ORPP&E Webinars
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Presenter: Kristina Borror, PhD, C. Karen Jeans, PhD, Soundia Duche, MA, MS

Soundia Duche: My name is Soundia Duche and I'm going to be one of three presenters today. We have Dr. Karen Jeans who is going to be joining, well is joining us, remotely and Dr. Kristina Borror, also remotely. So we're operating from three or four different locations today. In the room with me today is Lucinda Shouse whose helping to manage the presentation and, as you all know, Petrice is our administrator for the presentation today. So it's a real team effort.

As Petrice mentioned, this is the follow on to the two September Cyberseminars that ORD and ORO conducted and are goal is to; 1) We're going to be answering the remaining questions from both Cyberseminars. We've grouped them into topics, related topics and so Kristina, Karen, and I are going to take different topics and be responding to those questions. We are then going to speak a little bit about the Revised Common Rule and FDA regulated research. There's some recently released guidance how the provisions affect FDA regulated research. So we're going to comment briefly on that and then the remaining time is going to be an open Q&A session to address any additional questions you all have. So our hope is to break this up into two parts where it's kind of 50/50 where we leave about 45, 30 to 45 minutes for the open Q&A session at the end. Let me show my slides, let's see.

Right. So first always want to frame and remind people where we are. We are marching towards the January 21st, 2019, compliance date whereby any studies, all studies approved on or after January 21st, 2019, must be in full compliance with the Revised Common Rule, otherwise known as the 2018 requirement. The only provision of the Revised Common Rule that you will not need to adhere to is the cooperative research provision, and that compliance date remains January 20th, 2020. Our current Common Rule is also referred to as the pre-2018 requirement. The reason being, initially, the Revised Common Rule was set to go into effect this year, on January 19th, 2018, but we had two delays that delayed the compliance date until January 21st, 2019. So going on to our questions, our first group of questions is transitioning studies and I'm going to cover that.

So one of the questions we received that we couldn't get to was, what is the current timeline for updating VA guidance and requirements to synchronize with the Revised Common Rule? And, what's the current feeling in the various DC offices of the potential of this policy actually going into effect on January 21st, 2019?

Well one thing I want to say is the Common Rule is going into effect on January 21st, 2019. So no ifs, ands, or buts. And we fully believe that we will be ready to fully implement VHA Directive 1200.05 on that date. VHA Directive 1200.05 is in concurrence right now and our working timeline is that we hope to have it issued early November and begin our training on the revised directive towards the end of November. And we're going to have a number of

series of Cyberseminars specific to the changes in VHA Directive 1200.05. We are also in the process of developing a number of VA specific guidance documents. And our goal is that those, the critical documents will be released concurrently with the revised VHA Directive 1200.05, okay? So look out for, we really see everything kind of moving early January. And ORD and ORO we're also in the process of working with the other Common Rule agencies on supporting guidance for the implementation of the Revised Common Rule. OHRP has a lot of guidance that they're going to be developing and we've had the opportunity to look at some of them and comment on them. So there's going to be a lot of guidance that's going to be rolled out in the very near future.

When are changes being made to 1200.01 and 1200.12? Well 1200.01 is the VHA Directive that concerns R&D committee and 1200.12 is the handbook that covers data and data repositories in the VA. So both handbooks are currently being revised. 1200.01 is undergoing concurrence and 1200.12 is in the process of revision. So we have not entered the concurrence process for 1200.12. We anticipate that that will be issued sometime in 2019. We don't have a date given that it hasn't started the concurrence process. As soon as we hear more on 1200.01 and where that is, we'll be sure to let you know and, again, we'll be having training on 1200.01 as well to get everyone ready for that.

Our current IRB approved studies do not have to be transitioned to the 2018 requirements/ Revised Common Rule, correct? And that is indeed correct. There is no requirement to transition any study that was approved by the IRB prior to January 21st, 2019 to the Revised Common Rule unless; 1) The IRB decides to transition the study to the 2018 requirements and in order to do that, the IRB would have to document that decision and make sure that all of the requirements pertaining to the 2018 requirements are met for the research study or, 2) The study was approved prior to January 21st, 2019, and during, I didn't really talk about the three burden reducing provisions, we've talked about that previously but in this past delay, past six month delay, starting July 19th, 2018, the federal agencies allowed the implementation of three burden-reducing provisions. One of them was allowing the use of the revised definition of research, 2) eliminating continuing review for certain types of research and, 3) Removing the requirement to review the grant application. Now only two of those could be utilized by VA research institutes and that is starting to use the new definition of research and then elimination of the review of grant applications. So in instances where an IRB elected to start implementing one of those two burden-reducing provisions, that started the clock and those studies have to be transitioned to the Revised Common Rule on January 21st, 2019. But short of that, you do not have to transition any study approved prior to January 21st, 2019 to the Revised Common Rule requirement.

Next set of questions is about reclassifying studies. Great questions and timely topic because many of you will be thinking about how to best take advantage of some of the flexibilities that are afforded by the Revised Common Rule. So this question deals with studies involving data analysis or retrospective chart review only that were approved under the pre-2018 requirements that might now qualify for exemption under the 2018 requirement, how would those be transitioned? And could they be transitioned? And if they can't be transitioned to

exemption, could they be re-classified so that they no longer require continuing review, which is one of the flexibilities afforded by the Revised Common Rule whereby certain research no longer requires continuing review.

And so when you're thinking about how best to look at your portfolio and determine which studies are eligible for re-classification, if you're looking at studies that are expedited currently and trying to determine if they are eligible for exemption, and a number of them may very well be, in the example given where you're looking at research studies that are using chart reviews and pre-existing data in order to transition them or determine if they're eligible for transition to the Revised Common Rule and then make them exempt under the Revised Common Rule, the IRB would need to look at the criteria for the exemption, make sure that all the criteria are met for the study, and if they are, the IRB would then need to document that the research has been transitioned to the 2018 requirements. Now some of that research may not be eligible for exemption but you still may decide I want to transition it to the Revised Common Rule so I can take advantage of just some of the flexibilities, in particular, the continuing review that the individual asked who submitted this question. In those cases, the study will stay expedited. It was expedited under the pre-2018 requirements. It will continue to be expedited under the 2018 requirements but remember now, with the 2018 requirements, there's some additional IRB approval criteria that must be met. And so the IRB would need to review it and make sure that the new study meets both requirements. There might be some additional documentation that needs to be submitted, some forms completed, some waivers that need to be addressed. And if all of those criteria are met, at that point, the IRB would need to document that the research had been transitioned to the 2018 requirements in order for the research to no longer require continuing review.

In terms of steps that we can recommend to transition the study that was expedited under the pre-2018 requirements, it's kind of what I just was saying, you first want to look to see is this study eligible for an exemption? Does it meet any of the exempt criteria? If it does, the IRB would document that they want to transition it and it's being transitioned under exempt category, whatever it is. If the study continues to qualify for expedited review, it does not qualify for exemption, then as we just described, the IRB would review all the study materials and ensure that all 2018 approval requirements, consent form related issues, waivers, make sure all of those are met, and then document that the study has been transitioned to the 2018 requirements.

