Cyberseminar Transcript

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Session: Town Hall Q&A

Presenter: Molly Klote, M.D.

Soundia Duche: Good afternoon everyone and welcome to our town hall Q&A session. This is our first Q&A session for this year and we thought it would be a great opportunity to convene everybody in order to answer whatever question you may have. Obviously we expect the majority of questions will be on the revised common rule, but really it's an open Q&A session and so you can ask anything and everything that you want to know about. We are one week away from compliance with the revised common rule and so we've convened individuals from ORPP&E, ORO as well as VHA Privacy to answer questions that we've received in advance as well as questions that you're going to be submitting during the open Q&A session.

With me today presenting we'll have Dr. Molly Klote will be joining us a little later on. We have Dr. Karen Jeans who is also here with me. Dr. Kristina Borror from ORO and Stephanie Griffin who is the VHA privacy officer. So we'll go ahead and get started.

Okay. Again, we're going to be talking, going to first be focusing on questions that we've received in advance. Feel free to submit your questions. I will just say, some of you will have questions that I'm sure you'll already find in the slides. So if you can maybe hold off on submitting some of your questions just to see if we address them before we get to the open Q&A session. Once we wrap this up, we have about 25, 26 questions that we received in advance, then we'll go into the open Q&A session. We will run the open Q&A session up until 3:30pm. At 3:30 we're going to pause and shift gears and Dr. Molly Klote is going to give an update on the Mini Moonshoot. She's going to tell you all what that is and what to expect in the upcoming days. And then I will spend about five minutes at the very end going over some of our goals for our web-based training this year, the ORPP&E web-based training. We have, as I mentioned, we have Stephanie Griffin, who's our VHA privacy officer. She is only here for the first half an hour of this presentation, so we are going to jump right into the questions we received on privacy and information security because we did receive a number of them.

Stephanie, we have the first question. Everyone should be able to see it on their screen. VHA Directive 1200.05 has removed the paragraph on Privacy Officer and Information Security Officer Duties. Does this mean that the PO and ISO are no longer required to review research protocols prior to the IRB approving the study?

Stephania Griffin: So, no. So VHA Directive 1605.01 which is privacy and release of information still requires an information security and privacy review of research studies by the ISSO, the ISSO and the privacy officer. Now 1605.01 does not dictate at what point that review must be performed. And in addition, VHA Directive 1200.05 does discuss various actions for the privacy officer and the ISSO that implies a review is required even if it's not explicitly stated in that directive. But regardless, the review is mandated by VHA Directive 1605.01. But again, it doesn't go into specificity about that review. However, the privacy officer cannot conduct a review until after a study that requires IRB approval has actually received that approval because of some of the HIPAA requirements. So there is not a requirement that you have to do a preliminary review or an interim review before it goes to the IRB for approval. However that's strongly encouraged. And in addition, VHA Directive 1605.03, which is currently in concurrence, will give the privacy officers at least more directions on these reviews in terms of how to conduct the reviews and when they should perform the reviews.

Soundia Duche: Excellent. Thank you Stephanie. Moving onto the next question. VHA Directive 1200.05 in, it's either page 17 or paragraph 17, I'm not sure, requires that the PO and ISSO be non-voting members or consultants to the IRB. It is otherwise silent on how the review should be conducted as you just mentioned Stephanie, intentionally. Can you offer one or two recommendations regarding how this review should be conducted? For example, should this review be conducted before or after IRB approval? Must the ISSO/PO review the research activity and provide recommendations? Must the ISSO and PO approve the research activity, or both?

Stephania Griffin: As we were just speaking to, while VHA Directive 1200.05 does not provide details regarding the review, it is mandated by other policy and the revised VHA Directive 1605.03 once published will provide a lot of the detail and recommendations for the privacy officer for their review. As we said at the very least, review of the research study after IRB approval is required for the privacy officer. And that has to do with the HIPAA privacy rule and the waiver of HIPAA authorization requirements. However, we strongly encourage review prior to IRB approval. Often there are some suggestions that the privacy officer is making regarding the waiver or concerns about the waiver. There are suggestions about data protection plan requirements or what they're suggesting. There are [unintelligible 05:59] questions about audio recording. So a lot of times there are things that are helpful for the privacy officer to have reviewed prior to IRB approval so that they can discuss those with the IRB and the IRB can consider them when they're making their recommendations and so forth. The ISSO and the privacy officer do not approve research studies. That is the job of the IRB and the R&D committee. But they are to ensure that the security and privacy requirements are met for that study and that has to be paid attention to and listened too. The privacy officer does however approve the research HIPAA authorization. That is, the IRB has said for a very long time they don't approve HIPAA authorizations. That's actually not a requirement in the HIPAA privacy rule. They only approve waivers of HIPAA authorizations. So the HIPAA authorization is approved by the privacy officer, but they do not approve the study.

Soundia Duche: Very helpful.

Dr. Karen Jeans: Hi, and this is Karen here at ORD. I wanted to add to this one by also stating that as part of the revised directive, VHA Directive 1200.01, which is the research and development committee policies and procedures which we are expecting to be published any moment now, it will indeed have a requirement that as Stephanie is stating, that the ISO and PO review, not approve the research, prior to final approval of the study by the research and development committee. And as Stephanie is stating and we also want to reinforce here in ORD, it's really, in terms of these issues not, it is a best practice to have the ISOs and POs review this, for example on a [unintelligible 07:56] that requires IRB review, way before it gets to an R&D committee. As Stephanie has stated there are certain requirements that the privacy officer has to do regarding the HIPAA authorization, but with so many of our studies using apps and different types of platforms, it is indeed really needed as a consultation for many of these studies as part of the IRB process. So, that's just something again that we want to reinforce as part of this.

