

ORPP&E Webinars

Date: November 29, 2018

Session: The Revised Common Rule, Proposed VHA Directive 1200.05, and the IRB: Focus on Significant Changes

Presenter: Soundia Duche, MA, MS

Soundia Duche: Good afternoon everybody and welcome to this afternoon's Cyberseminar. My name is Soundia Duche and I'll be your presenter today. So what we will be focusing on today, I'm going to provide a status update on the Revised Common Rule and VHA Handbook 1200.05 which is going to now be a directive. We're going to spend a lot of time at the beginning of the training talking about what the significance of January 21st, 2019 is for VA research. And then we're going to delve into the significant changes in the revised rule and proposed VHA Directive 1200.05 and its effect on the IRB, okay? In terms of where we are with the Revised Common Rule. We are a little shy of two months out from implementation of the Revised Common Rule. January 21st, 2019, is the date that the majority of the provisions of the Common Rule will go into effect. It's the compliance date with the Revised Common Rule. And what that means is as of January 21st, 2019, all new research approved on or after that date has to be in compliance with that rule. Now there's one aspect of the Revised Common Rule that will not be going into effect on January 21st, 2019, and that is the cooperative research provision. That's the single IRB mandate for multi-site research. That compliance date was always January 20th, 2020, and that date remains January 20, 2020. And because we have some time we're not going to be focusing on cooperative research provisions in this lecture today. So where are we with VHA Handbook 1200.05? We know we had told you all our hope was that it would be issued in the beginning of November. I want to give you guys an update. So far all program offices have concurred with the directive. We're waiting for VHA's Office of General Counsel to give us the final clearance. They've reviewed it, we've responded to their comments, but they have to issue the final concurrence before it can then move on to what's essentially the last step which is the union review, review by the Office of Labor Management Relations. Once it goes there, then it's able to be routed to the Secretary for signature. I'm going to ask Karen if she wants to add any additional comments on the directive.

Dr. Karen Jeans: So hi, this is Karen. Everybody here is very well aware of the time sensitive nature of this, including senior leadership. So we would have loved, as Soundia had said, to be able to have this out. We had our working goal, November 1st. We are well aware we did not meet that timeline. But we are pushing this through as fast as we can and, indeed, what will be presented today as the revisions in the proposed directive 1200.05 are, indeed, those that, you know, pretty well have been cleared through. So what you're seeing is not going to be unchanged from what's issued which is why we are doing this presentation today. Since we can't give you the final one, this is pretty well the 99% version of it.

Soundia Duche: Right. So essentially what you hear today should be sufficient information for you to go on and, you know, finish updating you SOPs. Because I know everyone's already started that and you have your forms and everything almost complete and you're really just waiting to see what the VA specific requirements are. Well by the end of this lecture you

should have that information at your ready. So we are going to start with a case study. The case studies are back. I know the last two trainings we weren't able to do the case studies because of time. But we're going to be operating with some additional time today. And so we have an hour 45 minutes and we're going to try to use that wisely. But we have a number of case studies that we want to really spend some time on to make sure everybody understands the significance and the nuances of some of the aspects of implementation of the Revised Common Rule.

So first off January 21st, 2019. On January 21st, 2019, the following studies must be in compliance with the 2018 requirements. What we want you all to do is think through the most appropriate statement. A) All existing IRB studies. B) Studies approved on or after January 21st, 2019. C) Studies approved from July 19th, 2018, to January 20th, 2019, that utilize the burden reducing provision of elimination of IRB grant review. Both B and C, studies approved on or after January 21st, 2019, as well as those that utilize the burden reducing provision of the grant, Or all of the above. Petrice, if you could launch that poll so the audience can select their votes.

Dr. Petrice Longenecker: Poll has been launched. We'll give it about three more seconds. We've got about a 65% vote rate. Okay. I'm going to go ahead and close the poll. And share the poll.

Soundia Duche: Excellent. Now unfortunately, Petrice, I'm not able to see the poll results.

Dr. Petrice Longenecker: Okay.

Soundia Duche: If you could read them out.

Dr. Petrice Longenecker: Sure. Sorry about that. Okay. So for A) All existing IRB studies. We got a response of 7%. For B) Studies approved on/after January 21st, 2019, we have a response rate of 44%. And then C) Studies approved between 7-19-2018 and January 20th, 2019, without IRB review of the grant, we got 3%. And for both B and C we got 39%. And for, lastly, all of the above, 6%.

Soundia Duche: Excellent. Thank you.

Dr. Petrice Longenecker: I'll hide that.

Soundia Duche: Thank you. And so the correct answer was actually both B and C. So one, we are very pleased that everyone knows that all existing IRB studies do not have to be in compliance with the 2018 requirements. So that's wonderful. B, the option was studies approved on/after January 21st, 2019, about 44% of you said yes. That was the answer and that is correct. But also, if you recall, back effective July, sites/facilities were able to utilize one of two burden reducing provisions. There were three that OHRP allowed but VA only allowed two. And really only one was applicable in terms of its effect on our IRB review and operations. And that was eliminating review of the grant application. And because this is a provision that's

part of the Revised Common Rule, if the site elected to do that, which means they specifically decided that they would no longer review the IRB grant application as part of the study review, then they would have to designate that study for transition and those studies have to be in compliance with the 2018 requirements on January 21st, 2019. So the answer was both B and C which about 40% of you got. And we're going to be talking a lot more about, you know, the significance of January 21st, 2019, in a few other cases coming up shortly. The main take away though that we really, really want to stress, is the fact that because all existing studies do not have to transition to the 2018 requirements, IRB's across the country, really, federal IRB's will be operating under two sets of requirements. They're going to operate under both the 2018 requirements and the pre-2018 requirements for the foreseeable future. Because there's going to be some studies that you will just never transition. It won't make sense to transition them or the IRB will likely not want to transition them and so those studies will, until they're closed, be subject to the pre-2018 requirements. And then, of course, any study that's approved on or after January 21st, 2019, will have to be compliant with the 2018 requirements. And so this is going to create some interesting variables when it comes to making sure your SOPs and your forms are consistent with both sets of provisions. We're going to walk you through them and you're going to find that, really, for the most part they're very few changes of significance in the Revised Common Rule which we've talked about before. There are a few significant ones but a lot of them are minor. And then also when it comes to VA specific requirements, which we're really going to delve into during this presentation, we've done a lot of alignment with the Revised Common Rule. And so the few VA specific requirements that remain are very few and select. And really they're aimed at improving things and giving us a bit more flexibility going forward as we work with other IRB's once the single IRB mandate comes into effect and just various things, some things that have been maybe more burdensome for our researchers and our research offices. We've done our best to try to streamline some of those things which we'll talk about.

Now this chart here, this little table, kind of just gives you a nice summary. It's a lot of information but it's more of a resource tool for you as your thinking through the different requirements for research that's subject to the 2018 requirements i.e., those where the initial approval is on or after January 21st, 2019, and research that's subject to the pre-2018 requirements. I'm just going to highlight a few things. One exempt determinations. Any exempt determinations that the IRB makes on or after January 21st, 2019, obviously you're going to be using the 2018 requirements. So you're going to have to meet one of the eight categories there. The pre-2018 exempt categories there are only six of them. Now obviously you're not going to be approving any new exemptions under the pre-2018 requirements as of January 21st. But any existing exemptions should they submit amendments, and normally the IRB would review amendments to make sure that there are no changes that would take the research out of the exempt category. Those exemptions, when you're reviewing the amendment, you want to make sure that you're reviewing them in accordance with the requirements in effect for that particular study. So for a pre-2018 requirement study, that would be the pre-2018 exempt categories unless you designate that you're going to transition that study which is perfectly fine. But the IRB would have to designate that and make sure it fits into one of the new exempt categories and document that transition determination. Non-

exempt approvals, we've talked about that. Anything on or after January 21st, 2019, you have to meet the 2018 requirements. I do want to point out for studies that were approved prior to January 21st, 2019, while you have to be in compliance with the pre-2018 requirements, unless you elect to transition that study, you can incorporate some of the 2018 requirements so long as they do not conflict with any of the current Common Rule requirements i.e., the pre-2018 requirements. So now regarding study specific informed consent. For research that was approved before January 21st, 2019, again, you have to be compliant with the pre-2018 requirements. However, in cases where the elements of informed consent do not conflict with the pre-2018 requirements, and for study specific informed consent really they don't conflict, there are more requirements that have to be added but there's nothing wrong with going above and beyond the current requirements. And so there's nothing that prevents an IRB from deciding to start using, revising their informed consent template to be consistent with the 2018 requirements. That would be incorporating things like the key, you know, the summary of key information and any additional elements that are required, and there are very few additional elements, but incorporating those elements and then utilizing that for all studies even starting now. There's nothing wrong with that. The key though is, even if a study uses study specific informed consent form that's formatted and has the elements that's associated with the 2018 requirements, that in and of itself does not mean that that study is under the 2018 requirements as far as compliance wise. For broad consent, that's only permissible for research approved on or after January 21st, 2019. The reason being broad consent is not found anywhere in the pre-2018 requirements and so for any research study, a current existing study that wishes to use broad consent, that study would have to be transitioned to the 2018 requirements. And so there are a number of things that would have to go along with that which we won't cover in today's lecture but just suffice to say that you would not be able to use broad consent unless you transitioned that study. Informed consent waivers. You would have to meet the waiver requirements that pertains to the regulations that the study is under. And then with respect to HIPAA, because HIPAA is not found in the Common Rule, it's not impacted by the Common Rule, that's a privacy rule requirement. HIPAA authorizations, any new HIPAA authorizations would have to meet the requirement outlined in VHA Directive 1200.05. And because HIPAA privacy rules have not changed, any existing study that has a HIPAA form could continue to use the HIPAA form that's currently in existence.