Waivers of informed consent. So this question asks if a study involving a retrospective chart review is going to be transitioned to the 2018 requirements, would we have to obtain a new waiver of consent containing the new waiver criteria stipulating that the research could not be conducted without using identifiable private information? And in the text below here, you see the criteria for waivers of informed consent for minimal risk studies under the Revised Common Rule. Number three, in red, is the one new criterion that was added to the Revised Common Rule. And that is that the IRB must determine whether if the research involves using identifiable private information or identifiable biospecimens that the research cannot

practicably be carried out without using such information or biospecimens in an identifiable format.

So if you're going to be transitioning a research study to the 2018 requirements then yes, the IRB would need to make sure that that waiver criteria has been met, okay? Any research study that is transitioned to the 2018 requirement on or after January 21st, 2019, must follow all of the requirements. I really want to stress that. So anything to do with additional approval criteria. Anything to do with waivers, possibly consent form changes. All of those things would have to be taken into consideration. So the answer is yes.

All right. Informed consent. I'm going to pass the torch onto Karen. I think she's handling informed consent for this section.

Dr. Karen Jeans: Yes I am. It was a perfect lead in by talking about waivers of informed consent. So now we're going to answer some questions that we didn't get a chance to last time on informed consent. So the question is, if a study is approved under the 2018 requirements and it's collecting identifiable information

Soundia Duche: One sec. We're having a little bit of technical challenges.

Dr. Karen Jeans: Really?

Lucinda: I don't know how to give you back control.

[unintelligible 12:27]

Dr. Karen Jeans: Okay. Let me know when I can proceed. Okay? We're good to go now?

Soundia Duche: I can hear you now. We're back. Sorry about that.

Dr. Karen Jeans: Okay. No problem. Hey it is all good. So this question is about whether or not you need to require two separate consent forms. That if you're doing the standard consent form and that's one of the phrases that, you know, some call it the primary consent form but the standard consent form, and you're approving that consent form under the 2018 requirement and you want to use, you know, store the data and/or identifiable biospecimens for future use, do you have to have a separate consent form in order to do that? And you know, the regular or the standardized ICD, Informed Consent Document, with required new elements for current use, and a broad consent.

So the answer is, next slide, perfect. In the regulations themselves, it does not require two separate consent forms. Now the issue is is to make sure that if you do have broad consent, that it is very clear what is and is not part of the standard consent form versus the broad consent form. So subjects will understand if you do combine it what the subjects are agreeing to. And one thing that's really important here is the second bullet in that it's an option. Now

there's a misconception going on, and this is not within VA but outside the VA, we hear a lot of different topics. And one thing that's going around right now that I wanted to have the opportunity to address on this call is that there is a misconception, a rumor, that in order to reuse identifiable biospecimens and identifiable data or information for future use, if you have a study approved under the 2018 requirements, you must use broad consent. And that is not true in any way, shape, or form. And so if it's like it says on the second bullet, it is an option that applies to reuse of identifiable biospecimens, identifiable information for secondary research. If you didn't use broad consent, you still have the options that you have right now. You still can, you know, of course you can reuse de-identified information or biospecimens. But you also would have the ability, just like you do now under the waiver of informed consent requirements, if those informed consent requirements are met to be able to reuse that identifiable information and/or identifiable biospecimens for secondary use. So that's why we want to emphasize that. You know broad consent is an option. It is not a requirement for secondary reuse of identifiable information or identifiable biospecimens. And the last bullet is really important. Broad consent can never replace the informed consent that is required by the IRB for the initial collection of the data or biospecimens. Broad consent is for the storage and the maintenance and the use. It's not for the actual collection aspect. So you've got to have, you know, the standard consent for that aspect before you can proceed to the broad consent, okay? Next question.

Oh I didn't finish. Okay. And so on this slide here is talking about, you know, why you would want to use broad consent. And again, it's an option because exempt category 7 and 8 specifically speak to the use of, the secondary use of, identifiable data and or identifiable biospecimens, but the condition is you have to use broad consent. But there's a real big issue with broad consent and that's why it's an option rather than a requirement. You do have to track when you offer broad consent to somebody and document whether or not they refuse it or not. And this is why it's very limited in its use in terms of practicality for using for, what I call, you know, your clinical specimens. These are not your specimens that are collected specifically for research. So that's a major issue in terms of successful implementation of the broad consent. But one thing that has to be emphasized is even if a subject, you offer broad consent and they say no I don't want my identifiable specimens or my identifiable information to be used, it doesn't, because they refused broad consent, state that it cannot be used in a de-identified form. So that's a very important issue to remember about broad consent if you decide to use it, okay? Next question.

Okay and again this gets back into the tracking. Broad consents are difficult to monitor. Can an investigator simply exclude individuals who refuse to provide broad consent? And this is really not only to think about it in terms of broad consent but this is about when you have studies in which there is a secondary use of biospecimens and/or information involved whether or not it's a required versus optional component of the study. So that's what this question really is about. It's really not about broad consent, although broad consent is the question. It's can you approve a study if the subject says I'll let, you know, I want to do the standard study but I don't want to do the biospecimen repository for future use or the database for future use for identifiable information, in this case, since it's broad consent. And that's where you get into

study design in the IRB itself. Because when is it required, when is it optional? Is it ethical to conduct that research when it's a required component? Or is it ethical to say that it should be an optional component? There are studies which by the nature of their design it demands that there is a required banking component because it's necessary in order to do the primary study. But at the end of the day, that's why we have institutional review boards to evaluate whether or not it is an optional versus required component. And so that, that's what this question is about. So it all depends on the research design itself and whether or not the IRB approves it as a required versus optional component for future use of biospecimens and/or information that's identifiable. Next question.

Oh great. Does broad consent have to be documented in CPRS? There's no current requirement in ORD policy. It doesn't exist now that informed consent has to be documented in a VHA health record when informed consent is obtained for storage and future use of biospecimens and/or data. So there is no requirement in the Common Rule itself, as well as the 2018 requirement. But what's important to remember and this is, again, speaking outside of broad consent, is that we are a healthcare system in VHA. And so the onus is on researchers. And that's why the subjective opinion of the clinician, rather than something that's regulated in policy by ORD is that if you have a research subject and, you know, they are participating in a study where other healthcare providers need to know about that, you put what is necessary in the medical record in order to ensure the safety of this subject who is also a patient in our healthcare system. Next question. Oh. Okay. So my section is gone for now and so I will pass this over to Dr. Borror.

Dr. Kristina Borror: Thank you very much, Karen. It's a real pleasure to be able to talk to you some more about exempt research under the Revised Common Rule and answer some of the questions that we didn't get to in our webinar that we gave on that. And so this first question on exempt research is, would all retrospective chart reviews using data in CPRS collected for clinical purposes now qualify for exemption under Category 4? If so, would they no longer require a waiver of informed consent? Would they still require a HIPAA waiver?

And the next slide shows some of the details, actually this is sort of a summary of exempt category 4. And to remind you this is one of the categories for secondary research use of identifiable private information or identifiable biospecimens. This is an exempt category for secondary use in which it doesn't require broad consent but it has to meet one of these four criteria. And that includes that the information or biospecimens are publicly available or that the investigator is recording information so that the identity of the subjects can't be ascertained, and the investigator is not going to contact the subjects or try to re-identify them. Another possible mechanism for using this exemption is if the use of the data or the biospecimens are regulated as healthcare operations research or public health under HIPAA or if it's conducted by or on behalf of a federal agency. And then in that case, they're only using data that is collected or generated by the government for purposes other than research and that there is federal privacy standards to protect that information.