Soundia Duche: Thank you Karen and thank you Stephanie. All right, moving on. Next question. Still, this one's dealing with combining the informed consent form and the HIPAA authorization. So Directive or handbook 1605.01 on page 49 states the following:

An authorization for the use or disclosure of individually-identifiable health information for a research study may not be combined with the Research Informed Consent. This seems to contradict what is stated in VHA Directive 1200.05 paragraph 23a1 where we're now saying you can combine them. Stephanie, can you chime in on this please and help clarify the issue, this discrepancy.

Stephania Griffin: Certainly. Well the discrepancy is because directives and handbooks don't all go out at the same time. You know, 1605.1 was revised in 2016. At that time ORD still did not prevent, or allow, the informed consent and authorization to be combined. We're not on the same review cycle, so what happens is sometimes things get out of alignment. It is our expectation that when VHA Directive 1605.1 comes up for revision later this year that we will remove this restriction. Until that occurs we will provide guidance to our facility privacy officers on this new policy stance. Just for history folks, the VHA information [unintelligible 09:53] privacy was not, this was not a decision that we made. It was a decision that ORD made with consultation from privacy due to the issues on combining these documents early on in the implementation of the HIPAA privacy rule. HIPAA privacy rules now have been in effect 15 years. I think people are much more sophisticated in their understanding and so this is now moving VHA in the direction of a position that the HIPAA privacy rule does allow, which is combining these two documents. So we will get 1605.1 when it's reissued formally, revised to follow this new ORD policy stance. But in the interim we will issue guidance out to our privacy officers and if there are other formal means such as through a, I can't think of it, it's like a change, that we might, we will do that as well. But it is being allowed. We know there's this conflicting language and it just really has to do with the timing of directives.

Soundia Duche: Thank you Stephanie. Our next question. We're still on this whole issue about combining informed consent and HIPAA. So if a study team combines these two documents into a single document, must the privacy officer always review the HIPAA language in these combined documents? Is this true only when the IRB has determined that it needs PO consultation on a specific study?

Stephania Griffin: So for the first thing, yes. A privacy officer must always review the HIPAA authorization regardless of whether it's a separate form or it's part of the informed consent. That is always a requirement. In addition, to be honest, I can never think of a time that PO consultation is not needed for a human subjects research study regardless if the study is IRB-exempt or not. So I cannot even think of a time where the IRB can say we have a human subjects research study that requires access to health information, but yet we're not going to involve the privacy officer. If, someone else maybe Dr. Jeans has an example of where this question is coming from, but I can't ever think of an example where you have human subjects research where health information is being used, collected, disclosed or accessed regardless of whether it's IRB exempt or not where you don't need a privacy officer review.

Soundia Duche: Thank you. And if anyone has some examples please send them in and then we can talk about those because [unintelligible 12:43].

Dr. Karen Jeans: I do think the key is human subjects research. I do know there's other research that would fall outside of that, but when it's human subjects research I can't think of a situation where you would not be required to do privacy officer consultation.

Soundia Duche: Perfect, thank you. All right, moving along. The following question pertains to the VA informed consent HIPAA authorization template that was distributed during Friday's workshop on informed consent tools. And for those who did not participate, this is a draft document that was distributed as a template. Dr. Klote will be talking more about other documents that will be forthcoming when we get to the end of the presentation, but we did include this document in your handouts. So the question is, the first question was, is there language regarding participant access to their research related health records as on page three of the VA form 10-0493, the HIPAA authorization form. I believe the individual who asked this question maybe did not see this language in the combined document. So they were asking, is this required?

Unidentified speaker: And I'll go ahead and answer the first question just for easibility. The requirement to inform a subject if he will have access to his research record while participating in the study is not a HIPAA authorization requirement, but rather is a HIPAA privacy rule right of access requirement under, I'll give you the citation, 45 CFR 164.524 a2(iii). So it's a very specific requirement under right of access. And the requirement states that an individual's access to protected health information created or obtained by a covered entity healthcare provider in the course of research that includes treatment, may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered healthcare provider has informed the individual that the right of access will be reinstated upon completion of the research. So you'll see it's a very specific right of access requirement. You can suspend their right of access if the research involves treatment. So I guess, you know clinical trial, and you have to inform them that you're denying them access. They have to, as part of the consenting, and you have to let them know it will be reinstated once the research is completed. And when we did the HIPPA Authorization form 10-0493 based on discussions with ORD at the time, it was determined to include this requirement into the HIPAA authorization even though it is not a HIPAA authorization content requirement. It was thought it would help with easibility. That this would be a good place to put it and so forth. But that's why it hasn't been included in the informed consent by our office for HIPAA authorization required language because it's not a HIPAA authorization requirement. It is a requirement that has to be met. It has to be met in some way with the consenting process whether ORD wants to add it into this combined document, the combined informed consent HIPAA authorization, that I think is a decision that they have to address, but that's why you're not seeing it there right now as it's not a HIPAA authorization content requirement. It's actually a consenting requirement under right of access.

