's going to improve the public health and actually maximize the return on investment really.

So what is this about? The genome-wide association data -- and that's both phenotype and genotype then -- would come in under a peer-review process at the NIH. What we are proposing is that people who do this research with NIH support basically must share the data, again consistent with the consent. If subjects don't consent to having it be shared, it doesn't get shared.

We will, however, as we're creating the repository, be happy to receive data from non-NIH-supported investigators who meet the standards and are interested in sharing. I'm going to come back to this in a minute because this is actually something that's got quite a lot of interest, among other things, from industry who are remarkably interested in sharing.

The submitting investigators and the institutions at which they work are responsible for submitting the data using a random code, no identifiers, note any limitations of the use. Contact with the participants happens here. The code is maintained in the institution. NCBI and the NIH and the government have no way of knowing who anybody is.

So then these coded-linked genotype and phenotype data are put into this repository. It will be possible to get access to data which are aggregated, which won't give you, obviously, access to any kind of information about any sort of individual. You won't see anybody's single nucleotide polymorphism pattern through this repository.

If you want to gain access to anything beyond that, particularly anything which might give you access to the SNP patterns, you go through a controlled access process. There will be precomputed data from these that are posted on the Web.

This is designed, among other things, to make it so that the obvious associations are immediately available. This then becomes obvious and not patentable. The things that would be patented

would be things that would be downstream from those because they would have to involve manipulations of the data that are done by the secondary investigators.

As you can imagine, we're putting a tremendous amount of time and energy into discussing the oversight for each one of these steps. So the oversight of the repository itself, the oversight of access. Much of the oversight of the access is likely to happen at the level of the institutes and centers that support the original studies because they will be in a better position to be more accountable and to be able to look at what's proposed.

Anybody who wants to actually use these data then has to submit a request. It doesn't have to be NIH-funded, but it does have to be at an institution because we are going to ask the institutions to take responsibility for some oversight of who's actually getting access and what they're going to do with this. So they will have to tell us what they're planning to do. They have to agree not to identify any individuals, and this won't be easy anyway. But it is absolutely true that even now, some of this is potentially identifiable, and as some of these technologies advance, a lot of this is anticipated to change. And for protecting the data confidentiality. This thing goes through the Data Access Committee. They will have data set-specific access rights to these data.

There are, obviously, infinite numbers of implications here. There are privacy implications. There are patent implications, intellectual property implications, and the implications of what's actually done with this. This does create some burdens for the institutions which, first of all, have to tell us that the data that's coming is compatible with the informed consent that's provided by the participants and for the institutions where the secondary users are, again, which will be asked to vet the folks who have access to this.

There are a number of industry inquiries so far of people wanting to participate. What we've learned already is that most of the industry that's very actively involved in using genomic data are interested not only in using but in depositing. Amgen, for instance, has done this. One of the things that set off this discussion is a group of studies called GAIN, the Genetic -- I can't even remember.

DR. FROSST: Association Information Network.

DR. SHURIN: Okay. Which is funded not by NIH, but by the Foundation for NIH. The money comes largely from Pfizer. It is a public/private partnership. There is NIH money that's in it.

In the GAIN studies, the investigators tell us what phenotype data they have, and if they're approved investigators, then they send their samples. Pfizer actually does the genotyping. They then have access to all of that data. But the condition for the free genotype data is that they have to be willing to share with everybody else. So that is actually recently funded. We're just getting going on that, and it does require the wide sharing.

So the investigators who submit these data will have to provide a lot of information about what they're doing, the quality of what they're submitting, issues related to the subjects, assurance of compliance with applicable laws.

And the investigators who request the data are going to have to present a whole bunch of stuff as well, including telling us not only what they plan to do, but also we're going to ask them to tell us what they have done, among other things, to try to enhance the extent to which we can share the results of these studies with the participants. Now, we're not going to know individually who they are, but we can put it out so that people actually have access to it.