So the next slide gives a little bit about what the response is for this. And it is true that if you're doing retrospective chart reviews and there is identifiable data that was collected previously for non-research purposes, for instance clinical purposes in this example, that it probably would qualify for exemption 4 under the Revised Common Rule. And related to the question about whether or not it would require a waiver of informed consent, remember that exemption 4 is exempt from the regulations. And that includes exempt from the requirements of informed consent or the requirement to get a waiver of informed consent. This is one of the exemptions that doesn't required limited IRB review and it doesn't require broad consent. But remember, you know, because the other question was about whether or not it would still require a HIPAA waiver. As Karen mentioned, VA is a covered entity and so we are subject to HIPAA and there is a requirement for authorization or a waiver of authorization for any research using personally identifiable information. So in this case, that would be a requirement for this type of research.

Next question is, will the R&D committees be able to provide HIPAA waivers? Or will IRBs need to continue to do this? And basically HIPAA requires that a privacy board or a committee that meets the requirements of a privacy board under the HIPAA rule, is able to approve waivers of authorization. So if an R&D committee is constituted like a privacy board as required in the regulations, then the R&D committee could actually approve those waivers. And that is an alignment with directive 1605.01.

Okay. The next one is about exempt category 5 and whether or not you would need CRADO approval and who from VA would publish the list?

So what list are they talking about? And the next slide shows some of the details about exempt category 5 and this is for research and demonstration projects. And those projects can either be conducted or subject to the approval of department or agencies. And there is specific kinds of research and demonstration projects that are specifically designed to look at public benefit or service programs. And there's not a big change from the pre-2018 rule to the 2018 rule. There's mostly just some clarifications that in addition to applying to those types of research and demonstration projects that are conducted by federal departments or agencies that it also includes ones that are subject to approval. And it also gives some examples of the specific types of public benefit and service programs that could be covered under this exemption. And as it relates to the question there is a requirement in the Revised Common Rule that any federal department or agency that wants to support these kinds of projects and say that they're exempt has to publish a list of those before the research can start.

And so related to the question, first of all we expect that use of this exemption category will be pretty rare within the VA. And that the, when it talks about departments or agency heads that have to approve this type of activity, that would be the VA secretary. And that when you're looking at possible activities that could be exempt under 5, those are ones that are basically going to be conducted by VA or subject to approval of the Secretary. And they have to be designed to evaluate public benefit or service programs of VHA.

And the next question is a question about exemption category 7. And the question is, what is meant by maintenance for secondary use? And as a reminder, exemption category 7 says it is for storage or maintenance for secondary use for those kinds of activities for which broad consent is required. So it talks about storage or maintenance. And so the question was, well we kind of understand what storage is but what the heck does maintenance mean? And basically we consider these to be synonymous terms. There's not really any indication either in the rule itself or in the preamble that maintenance means something special or has a different meaning from what is generally understood from the dictionary meaning. And storage and maintenance basically mean, by and large, the same thing.

And the next question is about exempt category 8 and it asks, what are examples where the law requires returning research results to subjects? So why did the questioner ask that?

If you look at the actual language of exempt category 8 it talks about the secondary use of existing private identifiable information and identifiable biospecimens. And in this case broad consent had to have been obtained and documented or the documentation has been waived. Now one of the requirements of using category 8 exemption, you may recall, is that the IRB has to do this limited IRB review and they have to determine that there are adequate provisions for privacy and confidentiality and that the use that is being proposed in this exempt research is actually within the scope of what was consented to in the broad consent. Category 8 also has an additional requirement that the investigator doesn't include returning individual research results to subjects as part of the study plan. However, it doesn't prevent investigators from returning results if that's required by law. So if we look again at this question that it's asking about this, what would be one of these kinds of laws? And really, this is related to what are the rights of the research subject and whether they have a right under the law to request research results. And these access laws and whether or not folks have rights to access, for instance their medical record or research record, really depends on state and federal law and those may be applicable. And so we're, you know, continuing to have discussions with other federal agencies and even some none governmental groups looking also at public advocacy groups. And so this is an important issue and so stay tuned for that.

The next question is about ISO and so that's Privacy Officer and Information Security Officers and whether their reviews are required for exempt studies. So you have to remember that exempt research under both the pre-2018 and the 2018 requirements is human subjects research. And all human subjects research that is conducted by VHA has to be conducted in compliance with all applicable requirements. So if there are any issues related to privacy or information security that relate to any human subjects research, even if it's exempt, those issues have to be addressed and resolved before the exempt research can be approved and go forward.

So the next question it asks for clarification related to studies with private identifiable information or protected health information and whether or not that could be considered exempt. It says if there is information security/noncompliance issue that is determined by the R&D to be serious, the FWA requirements says these do not have to be reported to OHRP

because the research study is exempt, correct? It is correct that exempt generally means that that human subjects research is not subject to the requirements of the Common Rule except for, as I mentioned, the limited IRB review and those broad consent provisions. And so those kinds of exempt studies if there were, you know, serious or continuing non-compliance or anticipated problems, there would not be a requirement to report that to OHRP. So that's one requirement, right, that's in the Revised Common Rule. But remember there are other reporting requirements that VA research has to meet and that includes the requirements in VHA handbook 1058.01. And in that case, it doesn't mention that those requirements don't apply to exempt research. So any human research requires reporting of information security incidents or any serious noncompliance issues to ORO. And that's irrespective of whether or not it's exempt under the Common Rule. So make sure that you follow the VA requirements in addition to those requirements of the Common Rule.

So we'll switch gears a little bit and talk about limited IRB review. And the first question here is who does this? Who is the actual reviewer? And the regulations at 110 actually say that this limited IRB review which, remember is required for certain exemptions, this can be done by expedited review. And if you recall, expedited review is done either by the IRB chair or somebody that the IRB chair has designated from among experienced members of the IRB. So that they have to be IRB members that are designated by the chair and they have to be experienced.

And the next question is about limited IRB review procedures. And it says, is limited IRB review only required at the time of initial review or will the study continue to require limited IRB review at continuing review? So remember this is exempt research and exempt research doesn't require continuing review. But just to be absolutely clear, the Revised Common Rule states at 109 that continuing review is not required for research that requires limited IRB review. And again, remember, that's only certain exempt research. So just to be crystal clear, the Revised Common Rule spells that out.

The next question is whether there's a requirement for documentation of limited IRB review and approval criteria? While the Revised Common Rule doesn't include a documentation requirement for that, VA has a requirement that IRB approval criteria have to be documented. And so this would be part of those same IRB approval criteria. It's just done in a limited manner. So those would have to be documented under VA rules.