So let's start another case study. Kind of make sure we really make sure everybody is well versed in this issue of the pre-2018 requirements and 2018 requirements and what applies when. So case study two. We have a new study that's undergoing expedited review, but it's using forms that incorporate the 2018 requirements. So remember I said, there's nothing wrong with combining requirements in one form, provided the forms, nothing in the forms conflict with the pre-2018 requirements. Comments are sent to the PI on December 15, 2018, and revised documents are received three weeks later. On January 10, 2019, the expedited reviewer reviews the documents received and acknowledges that all issues have been addressed and the study can be approved. The expedited reviewer can, and we're asking you to select the best scenario, the correct scenario. He can A) Approve the study on January 10th, 2019, and the statement says if does so, the study would be subject to 2018 requirements. B) He can approve the study on January 10th, 2019, and the study would be subject to pre-2018

requirements. C) The reviewer can wait and approve the study on January 21st, 2019, and the study would be subject to the 2018 requirements. Then D) the option is he could do any of the above; A, B, or C. Or E) the final option is he can do either B or C. Petrice, if you could pull up the poll please.

Dr. Petrice Longenecker: Yep. Launching the poll now and I'll give you guys about 30 seconds to input your answer. Okay. We still have a few votes coming in so I'll give it another couple of seconds. Okay. I'm going to go ahead and close it and share the results. And what we see is that for option A) Approve the study on January 10th, 2019, study subject to the 2018 rule 10% response. For option B) Approve the study on 2010, I'm sorry, January 10th, 2019, study is subject to pre-2018 rule, got 12% response. And then C) Approve the study on January 21st, 2019, and the study is subject to the 2018 rule and that's 5%. And either A, B, or C we've got a 25% response. And then lastly, either B or C at 48%. And I'm hiding that. Back to you, Soundia.

Soundia Duche: Thank you. Thank you. And the correct answer is, about 50% of you got the right answer, it's either B or C. So let's talk about why A was not correct. If the investigator, if the expedited reviewer, approves the study on January 10th, 2019, which he can do, the study would not be subject to the 2018 requirements. Remember the 2018 requirements only come into effect on January 21st, 2019, okay? Very important. So any study that's approved before January 21st, 2019, would be subject to the requirements in existence at that time which are the pre-2018 requirements, all right? We're going to delve into the options that are available come January 21st, but as of January 10th, 2019, the study is still subject to the pre-2018 requirements. Some people got B, C. Those of you who said either A, B, or C, I hope we've covered why A's incorrect. And either B or C, C is an option because the expedited reviewer can hold off on issuing his final approval until January 21st, 2019 in order to ensure that the study is subject to the 2018 requirements, okay? Remember when we're told in the scenario that the study was submitted using forms that incorporate all of the 2018 requirements. And so it's perfectly fine for an IRB to start reviewing things that would meet the 2018 requirements before January 21st, 2019. The main thing here is that a final approval cannot be granted by a reviewer, in this case the expedited reviewer, until on or after January 21st, 2019, if the goal is for the study to automatically be subject to the 2018 requirements, all right?

Now I said we're going to push the envelope on this case a little bit more. So we have just found out the reviewer approved the study on January 10th, 2019, and so on January 21st, 2019, the approved study must now follow the 2018 requirements. That's the statement and we're asking you all if that is true or false. If you can go ahead and launch the poll, Petrice.

Dr. Petrice Longenecker: Yep. Okay. And so we've got an awesome response rate. I'm going to go ahead and close the poll. We've got 68% response rate and I'm sharing the results now. So for true, 16% responded. And for false, an overwhelming 84%.

Soundia Duche: Wonderful. We like overwhelming responses that are correct. The correct answer is indeed, false. Because the study was approved on January 10th, 2019, it will remain under the pre-2018 requirements until such time that the IRB designates that the study will be

transitioned. And that can occur on January 21st, 2019, or after or the IRB may say, you know, we're going to keep it under the pre-2018 requirements. The key is it's not automatic, okay? There has to be a conscious decision to transition a study and then the IRB has to look at the protocol and all associated documents and make sure that their review is consistent with the 2018 requirements. That all the approval criteria and all the requirements are met prior to transitioning a study, all right?

Part three, because we don't leave this investigator alone, right? So on January 21st, 2019, the investigator and the IRB may negotiate to transition the study to the 2018 requirements. Is that true or false?

Dr. Petrice Longenecker: Okay. I've opened the polls. Okay. We've got 68% response. I'm going to share the results. So for true, we had 89% response rate. And for false, 11%.

Soundia Duche: Excellent. Thank you, Petrice. And yes, about 90% of you said true which is the correct answer. So the decision to transition the study hinges on a number of factors. I would say in cases where there's no burden to the investigator, nothing has to be done really on the investigator part, the IRB can just decide on its own or, you know, to okay, this makes sense to transition the study. But there'll be other cases where there might be some things that the investigator would have to do in order to transition the study to the 2018 requirements. Forms may need to be changed in terms of informed consent forms. Individuals may need to be re-consented or notified of certain additional information now that the study has transitioned or is seeking to transition to the 2018 requirements. So in cases where there might be a burden to the investigator, it should be a decision that the IRB and the investigator come to jointly. The IRB obviously has their own requirements administratively in terms of when does it make sense for them to be able to transition the study. Some IRBs may stay out of continuing review. Some IRBs say okay you're submitting an amendment this would be, you know, an appropriate time. So there are many factors. But it is something, yes, come January 21st, 2019, or you know, later; 2020, 2021. You know at any point in time that decision can be made and it would be a decision based on what makes the most sense and is it worthwhile to transition the study or not.

All right our last case study in this series. The IRB reviews a protocol and consent form that's compliant with the pre-2018 Common Rule requirements, okay? They review that protocol on 30th December 2018. And they approve it with stipulated conditions. The investigator completes all of the required stipulations and the assigned IRB reviewer marks them complete on 22nd January 2019. I didn't put in here that this is a convened board review but let me just mention that the convened IRB reviewed the protocol, okay? And now they said that designated IRB member can sign off and make sure that the minor mods were met. So given that the IRB member marked them complete on 22nd of January 2019, the question is which set of requirements must the study comply with? The pre-2018 requirements or the 2018 requirements or you need more information in order to answer this question. If you could open that poll, Petrice.

Dr. Petrice Longenecker: Yes. The polls been launched. Okay. I'm going to close the poll and share the results. So it's almost an even distribution. We've got for our answer A) Pre-2018 requirements, 29% response rate. For the 2018 requirements, a 36% response rate. And then for need more information, 35%.

Soundia Duche: Excellent. Great. So the correct answer we felt was B, okay? Remember now we were told in the scenario that the IRB reviewed the protocol with conditions. They reviewed it on 30th December 2018. We're also told that the documents that were submitted were compliant with the pre-2018 requirements, okay? The date though, however, when the reviewer finally signs off and marks them complete is 22nd January 2019. That's the date of the effective IRB approval. Because that date is after January 21st, 2019, that study would have to comply with the 2018 requirements, okay? So we threw in a little kind of wrench here. Now we know, from the scenario, that it couldn't meet the 2018 requirements because it was submitted on documents, on forms compliant with the pre-2018 requirements. So what would have to happen is the IRB would have to go back to the investigator and say that he has to resubmit whatever information that's needed in order to bring the protocol and the associated documents into compliance with the 2018 requirements. Now hopefully this was just an oversight and it's something that the IRB would have caught way before it got to this point whereby they made sure that all the correct forms were being used and all the correct criteria were being evaluated. But to the extent that it was a mistake, you know, things didn't get done, somebody was sick, out of the office, this is something then that would have to be remedied prior to the study being able to be issued a final approval letter, all right? So think through that. Had the IRB been able to complete their review prior to January 21st, so let's say January 20th had they completed the review, the IRB, the designated IRB member had signed off that, yes, all the requirements had been met then yes, that study would have been approvable under the pre-2018 requirements. That IRB approval letter would have been able to be issued and they would have gone on and moved it on to the R&D committee for review, but that's not the case. So again, we wanted to highlight these are things, things happen, life happens. Maybe the reviewer intended to get to it and review the comments and just wasn't able to. Sickness, holidays, who knows? Either way though, that date of January 21st, 2019, is a hard cut-off date in terms of what requirements apply and, therefore, you really need to make sure that you are ready. If you're going to approve a protocol on or after that January 21st, 2018, 2019 date, I'm sorry, that it meets all of the requirements of the 2018 rule requirements.

All right. So I know we've kind of beat that to death and I'm sorry, but I think it was very important that we spend time to make sure everyone understands the significance. And feel free to submit your questions. We'll take those at the end. So we're going to move now and talk about the changes, okay?

First category that we're going to talk about IRB membership functions and review of research.

And so first issue is IRBs of record. And Karen do you want to comment on this because this is a very important flexibility that we're going to see going forward.

Dr. Karen Jeans: So hi, this is Karen. Under our current ORD policies in VHA Handbook 1200.05, there are only specific types of IRBs that the VA can use, the VA facility. That includes: your own IRB if you have one, your academic affiliate's IRB, whether they be an affiliated medical or dental school, the central IRB, an IRB of another VA facility, or an IRB of another federal agency such as the NCI, which many of us use. So what we've done is expand that. And this is just the beginning of an expansion because as Soundia referenced, you know in 2020 we're going to, you know, the .114 provision regarding single IRB review, unless there are certain exceptions, will be part of the revised, or in effect for the Revised Common Rule. And so this is the beginning of our movement towards that because we do support it. So in addition to those that we currently use, we're not taking any away. We're also stating that if a VA facility is conducting a multi-site study, and we're not talking just multi-sites within the VA only. If it's involving VA and non-VA, that the VA facility may use an IRB of a non-affiliated medical or dental school if that IRB has been designated that it can do so by the Office of Research and Development. And so a good example of why we're doing this is for the Trial Innovation Network where, you know, John Hopkins is one of the major hubs, one of the major single IRBs that serve multiple IRBs as part of the clinical trials initiative. And so we wanted to be able to use these type of IRBs without having to form an academic affiliation if they are able to do so and they are constructed as such. So this is the beginning, and I do say the beginning because there'll be further policy changes after this directive is issued to expand the types of IRBs that VA facilities may use. This directive will have this. In the future you will be seeing us move toward the commercial IRB model.

