Cyberseminar Transcript

Date: January 11, 2019

Session: ORPPE Workshop: Informed Consent Tools

Presenter: Soundia Duche, M.A., M.S.

Soundia Duche: My name is Soundia Duche and I'm going to be the lead presenter today, but I have the pleasure of being joined by Dr. Karen Jeans who's going to be here with me to chime in and answer questions, Dr. Kristina Borror from ORO policy and education is also available and on the line. And Lucinda Shouse is here with us helping to moderate things and will chime in as needed. Dr. Petrice Longenecker is backstopping this and she is not feeling well, but is holding on because we have this important training and so Petrice, thank you a million times.

All right, so just a few housekeeping issues. This training will be done in lecture mode, which means you'll only be able to listen in. We're not going to mess around, we're not going to fool around with our raising hands today. We're going to save that for after January 21st when we can afford to have technical difficulties again. But the session is being recorded and so we'll be posting the recording probably about sometime mid-week. So if anybody has sound issues and has to drop off, you will be able to access the full recording next week on the Cyberseminar web page; the Office of Research Protection, Policy and Education's web page.

Handouts for the sessions were distributed a number of different ways. And email was sent out to everybody who received an email announcing the training, you got the handouts that way. The handout, there is a handouts tab in the lower right hand corner. There are five handouts there. That's not all of the handouts, but unfortunately we're only able to upload five handouts so we kind of chose the most important ones. But again, all of the handouts went out earlier, I think it was maybe about 11 o'clock this morning and then again at noon for those who had registered, they received links for the handouts.

We have about 300-plus attendees, well 300-plus people registered for the training and we have about 190 so far that have joined in. What that means is, we're probably going to get a lot of questions. Because this is a workshop, our workshops are limited to one hour, and I know that's not as much time as some of you would want, but recall our Cyberseminars go almost two hours and many people have complained that those are too long. So this is how we've decided to manage it at least for now. What that means is, in this one hour we are going to dedicate about 30 minutes for content and try to reserve 30 minutes for question and answers. Those questions have to be limited to the topic at hand, informed consent. You can submit other questions, but Lucinda's really going to be only selecting the questions that are relevant to this topic. Just to remind folks, we have the town hall question and answer session on Tuesday so at that point you can ask any other questions and any questions that are submitted today that are off topic will be presented on Tuesday's call. So don't worry, your question will be answered but we're sticking to informed consent today. All right, I think I covered everything so let's get started.

If I could just get my thing to move, that would be helpful. There we go. All right, so we're going to just briefly begin by going over study-specific informed consent, broad consent, waiver of informed consent and waiver of documentation of informed consent. Briefly going over those topics. We covered all of these topics at length in July. There were two sessions. One done by Kristina Borror and one done by myself. So if you didn't attend those sessions, they're about an hour and a half each. You can find those on our Cyberseminar web page. But we're going to be moving somewhat fast, but we need to always lay the foundation because we have people who may still be new to this all and we want to make sure as we go into the tools people have some understanding of why we're doing certain things and why the tools reflect certain aspects of the requirements. Then we're going to be talking about forms, checklists, reviewer forms. I have all the links at the end of the presentation for people to access. Again, we sent those out in handouts as well. But I'm going to bring in the tools at different points as they're relevant to the topic at hand.

So when we're thinking about informed consent, I love using this term full disclosure. And I do that because informed consent is something that the common rule requires, FDA regulations require. And it really is talking about the process in which information is provided to prospective subjects, the process of giving them sufficient information so that they can make an informed decision about whether they want to participate or not. Here at the VA we are a covered entity and so therefore we are also subject to the privacy rule and HIPAA. And so while we are not going to be talking about HIPAA okay, don't worry about that. However, it's very important. I want people to always remember while we're talking about informed consent in this lecture, or we're talking about waivers of informed consent, HIPAA is still out there and we are still subject to HIPAA. So while we are not addressing HIPAA today, HIPAA authorizations, waivers, none of that goes away. We're just not discussing it today. Just for those who aren't as familiar, the privacy rule describes when written authorization is required before using or disclosing healthcare information for a purpose that's not a permissible purpose. So things like research, for the most part, generally speaking would not be a permissible purpose. And therefore, one would have to get authorization from the subject prior to using and disclosing their identifiable information for research purposes or a waiver. So we're not going to be going into that, but I just needed to make sure I explained that.

All right. This chart, you guys have seen it before. This table. I love it so I show it whenever I can. I borrowed it probably a decade ago from a PRIM&R presentation. Somebody presented it and I re-created it. I added the little diamonds that make it a little more pretty. But essentially what I love about this is it takes the Belmont report which was published in 1979, and that really summarizes the ethical principles and guidelines for research involving human subjects. That's the basis of our regulatory framework and ethics regarding human subjects protection. And the common rule then, it marries the two of them, taking the approval criteria, the 111 approval criteria and marrying the two of them and showing you when the three Belmont principles of respect for persons, justice and beneficence, how they relate to all of the approval criteria. I'm not going to go over this. I have it posted on my wall so you can do the same. But just want to look at that top left corner. Respect for person, that Belmont principle is really as we know, it's about treating individuals as autonomous agents and protecting those with diminished autonomy. And so where informed consent comes in is really when you're talking about treating individuals as autonomous agents, how do you do that in the context of research? It's making sure that one, you get their permission before you do things to them and in getting their permission you make sure that you provide them with sufficient information and an opportunity to decide whether this is something they want to participate in or not. And so that's really where informed consent comes in. It's the whole respect for persons aspect. And we're going to keep coming back to that throughout because the revised common rule has made points to explicitly make sure that treating individuals as autonomous agents and providing them the information that they need is front and center. Especially as over time we've evolved into extremely long, legalistic consent forms. And somewhere in that, in making sure we capture every single element and every single requirement that the lawyers want you to put in and everything, somewhere in that sometimes the patient gets lost in that in terms of making sure the patient gets the information in a way that they would understand it. And so we're going to see how this comes into play with the revised common rule. How they're really making a conscious effort to bring us back to making the patient front and center in the informed consent process. Not losing them, okay? Not losing them. Maybe that's a better way to frame that.