The next question, again about limited IRB review, is noting that if it's done in an expedited manner, which we noted it can be done, to move it forward to the R&D committee, does it need to wait until the convened IRB meeting to be documented in the IRB minutes? So the Common Rule, both the pre-2018 and the Revised Common Rule 2018 requirements, require that the IRBs have to have a mechanism for informing all IRB members of studies that have been approved by expedited review. And the IRB's have a fair amount of flexibility on how to do that and whatever method that your facility uses to notify IRB members of those expedited approvals can be used for limited IRB reviews if they're conducted by expedited review. And

this is basically just using whatever expedited review listing you do. Many do it in the IRB minutes, but I don't believe that that's required.

The next question is, again, about ISO and POs and it says, for limited IRB review I assume that it's not just the IRB that is reviewing the privacy and confidentiality requirements but also the PO and ISO? So as you may remember that for most of the exemptions that do require limited IRB review, one of the things that the IRB is looking at is the adequacy of the privacy and confidentiality protections and the research. And this slide notes that 1200.05, as was noted at the beginning by Soundia, that it's under revision and the revision will address this limited IRB review. And basically just remember that all VA research has to apply, you know, follow all of the applicable requirements and that includes VA directives. So if there is an issue that would require the ISO or the PO to look at, to make sure that the research is in compliance with those requirements, then those groups would have to be consulted.

And next we will turn it back over to Karen.

Dr. Karen Jeans: Yeah it's me, it's me again. I love talking about continuing review because there was a question that was asked on IRB forum today that I thought was very pertinent to this discussion so I'm going to incorporate that as we talk today, okay?

All right. First a question that's very specific to the VA. Will the R&D committee be required to conduct continuing review for expedited review approved under the 2018 requirement in cases where the IRB no longer is required to conduct continuing review? Excellent question and the answer is no. Under 1200.01, and I'm talking the current 1200.05, 1200.1, excuse me, which is the R&D committee handbook, the R&D committee is the approving and oversight committee for any research that is not under the oversight of another committee or subcommittee. Now even in these cases where, you know, there's an IRB research study that's eligible for expedited review is approved that way, it will no longer undergo continuing review unless the IRB specifically documents why it's going to be required to do so. So for these studies that no longer require continuing review when they would have in the past under the pre-2018 requirement, the R&D committee will not be required to conduct continuing review because these studies are still under the oversight of the institutional review board of record. Unless and there's always, I have this caveat here, it is required by a local policy. But the Common Rule itself does not require it and our current R&D handbook 1200.01 does not require it as well. Next question.

Oh and so that was the answer that I just discussed, okay? So next question. I do want to bring up one issue before I hand this over to Soundia. Today on the IRB forum there was a really good practical question that was asked. And it was, for those studies that were just in the example used in that question where there is no continuing review because the default position under the 2018 requirements for behavior studies approved under the 2018 requirements for example is they're expedited, what does the letter say to the investigator? How do you communicate to the investigator oh by the way, your study is approved under expedited category, let's say expedited category 4. Or you know, you no longer have to conduct

continuing review, what do you say to them? And so that was a topic of discussion because policy is silent in terms of our current, it doesn't exist in current policy, but become [unintelligible 42:25] silent on how that keeps up. So in terms of thinking about this, in terms of processes, in terms of successful implementation of the Common Rule, that is something that also has to be considered. What do you tell subjects? And one of the responses today was we're going to have some kind of check in. Now is it mandated by policy? No. Is it mandated by the Common Rule policy, I mean, no, by the 2018 requirement? The answer's no. But that was a very practical question of what do you communicate to investigators to let them know, you know, when you no longer require continuing review, it still means you're under the oversight of the IRB. And so how to convey that accurately to the investigator to ensure that they know, by the way, you still have to tell us if something is changing in your protocol, you know. You still have to keep up your adverse event reporting, your interim reporting that's required by IRB policies. And then, of course, so that the IRB has a process to know when to close the study. So that is just something that I wanted to relay because as you see on the screen today, these are all the different continuing review categories that are no longer required by the 2018 requirement if the study is approved or transitioned to the 2018 requirements. And this is the default position where continuing review is not required. And so what do you communicate in your letters? And how do you make sure the investigators know you're not off the grid? You're still human subjects research that is under the oversight of the IRB. So that is an issue for consideration that I thought was very relevant to today's conversation.

Soundia Duche: Excellent. Thank you Karen. It's very helpful. Why is this not working? Okay. So I'm going to talk very briefly about, excuse me, the Revised Common Rule and FDA regulated research. Now as a signatory to the Common Rule here at VA, we all know we're subject to both the Common Rule requirements and FDA requirements when we're dealing with FDA regulated research. And given that the Common Rule has changed and we're all going to be required to be in compliance with it as of January 21st, 2019, the question has come up multiple times, so what does this mean for FDA regulated research? Because while FDA intends to undertake rulemaking to harmonize to the extent practicable with the 2018 requirements, that has not been done yet and it's not clear if that will be done by January 21st, 2019. So it's very timely that FDA just recently issued a new guidance document. It was issued in October. Kristina was it just issued this week or was it last week?

Dr. Kristina Borror: It was issued on Friday, last Friday.

Soundia Duche: There we go. Hot off the press. So the title of the document is Impact of Certain Provisions of the Revised Common Rule on FDA Regulated Clinical Investigations. It's a short guidance document so it's not comprehensive. But it really talks about some of the key pressing issues that are going to come up and that study investigators who are subject to both requirements will need to know how to handle come January 21st, 2019. One of the things always to remember in cases where the regulations differ, usually the regulations that offer the greater protection to human subjects should be followed. That's always been the case and that

continues to be the case. But in this guidance document, FDA covers three specific things and comments briefly on them.

One, informed consent. And we all know there have been many changes to informed consent. There have been changes to waivers. There's been the introduction of broad consent. There's been the change in the informed consent process. The template's going to look different. We have to start with key summary information. So in this guidance document the FDA talks very specifically about what particular aspects of the 2018 requirement, as it pertains to informed consent, do not contradict FDA regulated research. Where they are silent, that does not mean you can proceed. So only where they mention that, hey, these specific aspects are not inconsistent with FDA current policies and guidance. And with respect to informed consent, what they state in the guidance document is that the 2018 requirements related to the content, the organization, and the presentation of information, including the consent process as well as the basic and additional elements of informed consent, are not inconsistent with FDA current policies and guidance. So essentially, the new template that many of us are going to be using for informed consent where we have the key information, the basic and additional elements, remember there were a couple of new ones, I think there was one new basic element and then there's a couple of new additional elements, none of those run counter to current FDA policies. And therefore, for FDA regulated research, you would not need a different informed consent process or template when you're dealing with kind of the typical informed consent. I really want to stress no reference in this document was made to broad consent provisions. So that is not a pass to use broad consent for FDA regulated research until we hear more from them. They were very specific on what aspects they feel are not inconsistent with their policies and guidance. The second thing is expedited review. Now you'll know that expedited review categories, themselves, have not changed yet. The Secretary's list that was published still remains the list that will be in place as of January 21st, 2019. What has changed, however in the Revised Common Rule, is the presumption that all research on that list is minimal risk, okay? Prior to this, currently what we have to do is we have to assess the study and make sure that all activities are minimal risk and then we look at the list. Whereas in the Revised Common Rule the presumption is that all activities on the list are minimal risk. What FDA is saying in this guidance document is they have not changed their stance on expedited review for now. And so you still have to comply with the current requirements for expedited review which is to determine whether the study activities are minimal risk first and then see if all activities fall into one or more categories on the expedited review list. So essentially what we've been doing, no change is what they're saying. And then for continuing review, so we know in the Revised Common Rule starting January 21st, 2019, for certain research undergoing expedited review as well as certain research that has gotten to certain points in the research activity, you no longer have to conduct continuing review. In this guidance document, FDA is clear that FDA regulated research must continue to undergo continuing review at intervals appropriate to the degree of risk but not less than once per year. So essentially no change in that. So until we hear more from the FDA. Until they actually publish their regulations, this at least should give you a sense for FDA regulated what aspects are okay when it comes to informed consent and then, specifically, for expedited review and continuing review you're going to continue to function as your functioning now.