So we met with OHRP to discuss what it is that we're planning to do to ask them the question of whether this secondary use of the data actually constitutes human subjects research. It's removed from the original participants. The secondary users have no contact with and no ability to have contact with the participants. It's stripped of identifiers. Under the discussion that we had with OHRP, they feel that this does not constitute human subjects research.

There may be pieces, however, for which it does constitute human subjects research. There are some studies, such as the gene/environment interaction studies which are currently underway, in which we may actually need to have some of the data which constitute identifiers under HIPAA or it won't be meaningful. I mean, you're not allowed to have anything that tells you anything smaller than the State that somebody lives in. Well, you may actually need to know what the ZIP code is in order to be able to make anything out of it.

Their suggestion was that we customize the oversight, whether it's an institutional review board or some other form of oversight, to the situation. So what we're trying to do now is to develop something. We're not expecting this to be one-size-fits-all. We're expecting to have to be able to do a certain amount of customization.

So the issues for participants I already sort of pretty much mentioned. There are a couple of things that are a very significant concern to us. One is the issue of genetic discrimination. We still don't have laws that prohibit genetic discrimination. This is a concern. And the information on any individual has implications for the family and sometimes a community from which people derive.

This is something we've been addressing quite intensely not only in the Framingham share project because we have a longtime relationship with the participants in Framingham. We're on to the third generation now. The participants in the Framingham study are actually part of the oversight here. We are embarking on genotyping of a number of the other cohorts of longstanding NHLBI studies, and again, we're going to be involving participants in those studies in the oversight process to address a lot of these issues.

We are involved in extensive conversations about all of the issues of the protection of the data, how we're going to do access. Again, I can't give you a simple answer because it's a complex question. So at the end of August, we put an announcement in the NIH Guide and in the Federal Register with our draft policy. We worked very, very, very hard to keep it short. Because it's short and it's really focusing on policy rather than on the implementation, of course, in many instances here, the devil is in the details, and so the implementation makes a lot of difference. But we tried to do it so that people wouldn't get lost. It's hard enough as it is. It's difficult to understand all of these implications.

As you can see, what happens is we have the experience that one usually has which is sort of the caboose effect, which is you go along with a low rate of responses and then as the deadline comes near, you get a little blast of responses. So we actually extended the deadline, and at the end of this month, we'll be closing out the public commentary period on the Web. That will be followed by a town hall, which will be on December 14th, to which you're invited, that will be webcast -- you're invited to participate on the webcast as well -- asking really primarily these questions: risks and benefits, additional protections, the proposals that we have for how we're putting this together, and any specific resources that investigators and institutions may need to meet the goals of the proposed policy. We're eager not to have totally unfunded mandates on our already overwhelmed institutions.

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If you go to the main NIH website, go down on the left side to "research," the first one under that is "genetic repository." Or, as Dr. Collins discovered, if you go into Google, and you put in GWAS, you come up with our GWAS policy, and that will take you to it as well. And this gives you, more or less, the same thing, which obviously isn't very helpful under the current circumstances.

So that's what we're doing. We're eager to have commentary. We expect that there will not be unanimity. Obviously, people come at things from different -- people will weigh the relative benefits and risks in different ways. So we're planning a process in which we'll be able to take these things into account and try to put in as many controls as we can. We cannot make any of this totally risk-free. On the other hand, the down side of not sharing the data is that we don't get the potential benefits of this incredibly valuable resource at a point at which we think we're just poised to be able to benefit.

I will be happy to take questions and comments.

DR. TUCKSON: Well, thanks a lot Susan. I think just the overarching thing -- you weren't able to be with us yesterday and today earlier, but we've put a lot of energy into this idea of, again, the databases and how those things connect. So one of the things that we hope that I would share, at least from my seat at the chairmanship here, is that you would -- just to make sure that the America's Health Information Community efforts, of which your boss, the Secretary, is so involved -- is that you are connected to that activity.

Can I just ask you? Is there an explicit conversation going on between this kind of data collection and what's going on in AHIC? Is that familiar to you?