And so, the 2018 requirements have a couple of new standards for informed consent and they're new standards but the principles are not new. We were always supposed to be doing this. One of the things though that the revised common rule explicitly states is that you have to have, when designing your informed consent process and providing information to prospective subjects, the information should be provided in a way that a reasonable person would understand the information and be able to make an informed decision on whether they want to participate or not in the research. The informed consent process needs to really facilitate the subject's understanding. And so again, in thinking about where we are now as a society, these long consent forms, yes maybe we can't get away from that because there are certain institutional requirements that have to be met, lawyers have their say in this. But at the same time we need to come back to making sure that the information is organized, it's not just a list of facts, but it's organized and presented to participants in a way that they can digest it, that they can understand it, that they can follow it and that they can know what this research would involve and whether it's something that they themselves would want to participate in. And so all of this now is something that the new revised common rule explicitly states. Not that we weren't doing this, but now it's explicitly stated. The revised common rule introduces another type of consent. Our traditional consent, I'm going to refer to it in this presentation as more study-specific consent because it's for a specific purpose, but now they've introduced an option called broad consent which is an alternative to study-specific consent for a specific type of research activity. And that is, broad consent can be used specifically when you're dealing with the storage, maintenance or secondary use of identifiable data or identifiable biospecimens. It's specific to future use and storing for future use. So it's not that it's an alternative to study-specific consent in every single way, but [unintelligible 10:20] specific aspect of study-specific consent. If you think about it, right now if we want to be able to store someone's information and use it for future use for other research, you normally ask them in our study-specific consent, can I use your information for X, Y and Z purpose? And they say yes or no. Or we say, if you're going to participate in this research study you have to agree to allow us to use your information for future reserach, do you want to participate? That hasn't gone away. That's still there, that's still allowable. Nothing's changed in that respect. But now, as an alternative to that, one has this option of using this broad consent mechanism to do the same thing, asking prospective subjects to be able to use their information and store it for future use. And we'll talk about that briefly in the ongoing slides.

I don't know why my cursor gets stuck. Sorry folks, give me one second. Ah, there we go. All right. Oh, did I miss something? Yes I did. All right.

Unidentified speaker: [Unintelligible 11:24].

Soundia Duche: Okay, that's okay. I think I'm good. Yes, okay here we go. So the required elements for study-specific informed consent or traditional consent: With the exception of broad consent, we now require, the revised common rule requires inclusion of a concise summary at the beginning of the informed consent that presents key information to the subjects. We'll talk about that in a second. But, back to the elements per se, because we're all very familiar with the elements so I'm going to go through that quickly. I'm not going to list the elements, you know where you can find them. I have a reference to the common rule at the end, but the eight basic elements of informed consent have not changed. There is one additional new element that's specific for studies that involve the collection of identifiable or private information or identifiable specimens whereby you now have to include a statement on whether the specimens, if subsequently de-identified, will be used for future research or not. So that's new. The current common rule we're under has six additional elements of informed consent. Those haven't changed either. The additional elements, why they're called additional is you use them when applicable. Use them as appropriate. So when it's appropriate you have to include the information. Those haven't changed, but the revised common rule has added three new additional elements whereby if it's relevant you are required to add them. So they're listed here. I'm not going to read them, but here they are. There are three new additional elements.

But what everybody wants to talk about and I know, I get it, is the key information because that's really new, right? This is something none of us are very familiar with, including I myself. And the final rule, it really doesn't specify the type of information that is required. It's not a list like our typical elements that say you have to include this, you have to include that, but there are some suggestions in terms of what should be included in key information. It's supposed to be brief. Of course brief is relative. Brief when you're dealing with a 20-page consent form might look like two or three pages. When you're dealing with a five-page consent form it may look like a short paragraph. So it really is going to be study specific. But some of the suggestions that are found in the preamble in terms of what is supposed to be included. You want to include the fact that the consent is being sought for research and that participation is voluntary. Remember, the whole point of this is again, bringing the subject back to the center. Giving them information that a reasonable person would understand. So upfront letting them know what this research study is about and let's provide you with the most pertinent information so you can make an informed decision on whether you want to participate. So you want to explain the purpose of the research, the expected duration, reasonable foreseeable risk or discomforts. And again, not all the risks, but the most pertinent salient risks that would really make them say yay or nay. Your top risks because hey, before they even get to the minor risks, if this is a risk that would really influence their decision, you want to put it up front and they may decide right then and there no, not really interested. This is not something that, in my opinion is worth me participating in the study. Also, benefits. Any significant benefits that a reasonable person would want to know. And then if there are any appropriate alternative procedures that honestly may influence their decision right off the bat on whether they want to participate in the study or not.