And then lastly before we get to the open Q&A session, just very briefly, we had a couple of questions that we received about educational opportunities, templates, things like that. So one of the questions was where can we find links to the previous Cyberseminars? Right now all ORD led Cyberseminars are on the PRIDE website. ORO led Cyberseminars are on a couple of different places. ORO just recently started using the GoToWebinar platform and so I think going forward their presentations will probably largely be using the GoToWebinar platform as well. But then some of the earlier presentations were using the VA [unintelligible 50:23] system which, yes, does require, I think, a VA sign on to be able to access it. But here's a list of where you can find the links to the previous recorded Cyberseminars and most of those links should also have the handout slides as well.

We received a question about PRIM&R. Will the PRIM&R Conference include any VA sessions beyond lunch with the VA on the first day? I just wanted to let people know ORD and ORO will be leading the joint session on November 15, 2018, from 11:45 to 1:00 PM. It's going to be titled a Dialogue with the VA. PRIM&R did not have very many openings for sessions so we were very happy to at least get this one. We will be hosting office hours and so anyone can feel free to stop in on November 16th at 4:30 to just speak with ORD and ORO. And if you just want to come in and introduce yourself and get to know us face to face we're always happy to know who you are and have a chance to chat informally. So office hours will be November 16th. And then separately, ORO is leading a pre-conference that is specifically for RCOs on November 14th, 2018. Now they did have a few open slots and so they sent out a message to the field recently, you know, asking if anybody wanted to attend because they had a couple of open spots and so they wanted to make sure this resource is available to others.

Tools and templates. We got a question asking about the informed consent document checklist and is anybody going to be creating one essentially that will include the identified changes that the field can use when reviewing the informed consent document for the IRB. Now as has always been the case, especially whenever, you know 1200.05 changes, there are probably going to be different templates floating around as different facilities exchange ideas and people are looking for examples of templates. So you know, I'm sure you'll hear from your other colleagues about examples of templates. With respect to ORD, is ORD going to be creating a template specific to the revised informed consent elements? I want to direct everyone's attention to our presentation in September on Overview of the Revised Common Rule. Slide 39 pretty much outlines the differences in the Common Rule elements under the pre-2018 requirements and the 2018 requirements, and so that can be used to create your checklist. That information you can find on the PRIDE webpage.

And then, again, a question was asked will ORD and ORO develop some sample protocol templates that can be used by investigators that include information needed for exempt research? ORD and ORO will be working on their guidance documents to make sure that everyone understands how to operationalize the exempt categories. But really for protocol templates, the protocols really vary greatly among the different exempt categories. As we know some of the exempt categories were expanded from two possible criteria to four and so

we will not be creating sample protocol templates, but you can look forward to receiving some guidance from us.

All right and so this brings us to the open Q&A session and we have about 35 minutes for that. Petrice you've got a lot of questions in. Okay and so Kristina, Karen, please just make sure and let us know if you can hear Petrice when she's reading out the question. We want to make sure our technology's working right.

Dr. Karen Jeans: Will do.

[unintelligible 54:10]

Dr. Petrice Longenecker: The first question is, if after the Revised Common Rule compliances [unintelligible 54:20].

Dr. Kristina Borror: I'm having a hard time hearing Petrice.

Dr. Karen Jeans: Same here, I can't hear. It's like an echo.

Soundia Duche: Because of the sound issues we're trying to figure out, I'm going to ask maybe Lucinda if she can read the question using my computer. Forgive us, we're still working out some of the technicalities to administrating this.

Lucinda: Okay. To repeat the question Petrice just read, if after the Revised Common Rule compliance date, a pre-2018 study that has not transitioned has a revised informed consent there is no regulatory requirement to follow the 2018 consent requirements, correct?

Dr. Kristina Borror: Yes.

Dr. Karen Jeans: Yeah. This is Karen. Yes, Kristina and I both agree. Yes, you're absolutely correct whoever asked that question. Yes.

Lucinda: Next question. Can you transition the study that had full IRB review but would have been eligible for expedited to the new Common Rule and change it to expedited?

Soundia Duche: Yep. Absolutely. Remember when you decide to transition a study, what you're going to be doing is looking to see if it's eligible for exemption, if it's eligible for expedited review. You're going to see what criteria has to be met. And there's nothing wrong with a study that was reviewed by the full board if it meets the criteria for expedited review. And it may very well, especially if you just elected to review it by the full board. You would go through the same, you know, steps that we talked about earlier in the presentation to transition that study and make sure all the IRB approval criteria for expedited have been met. Anything to add to that Kristina or Karen?

Dr. Kristina Borror: Yeah I just want to note that so far the expedited review categories have not changed. They're the same as they have been for the last 10 years. So I wouldn't see any reason why a study that was approved by the full board and, was required to be reviewed by the full board under the pre-2018 rule, would suddenly be expeditable under the 2018 rule unless I'm missing something.

Soundia Duche: I think they were saying that it was, it would be have been eligible for expedited but the IRB elected to review it by the full IRB convene board.

Dr. Karen Jeans: Yeah this Karen. Yeah I'll just back up again what Kristina is saying. But the categories are the categories and, again, an IRB always has a choice. It's almost like broad consent, you know, expedited review categories are an option. And so an IRB doesn't have to use expedited review procedures. It can, indeed, as this example said, do full board. But just like in the current Common Rule, there's not a difference that applies in terms of the application of the expedited review category based upon the 2018 requirement. It's the same exact process.

Soundia Duche: Thanks, Karen.

Lucinda: Next question. Did this week's SACHRP meeting result in anything major about the Revised Common Rule?

Dr. Kristina Borror: So there was a lot of talk about informed consent, in particular, and the exemptions. And basically I want to note that what SACHRP is actually, the Secretary's Advisory Committee on Human Research Protections, and the secretary in that is the secretary of HHS not the secretary of VA. And that said, VA is always interested in what SACHRP has to say. And I was present at that meeting and I'm sure there were others from VA who watched it on the web. And even for HHS, SACHRP does not speak for the federal government. It's an advisory committee. And so they can and do make recommendations to the Secretary of HHS and then it's up to HHS, and particularly OHRP, to determine and decide whether or not they want to accept those recommendations. But I think that the discussion that they had was very robust and very interesting and, you know, it will have to remain to be seen whether or not VA will also, you know, implement any of the recommendations that they suggested.