DR. SHURIN: I'm aware of what's going on. We're looking at it purely from a research standpoint.

DR. TUCKSON: I understand.

DR. SHURIN: We're looking at a slightly different aspect of the same picture, but I think we have a sense of the overall picture.

DR. TUCKSON: Okay, good.

Emily?

DR. WINN-DEEN: Do you anticipate, once you create a database of a certain size, that you'll also entertain what I would call sort of purely bioinformatic proposals from investigators?

DR. SHURIN: Well, actually the bioinformatics is a huge piece of this because one of the things that's a limiting factor in our ability to use these data is that we're not yet skilled enough in analyzing them. So actually one of the major things that we'd like to do as a part of this -- and this comes into the oversight piece that's over the repository -- is asking the secondary users to share their methods.

DR. WINN-DEEN: Okay. So there will be secondary users who can come in, never did a thing in the lab, never touched a patient, but who can just go in and analyze the data with new questions.

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DR. SHURIN: I think many of the folks who will be using these data are primarily statistical folks, bioinformatics folks, and very likely not to be people who have ever actually seen patients.

DR. WINN-DEEN: And you'll have a gatekeeper mechanism where you entertain specific proposals?

DR. SHURIN: Well, that's what that was all about, yes.

DR. WINN-DEEN: So part of it is just anybody who is getting funding to do the wet part of genome-wide is going to have to deposit their data.

DR. SHURIN: Correct.

DR. WINN-DEEN: And the other part is that then becomes a repository for the future.

DR. SHURIN: Right. Because the point at which people are getting the data that can be deposited, they are in contact with participants, and that's clearly human subjects research. The secondary users will not have such contact. So it's really totally separate oversight, yes.

DR. TUCKSON: Now I get the joy of flipping the order. So Kevin gets to go.

DR. FITZGERALD: Thank you very much for the presentation. I guess I'm fascinated, on the one hand, because I think this is an excellent example of some of the tension that we are going to be facing because the very power of this database in one sense for the research and all also raises the issues that are on the other side, say, ethical, privacy requirements.

I mean, I understand you're going to try and anonymize everything, but one of the things I'm thinking about is considering what's going to be in that database, both genotypic and phenotypic information, if something goes to a researcher who's involved with a particularly small patient pool, that the possibilities of identification just increase exponentially because there may be certain characteristics that allow for relatively easy identification, inadvertent identification, needless to say.

DR. SHURIN: Well, that was exactly my point not only about Framingham, but it's also the case for our other cohort studies.

DR. FITZGERALD: Right. So you mentioned you have participants in the oversight and all that.

That brings me, I guess, to the focus of my question. When you get to your informed consent procedure -- and as you mentioned, this is not a totally risk-free endeavor -- how is that risk captured in your informed consent? I mean, who decides what the risk is and how it's framed and how that's explained? And then how do you look ahead and describe the risk to future sorts of developments from this database? I'm fascinated to see how you capture that.

DR. SHURIN: It's a very touchy question because, in fact, one of the big issues that we have right now is that we have a lot of data and specimens, and is that original consent that was obtained 15 or 20 years ago compatible with data sharing? And regardless of what it says on paper, did the folks who signed it have a clue that this was going to happen? The answer is obviously not.

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So one of the big issues that we're dealing with is we think we're going to have to be dealing with retrospective studies somewhat differently from prospective studies. And we're going to do the best we can in terms of assessing the potential risks. We are not arrogant enough to think that we are going to be able to predict all of those risks. We think this is rapidly changing.

DR. FITZGERALD: Right. And when you say you're going to do the best you can, do you have a sense of what that procedure will be?

DR. SHURIN: Well, a huge amount of it is going to be the issue of how the repository is handled, whether or not folks can download the data, where it goes, and a lot of that kind of thing. The other piece, of course, is what it takes to be able to identify somebody, which right now really requires a comparison specimen or a first-degree relative to be able to do that.

