Simplifying Informed Consent

Misti Ault Anderson: Hello, everyone, and welcome to our session today on Simplifying Informed Consent. My name is Misti Ault Anderson, and I am here with my colleague, Yvonne Lau. We both work in the Division of Education and Development in the HHS Office for Human Research Protections. And we are looking forward to talking with you today about the informed consent process, the new requirements and how to use these to get a really meaningful informed consent in a more simplified manner to make it easier for you and for your research participants to understand and join your study. So thank you for joining us today. This session is scheduled for an hour and 45 minutes. We will talk for probably 75 to 90 minutes of that, and then we'll be opening it up for questions. If you have questions that you'd like to submit for us to answer, please enter them into the Q and A portion of the Zoom so that we can address them all through the Q and A as opposed to the chat. So again, please use the Q and A function instead of the chat for your questions. It will be a moderated Q and A at the end of the session, so please make note of any questions that you have and we will address them all at the end. So as we get started here, let me note that if we wander into the opinion territory, which sometimes we do, sometimes your questions aren't straight-up regulatory questions, but they involve some opinion, and if we do that, we will try to make note of what is our opinion, and please know that those opinions are ours as individuals and not necessarily those of HHS or of OHRP. All right. Learning objectives for our session today. After attending this session, you should be able to explain why meaningful informed consent is integral to enrolling participants in your human subjects research and describe what the important components of that are, both in general and specific to the new requirements in the revised Common Rule, and also to identify and use some techniques to simplify your consent documents and process in order to encourage a meaningful consent both in document and in process in what you obtain from your participants. Let's dig in. Research, according to the regulatory definition, is a systematic investigation that is designed to develop or contribute to generalizable knowledge. This is a specific regulatory definition, but it certainly encompasses even our colloquial understanding of research. One of the things, of course, that we understand inherently but that it's good to remind ourselves, right, is that research seeks to promote the common good, whether it's for a particular group or society as a whole, it is not for the benefit of any one individual. The research process and the goals of research are to benefit either a group or society as a whole. It's the common good. It's good to remind yourselves of that because in informed consent, this is something that we need to be able to communicate clearly to participants. So that being said and knowing that we understand that, for a lot of the research that we do, certainly for all of human subjects research, it can't be done without volunteers, right, without human subjects. That's why it is what it is, and so in order to get people to agree to be in our research, we need to treat them with respect, because without that, without having their trust, they won't volunteer for the studies. We cannot do the studies, and therefore we cannot advance the common good through our research. So part of our underlying goal always needs to be to focus on the respect and treatment of our research subjects, and this means protecting them from harms when possible. It doesn't mean eliminating all possible harms, but it means protecting them whenever possible. So this sets up an inherent ethical tension, right, where the goal of research is to ... we want to further research for additional scientific learning for societal benefits or the good of our population, of certain groups. We have societal common good that we are striving for through our research, but at the same time, we have a responsibility to protect the rights and the welfare and the well-being of each individual research subject, and those two things can come into tension. The classic historical example of this, of course, is the syphilis study of Tuskegee that most of you, I'm sure, have heard about and are familiar with, but it illustrates this tension very well because the scientific goals of the study, right ... it was meant to be an observational study of the natural course of syphilis as a disease. Of course, it is a fatal disease in the end, and so observing the course of the full disease would carry you all the way through to that end. When the study started, there was not a cure for syphilis. So studying the course of the disease was something that they set out to do. However, during the decades of the study, of course, antibiotics were discovered and became a treatment, and it became known to the medical community that that could cure syphilis. So at this point the ethical tension becomes very clear. The scientific goal of studying the disease is still a laudable goal. However, the researchers now have an obligation to offer this information to their subjects, and unfortunately in this case, they did not. They withheld that information. They did not offer reliable treatment, and they didn't provide it. This is why it became kind of a hallmark example of poor research ethics. Because this information could have helped participants. It could have saved a number of lives was not shared, and the treatment was not provided for the scientific goal of studying the disease. So that really illustrates this ethical tension that perhaps it's not to that same dramatic extent in our studies, but even so, there is a tension there, and it's important for us to realize this and to keep it in mind as we proceed with our studies. So let's start to focus a little bit on informed consent. What is the purpose of informed consent? Well, the purpose is of course to help individuals make their own informed decisions about whether or not to join your research. Okay. It seems pretty straightforward. This is all based on some ethical ideals that are laid out in "The Belmont Report," and the one that really supports informed consent, of course, is "Respect for Persons," and "Respect for Persons" has two important components. First is an understanding that individuals can decide for themselves, in this case whether or not to join your research, based upon their own values, what they see as the good and their own opinions and how they choose to live their life. That's their autonomy, and so "Respect for Persons" demands a respect for that autonomy. This includes the decision being a voluntary decision, and of course the regulations operationalize this ethical principal of "Respect for Persons" through the requirements for informed consent. The second part of "Respect for Persons," as described in "The Belmont Report," indicates that for people whose autonomy may not be fully developed or whose autonomy may be compromised, that those people deserve additional protections. All right. If they cannot make a fully autonomous decision for themselves, then there should be additional protections in place. So whether that is a legally authorized representative to make the decision for them, or the regulations also provide some other protections. So for example, it talks about vulnerable populations in a number of places in the regulations, and what they refer to is whether certain groups might be vulnerable to undue influence or coercion when being recruited for a research study. Undue influence of course is the idea that you offer something that is maybe out of proportion and is so good that someone would have a very hard time refusing. Or coercion is a potential threat, so you would ... that would be asking someone to join your research under either the threat of some sort of harm or the threat of a loss of a benefit of some sort. And finally of course there are subparts written into the regulations that protect some very specific populations as well and lay out regulatory protections that are a little more specific for certain populations. Informed consent is required by the regulations to be obtained before any research starts underway. Any research procedures at all, even those that proceed the intervention itself. This is true unless informed consent is waived and of course the regulations include requirements for when they can be waived, or when it can be waived. And this consent has to be done ahead of time because it requires that you provide the information to individuals that they need to decide whether or not to join your study. And that information must be provided in an understandable manner that they can understand and under circumstances of voluntariness, and we'll get into this a little bit more in just a couple of minutes. So what I really want to emphasize here, and this goes along with that ethical tension notion, right, is for us to remember that we should really see our research as a teamwork, right. In order to do the research that we want to do, that requires human volunteers and human subjects, right, we need to get their trust. We need to engender their trust so that they want to be willing participants in our research. It's necessary for the research to go forward. Without the subjects, the research isn't happening. So if they won't agree to join the study because they don't trust the research enterprise, or the researchers, or the study for whatever reason, then the research cannot go forward, no matter how wonderful the research would be. And so informed consent is the process through which we have an opportunity to provide information and gain their trust, to answer their questions, to help them understand what is going to happen, why it needs to happen and then decide whether or not they choose to participate. So the question becomes, "How do we do this?" Right? Informed consent has been required for decades, decades and decades. But the Revised Common Rule seeks to approach it in a slightly different manner, right? The emphasis now is not just on getting consent, but on getting a meaningful informed consent. So how do we make sure that prospective research participants have a fair chance of getting and understanding the information that they will need to make a decision about whether or not to join the study? That's really the focus of what I want to talk about today and what Yvonne will also talk about, and this is making consent more meaningful. And this gets at the ethical underpinnings of why we do consent in the first place, so we're really shifting the emphasis there. Some of the new requirements in the Revised Common Rule address this right at the very beginning. So this is new text right in the beginning of 116, and that is all about the information that you're going to provide in the informed consent document and process. It requires that the information that you give them be the information that a reasonable person would want to have in order to make an informed decision about participation. So this reasonable person, we're not going to dig into that too deeply here, but think about it likes this: The reasonable person is someone within the recruiting pool that you are seeking. So we're not talking about the every person on the face of the Earth. We're also not talking about just one individual and their in particular personal circumstance. What we're really talking about is for the group that you want to recruit. What is their circumstance? What is their context? And think about them in that context to in your mind understand who this reasonable person is. So how you would want to provide that information for people in that group to understand in a meaningful way to enable them to make this decision. And then once you have that ... you have your head wrapped around that, when you have the information to provide, it needs to be given in enough detail and has to be organized such that you're facilitating understanding, not just of the research, but also of why a person might want or not want to join your study. So it's, again, and this is important, this is new language in the regulations, it's not just even about understanding the research intervention or why the research was being done but going so far as to emphasize why they might want to join your study or why they might not want to join the study. That's part of the responsibility now of the research team in doing this through informed consent. So when you think about what information to provide and how to provide that information, I want you to think about these four main components, and the place to start here ... one of the things that I think really helps that we recommend when you're thinking about how to frame informed consent now is imagine it was you. Put yourself in this potential participant's shoes. What information would you need to make an informed decision about whether or not to join this study, and how would you want to receive that information? Right? So the four things that we really want you to think about when you're preparing your informed consent documents are the content, what information needs to go in there, the context, and we're going to dig into context a little bit here because there's the context of the research and there's also the context of your recruiting pool and your prospective participants that you need to think about, your presentation, which is how you present that information and then the language that you use in doing so. And all of these go into making your informed consent understandable. So let's kind of look at these a little bit. We'll walk through all four of these through the rest of the presentation. All right. Context. So as I mentioned, there are two different contexts that you really need to think about as far as presenting the content of information that you need to present. The first is the context of the research. So, where are the researchers coming from? Why do they want to do this research, and what do they hope to find out? All right. This kind of context is helpful for a potential participant to understand to decide if they want to join it. If it is worth their time, their effort, potentially putting themselves at risk of some sort of harm to do that. Is this something they feel is a strong enough good that they are willing to do that? But on the other hand, you also need to look at it from the perspective of the participant. What is the context that they are in when they're considering joining your research? And you need to understand that to be able to communicate effectively to them so that they can understand the information you're presenting in order to make a fully autonomous decision. So understanding your population. Is it a particular cultural group that it might be important for you to understand the culture in order to be able to communicate effectively with them and work towards gaining their trust? Is it a particular social group that you are trying to address? Are you recruiting from a pool of people in a certain profession and you want to approach it that way, say military personnel or healthcare workers, where understanding their context ... If you're wanting to do a study with frontline healthcare workers, sure, it might make a lot of sense scientifically to go to them first because they are going to be exposed to ... So say it's COVID research. They are more likely to be exposed, and that is a good reason, right, to use that population to recruit from. However, it's entirely possible that they're being approached quite a bit about this and they're under some pressure to join studies while also under their normal professional pressure of trying to deal with this ongoing pandemic, and understanding that context