Now, in looking at this, we're expected to receive some guidance from OHRP at some point. They said they're working on it, but we don't expect that guidance will be available by January 21st. And so what we did in our office here, we looked around at other institutions to find out if anybody has anything out there. And we reached out to the University of Kentucky because I have to say, I was thrilled when I found their form. I mean excited, really excited. So I'm going to bring it up here. Hopefully this works smoothly. You never know with technology. And this is actually their consent form template. So it's more than just the key information. But this first part, and you all have it in your handout, is the way they kind of structured their key information. They have the main categories that we talked about. What is the study about? What are the key reasons you might want to participate. Do you have to take part? I've highlighted here, under what are the key reasons you might choose not to volunteer, this is where they suggested you put the risks. What are some of the important risks that our subject would want to know about. And if any alternative treatments or procedures are available, they include that there. So I thought this was a nice example of a consent form and an approach. And actually, in some of the tools I'm going to show you later on that our office has been developing, we borrowed from their approach. And so we want to give them their credit because they worked hard on this and they've created an awesome document here. And of course, they didn't stop there. They did more. I mean, this is really impressive. Let me make sure I pull up the right document [unintelligible 16:28-16:29], okay. Oopsie, what just happened? Sorry, everybody. Okay. So then they also, they took what they have in their template and they gave some examples, real world examples. They took a study and kind of made a little summary. And so we posted this here because we think it's great for folks to be able to see because sometimes you can tell someone what to write but seeing how one structures it when it's for an actual study, is very helpful. And this was great finding it because honestly we were talking about creating one ourselves, so when we found this, we're like great we don't have to pull out a hundred-page protocol to come up with the key information. Karen, go ahead.

Dr. Karen Jeans: So this is Karen. And I think what Soundia is doing a really great job of reinforcing is that because the 2018 requirement language is not specific, it is very subjective, you have so much flexibility here. And so what Soundia is showing you are some great examples because one size will not fit all. And because maybe your institution is doing it different than another does not mean that you're doing it wrong or they're doing it wrong, It just means that it's different because a wide range can be done within this key information. And Dr. Borror, do you want to add anything on this.

Dr. Kristina Borror: No, that sounds great.

Dr. Karen Jeans: Okay.

Soundia Duche: Wonderful. And so anyway, they have a number, I'm not going to go into all of them, I've only posted two. They have about five of them or six of them for all different types of studies on their website. And so the link to their website, you can find it at the end under resources. But another example we received at 12:15 today from Marta Sears who is with the Roudebush VA in Indianapolis, when she got the packet of information that we sent out she said hey, might you guys be interested in seeing a summary that our affiliate has prepared? And that's the VA in Indianapolis. And so I know you guys don't have this. We will get it to you. Literally I just got it. I'm going to pull it up and the person who designed this form, I thought this was the niftiest thing I have seen I have to say. So I immediately reached out to the person who designed the form who was Kelly Anderson and she's actually on the call and Kelly if you want to say a few things about the form. It's a lovely way you guys have chosen to depict the information.

Kelly Anderson: Hi, as she said I'm Kelly Anderson. I'm a biomedical research compliance consultant at Indiana University. I'm part of the working group. We try to template, we did have a template on our website, it may still be there for the concise presentation and found it wasn't really adding value to the consent statement. So what we wanted to do was get creative, use visual elements and try to think in terms of flow charts, images and other ways to organize the information. We will have several examples on our website as well, as soon as we release them. This is what I came up with. And I tried to structure them in terms of the who, what, when, where and why so that it would flow nicely. You could almost think of it in terms of a recruitment material when you think about the flow. Because recruitment materials are concise by nature, we just need to make sure we have all the elements. So I used images and boxes to separate the pertinent details. So.

Soundia Duche: Thank you so much Kelly. This is sweet.

Dr. Karen Jeans: Yeah, it's really impressive.

Soundia Duche: Yeah, very impressive. So thank you. And thank you Marta for sending this at the very last minute. We are very thrilled to be able to include this. And we'll make sure we get this out to everyone.

Kelly Anderson: And we'll provide our website link so that people can see our other examples when they're ready.

Unidentified speaker: Perfect. Wonderful. Thank you Kelly.

Soundia Duche: All right, and so just moving on to a few other study-specific informed consent elements. If you're dealing with FDA regulated research and it's an applicable clinical trial you must include, you know there's a certain statement you have to include alerting people that this information may be posted, or will be posted on clinicaltrials.gov. So that's included. I've included also some additional VA-specific elements here. And then for studies with CoCs, the subject must be informed that a CoC has been issued. I'm not going to go back because I don't want to give you guys whiplash, but take a look at that, the University of Kentucky consent form. They have a very nice certificate of confidentiality section there. So take a look at that when you have a moment.

All right, requirements for broad consent. I already explained how broad consent is used. There are some additional specific VA requirements or limitations. Here at the VA, for VA-approved research, broad consent can only be used when data or biospecimens are collected solely for research purposes. Broad consent for us, here at the VA, has to be documented. The common rule allows IRBs to waive documentation of consent for broad consent. We will not. And you will see that explicitly stated in the VHA Directive 1200.05. And then finally, just want to reiterate that the broad consent form can be a separate form or it can be combined with a traditional informed consent form. If it's combined [unintelligible 21:56-21:57] the broad consent elements, and the fact that the subjects are providing broad consent for this future use, unspecified use, really have to be very clear to the subject. In terms of a template I did not, I did find one or two templates for broad consent. There were many out there. I chose not to post them for various reasons which I won’t get into here, but I will say if you would like to create a broad consent template, feel free to do so.

