Cyberseminar Transcript

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Session: ORPPE Workshop: Studies that Must Follow the Revised Common Rule (2018 Requirements)

Presenter: Petrice Longenecker, MA, PhD

Dr. Petrice Longenecker: Welcome. Good afternoon and good morning. I’m Petrice Longenecker and I'm here presenting the first ORPP&E workshop entitled, "Studies that Must Follow the Revised Common Rule 2018 Requirements”. Today we're going to try something a little different and open the lines for an open question and answer session. First we'll be operating in lecture-only mode and then once I finish my presentation I will unmute the lines allowing you to then unmute and mute yourself. And here are the instructions if you'd like to ask a question in this format. So use the raise your hand feature in your GoToWebinar menu. Once you've been called on, please unmute yourself, only then, ask your question, and once we've addressed your question please mute yourself again. If you would rather not be recorded or speak directly, you can always type your question into the questions box. So here with me is Ms. Soundia Duche and Dr. Karen Jeans to help us provide this targeted workshop. Okay, so let's get started.

Our objectives are simple, identify those studies that must follow the revised common rule. And then we will go through a sample form to give you some ideas of how to prepare for this transition as we get closer to January 21st.

[Unintelligible 01:14] to go through the timeline. Seems like we've been on this journey for a while now. So on January 19th, 2017 the final rule, revising the common rule, was published with an original effective date of January 19th, 2018. As you may know, that in January 2018 the first six-month delay was issued by the agency that apply to the common rule. And then six months later in June we received yet another six-month delay, delaying the effective date to January 21, 2019. We are currently in what's called the transition period. And so starting July 19th, 2018 there was the allowance of three burden-reducing provisions. As you [01:59-02:00], the VA could only take advantage of two of those. And here we are, one month in, one month closer to the January 21, 2019 implementation date. So this is the date where the revised common rule becomes effective for all studies. So we are almost there.

And it's a case of two common rules. And the question is, which rule applies? And remember that for a while, that we will live under both common rules depending on when the study received its IRB approval. And that is the definitive piece of information. The date that the study received its final, unconditional, IRB approval. But for studies that receive their IRB approval before January 21, 2019, they are subject to the pre-2018 requirement. For the studies that receive their final IRB approval on or after January 21, 2019, they are subject to the 2018 requirements or the revised common rule. Additionally, studies with IRB approval between July 19th, 2018 to January 20th, 2019 and used a burden-reducing provision, and that means they documented a specific use of a burden-reducing provision in line with the transition period, they too are required to follow the revised common rule come January 21, 2019. A study can only be subject to one common rule. This however does not apply to the FDA. So as the FDA exists now, a study can still be subject to both the common rule and the FDA regulations if they both apply.

So the question becomes, what does that mean to have IRB approval? So ORD has made a policy decision that for all studies with a final, again unconditional IRB approval date on or after January 21, 2019, that study must comply with the revised common rule even if the convened board approval generating in a convened board review, generating an approval with modifications is conducted before January 21, 2019. So this is when it's important to distinguish review versus approval. If the board reviews a study before January 21, 2019 but approves it after, it must comply with the revised common rule. And this can include any other reviews or approvals contingent upon final IRB approval.

Let's start with an easy study. So again, final unconditional approval or exemption determination on or after January 21, 2019. The convened board convenes on or after January 21. So at that point approval is going to be on or after January 21. Expedited review, the reviewer signs off that's approving the study on or after January 21, 2019. And for exemption studies or studies that are exempt to the common rule determination is made on or after January 21, 2019. So all of these categories of studies must comply with the revised common rule.

So example one. It's December 24, 2018 and the PI is writing their IRB protocol that requires convened board review. The next IRB meeting is scheduled for January 24, 2019. There's no way the study could be approved before January 21. So this study must comply, or is subject to, the revised common rule. The PI should be aware of this differentiation. That here we are in December and they're writing up their protocol, but if it won't get reviewed and approved until after January 21, it should be written consistent with the 2018 requirement. And the IRB should be reviewing the protocol according to the 2018 requirement.