and whether or not they might be experiencing that kind of additional pressure, what is too much? And what might be enough, what might be convincing for them, what might not be? But understanding that that's where they are would help you as researchers or as someone on the research team in approaching them and providing the information that they need for informed consent. I love this cartoon. Yvonne found this. I'm going to give her credit for that, and it's now my new favorite, but it really, I think, illustrates something else about context that's really important. As a scientist myself, I appreciate this, because of course when we're in the middle of a study, we study very specific things one at a time, right? We have to figure out pieces of the jigsaw puzzle before they can all be fit together to understand the whole thing, and in this cartoon, of course, we're looking at it, and we see this as an elephant, but every individual little scientist climbing all over this elephant sees something different. You see the one hanging on the tail saying, "Hey, look, it's a rope!" And someone else up on the ears saying, "No, it's a fan!" And then someone looking at the tusk saying, "It's a spear!" And they're all seeing different details, but none of the scientists here are standing back far enough to put all the pieces together and say what we can say, which is, "Hey, look, it's an elephant," right? So I think that's a really great illustration about context because each of these things is important, and it is, in fact, part of the elephant, but to put it all together in context we see what it is as a whole. So how does this relates to informed consent? Well, I think it does in a few ways. Part of it is seeing the big picture for us, from research and understanding as we started talking about that this is where researchers and participants come together and seeing this in context, right, putting the whole picture together, understanding that people that are likely to volunteer for our research may be very unfamiliar with concepts about research. We do this for a living. We live in this space. We understand all these concepts, and it's easy to forget that what seems to be very simple concepts for us about research and how research is done is not simple and everyday for people that are not in the research field, the people that we are likely recruiting to come into our research. And if we're doing health research, particularly clinical trials where someone may be already struggling with health issues, understanding that decisions about one's health and one's healthcare in and of themselves can be very tricky, right? They're deeply personal. They can be hard to make, even when we're talking only treatment and not research. And so when we overlay then some of the uncertainties that can come with a research study, that adds another layer of complexity for a potential participant, right? So there are health decisions, and then there are research related health decisions and the concepts of research. These multiple layers of complexity that it's important for us to understand as we're approaching the informed consent process so that we can help potential participants try to make sense of it, and hopefully it encourages us to be a little bit patient here because they are really putting a lot of things together in trying to make a deeply personal and important decision, and it's important for them, and it's important for us. Now, language will become a main point of course. It's always a main point, right? Language is, I think, one of the biggest complaints that we've seen historically around informed consent. People say I've got this document, it's 15 pages long, and it is all medical jargon, and all legalese, and I can't make any sense of it at all, and so a document like that is not helpful, right? It's not going to help someone understand what's going on, and it's not going to support an autonomous decision. So part of what we're getting at in these new efforts in the new requirements in the Revised Common Rule is trying to break that pattern, make it accessible and understandable and still provide the necessary information. So we've talked about context and a little bit about content, but Yvonne will talk more about the content, but let's talk a little bit about language here. So we need to provide some context for the language that we use, right, which doesn't just mean giving a straight-up definition, but it means putting that new word, right, in some kind of context. So the simplest example here is randomization. If you are asking participants to join a randomized clinical trial of some sort, you need to explain, of course, what randomization means, and one of the most common explanations that we see, of course, is randomization means that you will be assigned to a group, one of the groups randomly, like the flip of a coin, which is great. It makes a nice analogy. It is easy to understand, but what I offer to you here is that this is not enough, right? This only tells you how the assignment will be done. It tells you how the randomization is done, right? But what it doesn't do is tell the potential participant what it means, right? So if I'm going to join the study, what does it mean to me to be in a randomized study? Well, it means a few different things. So, first of all, it means you cannot choose the group that you're in. I have no choice here. It will be random. It will be decided by maybe a computer or something, but it will not be decided by me or my doctor or specifically by the researcher, which also means that the assignment of what group I get placed in is not based on what's best for me, right? So this understanding right here helps to combat a lot of misconceptions, right, the notion that, well, if they gave me this, it must be the test drug because surely it will help me, right? So we can even start pushing back against some therapeutic misconception here, not completely, but this helps. The idea that then you have ... if you're going to volunteer for this study, you have to be okay being in either of the groups or any of the groups depending on how many groups there are, but understanding that if it's a random assignment, you need to know up-front that you would be okay with being placed in any of those groups, and likewise that if you have a very strong preference for being placed in one group versus another then joining a randomized trial might not be the best thing for you, right? If you know that you really want to get this drug that you're testing, and you really want it, and you don't want any chance of not getting it then perhaps joining a randomized trial is not the best. If you have an option to get that through your regular doctor, that might be a better choice for you because you wouldn't have that level of uncertainty. So explaining these things in very clear and plain ways, right, this gives a lot more information about, what does it mean to join a randomized trial? Other than just saying, "This is going to happen randomly, like the flip of a coin." So we're pushing you to go kind of another step farther. Now, how you give information makes a very big difference. Here is a list of potential side effects taken from some drug intervention trial. It's not important what trial, but what you see here is a long list of some very specific facts. There's a lot of information here, right? It's also written in very medical language. This is mostly jargon. It's a lot of information, and it's not helpful. I say it's not helpful. Sure, this checks the legal requirement, have you listed all the potential side effects? Yes, but does this really help someone understand what they might be looking at if they were to take this test drug? And I would argue that no, it doesn't. That this is essentially ... this is akin to ... it's not in prose format, but it's very similar to a wall of text, right? One of two things is going to happen here. If you put this in front of me and ask me to join a study, and if I don't understand any of these medical jargons, I'm going to go one of two ways. Either one, this looks overwhelming and extremely frightening, and you're going to scare me off, or two, I take this in visually and I find it to be overwhelming and therefore I glaze over it, and I glean no information from it. Yes, you've done the legal requirement of put it in front of me, and I may still sign this document, however I have not gotten any information out of this that will help me understand what may or may not happen to me if I join this study. So My point here for you is that providing a detailed list of isolated facts does not necessarily facilitate understanding. You're providing information, but if they don't understand that information, you're not making it to your target, right? You're not helping them understand it to make a fully autonomous decision which is our goal. Here is another example. This is another list of ... an example of a list of side effects. Notice what's a little bit different here. So first of all, there's a little bit of explanatory text. I'm not reading this out because the details here are not important of the particular study, but what I want you to notice is that there's a little bit of context as far as explanation, and then there are two kind of smaller lists provided here, and notice how they're categorized. The first part of the list is listed as the most common side effects that might be included here, and then a list of more every day language, right, so abnormal liver function results, constipation, nausea, vomiting, decreased appetite, headache. Those are things that are easier to understand. They're not in the medical jargon terms, and then the second part of the list is less common side effects seen in one person in preliminary tested included dizziness, itching, shaking of arms and legs, that sort of thing. So what I want you to see the difference between the previous page and this is the language used but also how it is grouped, right? Instead of just a long list of everything, it's what's more common, what am I more likely to experience, and what's a lot less common? This helps people make sense of it, kind of put it into buckets to know what to do with the information and be able to say, "Oh, well, I could handle ... these things that are more common, I could handle that possibility a little bit more." Right? Those are the things I need to think more about. All right. Moving past just a list of side effects, thinking more broadly about your study, think about helping place the entire informed consent in a context that will make sense to the group you're recruiting from. So think about it from the perspective of the participant, and what can really help is thinking about what questions might they ask? Right? When you're writing your informed consent documents, try to think about questions that this particular group of people might ask, right? So starting with the general, right, what is the problem you're trying to solve? What's the question you're trying to answer? Why do you think that this drug that you want to test might work? And what are you hoping to find out specifically about this drug? And then, why are you asking me? Right? So this notion that you have a group that you want to recruit from, you've defined them when you designed your study. Tell them that. It may be obvious. We are testing a drug for liver functions, so we need people with this one particular problem with their liver. Okay, that's fine, so it may be obvious, but it may not be that obvious. And then a really important one is, what will it mean for me to participate in this study? What am I going to have to do? How long is it going to take? How will it impact my life during that time? What is going to mean for them to really and truly be in this study? And it can help to even present it in this way. Put things under sub-headings that might be these questions, right, so that as the reader ... as your potential participant reads, they look at us and go, "Oh yeah, why am I being asked to participate?" Well, here's that information. It helps them digest a lot of information in a better way, and then as you move past the general and get into the more specific, what kinds of things do you think your participant pool might be worried about? What kinds of questions might they still have? So things like this, for example, "If I participate in this study, could I still join another study? What if something else comes up that looks really interesting to me, or there's a different intervention that's being tested? Can I not do that if I sign up for your study, or could I do both? Or what happens if I join your study and it's moving along through whatever number of months, and you learn some important things, good or bad, but you learn some important things, will you tell me? What will happen? Will we finish the study out and I'll never know, and you won't tell me until the end, or will that be incorporated in, would something change? What would you do if?" And an important question that you are likely to get, especially if it's a treatment study, is "What happens if I get worse? What if I join your study, we're moving along, and I start to get a lot worse? What are the options? Will my treatment be changed in any way? Would I need to quit the study if I needed to change treatments? Will my doctor know? Can I still get other treatments after being in this study?" Those sorts of things. These are questions that are extremely reasonable questions and that people are likely to have. Depending on the kind of study, these might be more or less important, but they're definitely ones that you should be thinking about, and don't just be prepared to answer them. Give them this information. Lead with this information because you know it will be important, and be specific with what you know that might be helpful for the potential participants to know. So let me give you an example of what I mean here. If it's a drug trial, don't just say, "We're trying to find out if this drug is effective." Why doesn't that work? Well, because effective can mean very different things to very different people. Remember, the people that you're recruiting to be in your study are not necessarily scientists. They probably are not in many cases, so the word effective is going to mean different things. One person might hear that and think, "Oh, this will make my symptoms better." Someone else might hear it and think, "Hey, this is going to cure me." Effective could mean very different things to very different people, so this is not specific enough. If you have more specific information, give them more specific information. For example, "we're trying to find out if this drug might shorten your stay in the ICU." Or "we're trying to find out if this drug will eliminate these particular symptoms for you," or something along those lines. But whatever that information is that you have, give it to them. And one of the reasons I say that is if you're too general here and you go with something like we're trying to find out if this is effective, if some participants read effective as, "It will cure me," and that's not at all what you're going for, then you're going to have a trust issue at some point down the line, right? Even if it's a very successful trial and this drug seems to have worked and that's great, and then these participants are left thinking, "But I'm not cured. What do you mean it was successful?" So providing this information really helps to first of all give them the information they need to decide if they want to join, but also, it really helps engender trust, which is what you need to bring them into your study. Okay, I'm going to take a quick pause here. I'm going to hand it over to Yvonne. She's going to jump in here and take over with this next slide. So Yvonne, welcome aboard.