There are 12 elements of broad consent. One of the things, just to remember, you do not have to include the key summary of information for broad consent. That's required for regular study-specific consent and that's not limited to just documented consent. If it's verbal consent, if you're under a waiver of documentation consent you still have to give that key information. [Unintelligible 22:42] thing is making sure the subject had that information upfront. But that's not required for broad consent. So there are 12 elements which I've included here. Some of them are directly from the elements of regular, traditional consent. Some of them are from the basic elements. You'll see the bubble here, some are from the additional elements and then some are new and specific to broad consent. So you have that information. We're not going to delve into that too much. In terms of documentation of informed consent for VA research, one of the key things to note, and I just want to reiterate actually, maybe I didn't say this, but for broad consent, an IRB cannot waive or alter any of the elements. So those 12 elements that I just breezed through, those 12 elements have to be provided and here at the VA they have to be provided in a written consent form including all 12 elements. The IRB is not allowed to say, you know this one doesn't really apply. And that's per the common rule.

For our documentation of informed consent, VHA Directive 1200.05 now allows the informed consent and the HIPAA authorization form to be combined. And I'm going to show you a template at the end that we've created, that privacy has reviewed, that does combine it, so that you can see maybe what that may look like. And we'll get to that in a second.

For documentation of consent at the VA, most of you I think already heard this in some of our previous trainings, but just want to reiterate VA research no longer has to have the signature of the individual obtaining consent on the informed consent form. You don't have to obtain that anymore. You can choose to, but you no longer have to which was a previous requirement. You do still have to always have the signature of the individual who you're consenting or their LAR if that has been approved by the IRB.

All right, going on to waivers which we're not going to spend that much time on. But, there were two requirements, two categories of let's say research that you could apply for a waiver or alteration of informed consent. And those two still remain. One was really for a public service benefits program and that for the most part hasn't changed in terms of what stipulations you have to meet. And then there was one, which was the one we typically use more often. That's kind of the general waiver for minimal risk research. A new element has been added, you can see that in red. And that's specific to research subject to the 2018 requirements. So now into the four criteria, and there are five when you're dealing with research subject to the 2018 requirements. So I have this example of a form. Now this form is one of the forms that Dr. Klote in her efforts to create a number of tools for the field, our office has been working diligently to get some of these documents done. They're still draft documents, but her plan is to release a number of them. So we're starting to release some of them as we do specific training on them.

So this one is an example of a waiver of informed consent form and you'll see the investigator would check which waiver, which category they feel that their research meets in order to apply for a waiver. For the general waiver or alteration I've highlighted in yellow, this is the new criterion. So at your institution you would essentially want to add this information in yellow to your waiver. And you notice, I've stated here, “for studies subject to the 2018 requirements” because that's unique to studies subject to the 2018 requirements. All right. I think the last thing about this, is there anything else I want to highlight? I thought there was something. Oh yes, in red. Yes. And again now. So it's not sufficient just for the investigators to say yes, I meet this requirement because I have all five elements, but if the activity involves accessing identifiable private information, the investigator has to explain why they feel their research cannot be conducted or [unintelligible 26:43] can't be conducted without access to that information. So don't forget that. They've had to explain all the other things in the form, but as your revising your forms don't forget that it's not sufficient just to throw that in. You have to give the study team an opportunity to explain why and therefore something for the IRB to evaluate to say yes, it meets their criteria or no it doesn't.

So that's waiver. Let's see. The caveat for a waiver of informed consent is, oh yes this was the one key thing for broad consent. And this is huge. And this is why many people aren't using broad consent. If a prospective subject has been approached and asked to give their broad consent for a specific type of research or storing their information for X purposes, and that subject refuses and says no I'm not interested, an IRB cannot subsequently then say for another research study that comes down the road a year later or six months later that includes that subject’s information, an IRB cannot say okay, we waived the requirement for their consent for that you; can use that information. Now think about this. A lot of times, when it comes to information that's existing, a lot of times it does meet the criteria for a waiver because it's existing information, it's minimal risk research, the investigator and study team has described how they're going to protect the subjects and maintain the confidentiality or their data. But if that subject had previously said no, I do not want my information used for future research and it falls within that scope and it's very difficult to determine what all falls into the scope or not, well then that existing study that wants to include that subject cannot do that. And how to track and manage that becomes just a huge task and very resource intensive. And so, even when I was looking for broad consent templates it was very interesting. Many institutions smack on their website just state that we have decided and elected not to allow broad consent at this time. So that's one of the reasons why I experienced this difficulty. And it could be as time goes on and we get more tools and we get more guidance from OHRP and others, some of those institutions and some of your institutions who've decided and elected not to use it now maybe change your mind. But that's perfectly fine, you don't have to use it. But with the exception of broad consent, the IRB can approve a complete waiver of informed consent if the required criteria have met. And then lastly regarding this, and this goes back to that table that I talked about respect for person, the ethical principles of informed consent, the IRB cannot alter any of the general requirements of informed consent. The things that make consent, consent. So think about it. The IRB cannot say you don't have to worry about coercion or undue influence in your consent process. You don't have to provide the subject sufficient opportunity to determine if they wish to participate or not. Sure, you can go. They're on their way to an emergency procedure, you can go ahead and still approach them at that last minute and get [unintelligible 29:51] consent. Those types of things. You have to still do all of those things if the IRB approves consent right? If they waive consent then it's a non-issue. But if you're going to be gaining consent, whether it's written or verbal, these general, ethical foundations of consent cannot be altered. And that includes the key information that has to now be provided to subjects unless the IRB completely waives consent except for broad consent.