Lucinda: Next question. For the transition of a study involving a retrospective chart review, you talked about an issue related to waiver of informed consent. What about HIPAA? The IRB will still need to provide a HIPAA waiver, correct?

Dr. Kristina Borror: Yeah. That was, that question, I thought was asked and answered on one of the slides unless there's something about that question that I'm not getting.

Dr. Karen Jeans: And let me add on to that because I want to make sure, yeah, I think I'm like Kristina. If the study transitioned it doesn't change HIPAA and so you shouldn't, and I don't know the exact context of the question in terms of what's being thought of, but if there's a

HIPAA waiver that allows the, you know, the use of the PHI, you know, accessing it, it's not going to change because the research changed categories in terms of how HIPAA applies. So you wouldn't need a new waiver of HIPAA authorization if one was obtained. And it must have been obtained or a HIPAA authorization[unintelligible].

Lucinda: Okay. Thank you. For transitioning of a study under pre-2018 Common Rule to 2018 Common Rule it sounded like no new paperwork needs to be submitted by the investigator. That the IRB can use and review the current materials to transition a study, correct?

Soundia Duche: I wouldn't say blanketly [sic] no new material. If the IRB has in its possession sufficient information to address all the additional requirements of the revised Common rule than no. But if, for example, in determining whether waiver criteria is met, the IRB needs additional information from the investigator in order to specify whether the waiver criteria has been met, then they would have to request that information from the investigator. Karen and Kristina?

Dr. Kristina Borror: Yeah. Absolutely. And another example, in addition to the one Soundia just mentioned, would be if, you know, enrollment is ongoing and there's an informed consent document. That informed consent document would have to be Revised because it is unlikely that the informed consent document that the IRB approved under the pre-2018 requirements would actually meet the requirements of the 2018 rule which includes, you know, the key information up front and additional requirements for informed consent basic element.

Dr. Karen Jeans: And I want to add on as well, because this also brings up a process issue. In terms of process, how's the decision going to be made to transition? Is it going to be a process where the IRB decides to look at these studies when the time comes in January 19 and afterwards it's like, okay, let's start looking at this study to figure out whether or not we're going to transition things or not. This is a process issue. Or is it going to be one where, you know, you ask the investigator, you know, or if the investigator applies for it. And so in terms of that question of, is new paperwork required? It's also related to the process that the IRB and/or the institution chooses to use in order to transition research. And also, as part of the question I wanted to add, that we have received clarification within the Common Rule Group, that an IRB can [unintelligible 1:03:06] transition entire categories of studies. But again, it has to be documented. So great question. Thank you for whoever asked that question.

Lucinda: Now we have a couple of questions about the privacy board. In the slide where you stated the R&DC can serve as a privacy board as long as it meets the privacy board composition requirements, the privacy rule says that one member must be not affiliated with the entity conducting or sponsoring the research. This will now conflict with the 1200.01 requirements for all R&DC voting members to be compensated for time or permanent part time federal employees, correct?

Dr. Karen Jeans: I'll take this one. This is Karen. You are correct in that, again, that's why it has to be in alignment with, you know, 1604.01 is basically the implementation of HIPAA under the

VHA privacy office in VA. And so at the current time, our R&D committees could not. However again, we are looking at a revision of 1200.01, excuse me 1200.01. And so that's what that slide meant if it's an alignment with 1604 policy. So again, [unintelligible 1:04:40] that's for sure. In terms of what will happen in 1200.01, we do anticipate changes in how the R&D committee will be composed. I can't speak specifically on any of the actual mechanics of it but that is why [unintelligible 1:05:03].

Lucinda: And then that answers the next question that was submitted about the privacy board's requiring a non-affiliated member to be present during the review and approval of a HIPAA waiver and goes into this would not work unless the 1200.01 is changed to accommodate that.

Dr. Karen Jeans: Exactly.

Lucinda: The next question. Will IRB exempt studies still require annual review by the R&DC even though expedited research will not require annual review by any committee? And then it starts off with exempt studies and then it switches to expedited research.

Dr. Kristina Borror: Yeah. Read the question again.

Lucinda: Will IRB exempt studies still require annual review by the R&DC even though expedited research will not require annual review by any committee?

Dr. Kristina Borror: I think the answer is yes, right?

Dr. Karen Jeans: Yeah. You know we can't comment on what the revised 1200.01 will say. So we can only deal with what's currently in place. So that's why, you know, we can't comment in ORD on what it will do because we don't know until it finishes up concurrence. But in terms of the current requirement, it goes back to the issue of right now, the R&D committee is required, if there is no other oversight committee, to approve, as it does all VA research studies, but also to do continuing review. For expedited research, there is no current requirement, nor would there be a requirement if continuing review was eliminated, for the R&D committee to do continuing review for expedited studies if continuing review does not occur because it's still under the oversight of the IRB.

Soundia Duche: Thanks, Karen.

Lucinda: Okay. Will the VA Central IRB be sending a determination letter to the PI study chairs regarding the 1-21-2019 effective date?

Soundia Duche: I'm not quite sure what that question was referring to. A determination letter? Maybe you can send a follow on?

Dr. Karen Jeans: if this is talking about transition. But I think we're going to have to defer that question to the Central IRB so. We would, you know, because we really can't respond on behalf of the Central IRB so I'll defer that question.

Lucinda: Okay. We'll move on. Will VINCI accept the new Common Rule requirements regarding IRB review, specifically exempt and expedited studies?

Soundia Duche: I wouldn't see why not.

Dr. Karen Jeans: Yeah. This is Karen. It accepts approval now and so again it's an alignment with, you know, already policies regarding, you know, what is an approved study. These are the Human and Research regulations so I don't see a reason why VINCI wouldn't because it's part of VHA.

Lucinda: Okay. Will we get guidance soon on what key information in the consent will be?

Dr. Karen Jeans: Okay. Then I'll take that one. So there's, I think Soundia had referenced in her presentation, we are working with the other Common Rule agencies with HHS's lead to publish it's terms of informed consent guidance. And what's interesting about the question is that key information vary. Because it is something that is relative to the content. And the 2018 requirements really don't define what key information is. But the short answer to the question is that, indeed VA will be issuing it's guidance, not policy because we don't want to define it strictly in policy because it can't, in terms of, you know, what should be considerations for what is key information for informed consent.

Lucinda: Okay. If the study goes to data analysis it can be expedited?

Soundia Duche: If the study goes to data analysis can it be expedited? I believe one of the, under the current expedited categories is that that category 8 one of the requirements if only the remaining, you know activities are data analysis then it could be expedited under category 8. I don't have my categories in front of me.

Dr. Kristina Borror: Yeah there's a new, so the discussion about what doesn't require continuing review? Is research that's eligible for expedited review and limited IRB review and research that has progressed to the point that it involves only one or both of the following which are part of the IRB approved study. That analysis, including analysis of an individual identifiable private information or identifiable biospecimens… Oh that's what doesn't require continuing review. And the question was about expedited review. I'm almost positive it's eligible for expedited review.

Lucinda: Okay. Great. The next question. You know 1200.12 will not be revised until 2019. After January 21st, 2019, and until 1200.12 is revised, for repository protocols do we follow current 1200.12 or do we follow the Revised Common Rule? These policy documents

contradict each other particularly with regard to continuing review requirements and exemption status.