Yvonne Lau: Thank you. Let me just get to share my screen. So while I'm trying to do that, I'm just going to ... All right. Let me just do that first. Okay, can you see the slides all right?

Misti Ault Anderson: Yes, we can.

Yvonne Lau: Okay, great. Thank you. So, I'm Yvonne Lau. I'm the director for the Division of Education and Development, and I've decided to share this ... we've decided, Misti and myself, to share this presentation so that this being a virtual platform that you don't actually just get to hear one set of voice and that you get a bit of a variety. So I'm going to pick this up from the discussion of context and content, and I'm going to dig into this a little bit further. So context really determines the kind of content that you want to provide to your participants, and it is particularly important in clinical trials, studies that effect people's health. So this is a quote that I took from a research participant, somebody who was presented with informed consent and asked to participate in research, and we were asking them what of their impressions, and this is the response that we were given: "I didn't pay a lot of attention during the discussion. I was mostly thinking up questions I would need answered regarding my own care, the treatment plan being proposed, how I might be affected." This brings us back again to the point about when you actually present a clinical trial to somebody in the healthcare setting, obviously they're going to be taking in that information and thinking it in terms of how that would effect their health, their treatment plans moving forward. So it is really important for you to try and think about your research and how to put the information about your research into that kind of a context so you kind of anticipate and prepare the answers for those questions ahead of them asking you about it. And of course in the case many of you would know, clinicians would know, that not everybody know what questions to ask their doctors let alone researchers, and if you don't understand where I'm coming from, think about a different situation. I think about it in terms of going to the lawyer's, right, maybe getting a mortgage. I'm not familiar with that kind of thing, and they tell me a whole bunch of things, and I'm just sitting there absorbing or trying to understand the information, and I kind of feel a little bit paralyzed because, okay, so, how is that information going to help me? What other questions that I should ask here? Right? So if you're not in that field, it's really difficult for you to know what questions to come up with. So understand that, right? Anticipate the questions that your prospective participants might ask you. Okay, so what would it mean to participate? Explain the information in a way that would help prospective participants understand the pros and the cons, the why and why not. I'm going to give you an example. Let's talk about a randomized study here involving teenagers, right, and teenagers with idiopathic scoliosis. So they have this unknown reason during the growth of these teenagers, their spines start curving, and for a small number of these teenagers, the curving continues throughout the bone growth period, right, and people wonder there's this thing called wearing a back brace, a rigid back brace. If we ask teenagers to wear that rigid back brace for many, many hours a day for quite a few months and sometimes a year or so versus, okay, well, is it okay to just observe them and then maybe only do something about it at a certain point in time? So researchers were interested in randomizing teenagers to one group wearing the rigid back brace and then the other group, just putting them on observation. So think about it. So if you were the parent being asked about having your teenager maybe participate in this study, what would you like to know, right? So typically, in a randomized control trial is an intervention. So I guess the back brace might be like an intervention. Typically in the informed consent, the consent would start giving you a whole bunch of information about the back brace, wearing the back brace and what might be, if there are any problems with wearing the back brace, the risks and potential harms and maybe, what are the benefits? And it kind of listed in different segments. We want to suggest maybe there are better ways of actually presenting the information in a way that really kind of address how people think about these questions. One way is maybe framing it like this: What to expect if your child is assigned to the group required to wear the back brace? What could you expect if they're assigned to that? Okay, well, with that kind of a framing, what might be some of the information that you would put underneath this section? Right? So let's see, well, if the back brace prevents more curving of the spine, your child could benefit from slowing the curving process and less chance of needing surgery. That's the key benefit that researchers may be hoping to find, right, to see if it works. Notice how in the last ... in this sentence, we're also putting in specificity, right? It's not just whether it's effective, but effective for what? Right? And your child may find wearing a back brace inconvenient, restrictive and uncomfortable, and the brace could injure the skin, may lead to skin ulcers and that your child may feel stressed or embarrassed around others. So in a few sentences, you're kind of pointing out some of the key problems that a child might experience if they were put in the group to wear this back brace, right? They have to wear it for a long period of time during the day and for many months, and you know what teenagers are like. They could feel embarrassed about having something like that. They look different, right? They look different to others, and that could stress them out and could be embarrassing. They also could have problems from having to wear it for such a long time, and it's uncomfortable and restrictive. So those are the things that one could expect if the child was being put in that group, and you're laying it out in a way that is relevant, right, in the section that is relevant. That's when they are thinking about this. Now, if the back brace does not prevent curving of the spine, this is the question that we are trying to find out, then your child could experience these problems without receiving any benefits. So really laying it out. Now, guess what. What would be the next section? You want to turn the question around, and you want to put it in the perspective of, what about the group in the observation ... under observation and not wearing the back brace? All right. So what would you put in this? I would ... these are suggestions, right? I would say, "Okay, right away, your child will not experience inconveniences, discomfort, skin problems or stress." Pretty obvious. Yes, it's pretty obvious, but putting it right in front of them saves them from having to dig deep into all that information and try to find out, okay, how is being in one group versus in another group be different? You tell them also, "Your child's spinal condition may or may not progress further before bone growth matures, and if the curving continues to progress, right, what could you do? You and your child's doctor may not want to continue participating, and you might decide to find treatment outside, or the back brace prevents more curving of the spine, since you're not in that group, it is possible that your child may miss the window ... The optimal time to benefit from wearing it." Now, personally, I think that in making ... in asking people to make a decision to do one thing versus another, it's really important for them to understand, okay, what is the difference between the two options? If I don't understand the difference between the two options, it's really hard for you to ask me to try and make a decision about whether to do something or not, and I think that Misti has already pointed out that when you're randomizing people, it actually means to them, right, that they could be put in either group, not just the intervention group. So traditionally when we spend all the time in informed consent just talking about the intervention and the intervention group, we kind of already sort of put some bias into the kind of information that they ... and no wonder at the end of the day, after you've spent all the time and given all the details, people still come back and ask, "Okay, aren't I going to be in this group? When am I getting the intervention?" And you kind of say, "Did you not listen to me about that?" Well, you didn't really tell them clearly, right? The other thing is after seeing the information that we just showed, the next question is pretty obvious, right? What might be some of the reasons that I may or may not want to put my child through this study, right? So it would be nice if you can actually just point out some of the possible reasons. Some of these could be, "Well, I don't know really what's best for my child, and since doctors don't know either, participating seems like a reasonable choice." You don't have to make an actual decision, the decision is, "Okay, well, let's just do the study." And doing the study of course can help progress science, advance science, and whether or not it's going to directly benefit my child, other people could benefit in the future, and then there are also potentially very sort of reasons that are linked to our reality. Back braces are actually really expensive, I was told, and not everybody can afford it. So participation could be a way that my child could get access to the brace free of charge. What about possible reasons for not wanting to have my child participate? It could be that and could really be my child ... I know my child, there's no way that you can get my child to wear this heavy, rigid thing, and she's or he's really sportive and so on. So there's no way that they would accept that. Well, might as well forget not putting him in the study, right? Then there are also parents who are really, really sort of proactive and want to take action. "Let's just not wait. Why wait? Let's just get my child to wear this. I don't want to be randomized to have the uncertainty." And then there are other people who say, "Well, I don't know. I can't make the decision, but I don't want to leave it to the randomization process. I really want to just talk with my pediatrician." You have all sorts of things, and of course there could be other reasons, but just presenting some of these reasons could help start the thinking process, right, that these are the kind of decisions that we're asking parents or prospective participants. These are some other reasons for some other studies. The first few are kind of the same or similar, but I want to ask you to look at the bottom, the bottom ones. On the left-hand side, it could be participating in this research is the only way that I get a chance to try out this study drug, or participation in this research seems like a lot of fun. For a lot of the social behavior studies, they're kind of fun to do, right? So I just want to go through and have that experience, and experience could be valuable, and on the right-hand side and again look at the bottom bullet points since the top ones are kind of similar to the last one. You could be saying things like ... or it could be things like, "Well, I really won't be able to support my child through all the study visits and procedures." And we have heard that for a lot of studies that involve children, researchers really have to put in the effort to think about how to time it so that it would not affect school or that parents will be able to bring the child to wherever they need to go to to undergo the testing and to do the procedure. So your timing and effort becomes a real problem, and when researchers start having to think about these things, what to put in in the consent, and what might be some of the information that would be of interest and important for prospective participants as they do and go through this process? I personally think it could actually help improve your research as well because then you really start moving into the realm of thinking about how it is like for your prospective participants to participate, and are there things that you can actually