We're almost coming to the end. I'm getting ready for questions. Waiver screening and recruiting. So just want to touch on this because this is not a waiver. The new 2018 requirement allows the IRB to approve access to identifiable information or identifiable specimens without the subject's consent or without a waiver for the purpose of screening and recruiting or determining eligibility if one of two conditions are met. The investigator obtains the information through oral or written communication with the prospective subject or the investigator obtains identifiable private information or specimens by accessing those records. So again, this is not a waiver of informed consent. This would be something that let's say the IRB protocol or the application would pick up. So in the same way that the IRB has to review the study activity, this is a study activity, right? We want to be able to go into the records. We want to identify subjects. We want to reach out to them and so the investigator has to present that information somehow. Your forms need to capture that information. And then the IRB would approve it or not or say this is what you have to do in order for us to allow you to do this. Remember, full disclosure, HIPAA, consent. We are a covered entity. So this is dealing with screening and recruiting without consent. HIPAA still applies. And so you either need to have the subject's authorization or you need to apply for a waiver of HIPAA for recruitment purposes. And remember, this is specific to screening and recruiting activities. It's specific to that. Not for anything else. Anything else, if you want to be able to go into the records and actually do research, manipulate the data, do these types of things, you would need either the subject's consent or you would go to get the waiver and have to justify why you need the waiver.

Waiver of documentation of consent. There's now a third options for waiving documentation of consent and that is where subjects or their legally authorized representatives are a member of distinct cultural group in which signing forms is not the norm. That is now an option that you could use for waiving documentation of consent if you justify it appropriately. And so there's a waiver of documentation consent template. That's also one of the documents that we've been working on. And that's part of Dr. Klote's tool kit that she'll be releasing eventually, sometime soon let's just say. But you'll see highlighted here this third option. And so for waiver of documentation of consent, to be honest, for your form [unintelligible 32:55] pretty straight forward. You pop it in, this is another criterion that the investigator or study team can ask to meet. And then, in this form there's just the justification for waiving documentation. There's nothing specific to that so you would just justify which one of the criteria you feel you meet and why. And then the IRB would review it.

All right. I am watching time folks. All right, so templates. We've gone though, oh, no no I missed something. Posting clinical trial consent forms. Now, I just want to touch on this so that we're comprehensive since we're talking about consent. In the 2018 requirements you are now required to post a consent form, one IRB-approved informed consent form for research that meets the common rule definition of clinical trial. Which actually is broader than the, is it the FDAAA definition.

Unidentified speaker: [Inaudible 33:53-33:55] Yeah.

Soundia Duche: Yes. And so that's something to be mindful of. 1200.05, the directive [unintelligible 34:01] provides details on who exactly is responsible for posting the form. And also I think we include both links of where that form can be posted in the directive. But we're not going to talk about that too much since we're dealing with tools today, but I just wanted to put that in.

So templates. I've given you most of these already. We've gone over them. The only one I want to make sure I mention is, we've been working on a VA combined ICF/HIPAA sample form. And again this is still in draft. This is one of the documents that Dr. Klote has in her tool kit. And here, sorry I have to scroll. I'm afraid if I hit in the middle it's going to go too far. Shoot. But anyway, I'm not going to keep scrolling. But essentially in this document the key information section here, it starts with the key information and this was borrowed from the University of Kentucky document that they graciously allowed us to post and share. They just, we want to make sure we give them credit where credit is due. But again, you don't have to present your key information this way. These are just examples. In fact, this whole consent form is an example. We're giving you examples of ways you can think about doing this, so. It's just too hard to scroll through this so I'm going to leave it at all.

And then, the other document I just want to mention here is there's an informed consent reviewer form that was done. Now this form is actually for both informed consent and broad consent. Oh, I can do that, haha. Sorry, I think it's just going to be too complicated. You have the forms here so I'm not going to go into them too much except to say, I do want to point out that on this form because it's both combined informed consent and broad consent. And it's also, I think it says something here about, yes. If your form, if you have a combined informed consent and HIPAA authorization form, there's a section here just reminding folks that because if a HIPAA authorization form is embedded in your consent form, that HIPAA authorization form has to be reviewed by the privacy officer\_

Unidentified speaker: Yes.

Soundia Duche: \_Is that correct? And so while this is an IRB reviewer checklist, it's reminding the IRB reviewer hey, has this been sent to privacy to review. So just keep that in your mind.

I think that is all we're going to cover today in terms of the content. Your resources are there. Important links. And then these are the templates and that lovely form from Indiana University we'll make sure we get that out to you all. And so, I'm going to turn this part over to Lucinda who's going to be moderating the questions.

Lucinda: Okay, good afternoon. [Unintelligible 36:51] start with the questions in the order in which they were received. The first one is, is there a reading grade level that is suggested, or is it assumed that the person obtaining consent is explaining words to the potential subject?

Dr. Karen Jeans: So, this is Karen. So there's been informed guidance throughout the years by different groups that informed consent documents or delivery of presented content should be at the sixth to eighth grade level. You'll see many consent forms where it does the Kincaid test, you know, a software program for evaluating it. But the underlying, the general principle is that informed consent must be presented in a way that is understandable to the subject. So that really is the key issue here. There's never an assumption. I always hesitate when I hear is there an assumption. It is the IRBs responsibility, as part of their evaluation of the research and looking at the process and documentation of informed consent, indeed how will that be done. And so that's just part of the IRB evaluation. There is, again not a policy or regulation that defines what grade level it's at, but the issue is that, is it presented in a way that's understandable to the subject. And I'll ask Dr. Borror if she would like to also add comments on this.