Example two. Expedited review. It's January 15, 2019 and the PI submits their IRB protocol. We're still before the January 21 date. But it takes about a week to assign the expedited reviewer for this IRB. The expedited review is completed on January 22, 2019. Again, this study is subject to the revised common rule. Again, the PI should write their protocol to the 2018 requirements and the reviewer should be reviewing according to the 2018 requirement. But what is important here as we get closer and closer to the date is that the IRB inform the research community of all cut-off dates and turn-around times. So if you know it takes about a week to assign and get an expedited review completed, you'd want to make sure your PIs know as we get closer to that January 21 date.

So what if the review occurs before January 21, 2019? Now we're getting into the not-so-easy group of studies. The convened board was held on December 1, 2018. They give the study conditional approval or approval with modifications and then once those conditions or modifications are met, the PI resubmits their protocol to the IRB. And if the final approval is done on or after January 21, 2019 this study is subject to the revised common rule. But it's important that the PI understands which common rule they are subject to. Because if the PI wrote that study to the pre-2018 requirement, that study may need to be re-reviewed according to the 2018 rule. So it's important that both the PI and IRB understand which common rule applies to which study.

[Unintelligible 08:12-08:13] important. So you've got a convened board meeting held today, December the 14th. You have the review done, completed. You approve it with modifications. But the PI is on vacation and doesn't get those modifications back to the IRB until January 29. That study is now under the revised common rule.

Okay, another example. The study gets reviewed by the convened board on December 13, 2018. There's approval with minor modification. The PI returns the modifications on January 11, 2019. Boy, we're getting really close. And this then may also depend on the IRB structure and process of these types of approvals. If it only requires an IRB administrator to sign off that the modifications were done, then this study could be approved on January 11th or 12th. However, if it requires an IRB member or an expedited review to approve the minor modifications then that process may take a little longer. But in this situation, the PI returns the modification so close to the effective date of the revised common rule, the IRB has a choice. And the IRB has to decide what's better for their facility, the PI and that study. The IRB can try to get that study approved before January 21 to make the study subject to the pre-2018 common rule. Or they can delay final approval of that study to January 21 or after and therefore the study is subject to the 2018 common rule.

Let's talk about both options. For example three, again the PI returns the modifications on January 11. If the IRB decides to approve the protocol before January 21, 2019 and the study’s subject to the pre-2018 common rule, there's some things that the PI and the IRB must be aware of. The protocol can't take advantage of broad consent if that's something that your institution is going to do. It can't take advantage of screening, recruiting or determining eligibility for a study without consent or waiver. So those are some key components of the revised common rule that do not exist in our current, pre-2018 common rule. And this is why communication between the IRB and the PI is important. Because if the IRB has determined that any study that comes in after January 1st must be reviewed and approved under revised common rule, this PI must know that so they can write their protocol to the 2018 requirements and not the pre-2018 requirements. So this is about communication. So the IRB should inform the research community of all cut-off dates and turn-around times so they're aware of what to expect when they submit their protocol. Conversely, the alternative path is the IRB that's on the application delays approval until January 21 or after. And in this case, if the IRB chooses to do this, the PI could have written their protocol to the 2018 requirements to take advantage of broad consent if your institution is going to allow that. And screening, recruitment and determining eligibility without consent or waiver. So again, this is about what the IRB plans and how they want to proceed in this very pivotal time, right? Because we're just a little over a month before January 21. And so I'm sure for many of you, you have a lot of studies in flux at this very moment. And so if you're going to have an IRB meeting between now and January 21, you may want to consider making sure that all of those studies are going to be approved before January 21 if you're still using the pre-2018 requirements for review. If you have a meeting very close to January 21, you may want to consider holding off and making sure all those studies that come in are written to the 2018 requirements, the revised common rule and holding final approval until on or after January 21. But again, that's a decision the IRB needs to make.

And then example four. Study gets reviewed by the convened board on December 13, 2018. Approval with minor modifications. But the PI returns the modifications July 11, 2019. A whole seven months later. Things happen, you understand. So of course the IRB approves the study on July 20, 2019. That study is subject to the revised common rule. So this is why ORD made that decision to say that anything with final approval, even if it had review before January 21, if final approval is on or after January 21, it must be compliant with the revised common rule. So this can extend and go beyond a couple of weeks past January 21. There's no guarantee of when the PI is going to return those modifications. So it would be very confusing to the community for a study that had IRB approval in July 2019 to then be compliant with pre-2018 common rule. So this is for harmonization and consistency's sake.