Soundia Duche: Great. Thank you so much for that clarification Stephanie and we've made a note of it and we'll go back as we finalize some of these forms and tools and make sure that we include that. The next questions say, regarding this form as well, the instructions indicate that wording indicating the authorization will expire at the end of the study must be used, rather than including the other options including on page three of form VA 10-0493. And I believe they're talking about the end of the document, page 17 of this combined informed consent form. The specific language that's in yellow or green, one of those two.

Stephanie Griffin: The reason that not all expiration options were provided per my understanding is that not all apply when dealing with the combined informed consent HIPAA authorization. For example, the combined form should not be used when an optional database or [unintelligible 17:31] is part of the study as discussed on page 15 of the form. So including the database expiration language doesn't make sense. It doesn't apply. You're supposed to use the separate HIPAA authorization when that's the case. The option does not expire was not included though I mean it certainly can be, likely because it requires justification to be provided for approval by the privacy officer, that it was likely determined that it shouldn't be used except in exceptional circumstances. So if you have a study that you're going to say the authorization never expires, so it's good for basically indefinite, forever. Justification has to be provided as to why that is the case as opposed to the normal expiring at the end of the study when the study is over. So it's possible that this could be re-looked at [inaudible 18:48-18:50] to give it as a possible option if the justification is provided, but certainly that we would need to work with ORD to discuss if that's the direction you want to go.

Soundia Duche: Can I just ask you Stephanie just follow on to this statement that you said. This form, a combined informed consent and HIPAA authorization template should not be used if data banking is optional. Can you just chat for a minute or two more about this, just so everyone is clear on that and it's something we need to make front and center in terms of when to use this form, and when not.

Stephania Griffin: Well the HIPAA privacy rule is very clear when talking about authorizations that when a research study has optional components, like data banking or tissue banking to which the person does not have to participate in, in order to participate in the study, that the authorization for the research study only covers kind of what is the main study, what's the mandatory part of the study. And so you have to have separate authorization for those optional components under HIPAA. And that's a HIPAA requirement. And we address that in VA form 10-0493. That's why you see in page two, it's asking about data banking which would be a mandatory part of the main part of the study. And then page five is for optional data banking, tissue banking. And it requires, each piece requires a signature. And those are requirements of the HIPAA privacy rule though the informed consent HIPAA authorization combined document doesn't have that separate authorization for optional data banking and tissue banking that would require a second separate signature. And so that's why you see on page 15 of that document that it says if you're going to do optional components of data banking and tissue banking you really need to use Form 10-0493. I'll be honest. Someone commented that that comes kind of late in the combined form, so why would you put the HIPAA language in the informed consent and try to use the combined form if you’re still going to be forced to use the 10-0493. And I think the answer would be you probably wouldn't. So this is something you actually really need to think about at the beginning [unintelligible 21:33] not on page 15 which is if you have optional components to your research study for data banking, tissue banking, you just really need to know out the gate, you just need to have separate forms because you're still going to be required to use the 10-0493. So to go through the effort of putting all of that information into your informed consent to still have to do the separate authorization is somewhat causing extra work and [unintelligible 22:03-22:04]. So this is something to think about up front. If mandatory data banking, tissue banking, these are mandatory components, you have to consent to participate in this aspect to participate in the study at all, then that can be covered in the single combined informed consent HIPAA authorization because only one signature is required for that.

Soundia Duche: No, this is very helpful. Thank you. You know for typical research consent forms when we're dealing in the common rule framework, we're most used to putting the check boxes. Do you agree to banking? Do you agree to this? But what you've made very clear is from the HIPAA perspective, when you have these options it's not a simple check box. The subject actually has to sign and therefore that introduces another element when one is dealing with a combined form and whether it should be used or not. So thank you very much Stephanie for clarifying that and if anyone has any further questions, please submit them and we can talk more about [inaudible 23:07] later on.

Unidentified speaker: Though it wasn't a question I am going to make a quick comment. And the form states this on it, but I want to draw everyone's attention to it because this is where the problems were decades past. And that is, when you have a research study with individuals with diminished capacity, where the individual is not able to give consent. They have diminished, so they have Alzheimer's or some other condition that they have diminished capacity and cannot give consent, and so you have an LAR. If you have a study where you're going to have subjects that fall into that category, you cannot use the combined informed consent HIPAA authorization because the LAR can sign the informed consent, but they cannot sign the HIPAA authorization. The only people who can sign the HIPAA authorization is someone who has power of attorney over that individual or someone who has guardianship over that individual. The spouse is not the personal representative automatically and neither is a family member. They have to be a power of attorney or a guardian. And so when you have that study population, you can't really have that combined form.

Soundia Duche: That makes sense, thank you. All right, the last few questions on HIPAA. Question six. Just to clarify, in the common rule, does the term de-identified mean removing the obvious identifiers such as name, address, date of birth or does it also include removal of all 18 of the HIPAA identifiers, such as date or location of service that might be used to reidentify the data by a statistician with access to a wide range public data sources?