do and in order to minimize the burden on them, not just potential actual harms, but the burden on them? We talked about context, content, but how you actually present the information is also quite important. It really helps with how people could receive the information and understand it. So what are some of the things that we could do? You can break up the dense text with sectioning, pictures and icons, right? You could potentially compare information by simply putting information side by side. It draws our eyes directly to comparing the two sides, right? And you could include schematic diagrams for very complex studies with very complex procedures and processes. Some people are very visuals, others may not, and if you're a visual person and you look at a schematic diagram, it can immediately help you to picture the kind of things that need to happen. So presentation is not just about making something look pretty. I know that many of you researchers, you've spent all this time. You study science. You have your PhDs. You're doing research. You've done all these really serious and important things, and to you maybe drawing little pictures or putting colors on things are really not things that I care about. Sure, they're not a big deal in terms of the science, right, but if you want people to communicate your science, and communication has become such an important thing these days, we all know, if things are not communicated well to people, people don't accept it. People misunderstand things, and they get confused, and then they just don't want to work with you, right? So it's really important to learn about how to communicate things. Now, this is an example of just showing things in sections, the sections that have colors, and I used a bit of icons, right, to just pull things out. Now, I hope you would agree just looking at something like that immediately kind of catches your attention. It looks like, "Oh, everything is brighter," and it draws your attention to, "Oh, maybe I wouldn't mind reading this." So that helps, right, as opposed to a big, long list of text, very dense, very small font and no white space, right? So sectioning also helps, like Misti said. If you actually raise the sections, the headings, put the headings out as questions that really interest people. Then it helps because they go straight to, "Oh, why am I being asked to participate in this?" They look, and "Oh, this is the reason." "Why are they doing this study?" They look. "Okay, this is the reason." So it kind of puts things into sections. Then I talked about putting things side by side, a table like this, and you kind of immediately can ... people know, okay, you're trying to compare two things, right, and again, if you have a randomized trial situation, it immediately draws people's attention to the fact that it's not just one intervention or this group with the intervention that I want you to know about, right? There is the other group that I also want you to know about, and if you put them side by side, you can also list out how they're different. So let's just go through some of these. On the one side you have if you receive the test drug, the active drug, and this is a one-on-one randomization so you have a 50 percent chance of getting that, and the other side is if you receive the placebo, the inactive compound, and you have a 50 percent chance. So how do the two compare? So in one group, you will receive, say, the usual care and the test drug, and you will not know because it's a blinded study. You will not know whether you're getting the active drug or not, and then on the other side, okay, you don't know whether you're getting the inactive drug or not, or you'll be getting the usual and the placebo. What does it mean? We do not know whether the test drug will help treat your opioid use problem, but if it is effective, it may reduce your cravings for opioids, lessen your withdrawal symptoms and help you stay off opioids. On the other hand, if you happen to be in that group that has the placebo, you will receive no known medical benefit from the placebo. You will not benefit or be harmed, however, by a test drug because you're not getting it, right, and then you can go down the list to compare the two. So it really helps people kind of get the information more in a concrete way in their mind. Okay, there are two groups. This is how the two groups would compare. I can immediately picture, "Okay, I can be put into either one group and what I could expect. If I were in this group or if I was in the other group." So using a schematic diagram, again, it's also a nice way especially if you have complex processes, right, but the other simpler thing is that if you see a diagram like that, you know, like I said, it's not just intervention arm on the left here under group A that is important. When you talk about we're a randomized study, you do actually have two groups. You have the group A and you have the group B, and this actually tells you if I agree to participate, I could be in either ... I could be put in either group, right? And what more is that with this schematic diagram, it also reminds you that, okay, if you are pondering participation, you can definitely make a decision to agree to participate, but you can also make the decision of declining to participate. Now, this is a way of empowering your prospective participants. I get it. Okay, empowering, it's like telling them clearly that they could not accept to participate, and you might lose a prospective participant. Well, but that's the reality. You don't want to mislead, omit things to get people into the study because they're not going to stay if they find out. You're not going to build trust that way. So might as well just come out and be confident with how much you have done to make your study a good and sound study, how much you have done to minimize potential harms and have confidence in yourself that you can bring your participants on, right? But one way of showing confidence is to make sure that you give them, clearly, empower them to know that they could, well after listening to you, spending all the time, they could decline to participate, and let them know, right, okay, what would that mean? So we talked about presentation. Now let's move on and talk a little bit about writing in plain language. Like Misti said, this has been some of the things that people complain a lot about, so I'm going to point out what that means. It means using common, everyday words. I want you to think about these points as I go through them because in the subsequent slides, we're going to come back and visit them, and I want you to have them kind of in your mind and apply them. Use shorter words with fewer syllables. Long, complex words, they're really ... I have a British background. We like to use very long words, but they're just not good in everyday communication, right? Avoid jargon. Explain terms. Sometimes you can't avoid using some of the medical terms, so if you can't avoid using them, explain them. If you can avoid using them, use a simpler term. Use active voice if possible, right, and not put sentences into passive voice because passive voice requires ... it's a little bit tortured, the sentence, and again, I have a British background, and I like using passive voice because you can create a lot of nuances and diplomacy, but that's not what this is about. You're trying to communicate information clearly to your prospective participants. So use active voice whenever possible. It makes the sentence simpler and more straightforward. Write in a conversational style. Use short sentences and keep paragraphs short. Break up complex concepts into sections. Now, a lot of you are already aware and are already doing this, putting things into sections, under section heads. That really helps, right? So a lot of you already doing that in consent documents, but what many of you are still not doing is actually keeping the concept simple under the sections and using plain language. Let's look at an example. This is under ... this is taken out from actual informed consent. I don't know whose consent, so don't ask me what study this is, but then this is a paragraph taken out from where they wanted to talk about the study drug. I'm going to just leave you to look at this a little bit and think about all the things we just talked about. Don't use medical jargons, use very short words, active voice, keep ideas simple and not complex. This is really complex, right, and you can see ... one look at this and you know the investigator was just copy and pasting from the protocol that they submitted for peer review, right, and, yeah, it's probably one the scientific peer reviewers would want to see. They want to see and understand the science behind what you're proposing, and they of course will understand this, but this is in the informed consent document, right? Who on Earth is going to understand this? I have a medical training. I have a medical background, practiced medicine for many years. I actually looked at this, and it took me a long, long time to really even wrap my head around, words like upregulate, downregulate and all that. So not very helpful at all. So if you put something like that in your consent document and you complain your participants don't understand, of course they won't understand, and you're wasting space. I might as well just come on and say, "You're just wasting space." Right? That's not useful information. My next question for you is, can you convey this information more simply? I'm sure you can. Let's just look at this. So this is what I make up, right. For those of you who are immunologists might challenge me and say, "Well, that's not exactly it." Okay, well, fine, right, but what I'm trying to do is to illustrate a point. You can put some of this ... you can put this information basically into one or two sentences, and how do you do that? You think back about the context under which your prospective participant would want to receive this information. What is it about this information that would be useful to them, that they could understand that would be useful to them? And that is going to determine the content we put into this. All right. Let's look at another example. This is a slightly simpler one. It doesn't have all those upregulate, downregulate and all those immunology terms and monoclonal antibodies. This is more like a cognitive type of behavioral studies. I'm going to leave you to read it a little bit. Again, it has the same problem. Long, long words, right? Too many ideas in a sentence. It takes a long time for you to wrap your head around. So, can we make it simpler? I'm going to leave this on for a second, let you think about it. Any of you who actually can offer a simple way to say this, by all means, type it into the chat and let other people see it, and your version might be better than mine. Again, we are all playing around with this. We are all trying to get better. So my suggestion is possibly as good as yours, and you might come up with something that is even simpler than mine. So what about: "We want to know if doing brain training together with physical exercise can help older adults improve brain function more than doing just one alone." That's kind of the message that the investigators want to convey or need to convey, if you like. Okay, I'm going to leave you with this one and give you a few seconds to read through it, so more social behavior-like type of research. Okay, I think for the purpose of others, I'm going to read it nonetheless. "Injection drug use is the leading risk for HIV infection. In addition, hepatitis C virus infection among injection drug users ranges from 30 percent to 90 percent. These infections are an enormous public health challenge because they involve a chronic carrier state resulting in ongoing transmission and costly medical consequences for those infected. To date, there are no vaccines to prevent these infections, so a critical type of prevention involves reducing the risk of exposure. Reducing risks such as syringe and drug paraphernalia sharing and sexual behaviors among IDU, intravenous drug users, can reduce rates of infection. We know that some interventions to change behaviors have worked in IDU, but there have been no thorough studies in younger people who