Okay, so then the other category of studies that must comply, or are subject to the revised common rule on January 21, 2018 are those studies that were reviewed and approved by the IRB between, so I should say, approved by the IRB between July 19, 2018 and January 20, 2019. So final, unconditional approval. And they were approved under the pre-2018 common rule and requirements. But the study used one of three burden-reducing provisions. Just to remind you of those, the revised definition of research for activities specified and deemed not to be research. The elimination of IRB review of the grant application or contact proposal. And then, elimination of continuing review for a subset of studies. And again, VA did not allow the elimination of continuing review. So that burden-reducing provision was taken off the table for us. So for these studies, the revised definition of research is not as significant because if it wasn't research under the pre-2018 common rule, it's not research under the 2018 common rule. So those are fairly simple. But if your IRB chose to utilize the burden-reducing provision that allowed for the documentation of eliminating IRB review of the grant application or contract proposal specifically to use the burden-reducing provision, those studies that did so must comply with the revised common rule on January 21, 2019. So that's important because if you use that burden-reducing provision, those studies should have been identified and they need to know that they were [unintelligible 15:37] transition because starting January 21 they need to be compliant. So that's something that you need to work with your PIs now. You need to let them know that those studies will be transitioning on January 21. And we don't want them to be out of compliance. So I'll reiterate. If between July 19, 2018 and January 20, 2019 the IRB documented the elimination of federal grant application or contract proposal review during the initial IRB protocol review, in line with the burden-reducing provision at section .103 section D, the study must comply with the revised common rule on January 21, 2019. So those studies may need to start ensuring that they are compliant with the 2018 requirements now. Starting now. Because you don't want January 21 to occur, and it's a Monday, and have those studies automatically be out of compliance. So studies that must transition, they intentionally use the burden-reducing provision and it's documented must be compliant with the revised common rule as of January 21, 2019. So you may need to go back and re-review to ensure compliance. So is the consent language appropriate? Is there broad consent? Is there waiver of consent that meets the new requirements of a waiver etc.? You need to document that the study has transitioned. And in doing so you may also want to document that it is compliant with the revised common rule. And you want to consider the exemptions. So there are some groups of studies with activities that under the revised common rule are considered exempt from the common rule. And so for those studies that may transition from non-exempt research to exempt human subjects research, you still want to make sure they are compliant with the revised common rule, document that transition, and a limited IRB review may be required. So we would not want to automatically make changes. You want to make sure you're documenting those changes and those studies remain compliant. So again, big thing to consider is communication with the PI. Communicate, communicate, communicate.

[Pause 17:57-18:10]

[Unintelligible 18:11] go back to communication. So IRB communication. So there are some things that the IRB should be determining for themselves. So before you inform the research teams about dates and cut-offs, you make sure that amongst your team you have agreed upon the date of which you said this is the last date we'll take protocols written for the pre-2018 common rule. It could have been November 1, like the VA Central IRB. I could be a later date. It's up to your IRB. But you want to make sure you kind of keep things clean. So we advise that you pick a date and after that date, protocols should be written to the 2018 requirement and you can have some wiggle room if necessary. Go ahead and make your 2018 requirement's templates and documents available in advance. The PI should have access to this so they can make sure their protocols are written appropriately. And remember, the IRBs can delay final approval until on or after January 21 to ensure that those studies are subject to the revised common rule. It's up to the IRB so there's no need to rush and get it done on January 20 if you don't want to. You can delay it. And in that delay you may want to have the PI update their protocols to be compliant with the revised common rule. And then make sure you are documenting which common rule the study is to comply with. That's important to the IRB and it's important to the PI. It's important to the institution. What everyone should know, study A complies with this common rule from here on out.