Stephania Griffin: So this is an odd question for me and maybe Dr. Jeans will want to chime in because I'm not the expert on the common rule and I can't really tell you what the common rule means or doesn't mean in regards to a definition. What I can tell you is what HIPAA requires. For use of VHA health information for research, the definition of de-identified data under the HIPAA privacy rule must be used even if the common rule definition is different or less stringent. So if you're trying to use health records of patients, Veterans for a research study and you want to use de-identified data, you have to use the definition of de-identified data under the HIPAA privacy rule or the HIPAA privacy rule not to apply. I think I say this somewhere later, but under the HIPAA privacy rule there are only four ways in which you ever can access data. You have a signed written authorization from the subject. You have an IRB approved waiver of HIPAA authorization. You have de-identified data as defined by the HIPAA privacy rule or you have a limited data set with a data use agreement as defined by the HIPAA privacy rule. So you have to have one of those four things to use, access, collect health information on Veterans for VHA. So I don't know Dr. Jeans if you want to speak to the common rule's definition of de-identified data?

Dr. Karen Jeans: Definitely will, thank you. So yes, under the common rule the bar for what is considered to be de-identified is much lower because under the common rule it's that the investigator cannot readily identify that the data or the information that is being obtained can be associated with the identity of the research subject. So that is a much lower bar where it would not be stripped entirely because one could successfully argue, well if I just have a portion of an address such as a zip code alone, that probably is not, that usually is not making someone readily identifiable to the investigator. However, currently under our VHA Handbook 1200.12 which is the use of data and data repositories in VA research it states that in order for us to consider it to be de-identified in VA research, it has to meet both the common rule definition and the HIPAA, the privacy rule’s definition of de-identified. Now VHA Handbook 1200.12 will be revised. It will differ in the next reiteration, but for now VA ORD basically considers de-identified information to be the same as HIPAA. It is the exact same. All identifiers removed.

Stephania Griffin: This is Stephanie Griffin again. And I will say, this kind of, what I just said about the ways to use health information, that applies regardless of whether the research is IRB exempt or not. So because it's about use of the data for research purposes. And so that applies in both situations.

Soundia Duche: Thank you Stephanie. Our next question. The HIPAA privacy rule does permit alterations of authorization by an IRB or privacy board. This was something we stated on Friday's call, I think it came up and we definitely stated it before, that here at the VA one cannot alter the signature. This was specifically related to the signature of the individual one is trying to seek authorization from. Why is this not allowable for VA-approved research? Why can we not permit alterations of authorization for VA-approved research Stephanie?

Stephanie Griffin: Well it gets very complicated, but it really has more to do with all of the other privacy laws that VHA must comply with in addition to the HIPAA privacy rule. We have to [unintelligible 39:34] comply with the privacy act, we have to comply with Title 38, United States Code sections 5701 and 7332 and so it gets into the fact that you have to comply with all of these privacy laws and regulations simultaneously and not just the HIPAA privacy rule. And you know, to be honest, it fits into discussions with ORD, do we want to create what ends up being ten different scenarios where well, you could alter the HIPAA authorization, but only if these things apply but then if those things apply you couldn't, you know it just comes down to it's better not to allow it than try to get into it. A good example would be any study where you have a sponsor, the authorization couldn't be altered because of the privacy act. You would never be able to alter it because of the privacy act. Anytime you're making a disclosure as part of a research study to anybody, an academic affiliate, a contractor, you wouldn't be able to alter the authorization [unintelligible 30:44] privacy act. And so, and it goes on and on and on and on. And so you would end up with all of these almost flow charts to figure out what would be the specific answer for your specific situation. You know, trying to figure out does the privacy act apply, does it not apply. Does 5701 apply, does it not apply. And so really that's what it comes down to. Yes, the HIPAA privacy rules allows it, but all of these other laws still have to be applied to [unintelligible 31:18] the privacy of the research and the use and collection and disclosure of the health information.

Soundia Duche: Thank you Stephanie. This next question, question eight, we're actually going to skip it because the individual who sent it we were asking them for the guidance document and they were not able to find it. So we've discussed with them we'll discuss this question offline.

Unidentified speaker: I was going to say something about it. [Unintelligible 31:45] thought about this question, it kind of goes back to what I said under question six that again, we don't know what guidance document they're specifically talking about. But the HIPAA privacy rule does talk about use and disclosure and in most cases when you go to use protected health information or health records for things like treatment, payment, healthcare operations, you don't need anything special. You can just use the information. You don't need consent. You don't need authorization. But for research HIPAA is very clear. If you want to use or disclose, and use includes collection of health information, then again one of those four things have to be present. You have to have a HIPAA authorization. You have to have an IRB-approved waiver of HIPAA authorization. You have to have de-identified data or a limited data set with a data use agreement. And so I'm thinking the person saw a guidance document talking about use in general that wouldn't apply to the research agreement because there are separate rules around use and disclosure of PHI for research that are different than treatment payment healthcare operation.

Soundia Duche: Thank you. Thank you so much Stephanie. Thank you for your time, I know you were heading into another meeting, but we had a lot of questions about privacy and everyone really I think benefited from having you on the call. And so thank you. If we have any questions that were submitted specifically about privacy, we will be taking those offline. We won't be discussing them during the open Q&A session since we don't have Stephanie with us, but we'll be able to get back to you in the future on those.

All right. So now we're going to move on to informed consent. And Dr. Kristina Borror is going to take some of these questions. So I'll start you off Kristina and then you can continue whichever way you would like. For question nine, is there a definition of broad consent out there?