have begun to engage in risky behaviors to determine whether specific education programs can reduce rates of HIV and HCV infections among IDU by changing risky behaviors. Specifically, this study will test whether a program focused on peers teaching peers about high-risk behaviors in effective in encouraging the teachers to also change their high-risk behaviors." Excuse me if I didn't read it nice and smoothly. It's hard, actually, to read from your screen. All right. So I hope some of you have read through it and maybe had the chance to think about it. You can actually reduce the amount of information that is being presented here into three parts, right? So sectioning them out, if you like, called a section heading to help, but essentially what we're trying to say is, "HIV and Hepatitis C are infections that commonly affect IV drug users because of their habits of sharing contaminated needles. These infections cause serious long-term health problems requiring long and expensive treatment that are not always effective." So if you like, this is the problem. The second part: "The best option for IV drug users is to avoid getting infected in the first place by learning what they need to do to reduce the risks of infection." So you're kind of saying, "Why does it matter to you? I'm presenting this study to you as a prospective participant, IV drug users, and why does it matter to you?" And so the last bit is, how am I proposing ... how research is proposing to deal with this. We are doing this study to find out if teaching IV drug users how to teach others, like themselves, to avoid the risks of infection could also help the teachers reduce their own risks. Again, some of you might actually be able to do it better than I have here, but what we're trying to do is to use active voices, simple words, not very long words. I know that there are some long words here, but sometimes it's hard to replace a long word, and if you have to do that, you might end up with many sentences, and it may actually make it unnecessarily long. Sometimes words can be long, but they're still commonly used words, so you have to kind of balance and make a decision here, but you see what I'm saying here, right? I can tell you the font here on the right-hand side is much bigger, so in fact, if you work it out, it's kind of like 50 percent of the text to the left-hand side. And you put it all into sections, it's going to be easier for people to read, and if you put in headings and so on, it's going to make it easier still, hopefully. Now, I'm going to get into a slightly different topic now. So in the Revised Common Rule, there is a new requirement for a key information section. So what is it? It is a section where you provide concise and focused presentation about why one might or might not want to participate. So let ... The Revised Common Rule, isn't the informed consent document long enough already, and now I have to actually do another section where I kind of maybe repeat the same information that I put into my very long consent document already? Right? Okay. Let's look at what the SACHRP, the Secretary Advisory Committee board experts say, and their recommendation when they were looking at the information requirement, they say, "Well, this key information summary is really an opportunity to orient, guide and assist potential subjects in the decision making process." The purpose of this section is to orient, to guide and to assist. Now, how can we do that using the key information section? I'm a hiker, and I'm going to say I love when I go hiking, when I go to a new State Park or forest and I'm looking for hiking trails, and I see a hiking map like this. I'm delighted. I don't know the area. I don't know what trails are available. I look at this and I spend about 3, 4 minutes looking at it and immediately I kind of know. It tells you the different trails, the different options that are available to you. It tells you for a hiker, some of us like to walk on level ground. Others want to do something more challenging. I always like to go for the summit and panoramic views because I really like those. So I look at a trail map like this, and immediately I'm looking at places where I can look out, high enough where I can get a view, right? And then the next thing is, okay, well, is it too steep for me to walk, and what about ... am I going to spend 3 hours doing this, or am I going to be spending 1 hour doing it? Just a simple little square like this already gives me all the information as a hiker that I would need. Well, I'm not saying all the information, but the information ... the essential information I would need to do what? To make a decision about which route I'm going to take. And of course, there are people who might want to know, and then they obviously sometimes also ... if you choose the yellow trail, for example, sometimes at the park office you get additional information, right? And you get additional information about what's on the trail, what kind of vegetations, what kind of trees you might see, and so on. What kind of specific things that you might want to look out for, things like that.But for most people who want to make a decision about which route I'm going to take if I want to go hiking, that's almost more or less all the information I need. So this does the job. It orients, it guides, and it assists me to make that decision. I think that's the kind of mind set we have to have when we think about this key information section. And it's ... if you think about it, up until now with this presentation, it's more or less the kind of things we've been pointing you at. Plus we're not asking you to do a little square and have a map for your prospective participants ... to do that, fine, go for it. One thing I have to say, the regulations actually do not dictate how you do this. Do not dictate how you actually present the information. For those of you who are familiar with the regulation you say, "Well, 46.116, they have all these elements that you have to have, and the additional elements, information in the additional elements and so on as appropriate." Right? Well, yes, they tell you that those are the kind of information that needs to be in the consent document, but it doesn't say how they need to be presented and as long as you have them. So another thing I wanted to point out about this key information section is Dickert did a study and reported on it, and I'm sure many people have done similar kind of things looking at consent documents and so on. In this particular study, they were partnering with patients, and they were trying to get a really short informed consent for a study that is done in the acute care situation. So they want something that is simple and easy and fast to read, and so they were talking to their patient advocates, and this was a comment that was clearly, very clearly, conveyed to the researchers. The first page, and I'm going to just extend it a little bit, the first couple of pages of the consent document is critical real estate for communicating valuable information. This is pretty obvious, isn't it? In this day and age, we know how much attention span we all have, how busy we all are. Nobody Is going to have the patience to spend a lot of time reading through 20 pages document and still be able to focus. The first few pages is really where you could actually have the maximal efficacy of conveying information to people you want to communicate to. So it would be opportunity lost if the first couple of pages are filled with information that look really official, headers, technical titles. In fact, I've seen informed consent where there is a technical title and then there is any kind of a lay title and then a whole bunch of other information, generic introductions, generic instructions. Let's look at one. This is an actual consent that was used, and first two-thirds of the page is filled with this kind of information. And already ... and compared to this one, again this is not our own OHRP consent. It's just something that I found on the Internet. And I'm not commenting on language used or anything. I'm just trying to let you see how they compare. In the sense just visually, right away, you would find, okay, well, I can see on the right-hand side pretty much all the key important information that would help people know something about a study and maybe start to think about whether they want to make a decision. It's already right there on this page. Whereas on the one on the left-hand side, the first half of it, the first two-thirds of it is still, okay, well, what do I do with this information? Why do I want to know the investigator's address? And then I have also seen key information where people put in study procedures. Okay. Right. Again, what are we trying to do in the consent document? We're trying to get people information, the kind of information that would help them make a decision about participation or not, to make a decision about options. Now, yeah, study procedures are probably of some use and of some relevance here. But if you read this through, it is a very long and detailed set of study procedures. It's not a complex study. Basically it is ... if you read through it, it is a study. It's in the COVID era, and they're really trying to ask people to do a survey, do a few finger pricks and then give them the kit to do the finger pricks and the nasal swabs and then have it all sent back by post. Not a complex procedure, but these are the study procedures step by step by step by step. Think about yourself. To make a decision about whether you're going to do something or not, yeah, you need to know something about what you're being asked to do, nasal swabs, finger pricks, do a survey and send them back through the post. You don't actually need to have step ... day one, day two, day three, day four, day five information. You might need to know, okay, well, this study is going to last for 5 days or something, but how much information did I say was important for you to make that decision? Two sentences would be enough to probably help with that, right? So why waste space, especially not in the key information section. In the rest of the sections of your consent, maybe, and I'm just saying maybe because I'm not even sure that for a consent document where you're really just asked to make a decision about participation or not you need to know every single step, every single day of what you'll be asked to do. I'm not sure that's information ... That's the kind of information that is important once I've decided that I want to participate. So I then would need to have the instructions, what do I need to do in day one? What do I need to do in day two? What do I need to do in day three? But in order for me to make that decision probably all I need to know is sufficient information to let me know what the burden ... whether the burden would be in terms of time involvement or burden in terms of what other procedures that I might find embarrassing or that I would find burdensome, right? So really think about that, and that is going to help you. That effort is going to help you significantly come down on the amount of information that you put into your consent document. So we, OHRP, the Office for Human Research Protections, we started doing this initiative called Exploratory Workshop which is an event that we do once a year, and we started in 2018. The first workshop that we did in September 2018 was on informed consent, and we invited Steven Woloshin from the Dartmouth Institute for Health Policy and Clinical Practice to come and talk to us a little bit about in his research, what he's learned about what, in his opinion, based on the research work and all the experience that he has, what might be information that would be considered key in helping us make ... helping people, prospective participants, make decision about research? So he indicated this: Why are we ... Tell people why we're doing the study. What is the new idea? Why might it help? The purpose, specificity, what you're hoping to find out in the study. What are the trade-offs for people? A discussion of the pros and cons, in an integrated manner. Why would you not want to be in this study? Why would you want to be in this study? And how would the research be done, but in simple terms? Right? Not in