Dr. Kristina Borror: No, I agree with everything you said. You know, it really depends on the subject population. For instance, if your subjects are physicians, you may be able to use medical language that the general public wouldn't be able to understand and that would still meet the requirements and that I think it really depends on the population. And that's something that the IRB should consider when reviewing them.

Lucinda: Thank you. What if one does not know if in the future the de-identified specimens may be used for commercial profit? Does that new additional element need to be mentioned?

Unidentified speaker: We're all pulling it up. Yeah. [Unintelligible 39:21-39:23] talking about one of the basic elements of informed consent.

Unidentified speaker: I think it's an additional element.

Unidentified speaker: Oh, the additional elements of informed consent.

Unidentified speaker: For studies subject to the 2018 requirements, a statement that the subjects biospecimens, even if identifiers are removed, may be used for commercial profit and whether the subject may share in this commercial profit.

Unidentified speaker: Okay, thank you. So again it's a great question because what if you don't know. You can only do at the time that you're submitting, you know again it's not a get you situation so at the time what is accurate? What is true? So if that's not an issue that wasn't even a consideration because it was not applicable at the time, then that's how you do your consent form. That's a really great question. Thank you.

Lucinda: Okay. I thought the www.clinicaltrials.gov was removed from the ICD last June?

Unidentified speaker: Last June? You're talking about 1200.05? I don't think we did a revision of 1200.05 last June.

Unidentified speaker: No, this has nothing to do. Yeah, great question again. In terms of, clinicaltrial.gov for, we may need to follow up on this, but in terms of the requirement for registration of clinicaltrials.gov for those applicable trials, that is part of, well [unintelligible 41:00-04] so that's part of a law. In terms of the language that is required by FDA for inclusion in informed consent documents for those studies that are required as applicable clinical trials be placed, registered and have results submitted into clinicaltrials.gov. That again is FDA statutory requirements.

Unidentified speaker: Nothing's changed. [Unintelligible 41:28-41:29].

Unidentified speaker: Nothing's changed. Great question. I'm glad you're bringing that up because if there's a perception of that, that's what the great thing about having these kinds of questions are. So thank you.

Lucinda: Great. So moving on to broad consent. So how is broad consent different from the new element where all studies that involve the collection of identifiable private information or identifiable specimens include a statement on whether specimens if subsequently de-identified will be used for future research or not. Is broad consent then the continued use of identifiable information?

Unidentified speaker: Oh, okay so. And also Dr. Borror this is for you because you did an incredible presentations on broad consent, so would you like to lead this?

Dr. Kristina Borror: So, if I understand the question, and you can correct me if I'm wrong, although let me go back to the previous question. I don't know if maybe the questioner was asking about our office; ORO did take out looking at clinicaltrials.gov in the RCO auditing criteria.

Unidentified speaker: Oh!

Dr. Kristina Borror: So that might be what they were talking about, but it's not, it's still a requirement that those clinical trials be registered. And you know, we made it clear that it was still required. That those clinical trials are required to be registered. I don't know if the person was confusing that with the posting of the informed consent documents on clinicaltrials.gov. It's possible.

Going back to the broad consent question, and again if I understand the question, I think one of the issues, whether it's identifiable or not, if you're doing research with secondary data or biospecimens that are not identifiable; that the researcher cannot ascertain from whom that data or biospecimens came, then that's not human subjects research and there's not a requirement for any kind of consent, either broad consent or regular study-specific consent. So if you are using broad consent, the assumption is that the data or biospecimens are identifiable and that you don't necessarily want to get study-specific consent for each and every secondary use of that data or biospecimens. Did I answer the question?

Unidentified speaker: We think so. [Unintelligible 44:21-44:22].

Unidentified speaker: Whoever asked it, please follow up.

Lucinda: About a follow-up question. Okay, now we had a request for an example of what a researcher might provide to support the justification that the research could not practically be carried out without using such information or biospecimens in an identifiable format.

Unidentified speaker: Well, one of the things, and we see this all the time when it comes to being able to screen for eligibility. A lot of times they need access to that information to figure out who they're going to target. And so in that case, that would be more the data. Being able to have access to identifiable data and being able to see okay, does the subject, we're trying to ascertain our subject pool so we can know who to even reach out to. Who to contact. Who to send letters of introduction to explaining our study. And so that's one example I can think of.

Unidentified speaker: Exactly. It's why you need to have dates. Why you need to have the names. It's like if I'm doing a study involving asthma patients, all right. And I need a set of all patients who've been on, there's a medication called albuterol. And so I want to see how many times they have an exacerbation. Basically a worsening of their condition that requires hospitalization. So I need data. So I could do that, do I need identifiers like do I need the dates they were in the hospital? Demographics? It all has to do whether or not the research question that I'm answering, can it be done with or without? So the rationale is if the research question cannot be answered for example without having identifiers, that would be an example of one. Because if I'm trying to figure out how old they are and what part of the country they're from, I'm going to have to have identifiers. That's just a quick answer and really great question.

Unidentified speaker: I agree completely, And another example might be where either you have to cross-reference information that is in different databases. And so in order to know that this data came from the same person, you need to have some kind of identifiers in order to do that cross-referencing. And also, just to note that this addition of this new criteria in the common rule makes the waiver criteria more harmonized with the HIPAA waiver criteria.

Lucinda: Okay. If a potential subject answering an advertisement provides PHI to the study team, is a HIPAA waiver needed for the study team to collect the information if given to them by the potential subject?