Dr. Kristina Borror: There are several definitions of broad consent. Unfortunately none of them are actually in the revised common rule. The Harvard website has a definition and it says broad consent is geared toward repositories for which the primary purpose is secondary research use with the understanding that the latter use is not exactly known. Broad consent is permitted as an alternative to the standard informed consent requirements. And at an HHS workshop on broad consent, some slide said we define broad consent as consent for an unspecified range of future research subject to a few content and/or process restrictions. Broad consent is less specific than consent for each use, but more narrow than open-ended permission without any limitations i.e.: blanket consent. So there's not an official definition, but that last one is one that at least HHS provided at a seminar workshop.

Soundia Duche: So the next question is, we need to post informed consents for federally funded clinical trials. And this is part of the 2018 common rule at 116(h)(1). And this has to be done within 60 days after the study has closed to recruitment. And they quote "one IRB-approved informed consent form used to enroll subjects" needs to be posted. They note that in multi-centered trials there may be various versions and this depends on local IRB requirements and all the different contact information that would be included on the informed consent document. They ask, could we use the blank template or redact the contact information? And then they also ask, they were asking about the purpose of posting these informed consent documents on clinicaltrials.gov.

Dr. Kristina Borror: And basically it would be acceptable to use the template informed consent document with some caveats for posting in this requirement. It would be okay if it included all the information that was provided to subjects who were enrolled because as they noted the requirement of posting is one IRB approved informed consent document used to enroll subjects. And so that would be, if this information and the content was basically the same as that that was used to enroll subjects that would be okay. Related to the question about multi-center trials and different forms, it does note in the revised common rule that information may be redacted and in the VHA Directive 1200.05 it says that any proprietary personal information such as names and phone numbers must be redacted prior to posting the informed consent form. So that is such information as you noted such as contact information would have to be redacted before posting. And we acknowledge that there might be several versions, but the requirement is that only one has to be posted. And related to the purpose of posting these documents, the preamble gives us some idea about why this requirement was added to the 2018 rule. And it says the primary purpose of this provision is to improve the quality of consent forms in federally-funded research by assuring that contrary to current practices under which it is often very difficult to ever obtain a copy of these documents, that they eventually would become subject to public scrutiny and that they will provide useful models for others. The consent form plays a key role in making sure that someone asked to enter a clinical trial receives the information they need to be making an informed decision about whether to enroll in that trial. Accordingly, it also plays a key role in supporting and justifying the public's trust in the integrity of our clinical trial enterprise. So that gives you a real good idea of why we are asking folks to post the informed consent documents. Basically, this is to improve informed consent documents in the future and to increase the public's trust in research.

Soundia Duche: Thanks Kristina.

Dr. Kristina Borror: Sure. So the next question is a multi-parter and it's about studies involving FDA-approved drug that's studied for either unapproved or an approved use or dose and it's in a controlled, randomized, blinded clinical trial. And basically asking about how much information about the drug needs to be in the informed consent document. And some of the questions they ask: should the ICD contain a list of all known side effects? Major, minor or rare side effects? All known side effects don't generally need to be included in the informed consent document unless all of them are considered to be reasonably foreseeable. So remember that the regulations, both the pre-2018 and the 2018 common rule require that only reasonably foreseeable risks and discomforts to the subjects need to be included. And in addition, an IRB may determine that a reasonable person would want to have this information.

And so the next question is should the informed consent document list a percentage of probability of known or anticipated permanent side effects? So this is saying for this particular side effect, you can expect that 12% of subjects might experience this. And this is something that an IRB might decide that a reasonable person would want to have this information in order to make an informed decision about whether or not they want to participate. They also, and that's a requirement that the IRB has to include stuff that they think that a reasonable person would want to know. They also might decide that this, including these percentages would really organize and present the information in a way that facilitates comprehension. Another requirement of the 2018 common rule.

I’d say, would listing the characteristics of the drug on a separate brochure be a viable option? And this is a little bit tricky because if you put something that is separate, like on a brochure, and you don't include information on the actual informed consent document itself, you have to ask, is that brochure part of the informed consent document? And the answer is generally no. So all the information that is needed in order to meet the requirements of the common rule and of 1200.05 have to be within sort of the four walls of that informed consent document. So if you want to put some things in addition to that, in addition to say the reasonably foreseeable risks, if you wanted to add, have a document separate that had some risks that well we don't reasonably foresee that this [unintelligible 41:53] happen. This is a super rare risk but we're going to mention it on this separate document, that might be okay. But you have to make sure that the informed consent document itself has all the information that is required by the regulations.

The other question is, what if there's no accompanying investigational brochure? There has got to be a way that the IRB can determine what the reasonably foreseeable risks or discomforts of that drug are either from an investigational brochure, the protocol hopefully will mention that information or the investigator may have to do a literature review to find out what those risks might be.

It says, what about listing the reactions of the investigational drug with other drugs? Again the IRB may determine that it's necessary to list those reactions if the IRB has a reason to believe that subjects may be likely to be using those other drugs. So maybe not all drugs reactions, but maybe the ones that would be most likely to be in use in the subject population.

And then the last question on this slide is who is responsible for discussing side effects and reactions during the consent process? They say, PI, pharmacy or consente? And generally it's the investigator's responsibility to discuss the risks and benefits of the study with the subject.

Soundia Duche: Excellent. Thank you Kristina.