detailed, step-by-step, everyday thing. So basically kind of doesn't it resemble what we've been talking about over and over throughout this presentation? All right. So I'm going to show you ... this is just an example of a way of maybe conveying some key information. This is a study ... a simple study basically. It's just getting seniors over 65 because they have problem with maintaining balance, so researchers wants to do some research on how they could improve their balance. We want to first learn about how they maintain balance, how elderly senior citizens actually maintain balance or when they feel not balanced, how they maintain it, and then they want to also find out whether by using this method, they could actually help them improve their balance over time. So what they propose is to have the seniors walk on a treadmill first just normally and then second show them in front of them, move the image side by side. So it gives them a little bit of dizzy kind of feeling, and that could prompt them to lose a bit of balance and see how they can then regain balance. And all this is done on treadmill under supervision. There's a harness to protect. Simple study, relatively. I do want ... I tried to write, and this is my own exercise, where I tried to write a key information section for this and this is what I came up with. It's two-thirds of the page, and it's pretty much got most of the things on. And, I tell you what, if you have more that you need to say, you have the whole of the rest of the consent document to do it. Now, I want to actually point out one thing here is there is actually a randomization process in this particular study, and the randomization is a self-randomization so what they do is they will randomize some subjects to start by walking normally on the treadmill and then walking on the treadmill with the image moved side by side, and then the other group would be people who actually start by walking on the treadmill with the image moved side by side first. Then when they repeat the walking a few days later, that's just the normal without the image moving side by side. So this was a self ... a design that researchers did in order to ... for the scientific validity side of it for what they want to find out. I actually, if you look carefully at this description, I didn't mention anything about that randomization. I did mention that they would be asked to walk first without the image moving ... walk in ... do two times, do the walk two times on the treadmill. One time would be with image moving side by side, and the other time would be without the image moving side by side, but that's pretty much all they need to know. They don't need to know anything about the randomization, so the bit of information about the randomization is useless and pointless for them. It doesn't matter and doesn't help and doesn't stop ... doesn't effect their making a decision as whether they want to participate or not in the study so I took it out. Again, coming back to really paying attention to what would matter to your prospective participants. Sometimes the information that doesn't matter so much, so you can take them out, simplify the consent. Other times, they're really important information that would really impact on how ... and help them make decisions about choosing one or the other, and we've talked about framing information, putting information together, putting those information that are important together in a way that helps them, and not just for example talking about the group with the intervention but also maybe giving some information about the control group, right? So you don't need to look at the details about this, but all I'm trying to find out is really that there are some studies where right up-front. This was a phase-two study, and we're talking about looking at the effects of aspirin to see whether that could maybe reduce the chance of chronic smokers getting lung cancers, but this is really at the phase-two, early phase-two level, and I don't believe that in this study that the researchers are really looking at whether aspirin could really ultimately reduced mortality. But they're really just looking at some of the biomarkers and molecular indicators to see if there's an indication of that in fact. Enrolling in this study ... people who enroll themselves in the study like that shouldn't really be expecting any concrete health benefits to come out of this. So that is something that if there's a study that looks like a health study and people should not really be expecting to get any actual help, that may be key information that you want to put right at the beginning. This is a way of again, like I said, the commentary doesn't actually say how you need to present this information. You can do it the way you think is appropriate, but do it in a way that would help people ultimately. Help people understand the information and help them make a decision as to what decisions that they want to come up with. All right. So we're getting to the final part of this presentation. Coming back to this whole business about simplifying consent documents. Simplify is not just to make things shorter. Obviously that's one aspect of it, but in order to make things shorter and simpler, you have to probably start by looking at the context of how people ... what information needs to be conveyed to the subjects that would help them make decisions, and under what context the subjects would want to receive this information in order for that information to be helpful to them. A good understanding of the context is going to help you come up with, okay, what is the kind of content that needs to be put in there? Of course, because you are dealing with prospective participants who most of them don't actually know the science, here I'm not just going to say medical and health information, but you could be doing a behavior study and it could be complex, so what I'm talking about is really, they might not really have a lot of expertise. In fact, most of them won't have a lot of expertise and understanding of this kind of science that you're coming from. So what you want to do is think about the least amount of information that would actually make the point, if you like, for them, and in terms of coming from their perspective, give them the kind of optimal amount of information that would really help them make their decision. Not everything, right? Certainly not at least ... Yeah, so not everything under the Sun, but an optimal amount of information and organized in a way that they can actually receive and understand it. That's going to ... simplifying complex information is going to be decided by your understanding of the context, you really knowing your group of prospective participants, right, and then starting to think about how to organize the content. What content and how to organize in order to respond to what they might be looking for? Don't forget to use plain language, and this is something that one needs to practice. It is not something that one would get into right away, and you might, initially when you start, you might need to start with a version and then go back and ... can I simplify it even further? Then you have another version. So think about all those points we already talked about as to how you can actually render something in plain language. By all means, use visual aids. How can you actually present the information in a way that makes it not just that you have a lot of white space, that people actually can have room, mental space to digest the information? Sometimes having space is a good thing. It helps people to see the information, if you like, and putting things in colors and including icons ... Honestly, guys, I'm not talking about any fancy things that you need to do. All those slides that you just saw, those are just tables and finding colorful tables or putting a title heading in a different color, using a different font. Honestly, I'm not a computer guy ... computer gal, and if I can do it, those slides are made by Misti and myself, and if we can do it, you can do it. Neither of us are techy people. Have somebody to review it. Run it by a patient research advocate, somebody who is a layperson who may be from the prospective target population that you're looking at, and ask them to read through it and see if they can get it. And I'm going to just say, make use of the new key information section to orient, guide and assist people in making a decision about participation. Now, what I'm going to say now is just really totally my own perspective. Okay. I know that we have been fighting with lawyers and institution lawyers, and officials about, okay, let's try and simplify consent documents, but then they're going to say, "No, no, no, you need all this legalese in there, and no, no, you have to have it said like this, all tortured ways in order to make sure that it's accurate from a legal point of view because this is not just going to inform people, but it's going to serve another function to protect the institutions and the investigators." I'm not saying that protecting the institution from investigators are not important objectives, but then this is nonetheless an informed consent, and from OHRP's point of view, this is the opportunity to try and make people understand what's going on and help them make a decision whether or not to participate that corresponds to their value. And this is really important because it is going to help engender public trust. People are going to feel that they are part of the team, that they are respected. And this we have learned after all these years and recent period of time in particular, too, that it is so important and trust can be broken. Trust is very fragile and trust can be lost, and very difficult to regain. So we really need to do our best, and I would say that this key information section may be a way that we can actually entertain both, right? So I'm just going to say well, in my mind, I'm kind of thinking, "You know what, institutional lawyers, I get it. I respect your perspective, but can't we just at least leave me this key information section where I can really try our best to use plain language, simple ideas, simple terms to convey enough information for people to make that decision?" And then I still have the rest of the whole consent document where you can fill it up with what things that people think need to be there and may not be so important to put in the key information. That may be one way of doing it. Whatever, just an idea for you to ponder. The other thing I want to say is we have spent all these ... we're putting a lot of money into science, and obviously it is really important for investigators to put in the time to think about how to get their science into a really good level and that they are able to come up with experiments where they could really answer a good question and the question is going to lead to good common good. Yeah, absolutely, you absolutely should spend the time to do that, but don't forget if you're doing human subject research, a research study that involves human participants, they are the other half of the equation. They may not be the ones who actually help you design the study or at least not directly. I know there are some situations now where communities are asked to help and contribute to the design. That's fine, but they are the other half. Without the research participants, you're not going to be able to do your research. You know that. So it pays to spend the time to acquire the techniques, to spend the time to think about how you can make your consent document a document that people would find useful, that could help engage them. The other thing is happy clients are happy people, and you might not get them to agree to participate on this occasion but you do actually build up a long-term relationship. That hopefully would come into play, and I guess if you actually can get people to make a real decision because they have thought through it, and they're committing to it, then they are likely to continue to commit to your research, and you're going to have fewer losses for your time. So I think it's a really an important effort that you need to start thinking about spending time and putting some more work into it. Now, one more point I want to make about ...