Dr. Karen Jeans: So this is Karen. Whenever there is a direct conflict between the two, the later policy supersedes it. And so what we will be doing if we cannot get, you know, we were trying to get 1200.12 out. I do not foresee it happening by January 21st, 2019. Is that ORD will, indeed, specifically address this in term of how to deal with these conflicts until we get 1200.12 reissued as the new directive. And so we are indeed cognizant of that and really do appreciate that question because the last thing we want to do is produce unintended consequences from conflicts and regulations.

Lucinda: Okay. Moving on. Will the VA privacy and data security plan be required annually?

Dr. Karen Jeans: So this is Karen. I don't know what this is referencing because ORD doesn't require that. So that's not an ORD policy issue. So I can't respond, ORD can't respond to that question. Kristina, do you have any idea what this is referencing?

Dr. Kristina Borror: I do not.

Dr. Karen Jeans: Okay. So the person who asked could you type in, you know, what this document is and give us a little more information we'd be more happy to address it or refer it to the program office that's responsible.

Lucinda: Okay. Moving on. Will the 1200.05 have substantive differences from the draft version. If so, what are they?

Dr. Karen Jeans: This is Karen again. I will address that. We don't know. Great question. But the draft version is the draft. When it goes out for pre-concurrence we receive, you know, a lot of comments. Significant revisions were made. It's now going through the formal concurrence process. So I do not know yet. ORD does not know yet what those significant changes are because it has not finished the concurrence process.

Lucinda: Okay. So I think this is the follow up to the question about the VA central IRB. This says talking about transitions that the CIRB has determined need to be made. Please pass this on to the CIRB. Okay. Another question. The privacy and data [unintelligible] question is referring to the memo from Dr. O'Leary on January 15, 2018, that says a research data inventory must be collected annually as part of the review of protocols.

Dr. Karen Jeans: Oh this is Dr. Breeling's. Okay. Thank you for that. Yeah. That is a separate issue that was put into place. That is not part of the Common Rule. So until that memo is suspended, what was put in place by Dr. O'Leary remains in place.

Lucinda: Okay. Here's another question. Sorry. FDAA and NIH policy requires clinical trials be registered in clinicaltrials.gov, I think within 21 days of the first enrolled subject. The Revised

Common Rule requires consents to be posted within 60 days of the last subject visit. Are you recommending posting at the same time as registration? Somewhat related. Do you know if most VA investigators who are also the sponsor are aware of posting results within one year of the primary completion date?

Dr. Karen Jeans: So this is Karen. So let me take the first part.

Lucinda: Do you need me to read it again?

Dr. Karen Jeans: Yeah. Would you read the first part and cut it off on that one and then I'll ask you to read the second part, thank you.

Lucinda: FDAAA and NIH policy requires clinical trials be registered in clinicaltrials.gov I think within 21 days of the first enrolled subject. The Revised Common Rule requires consents to be posted within 60 days of the last subject visit. Are you recommending posting at the same time as registration?

Dr. Karen Jeans: So great question. No. No. Definitely not.

Lucinda: Okay.

Dr. Karen Jeans: And that's actually a regulation. And the reason is, in fact that the posting occurs after the last subject has been enrolled and so, no. They do not happen concurrently. I'm really glad that question was asked. Now the second half.

Lucinda: The second part. Do you know if most VA investigators, who are also the sponsor, are aware of posting results within one year of the primary completion date?

Dr. Karen Jeans: So this is Karen again. I don't know if VA investigators know that. I do know that it is a law. This is a FDA law. So if an FDA investigator is doing a clinical trial that is subject to the FDAAA 801, that is the responsibility of the investigator conducting the clinical trial. And you know, not having knowledge of the policy is not an excuse under FDA. And so it is the responsibility of an investigator who is conducting these studies to know the requirement. In ORD we manage that, of course, through the ART system. But it is an investigator responsibility to know that. And so we can take this information and we can, again, emphasize this in ORD field calls. But at the end of the day it is the investigator's responsibility whose conducting an FDA regulated study that's subject to the FDAAA to follow the requirement.

Lucinda: Okay. Moving on. For our study that was approved under the pre-2018 requirements and for which enrollment and follow-up have ended, e.g., open for data analysis only. If the study is transitioned to the 2018 requirements to avoid requirement for continuing review what are the typical actions that would need to be taken? Revisions of waivers, informed consent documents that are not being used? My facility has several of these and the IRB is

delirious, sorry, is desirous of eliminating unnecessary continuing reviews to the extent practicable. Do you need me to read that one again?

Soundia Duche: Yeah. Thank you.

Lucinda: For a study that was approved under the pre-2018 requirements and for which enrollment and follow-up have ended, that is open for data analysis only. If the study is transitioned to the 2018 requirements to avoid requirement for continuing review, what are the typical actions that would need to be taken? Would this be revisions of waivers, informed consent documents that are not being used.

Soundia Duche: That's a great question.

Lucinda: My facility has several of these and the IRB is desirous of eliminating unnecessary continuing reviews to the extent possible.

Soundia Duche: Kristina, has OHRP weighed in on this because this may be a good question for us to take up with them at our next call.

Dr. Kristina Borror: Yeah. I'm not aware that they have. I think that if they're only in data analysis so there's no new subjects, you know, the question about whether or not you have to re-consent subjects who have already completed all of their, you know, they're done with their research. They're no longer, you're no longer interacting or intervening with them, you know, I think that, you know, the question is whether or not you have to revise the informed consent documents for that. I don't know if we can comment about that. I think OHRP has said that they're not going to require the issue of whether or not if it was done under a waiver of informed consent and whether or not you would have to, the IRB, would have to look at that waiver to make sure that it meets the new criteria. I think that that would be required. Those are the kinds of things that I'm thinking of. I don't know if anybody had any other thoughts.

Dr. Karen Jeans: Yeah. This is Karen. I'll weigh in on this one as well. I absolutely agree with everything both of you have just said. ORD's position is in alignment with OHRP's as well. For this example, the question that Lucindia just read, if you've already finished consenting subjects, you know, enrollment is over. Then ORD would see no point in changing I think the consent form that's not going to be used. We would see no point in, you know, updating the informed consent form to meet the 2018 requirements when informed consent has been finished. We also would see no point in actually, you know, going out and, you know, sending a notification out [unintelligible] well here's the new revision to the Common Rule. Because they're really not that significant and so that that would be something we would not do. Absolutely agree that what you do have to do is look at the waivers. Because if you transition and any part of that study that is active, is undergoing a waiver of informed consent, was approved under that then you would have to redo it. But for example, it may not be applicable. Let's say you got a waiver of informed consent to screen subjects in order to identify those that you're going to consent. Well if that's true, you don't do another evaluation of waiver of

informed consent because the reason of that waiver of informed consent to be approved is not applicable any longer. And again, the big issue is in terms of what has to be done is the documentation. The formal documentation by the IRB that this study has been transitioned and that it will now be subject to the 2018 requirements and the date that that evaluation and determination was made.