Dr. Kristina Borror: So the next slide is related to informed consent and transitioning studies that have approved waivers. So this is asking about a study that was initially approved under a prescreening waiver and they transitioned the study. But they're no longer recruiting subjects so ostensibly they're no longer prescreening subjects either. And they ask, do we still need to reissue the waiver per the revised justifications? And there is no need to reissue a waiver of informed consent for prescreening activities for a study that had such a waiver under the pre-2018 rule and has now transitioned to 2018 rule. And one of, the second part of the question is, does the fact that the study still has data that was collected under the initial waiver mean that a new one needs to be issued under the 2018 requirements? And there's no need to reissue this waiver of informed consent even if the study still has data that was collected under the initial waiver. So remember that under the 2018 requirements, the IRB actually no longer has to waive informed consent for the investigator to not get consent for these certain kind of prescreening and recruitment activities. And I guess the questioner is wondering if the IRB has to just make those determinations if those criteria aren't met. And the answer is basically no because the study is no longer recruiting. So the question here didn't specify, it just talked about waivers and so we don't know whether they were talking about informed consent waivers or HIPAA waivers. I want to reinforce that if the study is transitioned to the 2018 requirements and has been previously approved by the IRB with a waiver of HIPAA authorization for recruitment purposes, that the IRB does not need to reapprove the waiver of HIPAA authorization just because it has transitioned.

Soundia Duche: Excellent, thank you. That's a really important point to raise Kristina. Thank you.

Dr. Kristina Borror: And the next question is related to, oh I think Karen is going to take the rest.

Soundia Duche: She is, yeah.

Dr. Karen Jeans: Hi everybody. So this is Karen. And the question is, VHA Directive 1200.05 does not address surrogate consent. Is there another handbook or directive that addresses this? Can we still use the procedure outlined in VHA Handbook 1200.05. So ORD took this out because we felt that it's already covered under the IRB approval criteria. Because as part of the IRB approval criteria, the IRB is required to evaluate [unintelligible 46:36] process and documentation of informed consent. That includes who consent is going to be obtained from. Now also under the revised common rule and the definition of a LAR, a legally authorized representative, that definition has changed as well so that if there's no applicable law such as state law, since ORD, common rule, FDA, there's not a national age of consent, age of majority, that if it's not there in your state law, then whatever the institution's policy is for who can provide consent in the non-research context, who is that person? Then that person can also do it in the research context. So, can you still use the procedure outlined in VHA 1200.05? The answer is yes as long as it does not conflict with your state laws.

Soundia Duche: Thank you Karen. The next question is about re-consenting subjects. Please clarify considerations for existing repositories, both data and specimens, if and when participants may need to be re-consented as a result of the 2018 common rule.

Dr. Karen Jeans: So this is Karen. And I'll take this one. So the issue for re-consenting studies, including repositories and research databases. You know, I'm not going to single out repositories and research databases because the question is really more a general issue. When do subjects need to be re-consented as a result of the 2018 common rule? And so you're really going into three different categories. If it's closed to enrollment, the IRB considers whether or not there are significant enough issues to require contacting subjects. And that's the issue. If it's open to subject enrollment and requires informed consent, then if it transitions, now this is not re-consent, they're going to have to be consented using the requirements of the elements of consent as defined in the 2018 requirements. Now, the big one is of course for studies that are open to subject enrollment and then you have previously consented subjects with continued participation. Again, it goes back to that issue, does the IRB feel that the consent form has changed in such a way that the subjects need to be informed or re-consented? Now, our position in ORD is that, regarding re-consenting, is that subjects usually shouldn't be re-consented for the sole purpose of transition. When you look at the 2018 requirements or just pre-2018 requirements, there's really not a lot of significant issues in terms of human subject protections. So that is the position of ORD. However, again we do not put that in policy. We will defer to the local IRBs. They make the final determinations because they ultimately are in charge of the process and documentation of informed consent. So that's where we fall there in terms of that category. In the interest of time, I won't go [unintelligible 50:01] further [unintelligible 50:02-50:03] talk about broad consent because that's a different issue, but that's the general consensus. ORD generally feels that there's not a need for re-consent as a result of transitioning.

Soundia Duche: Thank you Karen. All right, we received a few questions about continuing review largely dealing with R&D committee and when are they required to conduct continuing review? The major question here is, when is continuing review required by the R&D committee or another committee other than the IRB? And the individual, and we had a few individuals write us because they noticed some discrepancies in the various paragraphs in Directive 1200.05 that they said seemed to contradict each other. I'm not going to read them because you have them here, but let's just talk. Karen, can you tell us who requires continuing review? What committee has to do [unintelligible 50:57-50:58].

Dr. Karen Jeans: So centering in, let's just center in on the R&D committee and the IRB for purposes of this discussion. What these three questions, and they're very good, is they're looking at the different aspects as it applies to both exempt and non-exempt activities. And that's the key issue that you really have to think about. And there is a level of complexity, and I will use that word, in the 2018 requirements that previously didn't exist. We've got IRB limited reviews in the exempt categories, but it's not the same as IRB oversight. And so the critical issue in taking this out is, is it exempt or is it non-exempt? So, if you want to really boil it down to what is the bare bones of this, when you think about this, is two simple statements. If it's non-exempt research, it's under the oversight of the IRB. Case closed. It does not require continuing review by the R&D committee because it is under the oversight of the IRB. Now notice I said the word, non-exempt. Now when it comes to exempt research, that is going to require continuing review by the R&D committee unless it's under the oversight of another committee such as the safety review subcommittee. And even though there's a limited IRB review with four [unintelligible 52:32] categories, exempt categories, it's not continuing oversight of the IRB. So that's in a nutshell the very bare basics, very clear paradigm to use for this.