Misti Ault Anderson: Yvonne, Yvonne, I want to give you a quick ... I wanted to give you a quick time stamp. It's right about 2:30 and I want to make sure we leave a little time for questions.

Yvonne Lau: Yeah, absolutely, I will do that. So, I'm going to end soon, but one more point I want to make and that is people talk about, "Oh, consent is a process," and some people when they say that, they're also trying to tell you that the verbal part is really more important. Forget about the consent document. Let's just focus on the verbal one. I'm just going to tell you that having gone through this presentation and look at the effort we're trying to put into putting things in simple terms, explaining things accurately using simple language and everything, that needs time and effort. You need to spend the time to do that in your consent document, and guess who a lot of the times is not necessarily the PI who are actually going out to ... who know the study well, or person who actually writes the consent form, to be getting the consent ... undergoing the consent process and getting the actual consent and talking to the prospective participants. So, if I were the PI, I would probably want to make sure that whoever is actually doing that on my behalf, that they have all the right information put up in the right way. In a way that really would enable us getting the people to understand and engage. If I were the PI, I would want to make sure that ... I'm a control freak, by the way, so I would probably want to make sure that I have all the right language there before I pass it out to my very nice colleagues to do the job and not leave it to my very nice colleagues to say things and just use that verbal process and rely on that verbal process as a way to get consent. All right. Last 2 minutes. I just want to let you know that OHRP, we're not only interested in helping the research community to do better research, but we also want to make sure that prospective participants, people in the public, start to understand research more and understand the different terms about research and the different concepts about research. We developed these materials completely from the perspectives of how we can empower prospective participants, so we have questions, answers, short videos, a few minutes making sure that people don't have to spend hours looking at these videos, but 5, 10 minutes could give them good information, and we've developed these in Spanish as well. You can get access to this and tell your prospective participants, tell anybody to go to this site to look for reliable information that could them understand about research: www.hhs.gov/about- research-participation. Again, the information is in English and Spanish, and if you want to have these videos in their raw files, we're happy to provide them for you as long as you promise us to disseminate them to your [Indistinct]. And with that, I'm going to end, and I'm going to leave you with this contact information and resource list, and I'm going to leave it at that before I go to the thank-you slide. So we're open for questions, and I hope that you have found the presentation that Misti and I have presented to be useful for your work.