So here's two resources. So putting together this presentation, I found some great resources for us. These are transition checklists and I'm going to go over the University of Illinois with their permission. You also have these as a handout in the handout tab. So you have a presentation and a copy of both the University of Illinois at Urbana-Champaign's transition checklist as well as the University of Pittsburgh. But I'm going to go through screenshots of this transition sheet just to give you an idea of what one IRB has done. So this is just a model. Feel free to amend this. Feel free to do it a different way. In fact, the University of Pittsburgh document is really a resource for PIs. They're not supposed to even submit it back to the IRB. This one looks more like one that you submit to the IRB and you can have the same document so that everyone's getting the same information. So this one has actually four sections so we'll go through this. So when to use the checklist, [unintelligible 20:42] some instructions for the PI. Of course the acronyms are different. Different institution. Section one, protocol information. Section two is study status. And if I were to update this template, I would add for section two, a section on did the study use a burden-reducing provision because remember, those must transition. So you may want to document that as well. This checklist does not document that. I won't assume whether or not they allowed the burden-reducing provision, but if you had not, if your institution did not allow the burden-reducing provision then there's no need to worry about that.

Okay, section three are the required changes to consent documents. So key information needs to be at the top of the consent form. So these are all of the 2018 requirements that are different from the pre-2018 and they have identified them specifically for the PI to go through strategically. Has this been done? Does this need to be done? If not, explain why etc. So the specification of future use and then the waivers. Finishing up section three. So when applicable, this is our, so I'm going to go back one. So 3B is the only added, additional required element for consent. So the consent form must indicate that deidentified information and/or specimens may be used for future research without additional consent, or the consent form must indicate that information or biospecimens will not be used for future research. So one or the other must be noted in your consent form. And so then the next part asks well, if you don't have one of these two statements, why? Because you have waiver, enrollment is no longer taking place, the information is already included etc.

And then the revised common rule adds three additional requirements when applicable. And so sections 3C, 3D and 3E ask if those things need to be updated in the consent document. So commercial profit, whether or not clinically-relevant research results will be disclosed or returned to subjects, and then a statement about whole genome sequencing. So they ask if the revised consent forms are attached. [Unintelligible 23:22-22:23] longitudinal. Here's an important one, 3H. Is this project registered as a clinical trial? So the definition of a clinical trial has been updated in the revised common rule. And know that if your study is a clinical trial, after it's been closed to enrollment you must post a used consent form. Not a signed one, but one that was used to recruit subjects.

And then section four. Other changes. So waiver alteration of consent. And additional questions there. So if you have questions about this form, we can take them. But you have copies of them if you'd like to look into that.

So from here I'm going to go ahead and open up the phone lines. If you have questions. Well first let's ask, Soundia are there questions?

Soundia Duche: There are a few questions.

Dr. Petrice Longenecker: If we have any questions that have already been typed in we can go through those and then we can do the open session.

Soundia Duche: All right. So the question that we received. Let me find it again. On slide seven, they asked, is the policy pending VHA Directive 1200.05. This was the slide where we talked about when something is subject to the 2018 requirements versus the pre-2018 requirements. And the decision in the slide is based on when the final IRB approval date was. So if the final IRB approval date occurs on or after January 21, 2019 we say the study has to be subject to the 2018 requirements. Now, we don't necessarily have this in VHA Directive 1200.05, do we Karen?

Dr. Karen Jeans: Okay, so. So this is a great question in terms of this slide. Now, it is all relative. It's a policy decision that is consistent with the common rule regulatory text. However, and that's why we're having this presentation today, there are policy decisions that still have to be made regarding this. Specifically when we're talking about multi-site studies in which, for example, the VA is being added as a participating site after other sites have come on, like in clinical trials. While an IRB, let's say for this example, Johns Hopkins was the IRB of record for a non-VA site. And VA then came on as a participating site for purposes, since I'm in Little Rock, Arkansas, Little Rock VA was brought on. So let's say they were brought on in March, which would mean that the study would be approved by the IRB in March under the new common rule, but all the other sites would be under the pre-2018 requirements. So, there's still a discussion there in terms of policies that have to be made. And it's more like an interpretation of the common rule among the common rule agencies. So for purposes of the slide today, and what we're discussing, this is consistent on the slide with what is in the common rule test. However, this may change depending upon, as we get closer to January 21 depending on continuing discussion that VA has with the other common rule agencies.

Dr. Petrice Longenecker: So Karen, this is Petrice. But can I add that, I think for new studies, where they [unintelligible 26:56] or final approval for all sites just to start that study at any site comes on or after January 21, 2019 it must comply with the revised common rule.