Unidentified speaker: Okay, so I'm going to rephrase this Karen.

Dr. Karen Jeans: Please do.

Unidentified speaker: Karen, exempt research, regardless of limited IRB review, is exempt research ever under the oversight of the IRB?

Dr. Karen Jeans: No. No it's not under the continu\_. The whole issue is, is it under the continuing oversight. It's not. It makes an initial evaluation for those four categories, but that's it. It will never be under the oversight.

Unidentified speaker: Okay.

Soundia Duche: So the next question we have is, are there any plans to revise VHA Handbook 1200.01, which is the R&D committee handbook, to no longer require continuing review for all reviewed studies to bring it in line with 1200.05? The current version of 1200.01, the RDC will still require continuing review to be done for all exempt, expedited, limited IRB review and studies in the data analysis long term follow-up studies, effectively voiding 1200.05's removal of continuing review for studies where certain categories no longer require continuing review.

Dr. Karen Jeans: So this is a good question because it follows up to the previous question. So a little issue with this is that expedited studies, expedited studies, even if they do not require continuing review as allowed by the 2018 requirements, so the revised common rule, they still are under the oversight of the IRB. So because those are under the oversight of the IRB, they do not require continuing review by R&D committee. They're non-exempt studies by definition. So right now, the current 1200.01 will requires R&D committee review, continuing review, for all studies which are exempt unless it's under the oversight of another committee. Are there plans to revise 1200.01 to no longer require continuing review for all these types of activities? We are indeed looking at it. There are changes that will be made in the very soon-to-be published 1200.01 directive. But the answer is, yes. We are looking at that issue.

Unidentified speaker: So essentially, Karen, unfortunately the R&D committee though will see an increase in some of their review responsibilities given that we foresee an increase in the number of exemptions coming online because of the 2018 requirements that have broadened the applicability of exempt categories. Is that correct?

Dr. Karen Jeans: Absolutely. And a great example is the chart review studies. Chart review studies which are recording identifiable [unintelligible 55:41] private information, those under the pre-2018 requirements required IRB review and oversight, continuing oversight of the IRB. Those no longer will require IRB oversight. They are now in a category of exemption. So the issue will be then, okay so now the study is going to be exempt, it requires continuing review by the R&D committee under the revised 1200.01 directive. I do believe it's still going to require it at this time. But there is going to be a procedure which will be in place and I know we do not like to talk about proposed policy, but since it is imminent we will discuss it. There will be a review process that can occur outside of the convened R&D committee. Because of this increased workload everything cannot come back to their R&D committee so there has to be a designated review process. So that will be part of this revision of 1200.01.

Unidentified speaker: Okay. That's very helpful so stay tuned folks. All right. Conflict of interest. Continuing review. Is there any guidance for tracking investigator financial conflicts of interest for studies that will no longer require a continuing review? Right now we currently track financial conflict of interest at the time of continuing review, but as Karen alluded to, for expedited studies under the 2018 requirements, as well as some other studies that meet certain requirements, they will no longer require a continuing review although they are still overseen by the IRB. How are we going to handle financial conflicts of interest?

Dr. Karen Jeans: So this is Karen again. Two things. First of all, the directive that will be issued in 1200.01 will specifically address conflict of interest. But let's talk about this in relation to the IRB. So as we've been talking about, there are many types of research activities involving human subjects that will no longer come under the IRB. Are there no, a lot of activities that will no longer require continuing review by the IRB more importantly and they'll not be under the oversight of the R&D committee for continuing review purposes. So what is a choice that we are going to recommend is that institutions, and you don't have to accept it, but this is something that we do think would be prudent, they require [unintelligible 58:07] check-in by investigators in terms of a length of time that they feel is appropriate to make sure that nothing has changed in terms of financial conflict of interest statements. This is the big issue in VA. We've had several high-profile issues involving financial conflict of interest. So we do have to follow the ethics laws for employees of the executive branch of the government. Some institutions, and we're talking about non-VA, are going to every year check-ins and some as far as three years. And what is contained in that check-in is not prescribed. We are, we're hoping to issue it this week, the [unintelligible 58:50] continuing review guidance concerning what we believe should be in a check-in if your institution chooses to accept that type of maneuver. A statement by investigator that just says nothing's changed, can be fully appropriate. So that's the kind of guidance that we're thinking about right now as the current state of where we are with ORD.

Soundia Duche: Okay, thank you. Look forward to that. All right, we've had one or two, maybe two questions about vulnerable populations. So regarding individuals who lack decision-making capacity, and I believe we may have touched on this already, but VHA Directive 1200.05 has removed the paragraph on individuals lacking decision-making capacity. Are there no longer any VA-specific requirements that have to be met when conducting this research? I think you touched on that Karen already but go ahead.

Dr. Karen Jeans: I did. And this is, [unintelligible 59:44] first of all I want to reinforce, individuals who lack decision-making capacity by the removal of VHA, by removal of ORD's prior policies that went into length about protections that should be in place when VA investigators and IRBs are reviewing such research, we are not saying it's a free-for-all because it's not. I mean these are individuals that every precaution should be taken. However, we do feel as we looked at this, that our requirements are already being covered by other components of the IRB approval criteria. Not only that, but many of our policies in the now rescinded VHA Handbook 1200.05 were being misinterpreted. So they were not serving the purpose for which they were intended. And so we do feel very strongly in ORD that the removal of this paragraph does not compromise human subject protections for this population and that we do feel that the common rule requirements are in itself sufficient to do that. And so that's where we are with that.