Lyndi Lahl: Okay, thank you, Yvonne. There have been a number of questions, and let me start off, several questions about key information. Folks say that researchers complain because there's duplicative information. They have it in the key information and they repeat it, and they're interested if OHRP plans to develop any guidance on the presentation of key information. So if you could just speak to that.

Yvonne Lau: Okay, Misti, I see that your microphone is not turned on, but I'm going to take this question. So, right, key information. First of all, the first message to note is that I hope that after having gone through this presentation, that you understand that there is a purpose for the key information, and when you say duplicative, basically information that you have already put into the key information section, there is no requirement for you to repeat that information again in the rest of the consent document. Look at the consent document, key information or not key information sections, as a whole. Right? In terms of complying with regulatory requirements, as long as you have the information somewhere in that document, the required information somewhere in that document, that's sufficient. We really want to encourage you to pay attention and think about how you can utilize this opportunity of the key information where we're thinking about a page, several pages long and to utilize this opportunity to kind of convey information simply. The information that would help guide people make a decision. All right. So, Misti, do you have anything to add?

Misti Ault Anderson: The only thing that I would add is one that you can do is when you're thinking about what to put in the key information, for example if you wanted to list something about risks, you can always choose to give partial information there and a reference to somewhere else in the document. And if, say, the most pertinent information you need to give is key information, reference elsewhere, and then that also makes it really easy to not repeat the information because you're giving a direct reference.

Yvonne Lau: Okay, and I just want to say something about social behavior studies. Not all studies are like clinical trials that are complex and long and have a lot of risks and what not. Sometimes if you go back and look at the gate study, the balance and gate study earlier that I used as an example, I already mentioned that basically about two-thirds of the page ... So I used in this exercise and came up with the key information, and, literally, I don't know that there's a lot more that one could say after that. There may be a few more items of information that one could say, and I'm sure many sort of other legalese type of stuff, protecting privacy and confidentially in this particular case may not be so important, in other studies, it may be more important, but nonetheless you want to include that information, but I just didn't think it was important enough to be included in the key information. So that could be what information that you could put in the rest of the sections, and at the end of the day, your documents could still end up, for a simple study, to be maybe just two pages. But it still does help if you actually put up the information that guide, orientate and assist people to make decision right up front. Right? Because that is going to be your prime real estate. You don't want to waste it.

Lyndi Lahl: Great, thank you. So we've also had several questions about simplifying and shortening consents, recognizing that some consents are very, very long, and so there were several questions about, what exactly do you need to include in your informed consent form? So would the threshold be if it is a burdensome procedure, a blood prick, a physical exam? And what about the time commitment, how long it's going to take for each study visit?

Yvonne Lau: Well, I think that they're going to vary, right? Misti, go ahead.

Misti Ault Anderson: No, I was just going to say, so I think absolutely it will vary. Of course it needs to be said, and I saw this come out in a couple other questions as well, that there are required elements, and there are additional elements that are listed in the regulations, and obviously the required elements must be addressed and the additional ones as needed, which is if they are applicable. All of that content has to be in there. What we're really focusing on today is how to provide that information. In going beyond the basic, we're not going to get into what those required elements are here, but as far as the specifics about, what about time commitment and that sort of thing, for the most part that's important information that someone would need to have because if they're going to commit to this, they would probably want to know what the time commitment is. So that doesn't necessarily mean it's a minute-by-minute breakdown of what will happen at every visit, but the time commitment might be one visit a week over this number of weeks or that sort of time commitment and then as far as the details of the procedures, that's really going to vary on what the study is. We're not interested in making these a lot longer, which is part of the impetus behind Yvonne's earlier answer about not needing to repeat everything in the key information, but we encourage you to think about, and when you're providing the required information, to do it in that understandable way. So when you're talking about what the procedures are, describe them in an understandable way as opposed to all medical jargon. So you don't have to do both but you want to give it simply and understandably in a readable format.

Yvonne Lau: Yeah, and in terms of what information needs to go into the key information section, I think that's really something I hope after listening through this presentation that you've come to realize, that it's very contextual-based. We've already said several times what content needs to be provided and how very much depends on the context, and the context comes from not just some of the information, background information about why are you doing this research and the problematic, if you like, but really coming from what it is that your prospective participants, the people who you're going to be engaging as your target population, would think might be important to them. And again, we're not talking about an individual person. We're not talking about individual idiosyncracies here but really the group, as a whole, at least, what the group as a whole ... what would be reasonable for them. And in terms of making the key information, I think that those ... I'm coming back to my hiker's map. It's not a map that anybody could come up with without knowing what hikers would want to have in terms of information and would make more sense for them. You need to have that kind of understanding to start with, and one way to get that kind of understanding is really go and talk to your prospective participants. Other times, because you're doing that research because you have a lot of familiarity in that environment. So you yourself might already have a lot of information to help you with it, but that's where you get the source of what information would be considered or might be considered to them as key information. I'm not going to be able to tell you that, oh, well, for everybody, the time burden ... I mean getting people to spend a day in a clinic as opposed to getting people doing 10 minutes kind of activity everyday for a week. Is that time burdensome? I don't know. If you're talking to somebody who ... if your target population is retirees, getting them to involve 10 minutes a day for 5 days is probably not going to be very burdensome to them at all. But if you're having somebody who works and has three children to look after or you're talking about a very busy housewife or family, a woman who has a family to look after and work as well. Who knows? You need to know your target population.

Lyndi Lahl: Okay, thank you. I just want to say we have 4 minutes left before we're going to be cut off, so just keep that in mind. There have been a couple of questions on if the key information is needed, let's say if it's a really short consent form, maybe three pages, or if it's a really low risk study like a social behavior and educational research study.

Yvonne Lau: So I would also ... saying that, "Well, you know what, my whole consent is already short," but I think that you can still consider ways to organize your information in such a way that the most important information comes first. Right? Whether you call it ...

Misti Ault Anderson: Right, it may be encompassed, right? It may, in the end, only be a two-page document, and so you wouldn't need a separate key information necessarily, and you can enforce this as Yvonne is saying by putting the most important information first to make it more effective. But you don't have to add another page just to say you have a key information. I think it might ... does that make sense?

Yvonne Lau: But you do actually need ... there is a requirement for key information, but your whole consent could be called a key information if you like.

Misti Ault Anderson: Right, right.

Lyndi Lahl: Okay, very good. So, there ... somebody had asked if there are cultural differences within your population, you want to meet that reasonable person standard, but would it be reasonable to have different informed consents for the different populations that are being recruited? Or perhaps the same informed consent but different key information sections for the different populations.

Yvonne Lau: I guess it also depends on how different your populations are. I have recently an experience somebody who was helping to get a consent document, or rather to help with the consent process, to recruit Native Americans, certain tribal Native Americans, into vaccine studies for the COVID-19. The person approached me. They have very sort of deep knowledge working with this group of participants and what their concerns are, so he was particularly interested in including information that would alleviate their concerns about what ... "Again, we're being asked to be guinea pigs again?" That kind of thing, so that kind of idea, so he was trying very hard to knowing that they might have this kind of worries that he wants to include information that would alleviate that kind of concerns, and of course this study might not be a study just recruiting this group of people, but it could be recruiting other groups as well in the general population as well. So is there ... is it good to have a different consent or include ... It depends. It really is ... Don't forget, the consent the is going to help you with your recruitment as well, right? So it really depends. It's hard for us to say outright that you should have a different consent. Of course we try to reduce the work that is involved. Personally, I think that if you get a good grasp of the kind of information and the context from which people come from, I think that you will probably find that there is a lot of similarities. In fact, more similarities than not in terms of where people come from when they want to have ... want that information and how to digest it. There may be little things, and you may think that that is important enough to be included in the consent document. Or you may think that well, that's where your verbal part is going to make up for it. It depends. It's really hard for me to give you a concrete example. Misti, did you have anything to add?

Misti Ault Anderson: I don't, but I think that we are probably about to be cut off in the recording, we just crossed the line.

Lyndi Lahl: We are. Thank you very much. I think that we're going to be stopping now.

Yvonne Lau: Okay. Bye-bye everybody. Thank you. I hope you found the presentation to be useful.

Misti Ault Anderson: Thank you so much everyone for joining us.