Soundia Duche: Thank you, Karen, very helpful. In terms of IRB membership, and this goes right along with what Karen just talked about so why don't you take this one too, yeah.

Dr. Karen Jeans: I'll take this one too. So these are related because one of the limitations, and it is an issue right now, of being able to use other IRBs, whether the [unintelligible 31:54] may be an IRB of another VA facility, unless it's the VA Central IRB or another federal agency's IRB, are that of, you know, we do have as the current requirement, unless you're a small VA facility where you only are required to have one, you must have two voting members appointed to each of the IRBs that review VA research. And this was indeed originally put on there as a policy bias from the Office of Research and Development because we believed that was the best way that the VA's interest that could be served on an IRB. We feel there's other mechanisms that can be used that serve that purpose. The reason IRB members from VA's are put on these IRBs is because of their expertise in the clinical fields. They're not there for compliance. They're not here to recite VA regs. And so for that reason, we are taking away that requirement. It does not mean that if you have a local policy that you want to do it or, again, when you're working with other IRBs they, you know, if they want to have other, you know, you want to have the [unintelligible 33:02] IRB, if you're using another IRB that's fine, that's great. But it's not an ORD national policy as of the date this VHA Directive 1200.05 will become effective.

Soundia Duche: Perfect. So Karen, then, question for you. For sites, let's say, who have used our affiliates and have our VA IRB members on the affiliate IRB does anything change?

Dr. Karen Jeans: That's a great question. And so as of the date the directive will become effective you have a choice. You don't have to change anything. But it will no longer be current ORD policy. So it will become a local choice. So you know, it doesn't mean you have to yank them off.

Soundia Duche: Right.

Dr. Karen Jeans: But it doesn't mean that you have to have them either. It's your choice. Local flexibility.

Soundia Duche: Excellent. Thank you. All right. IRB function and operations. This is the paragraph in the Revised Common Rule that really just talks about the types of things the IRB has to have. And really there's been no material changes. IRBs still have to maintain IRB membership rosters. They still have to have their policies and procedures for how they plan on conducting reviews and such. And so the key thing to note here is that VHA Directive 1200.05 requirements are aligned with the Revised Common Rule.

For IRB records now. The Revised Common Rule has some additional justifications that are required when research that's subject to the 2018 requirements that does not require continuing review, and we'll talk about that in a little bit, but if the IRB chooses to conduct continuing review on such research then the IRB has to justify it. And similarly, if the research subject to the 2018 requirements are eligible for expedited review because it's found on the list of expedited review categories, if the IRB should deem that research more than minimal risk and therefore, then, have to be reviewed by the convened IRB, now it requires justification, okay? So because of that, because this is a change in the Revised Common Rule, VHA Directive 1200.05 has inserted this same requirement so that we're in alignment with the Revised Common Rule. But this is specific to research subject to the 2018 requirements. These two justifications are specific to the subject of the 2018 requirements.

For exempt research. Now we had a whole lecture on exempt research, an hour and a half, hour 45 minutes. Kristina Borrer did an excellent job of talking about exempt research and limited IRB review. So we're not going to spend much time on this. I only have one slide here. You can find the recording of her training on the PRIDE Cyberseminar webpage. But essentially, some key highlights. The 2018 requirements now have eight exempt categories, unlike the six that we are currently operating under. Exempt category six, that's the one that deals with food quality studies. That's the only category that has not changed. All the other categories have changed in different ways. And in many cases offering greater flexibility now for utilizing the exemptions for research being able to fall into the exempt categories. In terms of VA research, we're probably going to see a lot more utilization of exempt categories two and four because those categories have been expanded in terms of the requirements for the research study being eligible for those exemptions. For current exempt category three, that has been deleted and replaced with a completely new exemption that focuses on a concept called benign behavioral interventions. And so that's going to be something new that the IRB will pretty

much just come up to speed on and the forms would have to be revised, obviously, to be able to capture that information. And then there's two additional exempt categories seven and eight which are completely new. These are specific to secondary use or storage if broad consent was obtained. Again, this is the quick, quick summary of it. The key thing to note is that VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 requirements, okay? Key thing to note there. Yes, Karen.

Dr. Karen Jeans: Yeah. Just so to basically reiterate what Soundia is saying is what you see in Revised Common Rule is what VA is doing. We are doing the same categories. There's been a rumor going around. I heard it at PRIM&R. It did not come from VA. That VA was not accepting some of the categories. And that is an urban myth. We are accepting the exempt categories as written. They are exactly.

Soundia Duche: Excellent. Thank you. And what you will see is when the directive finally becomes published, we will have an appendix A that covers the exempt categories under, I don't know which one it is but let's just say the pre-2018 requirements, and appendix B will cover the exempt categories under the 2018 requirements verbatim.

Dr. Karen Jeans: Verbatim.

Soundia Duche: So that's all we're going to say about exempt categories today. So IRB review of research, okay? IRB approval criteria. Essentially there's only been one change. It's significant because it brings in a whole new type of review but all the approval criteria for the Revised Common Rule are identical to the current approval criteria that we're operating under with the exception of one. There's a new approval criteria and that's specific to limited IRB review. And limited IRB review is used for certain types of activities that are eligible for exemptions. So you'll see this here. This is a summary. Again Kristina Borrer's presentation covered this in detail and so you can refer to that for more information. But again, as we just mentioned before with exempt categories, same with limited IRB review, VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule. So we follow the same exact requirements when it comes to limited IRB review for research subject to the 2018 requirements, okay? Limited IRB review is new and only applies to research subject to the 2018 requirements. And so you'll see that in the directive once it's published.

In terms of VA specific requirements, however, we had a few VA specific requirements that we have now removed. One of those is the, I'll start with the second one actually. Relevance of the research to the mission of VA and the Veteran population that it serves must be considered by the IRB. If non-Veterans will be included, the protocol and related materials must justify the inclusion of non-Veterans in the research. That specific justification is no longer required. However, the protocols that the investigators submit still have to include information of the relevance of the study to the VA and the mission that we serve. So that hasn't changed. It's just that the specific IRB approval criteria, which was VA specific, has been removed. Again as we kind of move to be more in alignment with well the Revised Common Rule, the first bullet point covers the issue about conflict of interests. Now this, again, was a specific VA

requirement whereby the IRB had to make sure that mechanisms were implemented to manage, reduce, or eliminate potential or actual or perceived conflict of interest. The specific VA approval criteria has been removed. But investigators, though, still are required to inform the IRB of any conflicts of interest. So they do still have to inform them. But in terms of the IRB being the responsible entity for managing any conflicts of interests, that is no longer within the directive. Do you want to say anything about that, Karen?

Dr. Karen Jeans: Actually I want to talk about both just very, very, very briefly.

Soundia Duche: Okay, sure.

Dr. Karen Jeans: The reason why, as Soundia has referenced, we are removing the relevance again of making it the IRBs determination that they have to justify whether or not that criteria is met, that non-Veterans are allowed to be placed in VA research, is that, again as we move towards a single IRB model, we anticipate using many more external IRBs and that's really not within their authority. So again, we're trying to take out those things which are VA specific which would be sorted by other functions within the VA institution and not by an IRB. When it comes to the conflict of interest, you know, the person cannot have a conflict of interest. For example, be doing a study in which they own the company and then be doing the study without that conflict of interest being disclosed. We're making it now where the IRB is not the focal point where all this is coming in. Those are managed outside of the IRB. And so we're trying to make it where the IRB is not the focal point of every single thing that are institutional responsibilities rather than human subject protection issues.

Soundia Duche: Excellent. Thank you. I want to talk very briefly about privacy officer and ISO review. Again in the handbook, our current handbook, we have a VA specific requirement about the privacy officers and privacy and confidentiality provisions being reviewed. Now while that specific approval criteria has been removed, it is still something that's going to be reviewed by the IRB because the Common Rule covers that. They cover that in the IRB approval criteria. I believe it's number seven that deals with privacy and confidentiality. Whereby the IRB has to ensure that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of their data. So we have already covered it there. So we've removed it as a VA specific requirement. In terms of the PO and ISO's role, they continue to serve as advisors to the IRB as either non-voting members or consultants. That hasn't changed. With respect to disclosing information, individually identifiable information, the privacy officers still have a role in that process. So none of that has changed. In terms of, anything else about the PO's and the ISO's and their responsibilities that we just want to touch on here?

Dr. Karen Jeans: So it really is, there's a lot of confusion right now based upon our Handbook 1200.05. When the ISO's and PO's do their review functions and final reviews, and the bottom line is what Soundia has stated, is that in the IRB approval criteria, there is an approval criteria dealing with the privacy and confidentiality of the subject and how it's going to be maintained. Now that function is different then what we do for information security and privacy at the institutional level. So there's the ethics component versus the institutional component. So this

was getting intermingled with our current handbook and so that's why we took it out. It does not mean that VA researchers and institutions are not required to follow all relevant information security and privacy requirements. In our privacy requirements, in terms of disclosures, use, PHI are covered in VHA Directive 1605.01 which is about privacy HIPAA. So we're just not duplicating in ORD policies that which is covered by another.