Dr. Karen Jeans: You're right, exactly. I'm really glad you made that clarification because we are talking about studies. As Petrice stated [unintelligible 27:18-29:19] where for example, a new study that is being initiated by an investigator, I'll say a new merit study, it's coming up to the IRB, it was submitted to the IRB in December and even if the IRB, the convened IRB, it had to go through that, reviewed it on January 15th let's say. And they approved it with modifications that needed to be completed, but those modifications were not completed until after January 21, 2019. Then that study must comply with the 2018 requirements. It wouldn't go under what we call our current common rule, pre-2018 requirements.

Dr. Petrice Longenecker: Right. So this question came up when we talked about review versus final approval versus continuing review. So it's my understanding that for some institutions, OHRP allows continuing review, the date's set for continuing review to be the date for the convened board review which is not necessarily the date of final IRB approval. And though so far our service areas that issue merit awards, they document in their protocol, in their portfolio, the date of final review, not necessarily the date of convened board review. So we wanted to make sure that the policy, or that all of our procedures are clean. Such that the date that the SPM notes in their portfolio matches up to the appropriate common rule that study should be subject to.

Soundia Duche: Thanks Petrice. We've got a few other questions before we open the lines completely. One individual asked for an update on the status of 1200.05 on the revised directive.

Dr. Karen Jeans: So this is Karen. I'll take that. So as the current status is that we're still undergoing the concurrence process. We're still awaiting the Office of General Counsel's final concurrence that it can go through the last step, labor management review, and then sign off. So, again everyone is very aware of the time-sensitive nature of this and that's why we're presenting so much that we have here that is not contingent on whether or not 1200.05 is issued today or tomorrow or next week. Because the common rule is the common rule. The 2018 requirements will go into effect regardless of what happens with 1200.05 if it comes out today, tomorrow or in ten days. And yes, we want 1200.05 out as quickly as possible. And so that is the status, is that we're waiting on OGC to finally concur and they go through the final concurrence process. Then it will go to Labor Management Relations and it will be signed off. So that's where we are right now. But again, do not wait. And that's the whole purpose of all these presentations we're doing, all of these things, these policies can be rewritten because of that deal with the common rule. Because we had accepted the common rule, VA, as one of the signatory agencies that agreed to follow and apply the common rule to all of our human subjects research.

Soundia Duche: Thank you Karen. The next two questions are similar so I'm going to try and combine them the best way possible. Essentially the question is, if a study is submitted and reviewed under the pre-2018 requirements, but does not receive final approval prior to January 21, 2019, must there be a full re-review of the whole study or just for the new elements of the 2018 requirements? And so, if the study, you wouldn't require a full board review let's say if the study was reviewed by the convened board.

And I think, I don't know if we have an OHRP guidance on that. I will say though, many of the requirements for the 2018 requirements are fairly minor. We're talking about an additional waiver criteria for example, whereby you have an option now of an additional waiver for documentation of consent. So I think part of it would be what requirements apply to your particular study. So, if you aren't waiving documentation of consent in the study to begin with, well then that wouldn't necessarily be something that would even be reviewed. So one, it would be on a case-by-case basis. If the consent form, for example, needs to totally change and you need to put it in the new template because you did not review it with that template, there might be some additional things that if the study was a convened board review, that they really do need to bring it back to the convened board to review and be able to say yes, it meets the requirements. And so it really will be on a case-by-case basis. But also you're really basing it on what issues apply to your specific study. Not everything in the revised common rule will apply to every study. I don't know if anyone wants to add anything to that before we go on?

Dr. Karen Jeans: This is Karen. Soundia I have no additional comments. I think you absolutely summarized exactly the key issue here.

Soundia Duche: Thank you. Next question was, does key information include alternative procedures if applicable, as in the hyperlink in the document for the University of Pittsburgh? So let's go to that document. And if you recall, one of the main differences in the consent form template requirements is that all consent forms for studies that are subject to the 2018 requirements does need to include the key information. Now in terms of alternative procedures, [pause 33:28-33:35]. I think I have to see exactly where in the document the key information [inaudible 33:41].

Unidentified speaker: Oh, it's a link.

Unidentified speaker: You have the link?

Unidentified speaker: You have to find it here.

Unidentified speaker: Oh, I see. So in there, I don't know if you'll be able to access that document. You'll have to just try and if not reach out to the University. I'm really not sure if that guidance document is available or not for the key information consent summary.