Lucinda: Okay. Next one. For CIRB studies you currently do not need to submit personnel changes for non-key study personnel until continuing review. For expedited studies under the 2018 requirements, will we need to submit changes in personnel via amendments since Continuing Review will no longer be required?

Dr. Kristina Borror: So I want to point out something that I think Karen said during her part of the presentation. That just because continuing review is no longer required doesn't mean the research is not still under IRB oversight. So all changes to the research still have to be, you know, have to get IRB approval before you can implement them. Any unanticipated problems involving risk to subjects or others have to be reported. Any serious or continuing noncompliance has to be reported. So the only requirements that are not required for those research studies is continuing review but it is still under the oversight of the IRB.

Lucinda: Thank you. For exempt category 3, will there be any additional VA guidance on what will be considered benign?

Dr. Karen Jeans: Oh this is Karen. I'm glad somebody brought up SACHRP because SACHRP has had a lot of discussions about this. All of us in the Common Rule agencies have had discussions on it. Yes there will be guidance on it. And it's not really a VA specific issue because we shouldn't be considering VA, what we consider benign intervention versus, for example, EPA or the university whose trying to implement it. So we are working with the other Common Rule agencies on a guidance document regarding this new concept of what is a benign behavioral intervention. For those of you that have listened to SACHRP in the past, I mean, there was like a two hour discussion on whether yoga is considered to be a benign behavioral intervention. And so it's not as easy as one thinks. So yes we have recognized the issue, especially in this new category. And so you can anticipate, yes indeed, guidance on this. It will probably not be VA specific. It will be part of the common guidance that we're issuing among all the Common Rule agencies.

Lucinda: Okay. Next question. For studies not requiring continuing review, if there is a decision to conduct continuing review anyway, must the documented reason be study specific or can there be a general policy? For example, FDA regulated studies until FDA regulations harmonize.

Dr. Karen Jeans: So this is Karen. I will take this one. The answer's yes. You can do whole categories but it can't just be a generic "because we want to". So indeed, you can have an entire category of studies that, if they fit in that category, automatically will require annual continuing review by the IRB as long as that is clearly, as the category is clearly is written.

Soundia Duche: Okay. We only have about two more minutes, Lucindia. So where we at with questions?

Lucinda: Okay. FYI the researchers source guide, RRG managed by CSP, is a nice resource to find info links about the Common Rule. It has links to ORO and ORD webinars. So I guess that's just an FYI.

Soundia Duche: Oh great. Thank you for that.

Dr. Karen Jeans: That's nice. Thank you.

Lucinda: I think that may be all.

Soundia Duche: I'm just scanning to make sure there's not any.

Lucinda: Here's one. ORD indicates use of a single IRB is not addressed in 1200.05. Does this mean use of a single IRB is not allowed until the directive addresses use of a single IRB or will use of a single IRB be allowed under directive 1200.05?

Dr. Karen Jeans: So this is Karen. We are not, at this time, and this directive in 1200.05 will not address the cooperative research provision which is the single IRB mandate because it does not take effect until January of 2020. And so there are many different types of issues that have to be addressed. And so we are using this time to look at a lot of different options for us to be able to do that as well as to point out the specific exclusions that will apply. When something that would require single IRB under the policy would be an option to not require it because that's also why the Common Rule, the 2018 requirement, allows for a federal agency to decide when is it something that should not happen or it's an option? So that is something we are not doing in this directive but you can anticipate some things that will indeed facilitate different alternative IRBs even in this directive.

Lucinda: Okay we have two more questions. The first, what is broad authorization and how does it impact those studies that will be used in broad consent and current studies using a consent for banking?

Dr. Karen Jeans: So this is Karen. I'll take this one. Broad authorization. Okay. This is talking about HIPAA. Now HIPAA, years ago, basically stated that it allowed a broad authorization. Now until then, every time that you wanted to use, collect, analyze, access PHI you had to get a new HIPAA authorization or you had to get a waiver of HIPAA authorization for every use. So a few years ago that was changed. However, VHA does not recognize that. We don't. And so what happens is like we do currently. If you want to use PHI for research, you get a waiver of HIPAA authorization. And so it really doesn't change anything of how we're doing things currently in terms of broad consent, in terms of reuse of identifiable information because we currently don't recognize a broad HIPAA authorization. We may get a primary HIPAA

authorization, you know, when we're initially consenting subjects. And if we're going to do a reuse of their identifiable information, we then get a waiver of authorization for that secondary use. So it doesn't change anything into how we're doing it because that's what we've always done. At the current time. That may change in the future, but this is something that VHA is, we're currently doing in VHA.

Lucinda: Okay. This is the last question for today. What topics will the VA specifically [unintelligible 1:31:17] those requirements relate to paying no impact implementation of the Revised Common Rule.

Soundia Duche: I believe the individual's referring to in the revised handbook/directive 1200.05 what might be some of the VA specific requirements down there? Is that it? And one of the things that is in 1200.05 we are trying to streamline it and make it as close as possible to the Revised Common Rule. Some of the things, Karen if I may say, some of the things may be related to broad consent, the documentation of broad consent. We may have some VA specific requirements pertaining to that that might differ slightly from the Common Rule. Anything else specifically, Karen, you might want to mention?

Dr. Karen Jeans: No. It really is, again like Soundia said, in terms of streamlining. So what you may see, again, we really hesitate to comment on proposed policy because we don't know what it will finally look like as it finishes concurrence. But we're also looking at taking away some things that are in the current 1200.05. So the changes may actually, don't think of additions, but also deletions and so. But until we see what comes out of concurrence, we really can't give any specific comments.

Soundia Duche: Excellent. Thank you, Karen. So right now we're going to kind of wrap things up. One thing I just wanted to point out is that we do have some upcoming training in November. We had scheduled some training pertaining to VHA handbook 1200.05 and our goal is that if the directive is issued early November as we hoped, that we will proceed with this training. We realize that that's going to be the week of Thanksgiving. Worry not. We will be recording all our sessions and we will be scheduling additional sessions. So what you see now is just one session pertaining to the revised directive in November and one in December. But we will definitely be scheduling more trainings before the end of the year on the revised directive. Kristina, Karen, any final comments before we wrap up?

Dr. Kristina Borror: I don't think so.

Dr. Karen Jeans: Me neither. I think it's just that we're all in this together and so we're all, it's a new rule and so, you know, we're all problem solving this at the same time so this helps us so much.

Soundia Duche: Excellent. Thank you everyone. Please complete the survey that's going to pop up at the end because you're going to give us some feedback in terms of what information we still need to provide you with as you all ramp up. I know everyone's working diligently on

revising their SOP's and their forms. As we mentioned, with the release of 1200.05 we'll also be releasing some guidance that will be helpful in the implementation. There's also going to be guidance coming out from ORHP that will be very helpful as well to implementing the Revised Common Rule. The VHA CO ORD regulatory mailbox is available for questions so continue to send questions there. And we will see some of you at PRIMR and then the rest of you we will see back here on our next call that's right now scheduled for November 20th. If for any reason we need to reschedule that, we'll be sure to let you know in advance. But right now our plan is to proceed with getting some of that training in in November and then we'll be going full speed ahead in December. So expect to see more trainings on our calendar. Thank you everybody and have a great evening.

[END OF AUDIO]