Soundia Duche: Excellent. To move on briefly and just touch on expedited review. One of the key things to note is that there's no changes in the expedited review list. We mentioned that during our previous presentation on expedited reviews. However, the process of determining whether a study qualifies for expedited review has been changed a bit for research subject to the 2018 requirements. And essentially, in brief, that is that any research that's found on the secretary's list, and for all those who get confused when they see that the secretary's list is just the expedited review list, so any research activity that's currently on that list is presumed to be minimal risk. And so what that means is by default now, the IRB is supposed to deem that minimal risk and, therefore, expeditable. If the IRB reviews the activity and feels no, in their opinion it is not minimal risk, they now have to justify that. Which essentially means they have to document why they feel it's not a minimal risk activity and therefore not subject to expedited review. So that's a change in the Revised Common Rule. Also, we talked about limited IRB review already. The Revised Common Rule states that that can be done by expedited review. So VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule. No difference when it comes to research subject to the 2018 requirements and how the expedited review procedure works. I do want to note though, that FDA has not adopted the Revised Common Rule approach to expedited review. And so for FDA regulated research, until we're advised otherwise, FDA regulated research will continue to be subject to the current expedited review requirements, okay? So until we hear otherwise, FDA research will continue to be reviewed as we currently are doing when it comes to expedited review.

Expedited review listings though, now this is specific to the VA and there's been some very positive changes here. I think many people, I'm sure I hear some rejoicing going on, but a VA specific requirement that we have was that in the current handbook we stipulated when and how the IRB was informed of expedited review decisions. And essentially we said that the expedited review decision and the eligibility category must be included in the IRB minutes of the next available convened meeting and in the written notifications in the **investigated** R&D committee. And now in the revised directive, in the proposed VHA Directive 1200.05, what we've done is taken a step back and said you know what, we're going to give each local facility flexibility to determine how they're going to implement the notification process. We're not going to be as prescriptive. You still have to include in your SOP's, though, how the members and investigators and the R&D committee will be informed of the decision. And you still do have to include the expedited review eligibility criteria category for any expedited review actions. But prescribing the timeframe that it has to be in the minutes of the next available convened meeting. that has been removed.

So in terms of continuing review, the Revised Common Rule has made some changes that we are on board with for research subject to the 2018 requirements. There've been some changes

where continuing review is no longer required if the research falls into certain categories and meets certain criteria which you will find here. And so VA is in alignment with that. I think I had mentioned this before, if an IRB conducts continuing review on research that no longer requires continuing review, a justification has to be made. Again, we are in alignment. So there's no additional changes, no VA specific requirements when it comes to conducting continuing review or not having, rather, to conduct continuing review for certain categories of research that are subject to the 2018 requirements. The VHA Directive 1200.05 does clarify, and so that there is no confusion, that the R&D committee is not required to conduct continuing review on studies that are under the oversight of the IRB. And what that means essentially is that even though a study, let's say that's been reviewed by expedited review that no longer requires continuing review, that study is still under the oversight of the IRB. So the fact that it doesn't require continuing review by the IRB does not mean then that the R&D has to conduct continuing review. In fact, the clarification says exactly the opposite. The R&D does not have to conduct continuing review because it remains under the oversight of the IRB.

Suspension or termination of IRB approvals. The Revised Common Rule really did not have any changes in this category. VHA policy, our handbook, we didn't really mention, specifically, that the ORD funding service has the authority to suspend or terminate research. So what we've done is made sure we included it this time. Because that was always one of the options that they have, given that they're funding the study, but we wanted to be clear in the new directive and so we put that in there. Yes mam.

Dr. Karen Jeans: Yeah and so this is Karen. One of the reasons that we put this into ORD policy is that it does happen. It's rare. But ORD has had, even in the last year, had to like, for example, suspend one of the studies that we were funding. And there was surprise and shock saying well ORD can't do that. Of course ORD can when you're funding the study. And so to make it very transparent because there should be no surprises that is why this was put in just as a point of clarification.

Soundia Duche: Thank you. Certificates of Confidentiality. Not going to really talk about this that much. We're going to come back to this in a later training because there's still some negotiations between the various agencies on this issue. But essentially the 21st Century Cures Act has updated the definition of identifiable sensitive information which then changes the types of studies that are then eligible for a Certificate of Confidentiality. And so the proposed directive adopts the new definition and it makes certain changes. For example, it makes certain changes regarding the permission of placing informed consent forms in the medical records for studies with the COC. We've now clarified that that can be done provided the subjects are informed of this as part of the informed consent form process. And then made it very clear that the written informed consent form, if there is one, has to include a statement that the study has been issued a COC. I think that's all I'm going to talk about because this was a whole lecture in and of itself so.

With respect to informed consent and HIPAA. Again, we conducted two trainings in July on informed consent. Kristina Borrer conducted a training on informed consent and broad

consent. And I conducted a training on waivers of informed consent and HIPAA and so we're going to go through this very quickly because those resources are already available. But essentially the changes in the Revised Common Rule with respect to study specific informed consent, VHA Directive 1200.05 is in alignment with those. We've adopted all of the new basic elements. We've actually eliminated a few VA specific elements saying that you don't specifically have to include information on things like payments to the subject and any real or apparent conflicts of interests by investigators. You don't specifically have to put that in the consent form. Again, this was all part of bringing us in alignment with the Common Rule. That doesn't mean you don't have to though. It's still a good idea to include information on whether subjects are being paid. That's useful information that they want to know and the schedule of the payments. But again, we're aligning ourselves with the Revised Common Rule. So in terms of the requirements, whether it's a VA specific requirement, that has now been eliminated.

Broad consent. There are some VA specific changes compared to what the Common Rule requires. One of the main things is that for broad consent which is, just want to remind people, it's specific to storage, maintenance, and secondary use of identifiable data or biospecimens. For the Common Rule you're allowed to use it even if the information's collected for non-research purposes. For VA, we're saying specifically you can only use it if the information is collected for research purposes. That's one of the key changes there. Let me see. All the elements of broad consent we've adopted. We're in alignment there. And in terms of if the broad consent is a separate form or combined with the traditional informed consent form, we do allow it to be combined. The Common Rule is really silent on that. But we just want to clarify with folks, yes, you can combine it. But if you choose to combine it, then the information provided to subjects with a broad consent form, process, must be very clearly discernable from the research specific consent, okay. And that's something, again, we can talk about at length going forward. Did you want to say anything about that, Karen?

Dr. Karen Jeans: Yeah and also a way we deviated and it goes to this bullet, the third bullet that Soundia has on the slide, is the Revised Common Rule, the 2018 requirements allow broad consent to be obtained both by written or through waiver of documentation of informed consent. VA specific policy, we are not going to allow a waiver of documentation of informed consent. It must always be obtained through a written informed consent document. So that is a VA specific policy requirement that will be more stringent than the 2018 requirements.

Soundia Duche: Excellent. No thank you for mentioning that, Karen. All right. We're going to go on, take a little, short little break. We have another case study here. And this is about documentation of informed consent. So the scenario is that we have a researcher who'd like to establish a tissue and data repository for future research on chronic degenerative disease. The researcher is planning on collecting information on identifiable blood specimens, demographic and health information, as well as identifiable health information obtained from CPRS. The researcher plans on obtaining documentation of informed consent from the subjects. And what we're trying to find out is, what should the investigator submit to the IRB for review given this. Should they submit just A) A study-specific informed consent form for the collection,

storage, and future use. B) A broad consent form covering the collection, storage, and future use. Either one, or do you need more additional information in order to make a decision.

Dr. Petrice Longenecker: Okay. I'm launching the poll now. Okay we've got about a 51% response rate so I'm going to close it and share the results.

Soundia Duche: Okay.

Dr. Petrice Longenecker: So for option A) A study specific ICF for collection, storage and future use received 28% of the responses. B) A broad consent form for collection, storage, and future use received 24% of the responses. And either A or B received 35%. And then, lastly, additional information is needed received 14%. I'll go ahead and close that out. And there you are, back to you Soundia.

Soundia Duche: Great. Thank you. Thank you, Petrice. Well this one clearly shows that, yeah, we're all going to, kind of trying to understand broad consent and study specific consent. The answer is A, okay? What they want to just reiterate is that broad consent is an option, okay? It's an optional, alternative to study specific informed consent. You can always use study specific informed consent. So those who went there probably weren't wrong. The issue in this case though with why broad consent would not be an option, so that eliminates B or C, is because, as we mentioned, a VA specific requirement for broad consent is that you can only use it for the collection of data or biospecimens collected solely for research purposes, solely for research purposes. In our scenario here, our investigator is collecting identifiable blood specimen, identifiable demographic and health information, collected from a questionnaire so that would be fine, but then he also, he or she, is also collecting identifiable health information obtained from CPRS. And that information would have been collected for clinical purposes, okay? So it's a small little nuance but significant because of our VA specific limitation on how and when broad consent can be used. So I hope this case just highlights that. And we can talk about this more in the future.

In terms of the waivers, I'm going to breeze through these. The Revised Common Rule has incorporated an additional element for waiver of informed consent for minimal risk research. And you can see that in red. The requirements for waiving informed consent for public benefit really have remained unchanged. And all these cases, VHA directive has adopted the requirements of the Revised Common Rule for research subject to the 2018 requirements, okay? So we're verbatim what the Common Rule says in these for waivers. We agree and you'll see the same language in the directive.

In terms of some caveats with the Revised Common Rule, the IRB isn't allowed to waive or alter any of the elements required for broad consent. The IRB cannot waive consent for the storage or maintenance or secondary use of identifiable information if a subject has refused to agree to broad consent. And again, you can find more information on this in the training that Kristina Borrer did. And then with the exception of broad consent, the IRB can approve a complete waiver of informed consent if the prior criteria are met. All of these stipulations we are in

alignment with and so VHA directive repeats what the Revised Common Rule says regarding the waivers of informed consent, these caveats verbatim.

Similarly, there's some additional alterations whereby essentially when you're doing informed consent, altering informed consent, there's certain caveats, things you still have to do. You still have to have a true informed consent process that is tied to the Belmont report where you're respecting people, respecting them in the sense of the information you give them, that you give them sufficient information to make an informed decision. You give them information in a context that there's minimal coercion and no undue influence. All of these types of things. No exculpatory language. When you're altering consent you cannot alter any of those elements that would affect the respectful persons aspect of informed consent. And again, VHA directive work in alignment with the Revised Common Rule when it comes to that as well.