Unidentified speaker: I'm sorry, I misunderstood.

Lucinda: Okay. If a potential subject answering an advertisement provides PHI to the study team\_

Unidentified speaker: Okay.

Lucinda: \_is a HIPAA waiver needed for the study team to collect this information if given to them by potential subject?

Unidentified speaker: In order for VA, as a covered entity, to use, collect or access PHI, we have to have the authority under HIPAA. Either under a HIPAA waiver or under a written HIPAA authorization. So for us to be able to use it for research purposes, we would have to have some type of authority. Either through a HIPAA authorization or through a waiver.

Lucinda: Okay. Who is responsible for posting the consent form on the government site?

Dr. Karen Jeans: So this is Karen. And we will have a dedicated guidance document as well as a dedicated Cyberseminar just on this sole topic because it is tiered. What we have put into policy is that if it's an ORD-funded study, it all depends on whether it's funded or not funded. And who funds it. If it's ORD-funded the directions on who will be responsible will come from the funding service. If the clinical trial is funded or supported by our federal agency or department outside of VA such as the NIH, Department of Energy, Department of Defense, the awardee, whoever is the awardee of that is responsible for posting it. If it's a clinical trial funded or supported by a non-federal agency, such as a university, industry, the VA investigator who's conducting that study is responsible. And if there's multiple sites involved there will have to be an agreement specifying who is responsible for posting the informed consent form. And the reason for that is because there's only one informed consent form that is required to be posted. That's it. Just one. And so, again it's trying to meet the requirement without multiple copies of that consent form having to go up. And trying to make it where it's not burdensome, although we do recognize it is definitely a regulatory requirement that will have its own implementation issues. So that's why we will have one dedicated seminar and guidance document specifically for this. So thank you.

Lucinda: Now a practical question. How do you delete page one from the consent template?

Unidentified speaker: We get a degree in information technology. Yeah. Our documents are so darn tricky.

Unidentified speaker: Which document?

Unidentified speaker: Yeah, the informed consent template. You know, the instructions.

Unidentified speaker: Oh, the instructions.

Unidentified speaker: Yeah, directions to use this template [unintelligible 50:22] get back to you.

Unidentified speaker: We can take this.

Unidentified speaker: We can get rid of it [unintelligible 50:26-50:27] just have it as an instruction sheet as a separate document. That [unintelligible 50:30-50:31] more sense. Thank you.

Lucinda: Okay. The next question is multi-part so I'm going to read each part and then pause after it for the question so we don't get confused [unintelligible 50:42]. On the provided VA informed consent HIPAA authorization template, number one, is there language regarding participant access to their research-related health records as on page three on 10-4 [unintelligible 50:55]?

Unidentified speaker: All right. I'm opening up the document. I'm not going to pull it up online because it's going to get complicated. This form, I will say I know where you're going [unintelligible 51:07] because it looks very different from the 10-0493 and one wonders if it has all the information. We may have to refer to privacy on your specific question, but privacy did look at this document.

Unidentified speaker: Yeah, privacy has evaluated this.

Unidentified speaker: And remember because it's a combined document\_

Unidentified speaker: Exactly.

Unidentified speaker: \_some of the requirements, elements of HIPAA that you saw in 10-0493 are in other parts of the consent form possibly. But\_

Dr. Karen Jeans: Yeah, this is Karen. Yeah this, I will defer the question because I would need privacy to pick up on this, but VHA privacy has evaluated this document for compliance that a combined informed consent HIPAA authorization template does meet the HIPAA requirements according to VHA. So we can indeed refer that question because it's critical we get these questions.

Unidentified speaker: Yes, absolutely.

Dr. Karen Jeans: So, do know that me just saying that doesn't mean that we're ignoring it. We will refer this question so thank you.

Lucinda: Okay, so the next part of this question is, the instructions indicate that wording indicating the authorization will expire at the end of the study must be used. Rather than including the other options included on page three of 10-0493 e.g. does not expire.

Unidentified speaker: I mean that's true. It can be done either way. This again is just a template. This is an example. It doesn't change the fact that it can be either of the options. Again, we will go back and check in with Stephanie, but HIPAA does allow that.

Lucinda: Okay, the next part. There are some instructions on page nine that seem to be intended to address the new requirement to specify whether or not de-identified info and/or specimens might be used in future research. However, those instructions only address future use of specimens and do not prompt you to specify this could happen without further consent.

Unidentified speaker: Okay. On page nine. I may have to get back to you on that one. And if it's something that's wrong with the form, thanks for bringing it to our attention. We have your question recorded so I think once we're offline we'll look at it and be able to look at this document. Like I said, this document is still in draft form. I assume they're talking about the informed consent template, right?

Unidentified speaker: Yeah, they're talking about the informed consent template. So we will look at this template and if there's something that's not right or missing we will definitely have it addressed. So thank you.

Lucinda: There's one more piece to this. Does this version meet the requirements for unconditioned authorization when there are optional components e.g. banking to a study?

Unidentified speaker: Let's defer that because that's a HIPAA question\_

Lucinda: Okay.

Unidentified speaker: \_and keep this on informed consent. For now.

Lucinda: So, do we have the option of not implementing broad consent in our research program? Our affiliate IRB is not allowing broad consent.

Unidentified speaker: Yep, it's an option. You don't have to use it. It's an alternative to study-specific consent whereby in study-specific consent you say hey, we would like to use your information for future purposes. You can still do that. So that covers you. You don't have to use broad consent. And as I mentioned, many institutions are electing not to use it at least for now. And this is not just VA institutions.