Unidentified speaker: I'm going to try and pull it up and see if we can get to that document. So we'll move onto the next question until I pull it up.

Soundia Duche: Regarding 2018 informed consent form requirement, r.e. future uses of data. There are two language choices [unintelligible 34:29-34:31] allowing the participant to choose between them or must it be one or the other? I do not have the ICF requirements, oh yeah.

Dr. Petrice Longenecker: It's one or the other. So for the one about deidentifying data. So the revised common rule has it at the, let me just [unintelligible 34:55] get to the, so section 116, is the general requirements for informed consent. So and the basic elements of informed consent, so paragraph C item nine. One of the following statements about any research that involves the collection of identifiable, private information or identifiable biospecimens. So one of the two. So option one, a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens, and that after such removal the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally-authorized representative if this might be a possibility. Or, this is the second option. A statement that the subject information or biospecimens collected as part of the research even if identifiers are removed, will not be used or distributed [unintelligible 35:58] research study. Those are the two options.

Soundia Duche: Thank you Petrice.

Dr. Karen Jeans: This is Karen. I'm going to add one extra thing here [unintelligible 36:06] And the reason this was put in is because under the current common rule there is no requirement under the common rule to inform subjects that hey, by the way, we may strip your identifiable data, strip your identifiable biospecimens and reuse them. And this was an issue of concern to the public, by the public, which was raised to the White House [unintelligible 36:30] the common rule agencies. So this was a way again of just, if there was any possibility of doing it that research subjects have the right to know. And so that's why it is an either or.

Soundia Duche: Great. Thank you Karen. I think we have a couple of hands raised. We're going to try to, we want to test this functionality. William, where are the [unintelligible 36:58-36:59]. So I've got Ellece Pappas, Ellece. You should be able to unmute yourself Ellece. So I've unmuted you Ellece.

Ellece: Yes.

Soundia Duche: Okay, great. Go ahead with your question.

Ellece: I did not have a question.

Soundia Duche: No, we're not hearing you. And if you can speak up too. Close to your mic.

Ellece: I'm sorry. I'm dealing with [unintelligible 37:38] virus and home sick. I did not have a question.

Soundia Duche: No, okay. Thank you. [Unintelligible 37:43-37:45]. No worries, thank you. Okay. Brenda Rich. You've been unmuted. Okay Brenda, are you still with us? Okay, we'll move on to the next person. Brenda if you have a question please raise your hand again. And Sherry Lindsey? Hi, Sherry?

Sherry: [Unintelligible 38:17].

Soundia Duche: Sherry, we can't hear you. Okay, Sherry you muted yourself. Okay.

Unidentified speaker: Let me go on to the next question that we received then we'll come back to the hands\_

Unidentified speaker: Okay.

Unidentified speaker: \_raised.

Unidentified speaker: Oh, this is a great question. When the IRB re-reviews studies to see if they meet the new common rule, will that change the continuing review date?

And I think I'm going to make one or two assumptions which you can clarify. I'm assuming you're saying when they re-review it to transition a study, so that study was already approved and now they're re-reviewing it to see if they meet the new common rule requirements so they can transition the study. Would that change the continuing review date? In that scenario my response would be no it wouldn't because the study has already had initial approval, you are now transitioning it to the revised common rule. If you're re-reviewing a study that has not received approval yet though because maybe you found yourself in the middle of a review and therefore you couldn't meet the pre-2018 cutoff prior to 21st January date and now you have to re-review it to make sure you're fully compliant, well then it's at that date when you do your first approval. That would set your continuing review date. Karen or Molly, do you guys want to add or clarify anything there?

Dr. Karen Jeans: I'd like to jump in, it's Karen. Soundia I absolutely agree with you. This is consistent with the position of OHRP as well. A great analogy is what we currently do in terms of when you have a study that undergoes convened IRB and requires modifications to come back [inaudible 40:01-40:15] the second day. And it all depends upon what [unintelligible 40:18] that second date. So again, when it comes back to the situation like Soundia has described here, when the IRB is looking at it to see whether or not, what needs to be revised, what needs to be reevaluated in order to ensure that it meets the 2018 requirements, it all gets back to looking at whether all the IRB approval criteria were met. It does not have to move to the new date, but if at the time of that second review for the transition date that again, all the IRB approval criteria were reevaluated, you actually could choose as an IRB to use that date. That's a choice that can be made [unintelligible 41:05-41:06] when you have studies that have to come back [unintelligible 41:10] convened IRB for re-review of modifications. So as Soundia stated it does not require moving to that new date.