The Revised Common Rule has a new requirement or ability whereby you can, the IRB, can approve the use of screening and recruiting activities under certain conditions without a waiver. I'm not going to go into that because we've talked about this in previous lectures and you can see the information here. But essentially, we're in alignment with the Revised Common Rule when it comes to screening and recruiting activities, the IRB being able to approve those without requiring a waiver. You can still use a waiver but it's not required. And that is a waiver of informed consent I want to stress. HIPAA waivers for screening purposes would still be required.

With respect to posting clinical trial consent forms, the Revised Common Rule has certain stipulations in terms of when an informed consent form has to be posted for research that meets the new definition of a clinical trial. VA is alignment with those requirements and so you'll see that in the revised directive. But we also give some additional details to clarify for our purposes, here in the VA, who is responsible for posting the consent form. And so you'll see that here. I'm not going to read it but essentially the directive gives specific individuals or entities responsibility for posting the informed consent form to meet this Common Rule requirement for research that is determined or meets the definition of clinical trials.

Documentation of informed consent form. Really there have been no material changes to the Revised Common Rule. There have been some clarifications and you can see those here. Again VHA directive, we're in alignment with the Revised Common Rule when it comes to documentation of informed consent. And in fact, we've gone one step further because previously we had an additional VA specific requirement whereby we required that the individual obtaining consent had to be, had to sign the document, had to sign and date it. And that was never a Common Rule requirement, actually, that was always a VA specific requirement. And so as part of streamlining things and getting us on board with many of our other federal colleagues and agencies, we've removed the VA specific requirement that the individual obtaining consent has to sign and date the consent form. So that is a VA specific change you'll see in the directive. And so that should also help to eliminate some of the non-compliance I think we've seen over the years when people either just, you know, forgot to sign or put the wrong date. Now effective, once the VHA Directive 1200.05 is published, that

requirement will no longer be in effect. The last bullet point there just talks about the fact that we had this waiver of signature. The IRB can waive the signature of the individual obtaining consent in certain instances where there was no physical contact with subjects. That was because we required the signature. Now that we no longer require the signature, that option to waive it is now removed. There's no need to include that.

All right. We have another case study. We're coming towards the tail end here. So we're talking about signatures. So let's continue. In this scenario we have an investigator who submits an amendment to remove the signature of the individual obtaining consent from the consent form of a study that is subject to the pre-2018 requirements. So this study was approved before January 21st, 2019, but now he wants to remove the signature so that he doesn't have to have the individual obtaining consent sign. The amendment is submitted after the issuance of the revised VHA Directive 1200.05. Can the IRB approve the request? First answer is yes. B is no. Or C additional information is needed. And Petrice, if you could open the polls.

Dr. Petrice Longenecker: Okay. The poll is open. Okay we have about 50% of responses in and so of those responded, and we got for yes, 52% of the responses. No 29%. And additional information is needed is 19%.

Soundia Duche: Okay. Excellent. Thank you. And we agree with the 52% who said yes, okay? And the key is and this is where it can get a little tricky because we keep talking about the Revised Common Rule changes, Revised Common Rule changes. But remember, when a VA specific requirement has been either added or deleted, that's not subject to the Revised Common Rule requirement. So in this case because this was a VA specific requirement, once the new directive is published any VA research study could apply to use that. And apply meaning they can submit an amendment to be able to start utilizing this new flexibility because this was a VA specific requirement. So provided the directive has been published, an investigator for any study can submit an amendment to the IRB. Now you'd have to revise your form, you know, you'd probably want to remove that signature. Because if you leave that signature there then you have all kinds of other problems. But you can, you know, submit an amendment to remove the signature.

If the IRB approves the removal of the signature of the person obtaining consent, does the study have to transition to the 2018 requirements? A) Is yes. B) Is no. And C) Additional information is needed. If you can launch that poll, Petrice.

Dr. Petrice Longenecker: There it is. It's been launched.

Soundia Duche: Excellent. Thank you.

Dr. Petrice Longenecker: Okay. The responses have slowed down. I'm going to go ahead and close and share. So I've got for yes, 29%. For no, 68%. And for additional information is needed, 3%.

Soundia Duche: Excellent. Thank you, Petrice. And yes the answer is indeed, no. Which about 70% of you said. Remember as we just described, this was a VA specific requirement. This has nothing to do with the Revised Common Rule requirements. And so the fact that we remove it does not mean that the study now has to transition to the 2018 requirements, okay? Now if an investigator wants to submit let's say something that is subject to the 2018 requirements and that's specific to the 2018 requirements. So it's something that would contradict or conflict with the pre-2018 requirements. For example, broad consent. In order to utilize that, you would have to transition the study to the 2018 requirements and meet all of the criteria of the 2018 requirements, all right?

All right, waiver of documentation of consent. The Revised Common Rule has introduced one new additional element, or option, for waiving documentation of consent. You can see it here in red. VHA Directive 1200.05, again, is completely in alignment with the Revised Common Rule and so for research subject to the 2018 requirements you will now have three options when it comes to waiving documentation of consent.

HIPAA authorizations. HIPAA is not part of the Common Rule, remember, I mentioned that's the privacy rule. But there have been some changes to VHA Directive 1200.05 for HIPAA. You want to comment a bit on that Karen?

Dr. Karen Jeans: I'll take this part, okay. So again, we listen to you and so there have been a lot of complaints, a lot of requests to please put back in the options that were available pre-handbook 2014 when this version of Handbook 1200.05 is issued. Currently we have a standalone policy. It is no exceptions unless it is waived by the undersecretary, or the executive in charge in our case, in which if a written HIPAA authorization is required, you must use VA form 10-0493. What we have put in the proposed VHA Directive 1200.05 is that you have one of two options. You can do the standalone. If you do a standalone written HIPAA authorization, you must use VA form 10-0493. However, you also have the option to combine the elements of the valid HIPAA authorization with the written informed consent document. And so that is the two options that will be available for VA research once VA Directive 1200.05 goes into effect.

Soundia Duche: Excellent. Thank you.

Dr. Karen Jeans: You're welcome.

Soundia Duche: And so with that, we're going to have a case study. That's not the right one. All right. So case study six is about the HIPAA authorization. So in what situation might it be advantageous to combine the informed consent document and the HIPAA authorization for research? You want to select all that apply. A) When there's a longitudinal study in which re-consent is obtained every 2 years. B) A study asking VA employees their opinions about care services. C) A study involving individuals with impaired decision-making capacity. D) A study

assessing obesity and cardiac health in healthy adults, or E) None of the above. And if you can launch that poll.

Dr. Petrice Longenecker: Yep. The poll's been launched.

Soundia Duche: Great.

Dr. Petrice Longenecker: Okay. The responses are slowing down so I'll go ahead and close and share. So I've got for the first answer, longitudinal study re-consent is obtained every 2 years, 65%. Second answer, study asking VA employees their opinions about care services, 18%. Study involving subjects with impaired decision-making capacity, 38%. And then study assessing obesity and cardiac health in healthy adults, 26%. And for lastly, none of the above, 14%.

Soundia Duche: Very interesting, very interesting. All right. Now maybe I didn't word this question the best. In what situation might it be advantageous to combine the informed consent document and HIPAA authorization? We only had one answer and that was D) A study assessing obesity and cardiac health in healthy adults. Now let's go through why. A) Where there's a longitudinal study in which re-consent is obtained every 2 years, that probably would not be the best type of study to combine the documents because every two years you're going to have to re-consent the subject. However, for HIPAA authorization, that really is a single event. You don't have to get another valid HIPAA authorization. So you get your one single HIPAA authorization on a separate form, you're one and done. Every two years, your consent form if it's separate, you would re-consent on the consent form and if new information becomes known because it's a longitudinal study and you want to put that in the consent form, again, easier to do it when it's a separate document, okay? For B) A study asking VA employees their opinions about care services. This was just a little tricky one and most of you guys didn't fall for it. So that's good. Because we're talking about VA employees and we're talking about their opinions about care services, really there's likely to be no PHI, no protective health information there. And so, therefore, HIPAA wouldn't even come into play. All right? So you wouldn't have a HIPAA document to combine. So most of you all didn't fall for that so that's good. C) A study involving individuals with impaired decision-making capacity. Again, what we're trying to just highlight here is in cases where you might have to re-consent somebody you probably don't want to combine the document. Additionally, there's an additional element where for HIPAA authorization forms the individual who's authorized to sign, in cases where someone has impaired decision making, is the personal representative. For the informed consent form, that's the LAR, the legally authorized representative. Sometimes those individuals are the same, sometimes they are not. And so, again, when you're dealing with impaired decision making capacity or fluctuating capacity, probably not the best idea to combine the forms. And Karen wants to break in.

Dr. Karen Jeans: Hi. And also in some of these studies with impaired decision making capacity, particularly when it comes, for example in my area, which is septic shock, we have seen studies in the past in which, you know of course the IRB has to approve a written informed consent

form, we'll say it's an investigational drug study involving, you know of course, the subject or the subject's legally authorized representative. But in working with privacy, sometimes these studies have a waiver of authorization, a HIPAA authorization. So again, this almost gets back to the one like B depending upon whether or not the waiver of HIPAA authorization are met. you wouldn't have a HIPAA authorization written for research. So that's why, again, this is a subjective question.

Soundia Duche: Yes. Yes.

Dr. Karen Jeans: This is not, you know, you can do it but the issue is, might it be advantageous.