But increasingly, as we're able to analyze these data, we're going to be able to sort of make predictors about phenotype from the data itself, and I think we're anticipating that that's likely to happen. I think we're going to have to just sort of say -- we all make these kinds of risk assessments every time we cross the street, every time we use an ATM, every time we buy from Amazon.com. So basically what happens is the people who really aren't willing to assume any of that risk probably will not permit the data to be shared.

Again, there's going to be a tradeoff. We're going to try to be very honest with folks. We need them to trust that we will do the best we can, but we also recognize that we're not all-powerful in this. These data, whether we hold it at the NCBI or whether we contract with somebody else, will be subject to FOIA because even if it's held by a contractor, it's basically on our behalf.

We're in a situation now. We're in territory in which the science is way ahead of the law. So we think a waiver needs to come out for that. And we think there are approaches to a number of these things. But certainly laws against genetic discrimination -- because we're sort of saying, okay, it's completely deidentified. Therefore, you have this set of privacy issues, and then you turn around and you say, oh, but this is the ultimate identifier. Well, which is it? And the answer is, of course, it's both.

DR. FITZGERALD: Just one last one. You keep saying, we, we, we. Ultimately, I guess my question is, who is going to decide if what you have done is adequate? Is this an in-house decision, or is there some --

DR. SHURIN: Well, we feel that we need to assume responsibility for it because I think the biggest way we'll get into trouble is if we don't have accountability. So at a final level, we're going to have to. We think this is going to be an iterative process, and it's going to be one in which not only we take the current level of public commentary, but we also take ongoing public commentary as this goes forward. So we are listening hard. I really mean it when I'm inviting you to comment, and we are, indeed, listening hard. But I think the big issue is that if we get to a point where the responsibility is too diffused, then it becomes too easy to sort of say, well, it wasn't my fault when there's a problem, and we do want accountability.

DR. TUCKSON: Good.

Robinsue?

DR. FROHBOESE: Hi. I'm Robinsue Frohboese from the Office for Civil Rights. And as always, we offer our technical assistance with the privacy rule issues.

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But on another point, you've mentioned ongoing public input and comments, and I know that when the press release came out at the end of August, you talked about a public forum in early December.

DR. SHURIN: I just said that. It's the December 14th town hall meeting.

DR. FROHBOESE: Okay, all right. Thank you. And where is it?

DR. SHURIN: It's out in Bethesda. We were hoping to gather the commentary that's come in to us to sort of frame a big piece of that discussion.

DR. RANDHAWA: Can I ask a question?

DR. TUCKSON: See, that was the payback for the earlier.

DR. RANDHAWA: I have two questions. One is the data that I understand will be deidentified.

Will it be available as individual-level data or as aggregate-level data?

DR. SHURIN: For the people who are using it to reanalyze it, it will be individual data because it has to be linked to the phenotypic data.

DR. RANDHAWA: So that gets to the second question about phenotypic data. How phenotype gets defined is fairly challenging, you know, how one defines diabetes or hypertension or early stage or late-stage breast cancer. Is there going to be some sort of a guidance or a glossary from NIH as to what would be the definition --

DR. SHURIN: I think I mentioned at the beginning that one of the things that we're involved in now is establishing what the standards will be for the phenotypic information. We actually won't accept data that aren't in accord with the phenotypic standards. We anticipate that that's going to take a significant amount of time. In the GAIN initiative, for instance, a huge piece of whether or not a given project was funded had to do with the quality of the phenotypic data, that if the phenotypic data isn't tight enough -- it's actually much more difficult. The phenotype piece of it is more challenging than the genotype piece.

DR. FERREIRA-GONZALEZ: I strongly agree with you that the phenotype is a lot more difficult than the genotype. So I would strongly encourage to develop very clear standards.

My question actually is about intellectual property. As these specimens are deposited into this database in which there is access and already analyzed data, one can start identifying patterns with the association of different phenotypes. How is the policy going to deal with development of intellectual property?