Soundia Duche: Thank you Karen. We're going to stick to questions related to transitioning to the new common rule requirements. So what studies have to meet the 2018 requirements. So if I don't ask your question it's because of that. So the next question is, if we transition a study that's in expedited category five to the new common rule and it now falls under exempt category four, do we need to do a limited IRB review as it was already an approved project?

Dr. Petrice Longenecker: So this would be a study where you may be obtaining consent if it was already ongoing. And I know that we give that a lot of thought here, so Karen I don't know if you want to weigh in, but I think that's the critical piece here. The limited IRB review is one piece of it, but also transitioning a study that had expedited review and may have consent or waiver of consent to an expedited study.

Dr. Karen Jeans: So yeah, that's exactly it. Looking at the different scenario here. When you've already looked at the study for a limited IRB review, again for it to meet all the IRB criteria, and there's no additional elements required it would be a re-review of the limited IRB review criteria. But it's more when you're looking at this, when you're transitioning a study to ensure that it meets 2018 requirements, one could indeed document yes, it does not require a re-review of a criteria that was originally approved under. And I think that's the question that's being asked here. But the IRB still has to if that's who's looking at this. There has to be a decision made on yes, are all the applicable criteria met? So that's the answer to this question is that, and I'd like to actually, this is actually a great guidance question that we would like to address as well because this issue of going from expedited to exempt is in some ways just as complicated as dealing with the informed consent elements. So there are lots of questions about this. And so we are indeed writing all these questions down so we can put these into guidance documents.

Soundia Duche: Thanks Karen. The next question is, I am pretty sure I know this answer, but the transition only applies to IRB approval, RDC or institution approval can occur after January 21, 2019?

And the answer to that is yes, we're talking about IRB approval. And we talk about meeting the 2018 requirements on or after January 21, 2019.

Let's see. Question was, are things on track for PRIDE and ORD to provide sample forms that IRBs can use next week? Dr. Klote are you on the call? [Pause 44:23-44:30].

We are working towards, Dr. Klote is working on SOPs, forms, approval letters, basically an HRPP that sites can use as examples. I think you are needed Molly.

Dr. Molly Klote: Yeah, I'm unmuted. [Unintelligible 44:50-44:52]. We are working very hard on [inaudible 44:54-44:56] sample forms and templates all put together. We are working very hard to get them out by next Friday, the 21st. The sites will hear from me [unintelligible 45:11-45:15] a little bit. But we are really trying very hard to get you guys something that you can all use. It's been harder than we thought to pick a single sample from a single site and try to make it general enough for everybody without completely destroying it. And so what you're going to get are going to be things that are going to need local massaging to put back in some context for you locally. And as we hear on these calls, we have meetings with the federal agency every Friday that Dr. Jeans has set up, is that we're going to continue to get guidance from HHS throughout the next year and so we are going to have to systematically and periodically send out updates to the common core documents for all the sites. But I think having this set of documents that everyone can at least refer to, so that when we have to send out a change or an update I think it will make it easier across the board to identify where those changes affect these common documents. We hope you'll find them useful and that they're not more of a burden on you, but they will at least be the bare boned, minimum requirements of what has to be done. And you can't just adopt these without doing anything to them. You're going to have to edit them for local context before. But if you don't adopt them you can at least use them as a template to see where the citations and regulatory text may need to change in your own local documents. I hope that answers the question. Over.

Soundia Duche: Thank you Molly. Next question is, if a multi-site protocol is approved prior to January 21, 2019 but additional sites are added after January 21, 2019 is the study required to be amended to meet the common rule requirements? I'm going to ask Karen to chime in on this one.