Soundia Duche: Yes. Exactly. Good point. Thank you. And then that was it. E) None of the above. Okay. Oh, oh, sorry, no D) A study assessing obesity and cardiac health in healthy adults. What we're really just trying to hone in on, you know, in this case you have a healthy adult so you're probably not dealing with capacity issues. You're not dealing with children who then maybe, you know, when they were first consented they were under 18 and now, you know, they're over 18 and you have to re-consent. We're kind of dealing with our straight vanilla, you know, regular study. And we included that you are collecting, you're assessing obesity in cardiac health so that you guys thought that, okay, there probably is some protected health information there and so likely you would have a HIPAA authorization. In a case like that, straight forward case, yeah, it probably would make sense to combine the form because you probably wouldn't be re-consenting. There'd be one form. That would be an example of where it's advantageous to combine the forms. Again as Karen said, it's subjective. But again, just wanted to highlight the types of things you want to think about. That's all.

Dr. Karen Jeans: Why it can be an option. You know why there are going to be options.

Soundia Duche: Yeah. Yeah. Okay. All right. So we're coming on to vulnerable populations but we're running out of time. So what I'm going to do is, because we have our next training in December, again focusing on 1200.05 and we're going to kind of tweak our approach, we're going to hold this section off to that training. You have all the information here though. So you can use it as a resource, okay, as you start going through your forms and finalizing things. All the content is in the forms. So we're not going to go over this section now. We're going to be scheduling some additional trainings in December. I think we have one already on the books, that's on the calendar but we'll be scheduling some additional ones. And so if, Petrice, we can line up the questions I'm going to just move forward here. Oh I'm sorry, let me just say one thing. Again, this is a resource. Definitions. This section talks about some of the changes in the definitions and, again, great resource for you to come back to but we're not going to focus on that today. Important links.

Dr. Petrice Longenecker: Okay. I'm ready with the questions. Oh, sorry.

Soundia Duche: Perfect. Thank you.

Dr. Petrice Longenecker: Okay. I'm ready for the questions when you are and we have quite a few so we will keep a log of all the questions that have been received and we can figure out how we can address the rest of them as they become important, or as we can address them. The first question is, regarding the 1200.05 change that would allow us to combine the ICD and HIPAA authorization, I'm considering making a recommendation to our research service and our affiliate IRB to allow this and to require only one signature from the subject to consent to both in the interest of reducing burden on staff/subjects and increasing compliance rates. Before I make the recommendation, I am conflicted by California civil code section 56.11B which states the authorization shall be "separate from any other language present on the same page and is executed by a signature which serves no other purpose than to execute the authorization." In a prior consultation with OGC/ORD on a separate HIPAA issue, it was stated that we should not follow state law on the 14 point font requirement because there was a business reason to use VA form 10-0493. Now that there is not a business reason to use the form, if combined with the ICD, do you have an opinion on whether we must/should follow state law? I have a follow up to a prior question also.

Dr. Karen Jeans: I would rather have OGC on the line for this before we give a formal answer to this. So this is one of those where we do need OGC STAR on the phone along with ORD so that we can, indeed, answer this from both ORD policy and law. Because it is about applicable state law and I do know exactly where we're coming from here. So I would like to defer that question until we have OGC STAR on the phone as well so we can answer this for your specific site.

Dr. Petrice Longenecker: Okay. And I have a follow up to a prior question regarding the broad consent required element of having a statement that clinically relevant research results, including individual research results, may not be disclosed to the subject. I am still unclear when a laboratory result from a non-CLIA certified lab would be part of the designated record set. If I had to choose between breaking the CMS policy/law or HIPAA privacy rule, I would probably follow 45CFR 164.524 which states, "An individual has a right to access, to inspect and obtain a copy of protected health information about the individual in a designated record set for as long as the protected health information is maintained in the designated record set." I read the privacy rule definition of designated record set which I interpret would usually include non-CLIA certified lab results. In what instances do you think the lab result would not be part of the designated record set?

Dr. Karen Jeans: In VHA research, the agency has made the decision that research is part of the covered entity. So in terms of the laboratory results that we obtain as part of research, if it's a research record, it's going to be part of the designated record set. And so there's always been, and this is ever since the update to HIPAA came that indeed I reference this, there's always been a conflict between CLIA and between HIPAA. And so, you know, there's no question under HIPAA that people have the right to request what's under a designated record set. And these are two conflicting laws. And we have had a situation here, in the Office of Research and Development where we've consulted with legal to do what has been requested by the VA subject. So this, again, is dealing with a privacy issue rather than a 1200.05 issue. So you know,

I'd like to keep it to 1200.05 for now but if you want to have a follow up we can, indeed, have that. But yes this situation does exist. It is in the designated record set and HIPAA is very clear that individuals have a right to request the data in their designated record sets.

Dr. Petrice Longenecker: Okay. So this next question is related to one of the case studies and I don't know which one you were presenting at 2:30 exactly but they didn't find the case, as written, particularly helpful saying that as a study coordinator I need to know what changes do I make in my submissions to the IRB. Thank you.

Soundia Duche: Well maybe they can send me an email offline and we can talk about it more. Because I'm not sure which one.

Dr. Petrice Longenecker: So I think it's the one where if it's in the middle of the review and the reviewer was going to... So it's January 22nd, and the reviewer has the updated protocol, I think that they're asking kind of so what were the changes that the investigator or the study coordinator needed to make to update the protocol for the 2018 requirements?

Soundia Duche: Right. And you know, we didn't include that information in the case study because it wasn't really pertinent to the point we were trying to drive home on that particular case. The main point of that case is essentially that if the final approval comes after January 21st whether that was by chance, whether, you know, things fell through the cracks, whatever happens, it has to meet all of the 2018 requirements. And if I recall that scenario correctly, what we said was that the protocol was first submitted sometime in December using the pre-2018 requirements. One could assume that they had every intention of approving it prior to January 21st because of that. But it didn't happen. And therefore, then, the requirements have to meet the 2018 requirements. What those are, are all the things that we've been talking about in this training and in our previous trainings. Things like the waivers, you have to add that additional element if a waiver is being requested. Things like the informed consent form. Additional elements that are specific to the 2018 requirement that have to be included in the informed consent form that may not have been included if it was submitted under the pre-2018 requirements and they had not revised the consent form. So those are the types of things that would need to be included in order to make sure that the protocol, a study could be approved under the 2018 requirements.

Dr. Petrice Longenecker: And I think this is a good time to bring to your attention, again, to the second handout that's available in the presentation. So Dr. Klote has drafted kind of a checklist, so to speak, of the things that the IRB and even our investigators can start to change now in preparation for the Revised Common Rule. And so that would include and gives guidelines to our investigators and IRBs on the things that need to be updated. So as you're transitioning studies or as you're looking at studies that kind of come in that gray area, you'll know what needs to be updated in order to be prepared for the 2018 Common Rule. So that handout is available in the handout section of the GoToWebinar toolbar.

Soundia Duche: Thanks, Petrice.

Dr. Petrice Longenecker: And so the next question. Does a transition decision require full board ruling?

Soundia Duche: No. I don't see why, no. If the study is eligible for expedited review then it would go through the expedited review process and the documentation of the fact that the study has met all the 2018 requirements, would be included in the reviewer form, or the minutes, or whatever your local process is that you determine how you're going to document that a study has been transitioned.

Dr. Karen Jeans: Yeah. And it's real important and, Petrice, I don't know if I understood the question correctly. But you know, the decision to transition versus the date it was actually transitioned are two different things. So the decision can be made, you know, maybe it's a policy. Speaking from an IRB side, one could have a whole entire, as an IRB, categorical decision that all these studies are going to be categorically transitioned and that's the policy. And then the IRB determines a date. What the transition date will be because that's important for compliance, as well as to tell the investigator as of this date it's 2018. And what does it mean? So the decision can be made outside of the IRB but only the IRB has the ability to decide when does it actually transition. What is the date of transition?

Dr. Petrice Longenecker: And does that need to be a full board decision or can that be done in the "expedited procedure," one person making it.

Soundia Duche: Depending upon the study.

Dr. Karen Jeans: Again it goes on the study because let's go back here. It's a great question, by the way, whoever asked it. So let say it's a clinical trial. And you have an active clinical trial and, again, you're going to have to, let's say that informed consent has to make major changes. For example a summary of, you know, key information. And that is not something that can be done by expedited review. I mean it's going to require an evaluation. And so that study that was going to a convened IRB, and I'm just thinking out loud right now for a good example, may go back to the convened IRB. But there's other studies that could be done by expedited review. So it's not necessarily a default expedited review decision. It is going to depend upon the study itself.

Soundia Duche: And we do plan on having additional training as part of the lead up to the January 21st, 2019, compliance date on transition. So we'll be delving into those details in the future.

Dr. Petrice Longenecker: Okay. Our next question. Our institutions in the past were told that the date of IRB approval is the date the protocol was approved by the IRB not the later date that additional contingencies requested by the IRB were completed. We were told by our national office that the official date of approval is the date the convened IRB approves the

study regardless of whether any contingencies were attached or not. Clearly this is not universal?

Dr. Karen Jeans: This is Karen. It's very important to differentiate the date for which the clock sets for continuing review. Which is the date of the convened IRB that it was approved versus the date that the study, and I'm going to say that this is for initiation of the study that the date is considered, that the IRB is considered to approve the study in order for the study to be initiated. And so there's two parts of this question. So indeed the date that the convened IRB meets is the date that the clock is set for continuing review for the next year. The date that those modifications have been approved, if this was, for example initial review, is the date that, from an IRB side, is considered to be approved without any conditions.

Soundia Duche: Nothing can begin until those modifications have been cleared and the approval letter has been issued.

Dr. Karen Jeans: And in the VA, of course, we have an R&D committee so that's.

Soundia Duche: Yes. So that's a different.

Dr. Karen Jeans: But if we're just talking IRB that is the policy of ORD.

Soundia Duche: And a lot of times you'll hear me refer to it as the effective date of final approval. That's the same thing. It's the date by which the IRB approval letter can be released because all requirements can be met and the study is now approved.