DR. SHURIN: Well, we would like people to develop patents. We would like people to protect intellectual property as they move along and start to find targets which may be useful for diagnostics and therapeutics because they won't get developed unless people do that. So I think it's important to understand we're not discouraging patents overall. We're trying to ensure that what is patented is not at such an early stage -- sort of like not patenting a gene. If things get patented at a point at which you actually can't do anything with it and then it locks up a whole lot of other things, it doesn't achieve the goal.

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DR. FERREIRA-GONZALEZ: How are you going to do that? How are you going to achieve that people don't patent things very early --

DR. SHURIN: When we post the data, we will post the first line through on the biostatistics. The linkage disequilibrium and the number of the simple associations that we've identified, those will be out there. And because they will be out there --

DR. FERREIRA-GONZALEZ: Then it will be publicly available.

DR. SHURIN: Yes.

DR. FERREIRA-GONZALEZ: That will not be patentable.

DR. SHURIN: Yes. That is what makes it obvious because we will put it out there. So it then is in the public domain and it's obvious and therefore not patentable, we hope. That's the idea.

DR. FERREIRA-GONZALEZ: I'm not following this. The data or the association is going to be --

DR. SHURIN: The association.

DR. FERREIRA-GONZALEZ: You're going to do the associations and you're going to put publicly available data.

DR. SHURIN: Yes. That will be posted -- the first pass through, that will be posted with the data. And the secondary users, as they come up with new things, then presumably, hopefully, will be developing targets for diagnostics and therapeutics. And we'd like them to patent that because that will encourage them to develop the products. But those will be what would be called nonobvious.

DR. FERREIRA-GONZALEZ: Is there anything within the NIH policy to look at restricted patents or --

DR. SHURIN: We can't do that.

DR. TUCKSON: Well, thank you.

By the way, one last quick one as we get ready. Linda, you might want to start. Do you have slides?

DR. BRADLEY: Yes.

DR. TUCKSON: We'll give you a chance to fiddle.

The ethics consultation that you spent a lot of energy on in the first part of your presentation. Where do you get that resource from? The ethics infrastructure. Did I miss something? You talked about some of the ethical --

DR. SHURIN: We see the ethics as totally integrated into --

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DR. TUCKSON: But where does the expertise come from? Do you own that? Are the employees who do the ethics consultation part of your institute, or do you have to go outside someplace in NIH to get it?

DR. SHURIN: We haven't gone outside.

DR. TUCKSON: It's all inside?

DR. SHURIN: We've looked at this as so inherent and intrinsic to the entire process that it's not something that's a separate process.

DR. TUCKSON: Kevin?

DR. FITZGERALD: Just on that note -- and I thank you again for explaining this in some detail -- I certainly commend the desire to take accountability and responsibility for what you are doing. I think that's absolutely imperative. But in that process, it may actually require you to go outside to have some sort of oversight or ethics response from a group because you might need that perspective in order to be able to go to the public and say, we have been accountable. We're not just relying on ourselves.

DR. SHURIN: This is actually part of the public consultation. We would like people to comment, and there will be ethics people involved in the oversight of various components of this.

DR. FITZGERALD: Oh, they will. Okay.

DR. SHURIN: Well, they are in most of our advisory bodies.

DR. FITZGERALD: But, again, are they in-house or are they outside ethicists?

DR. SHURIN: It depends on where they are in this. It depends on which component.

DR. TUCKSON: We had been having some earlier discussions about this idea of sort of where do you go and how is it integrated. You looked at me like I was completely nuts. It's terrific. It's so integrated in what you do you don't even think about it.

DR. SHURIN: (Inaudible.) My goal, as we set up that, is that we would have everything that we did so integrated in the conduct of research that it would not be identifiable as a separate activity.

DR. TUCKSON: I'm sort of noodling over the large pop activity where we sort of thought about this issue of do you have this activity sort of above it that provides advice. But that's fine. We'll keep at it.