Dr. Karen Jeans: I would love to. So again, this is one of those issues that are we going to have a black and white answer on this. And I want to reinforce what Dr. Klote just stated. We want to get something out there that you can use almost like an outline and modify it to your sites. This is another question concerning about absolutes. This is an issue that we actually have brought up to the department of health and human services. I cannot reinforce enough how much that these questions that you're asking when, they are relevant to the entire regulative research community across the country. This is an issue that ORD and ORO had already been queried by some of our, by you and that we elevate it all the way up to the other common rule agencies. We are in the middle of having a discussion on this because it does, you have the literalness of the regulatory text and then you have, well it doesn't make sense to have a clinical trial like you just discussed here, that needs to be modified when it's already been ongoing with sites that were under the pre-2018 requirements to come to the 2018 requirements. Does it serve the purpose of human subject protections? And so I cannot give an answer of that today. I will tell you that before January 21st we will have a position on this. But one of the issues, why we're not answering it today on behalf of VA is that all the common rule agencies need to be in alignment. And so that's why, so that [unintelligible 49:31] cause chaos across the regulated community. So thank you for the question. This has been elevated all the way up among all of us in the common rule agencies. We will have further guidance and a position on this within the next few weeks. Thank you.

Soundia Duche: Great, thanks Karen. The next\_

Unidentified speaker: Can I, I just want to go back to the question about key information. So we did find the link that was mentioned. And so as it said, there's no federal guidance exactly defining what key information is. So the University of Pittsburgh has identified their own elements for key information. VA has not adopted those. So we won't be using those specifically, but a local institution I think at this point can figure out what's important for you all. But ORD does not yet have any central office policy regarding what exactly key information means. I want to make sure we went back to that and touch on that for a minute.

Soundia Duche: We've got a couple more questions. I'm going to try and get us through those even if it takes a few extra minutes because these are important questions. If our site chooses to wait on transitioning studies, must that policy specifically address this in some way before they are eventually updated with our determined processes?

And just want to mention that remember, you don't have to transition a study at all. You can keep all your pre-2018 studies under the prior common rule and then as of January 21, 2019 anything approved by the IRB on or after that will fall into the 2018 requirements. So there's nothing that requires you to transition a study. I will say this. It's helpful I think for everybody in the institution to understand what the IRB's plans are and what your institution's plans are and philosophy is with this. So to the extent that this is your choice or you plan on waiting, if it's your SOPs or if it's just your website or some kind of FAQs to talk about how your local institution is going to handle these changes, I would encourage you to inform your leadership and inform your research community somehow on what your plans are. But there is no requirement to transition a study.

Next question. We have already received IRB approval but just submitted an amendment. If the amendment isn't approved before January 21st will the study still be subject to the old common rule?

Again, anything approved before January 21st, and we're talking about initial approval so maybe we need to clarify that. The first time the IRB grants final approval of a study, anything approved before January 21st is subject to the pre-2018 requirements. That study will continue to be subject to the pre-2018 requirements through its life unless you decide to transition it. What that means is continuing reviews, amendments, anything that occurs that's related to that study will fall under the pre-2018 requirement. Okay? Of note there aren't really any significant changes for amendments to the revised common rule. But just because you have an amendment, I just want to point out, that doesn't kick you now into the 2018 requirements. If the study was approved before January 21 by the IRB, everything that subsequently occurs with that study stays under the pre-2018 requirement.

Just want to see if there's any additional questions that's specific to the topic at hand today. We want to stay as focused as possible. [Pause 53:08-53:15]. I think that is it actually. And we're right at, just a little over 2:02. But we thank you for your participation. Thank you so much Petrice for the presentation. Karen and Molly again for your participation. We apologize for some of the technical issues. We're still working through this. And we'll try again one more time with the hand raising but we may find that it may not be worth the effort. But thank you again. Please respond to the survey that's going to pop up once you close out.

And we have a training on Tuesday. Our monthly Cyberseminar. It's December 18th. And that's going to be a continuation of our training on November 29th where we're going to continue going over the revised common rule, proposed VHA Directive 1200.05 and the IRB. We didn't get through as many questions as we wanted to last time and so the plan for Tuesday's Cyberseminar is we have two more sections that we need to cover, vulnerable populations and definitions and then we're going to go straight into the questions that we did not get to, followed by an open Q&A session. Our Cyberseminar on Tuesday is scheduled for an hour and a half so we'll have more time. And some of you who asked questions that were not specific to the topic at hand today and therefore were not asked, please be in attendance at the Tuesday training and you'll be able to get those questions answered then. Thank you everybody and have a wonderful, wonderful weekend.

[ END OF AUDIO ]