Dr. Petrice Longenecker: Okay. Next question. Case study number three. Doesn't this depend on the IRB SOPs? It was my understanding that conditional approval can be the date of conditional approval or the date that the conditions are met. And maybe you just answered that.

Soundia Duche: Yeah. I think we just answered that. We just answered that question.

Dr. Karen Jeans: I think we just answered that question.

Dr. Petrice Longenecker: Okay. So for clarity, will there be a list for academic IRBs that are already approved by ORD on January 22nd, 2019? And how can we get academic IRBs that are not on the list to be added to the ORD list?

Dr. Karen Jeans: So we will not have a list on January 21st because we actually have not been asked yet. We already have four in mind that we intend to put on that list and we want to speak to those IRBs first to make sure that, you know, we've been speaking with them for the last year. But then if you did have an IRB, it's a great question, and we will have guidance on this, the procedures for requesting and the criteria which ORD will use, there would be a request that would come in through our office to Dr. Klote. And we will have that procedure

put on the web through ORD guidance on how that will be done. We do not anticipate to have, you know, 6000 IRBs that can be used within the VA. But indeed, this is again, to look at this and to be able to evaluate certain criteria. So this will be a transparent process. So yes, there will be a request process that can be used to do this. With the Office of Research Oversight because this is a transparent process. It doesn't involve the STAR Office at all so it involves the Office of Research Oversight.

Dr. Petrice Longenecker: Sounds good. Regarding the IRB of record change, will this apply to all external IRBs or only academic affiliates?

Soundia Duche: Are you referring to the ability now. I think the expansion of who can be an IRB of record through the VA.

Dr. Karen Jeans: I'm not understanding the question.

Petrice Longenecker: So is it the removal of the VA representation maybe?

Soundia Duche: Maybe we could ask the submitter to submit a follow up and then we can move on.

Dr. Karen Jeans: That is true. The requirement that an IRB, a VA facility that is using the IRB of another VA facility or an academic affiliate. If it's using either, and, or both, it's no longer a requirement as of the effective date of VHA Directive 1200.05 for one of the small VA, I mean a VA with few protocols, 10 or less, or greater than 10, where you would have two members, you will no longer be required by national ORD policy to have representation on that external IRB.

Dr. Petrice Longenecker: Okay. Will affiliate IRBs be required to have any other type of VA representation, for example, WOC appointments?

Dr. Karen Jeans: ORD is not, I mean in terms of if we're using, if a VA facility is using an IRB of its academic affiliate, ORD will have no requirement that a VA facility must place, designate a VA employee, whether that be a paid or a WOC employee, to be on the academic affiliate's IRB. That is a local decision.

Dr. Petrice Longenecker: Okay. Sorry. We are one site in the upcoming NIH multi-site study with John Hopkin's University serving as single IRB of record. Presently, we as VA, have been deemed exempt from this rule. Can we expect that if we don't receive approval prior to January 21st, 2019, we could cede IRB review to John Hopkins?

Dr. Karen Jeans: In order to, one of the reasons that we put this policy in was indeed recognizing the TINs, the Trial Innovation Network. Which indeed, as we support the single IRB initiative, we also support the TINs. And so I do have follow ups in terms of when is that study starting because you don't want to be transitioning in the middle of the study. I don't know the status of it, but this would be one that we cannot do it until 1200.05 becomes effective. But

this is, indeed, a great scenario in which you could indeed request ORD to approve John Hopkin's IRB as a TINs, you know, to cede IRB review if John Hopkins would also agree with this and we would be working with the Office of Research Oversight.

Dr. Petrice Longenecker: Okay. Next question. Can an exemption determination be made by the full board or does it have to be done by an individual?

Soundia Duche: I mean there's no restriction. You can do it by the full board. I don't know why you'd want to.

Dr. Karen Jeans: Yeah. There's no requirement. There's never been an ORD policy that the convened IRB has to make the exempt determination. Excellent question.

Dr. Petrice Longenecker: Okay. It would be useful to have a future education on how things will work when another IRB, such as Hopkins, is the IRB of record. Will the local IRB need to do anything? What is submitted to the R&DC? Also, how does a non-VA IRB get approval by ORD? Does it make any sense for VA university affiliate to apply for the status to enhance affiliate VA collaborative research while the VA keeps its own IRB for VA only research?

Dr. Karen Jeans: I agree. And because, you know, it's very interesting in terms of what is the role of the IRB. For example, like when we're using NIH's IRB. They are not a covered entity. And we are a VHA healthcare system that is a covered entity. And so, you know, they are not able to issue waivers of HIPAA authorization. And so when we are using external IRB's, and I'll use that phrase, where that IRB does not want to assume HIPAA functions, it's got to be done by someone else. And so this is actually a very, very good topic and it's something that we hear you loud and clear. And again, in order for the single IRB initiative to be facilitated within our agency, it does have to become very transparent what are the institutional versus the IRB responsibilities. So absolutely, 100%, right on with what you just said. Absolutely concur.

Dr. Petrice Longenecker: Hey Soundia we're at 3:44. I don't know if you want to take a few more questions or.

Soundia Duche: How many more questions do we have, Petrice?

Dr. Petrice Longenecker: We have quite a few. We have got a total of 52.

Soundia Duche: Why don't we take three more.

Dr. Karen Jeans: Let's take more.

Soundia Duche: Let's take a few more.

Dr. Petrice Longenecker: Slide 26. Do exemptions to II (iii) and exemption 3 (ic) need a PO and ISO input?

Soundia Duche: Are these, I think they're referring to most likely the limited IRB review requirements. I think those exemptions trigger the limited IRB review for the privacy and confidentiality.

Dr. Karen Jeans: The issue is, it all goes back to any, almost any, study you do. You know it depends on what you're doing whether or not it needs PO or privacy officer review. Because even non-exempt studies will usually need a privacy review to make sure that the data is de-identified. So it's a relative question.

Soundia Duche: Right. Right. So remember, you know, the ISO's and PO's serve as advisors to the IRB in the same way if you had a study that dealt with a specific population and you needed to get expertise you would bring an advisor on to weigh in on that issue. So if there are certain privacy and confidentiality issues that need to be reviewed by your advisor, your PO, ISO, you would take it to them for their input.

Dr. Petrice Longenecker: Okay. A couple of questions about the conflict of interest. Will the IRB still be required to have investigators fill out the current financial conflict of interest form, FCOI?

Dr. Karen Jeans: So in terms of the, it's actually not an IRB requirement. It's actually the Office of General Ethics. The ethics lawyers developed the ALT-450 because VA, as part of an IG issue, needed to have a standardized form for VA investigators to report conflicts of interest. And those conflicts of interest would then be vetted through some type of process. Now we do not have a VA national policy on COI yet. It does not mean that that form does not have to be completed because this is, indeed, the recommendation of the Office of Government Ethics within VA and indeed that form was developed [unintelligible 1:39:56]. So investigators still have to complete those forms. It's just that the IRB does not have to be the gatekeeper. Financial conflict of interest is a legal determination. And so whenever there is a positive response to that, those responses should be vetted to the appropriate authorities to determine whether or not a financial conflict of interest does exist. Then it goes back in terms, if there is one, then that is something that should be reported to the IRB. But the management of it in terms of them being the force that processes the forms, vets the forms, that's not an IRB function.

Dr. Petrice Longenecker: Okay. Will some of these changes regarding COI and Veteran relevance of research be the responsibility of the R&D committee? And will there be any updates to the R&D Handbook?

Dr. Karen Jeans: There will be updates to the R&D Handbook. You're exactly right. Because it's more institutional rather than IRB. Excellent question.

Dr. Petrice Longenecker: Okay. Regarding privacy provisions in 1200.05, the proposed 1200.05 refers to the alteration of HIPAA authorizations, however, the VA Privacy Office has stated that they do not allow alteration of HIPAA authorizations. Has their position changed?

Dr. Karen Jeans: No their position has not changed and I do believe we have addressed that in the version that is currently at OGC. But you're correct, yes, VHA privacy does not recognize an alteration in HIPAA authorization. And I think Soundia's slide is about alteration of informed consent. So we do not recognize an alteration of HIPAA authorization elements in ORD.

Dr. Petrice Longenecker: Or maybe they were just talking about the change from having a separate form to allowing it to be included into the informed consent document as one document.

Dr. Karen Jeans: It's not an alteration.

Dr. Petrice Longenecker: Right. But the actual elements have not been altered, correct?

Dr. Karen Jeans: No the elements haven't been altered. The elements are the same. Even if you put them out on a separate form, I mean, the elements are unchanged. The format can be stand alone or combined but the valid elements of a HIPAA authorization must be present in either. No exclusions.

Dr. Petrice Longenecker: Okay. Next. Regarding the removal of the PO ISO requirement, does this mean that the ISOs and POs will no longer have to do a formal review?

Dr. Karen Jeans: What we're doing is saying that as part of ORD national policy, that we are not interjecting ourselves into mandating that these individuals be on the IRB, mandate their appearance or their presence on our committees. We are saying that it is the responsibility of all investigators to conduct research in compliance with all applicable privacy and information security of human subject regulations. So at the end of the day, we've taken out the requirement of when it happens. It doesn't have to happen before IRB review. But if the study has an issue, for example, I have a study right now that is dealing with apps. There's no way this study can go through with apps without having an ISO review. That ISO review can occur during the IRB review period, if it's applicable to the IRB approval criteria, or it can occur during the R&D committee as part of an institutional issue. But an ISO has got to look at it because it's not the ability of the IRB itself to decide whether or not this app can be used for this VA research project. So it really, you know, it depends upon the applicability of it. But if it is an ISO issue, they have to be involved.

Dr. Petrice Longenecker: There's been a request for further education on the role of the ISO and PO in the approval process. Okay.

Soundia Duche: Next question.

Dr. Petrice Longenecker: I'm sorry?

Soundia Duche: We'll take note of that for sure.

Dr. Karen Jeans: Thank you. Thank you.