Lucinda: So if we back up to the previous question that had four parts. The person who posed that question says, please ignore part four. I found the related instructions.

Unidentified speaker: Wonderful! [Unintelligible 54:40-54:42].

Lucinda: Okay. I am unclear about slide 18, informed consent and screening and recruiting activities.

Unidentified speaker: Okay.

Lucinda: Are you saying the IRB must document that whether they approved the study team to access identifiable information or biospecimens for recruitment and screening activities?

Soundia Duche: Right. No. I'm not saying they're required to document. And I'm going to ask others to chime in, but normally when we think of document we think of you document your approval criteria. It is not one of the 1-11 approval criterion. However, we do often document other things in our minutes to cover ourselves. Or in our approval letters to cover ourselves. And so one could say, in your approval letter for example, the IRB has approved access to the information without consent. I definitely would say it needs to be found somewhere in the protocol file and so it needs to be captured in the application or the protocol that the investigator provided information, that the IRB could make the determination that they met the criteria. And so in that sense you want to make sure that the investigator has given you that information and it's very clear. And one of the ways to do that is make sure in the reviewer form at the very least, the IRB can check it. But it's not a formal documentation in the sense of document the approval criteria. It is not one of the 1-11 approval criteria. And I'm going to ask Karen and Kristina if they want to chime in on that. And correct me if I'm wrong.

Dr. Karen Jeans: So I'll start and then I'll defer to Dr. Borror. So Soundia is correct. In terms of the regulatory language, unlike some of the language which specifically requires the IRB to document the criteria, the regulatory language which VA also follows, it says the IRB only has to find whether or not one of two conditions are met. It is not required in VA policy to specifically document which condition was met. So, now best practice would be a recommendation, because you're going to have to evaluate in order to determine whether or not one of the conditions are met. That one indeed [unintelligible 56:51], but again that's a best practice. It's not required by the regulations. And now I'll defer to Dr. Borror.

Dr. Kristina Borror: I agree completely with Soundia and Karen.

Lucinda: Okay. For clarification. When auditing, does the subject's signature need to be present on the informed consent form in HIPAA?

Unidentified speaker: Yes.

Unidentified speaker: Yeah, if the IRB requires documented consent.

Unidentified speaker: Yeah and informed consent with a\_

Unidentified speaker: The only thing that's been removed is the requirement for the person obtaining consent.

Unidentified speaker: Please, please, please make sure you get the signature if the IRB requires documented consent you get the signature of the subjects.

Unidentified speaker: Signed and dated?

Unidentified speaker: Yes. And again you'll have those one-off situations where you'll have a unique situations where an X will be approved by the IRB. Again, we're talking about those rare situations. But I think the general question is, yes.

Lucinda: Okay. Is VA form 10-1086 going to be modified or do we use modify it per individual study?

Unidentified speaker: VA form 10-1086 is the research consent form. ORD has basically stopped requiring the use of that form in two thousand fourteen. And so, we have no plans to update that form because the entire research community is moving towards electronic formats, different type of templates. It does not lend itself to an electronic format so no, there is no plan to update that form.

Lucinda: Okay, thank you. Do privacy officers need to review the HIPAA authorization embedded in the informed consent form? What if the IRB grants a waiver of documentation of informed consent? Is HIPAA authorization via Form 10-0493 required or can documentation of HIPAA be waived?

Unidentified speaker: One cannot waive documentation of HIPAA. There's only one of two things that can be done with HIPAA. There's either a written authorization is required or you waive alteratio. Excuse me, you waive authorization. It's one or the other. So, it's either going to be authorization is required which is a written authorization, or you're going to waive. That's it.

Lucinda: Okay. Any suggestion of how to track participants who decline broad consent?

Dr. Karen Jeans: So this is Karen. This is why it is extremely problematic. Why the research community at large, and why VA, we made a very restrictive use of it. Because it is a logistical nightmare in terms of the full [unintelligible 59:48] of broad consent, the way it was written in the regulatory text. So indeed, if you're talking about those that reject it, you would have to document in any records that it would apply to which is why we've only made it to where it's research specific content.

Lucinda: Okay. One more question. I think we're out of time. Can you talk about best practices when one might want to mail consent form and HIPAA authorization to a potential subject versus obtaining oral consent and getting a HIPAA waiver?

Unidentified speaker: That's [unintelligible 1:00:21] longer than, can we kick this over to Tuesday? [Unintelligible 1:00:25-1:00:27].

Unidentified speaker: So one last question.

Lucinda: Well, and the other questions that we have pertain specifically to HIPAA.

Unidentified speaker: Okay.

Lucinda: Do you want [unintelligible 1:00:34], so we'll just\_

Unidentified speaker: Okay, so perfect. So we are at the top of the hour. It is just turning two o'clock. We want to thank you all for joining us on a Friday afternoon for this workshop, We want to remind folks that Tuesday we have an open town hall Q&A session with representatives from ORO, Dr. Kristina Borror will be there, Dr. Karen Jeans, Dr. Molly Klote, all of the Office of Research Protection, Policy and Education staff will be here. And so, any question that we did not get to today that were submitted, we have them in the system and we will then convert them and focus on them on Tuesday in the first half of the training before we open it up to open questions. So thank you all for participating. Please do complete the survey that's going to pop up when you log off because it gives us much valuable feedback. And hopefully we'll see some of you all on Tuesday. Have a wonderful weekend everybody.

[ END OF AUDIO ]