Dr. Petrice Longenecker: What is the IRB responsibility if a conflict of interest is reported? Can they approve the study without a management plan in place?

Dr. Karen Jeans: Well again, it's all about the ethics. And this is where, you know, it gets back to the ethics of the research. So the IRB has to decide whether or not if the person has a conflict of interest as determined by, let's say financial conflict of interest, okay can it be done ethically? What needs to be disclosed to the subject? Should the subjects be informed of that? Is that something that would affect whether or not their decision to participate in a study, particularly if that study is a high risk study and that, for example, there's a patent involved? So you get into more of the ethical issues when there's a conflict of interest. How do the ethics of knowing that information involve the approval of the study? And what should be disclosed to the prospective subjects that may affect their participation in that study?

Dr. Petrice Longenecker: Okay. Under the past rules, IRB's were not required to do expedited review. It was an option, even if the study qualified. Is this option now not available?

Soundia Duche: No. It's still an option. An IRB can, you know, only do convened board reviews. What has changed is that if your subject to the 2018 requirements and you conduct a convened board review on a study that's eligible for expedited review, you will now have to justify that.

Dr. Karen Jeans: Exactly.

Soundia Duche: That's the key. Whereas before you didn't.

Dr. Petrice Longenecker: Great to hear about the VA's approach to continuing review and the R&D committee not needing to have to do continuing review. I think about those expedited studies that won't require continuing review for the Common Rule. What about exempt human research being followed by the R&D committee? Do those studies no longer need yearly continuing review by the R&D committee?

Dr. Karen Jeans: You know our current policy, if the exempt study is not under oversight of any other committee such as, you know, the IRB, the IACUC, or SRS, then it still requires continuing review by the R&D committee. That's the current policy of 1200.01, thank you.

Dr. Petrice Longenecker: Okay. If a study is greater than minimal risk and later goes into data analysis phase, so data analysis only phase, continuing review would no longer be required

even if the IRB didn't change the risk level to minimal risk once it got to data analysis phase, correct?

Soundia Duche: Yup, if it is subject to the 2018 requirements.

Dr. Karen Jeans: Right. Yeah. Because it's all about, even under the current Common Rule, you know, it's eligible for expedited review now under the 2018 requirements. It's basically under that type of area where it does no longer require continuing review. Is a study was initially approved as greater than minimal risk but the current activities are minimal risk.

Soundia Duche: Yes.

Dr. Petrice Longenecker: Okay. Has the VA, as an organization, taken a specific position on implementing broad consent or will the decision to implement broad consent be on a VA specific location?

Soundia Duche: No I think what was clear through the slides, hopefully, is that VHA Directive 1200.05 will be in alignment with the Revised Common Rule except for specific issues, or specific aspects of broad consent which we talked about. The documentation, we will require documentation of broad consent and we also will require that broad consent only be used when information data or specimens are collected solely for research purposes. Those were our specific caveats.

Dr. Karen Jeans: That's it. That is the position of the agency on very narrow use. Broad consent is very, you know, complicated. So it can only be used in very rare circumstances within the department and so that is going to be the agency's position as will be reflected in the policy.

Dr. Petrice Longenecker: Okay. Regarding slide 36, if a broad consent is combined with a traditional informed consent form, does the broad consent need its own signature block for the participant separate from the signature block for the traditional ICF?

Soundia Duche: No. No. What we just said was that if combined, the information provided to subjects for the broad consent, so the part that will be used for storage and future use, must be very clear and separate from the study specific one. Now does that mean that, you know, do you have a checked box per se, or not? Maybe, maybe not. But we're talking, yes, about signature's specifically.

Dr. Karen Jeans: But again, you have to be careful here because, again, you're talking about design. So I'm going to be, again, we're on this format but, again, is it an option? Because you're dealing with broad consent. So I'm assuming this is an optional component, otherwise, it would be a mandate. So this really works for optional components. And if it's an optional component, then you're going to have some way to differentiate between the primary consent for the primary study. And then the second consent process, which is for the secondary use of

identifiable, you know, biospecimens and end data, and or data, depending on what that situation is.

Dr. Kristina Borrer: Hi. This is Kristina. I just want to echo that and that basically you can't condition, you know, participation in a specific research study on the subjects signing a broad consent form for unspecified future research.

Soundia Duche: Thank you.

Dr. Petrice Longenecker: Okay. Regarding case study four, I don't know if you want to pull that one back up, Soundia, do CAPRI and JLV equate to CPRS (not collected for research)?

Soundia Duche: CAPRI? I assume they're talking about various VA databases. Because the example we just talked about CPRS. So the question was, do CAPRI and what else, Petrice?

Dr. Petrice Longenecker: That's JLV?

Soundia Duche: JLV. We're just, unfortunately, maybe you can send that question to us. We're not sure. The key thing is if the information was collected for non-research purposes. So if that information, if CAPRI is collecting information as part of clinical care and then CAPRI is accessed for research purposes, they could not use broad consent for that because the information that was used to populate CAPRI or JLV was obtained for clinical purposes.

Dr. Karen Jeans: Exactly.

Soundia Duche: I'm not familiar with those two specifically, but I think.

Dr. Karen Jeans: Yeah. It's like if you say you were populating for CMS, no. CMS you know, is Center for Medicare/Medicaid Data, that is not a research database. It's getting data from, you know, it's for clinical payment issues.

Dr. Petrice Longenecker: Okay. We have a statement that I think maybe you want to clarify it. Going to need more education about broad consent for data collection for research studies seems like eliminating the ability to use data collected from CRPS and put into a study database is too restrictive.

Soundia Duche: And we can take that up but that is our policy.

Dr. Karen Jeans: Yes. For broad consent. The implications are huge. If the subject says no, for the rest of that subjects life, basically forever, even after, you know, that data can never be used by anybody, anywhere, no researcher, no anybody. Because the subject has said no. They don't want that clinical data that you asked to be used for research to be used for research. Point blank. So that is why broad consent is being cautioned. Many, many people are very, very concerned about this outside of the VA. At the PRIM&R Conference there were quite a

few interesting things said about it. But this is the way that our agency has chosen to best manage it and to deal with it.

Soundia Duche: I think, Petrice, let's just do two more and then we're going to wrap up.

Dr. Petrice Longenecker: Okay. So let's see, how does the IRB know what HIPAA information is necessary in a combined informed consent and HIPAA document?

Soundia Duche: Well there's certain required elements of HIPAA and the fact that you combine it with an informed consent does not negate the fact that you have to still have all of the required elements of HIPAA. So in terms of how does the IRB know? Your privacy officer would be a good source here, 1605.01.

Dr. Karen Jeans: Yeah. HIPAA. The privacy rule, by law, states what are the elements of a valid HIPAA authorization. So it's a law. And VHA Directive 1605.01, again is VHA's operationalization of what is required for a valid HIPAA authorization. So those authorization elements are there. We do plan, prior to January 21st, 2019, to issue an example template. For example, the Central IRB is working on one right now. And so we do, indeed, plan to publish some so that you can, indeed, see what's a good example.

Soundia Duche: Excellent. Thank you.

Dr. Petrice Longenecker: Okay. We'll close on this last one. Will there be any VA specific requirements that are not addressed in this material? If so, could you please let us know what they are or at least the topics or areas.

Dr. Karen Jeans: So there are, indeed, other VA specific requirements which are not in this presentation. Some of these are because they are issues that we are dealing with The Office of General Counsel. So we really can't, we don't know what direction those will go in. We do not talk about the vulnerable populations but those are in the slides. There's some small nuances as well that we didn't cover today and we will, what our plan is, is to hopefully be able to publish even the proposed 1200.05 after OGC concurs prior to publication but we'll have to get a sign off on that. And so as soon as we know the final version, you will see it as well. So this today, is a very good comprehensive overview of where we are in alignment and where we are not and what we've done for VA specifics. And along with the tool that was uploaded, we strongly encourage you to use that tool. We'll be issuing others to move forward because at PRIM&R there was a rampant rumor as well that this is not going to happen. It is. It is.

Soundia Duche: It's here.

Dr. Karen Jeans: There is no more delay. So it will happen on January 21st.

Soundia Duche: Right. Right. And so for everybody the PRIDE Cyberseminar webpage has all of the recordings. And I really encourage folks to go back because you'll get all the information

you need. Each of those trainings, as I mentioned, an hour and a half, hour 45. Our upcoming trainings that we currently have scheduled, we will have additional trainings. But currently scheduled, ORO will be presenting on December 4th, External IRBs and FWAs. They'll be talking about that. And then right now we have scheduled on December 18th, another in-depth focus on VHA Directive 1200.05. But we're going to pick up on the vulnerable population section that we didn't touch on here. We'll be able to answer any questions that we weren't able to get to. So I'm going to get those from Petrice. And then we'll also, you know, delve into a bit more of 1200.05 and try to tweak it and approach it from a different angle. Our goal is, really, to keep, you know, bringing you more information as we, you know, lead up to the January 21st date. We will be having training on transitioning and we're working on some guidance on that for you as well.

Dr. Karen Jeans: And we will be publishing a list on what guidance's we are planning to issue as well as releasing those as we go. We are not going to hold them all and release them all at once.

Soundia Duche: Right.

Dr. Karen Jeans: So you'll be seeing that list very shortly, along with more guidance documents.

Soundia Duche: Right. I want to thank everybody who stuck in. This is an incredible amount of information. And so we apologize that we went over but we wanted to be able to answer questions. We wanted to be able to get everything to you and, as you see, we still had a whole section we weren't able to. But we will pick up on that on December 18th and publish our list of additional trainings in the near year for you. There is a survey that's going to pop up when you exit. Please complete it because that will really tell us, you know, what else do we need to focus on particularly between now and January 21st to be able to have everybody ready for implementation of the Revised Common Rule. Thank you, everybody, for your time. We really appreciate it. Have a great evening.

[END OF AUDIO]