Soundia Duche: Perfect, thank you. And as you had mentioned in the previous question when you addressed this Karen, they can still use and refer to the guidance\_

Dr. Karen Jeans: Yes.

Soundia Duche: \_in that paragraph from the previous handbook, correct?

Dr. Karen Jeans: [Unintelligible 1:01:08] still use it. It does not contradict, so that's the great thing about I think Directive 1200.05 is we took a lot out, we did not add a lot in.

Soundia Duche: Thank you. All right, the next question is about research involving children. And this one is a little bit detailed so I'm going to just read it. Per VHA Directive 1200.05 paragraph 21, the VA director, facility director, must approve participation in research studies that include children. It also says de-identified data on children is still considered to be research. So by saying that, are you implying that it’s still considered to be human subjects research and therefore local IRB review approval is required?

Dr. Karen Jeans: So I'll take this. So in terms of this specific case, a PI who wants to collaborate on a study taking place elsewhere and if his, we're going to say it's a he, role involves receipt of de-identified data in which he does not have access to the key or any way to identify, to re-identify the subjects, then he is not involved in the conduct of human subjects research. ORD is not saying that it is human subjects research. It's not. And the IRB is not going to review that if that was his only activity to say oh, this is under the IRB. It's not. In fact, the R&D committee will have to review it because this individual is involved in a research activity. So in this scenario [unintelligible 1:02:44] presented on the slide, the IRB does not need to review it because he is not participating in human subjects research. In fact, he does not have any identifiable information and no way to link it. In terms of a change that we've made, in terms of how the VHA Directive 1200.05 will apply to the facility director approval, this is a change that we will be issuing as guidance again trying to prevent things that were previously sent to the director that didn't need to be. So in Directive 1200.05, we state that the VA medical center director must approve participation, and that's the key word, in the proposed research that involves children. And so by that what we are meaning is, we're going to take that word participation literally. So that means interventions, interactions, observations. It does not count for this situation right here. All the investigator who's receiving this data here, the de-identified dataset, he knows they're a child. All right, so why should the facility director have to certify that? It does not serve a purpose in terms of institutional issues. It does not serve a purpose in terms of human subject protection issues. Same way with the issues involving review of, let's say, identifiable subject data, children's' data. Again, we are stating that facility director certification or approval is not required for such research because when it's dealing with identifiable data, those protections are going to be seen by the IRB of record because it's going to fall under the children's [unintelligible 1:04:21] for review. So that is the way again, we will be issuing the guidance should come out by next week clarifying this key point that again [unintelligible 1:04:30], I think it makes it much more logical regarding when facility director certification is required for research involving children.

Soundia Duche: Excellent. Thank you. So then there were a number of other questions that, kind of one-off questions, so we're going to go through those. And all of these questions were questions that you all sent in ahead of time. So this one is about limited IRB review and this guidance on assessing adequacy of privacy and confidentiality measures. The regulations reference the fact that HHS will be issuing guidance on this. And so the question essentially, the individual wants to know when is this information coming? When can we expect it? Dr. Klote?

Dr. Molly Klote: Yeah. So hi everybody. We speak to HHS pretty regularly. Almost every Friday. And they've made it clear to us that they're going to be releasing guidance at their own pace and based on the priorities that they are setting. We can give them feedback on what we would like them to publish on, but again, they're setting their own time frame. What they have told us in those phone conversations is that the guidance on, you know there's so much guidance that needs to be put out for the new common rule. They will be releasing it over a period essentially of the next two years. What they have also told us is that studies, because we asked this question specifically, studies that were previously approved under expedited IRB review procedures, or even as a full board review, that can now be transitioned to an exempt category where you would have needed the new limited IRB review, do not need to undergo a new limited IRB review because the privacy and confidentiality requirements under the dot 111 criteria include a privacy and confidentiality review. And what we have been doing as the full IRB, or even under an expedited IRB review procedure, is adequate to meet the conditions of the limited IRB review. So there's nothing additional that needs to be done with that. So whatever your IRB is currently doing for privacy and confidentiality is adequate at this time for limited IRB review so continue to apply those standards until we get further guidance from HHS. Thank you.

Unidentified speaker: Thank you. And I think you'll see when Dr. Klote later on talks about the Mini Moonshoot and some of the documents from that, there might be a form that you all might find useful when it comes to limited IRB review [unintelligible 1:07:16] IRB review [unintelligible 1:07:17], but just a little heads up there.

All right, next question is about research involving non-Veterans. Again, this was another [unintelligible 1:07:24], this is a section that was no longer found in 1200.05. So the question is, who is responsible for determining whether non-Veterans can participate in a research study? In the previous version of 1200.05, the IRB had to make this determination. I think it was said on one call that this will now be the responsibility of the R&D committee. VHA Directive 1200.05 has removed that paragraph so we don't have any information. Can you provide some insight?

Dr. Molly Klote: Sure. So it's Dr. Klote again. So the new Directive 1200.01 which should be signed and released any day, any moment hopefully, puts the responsibility of determining whether non-Veterans can be used in a research, or can be included not used, included in a research study at a VA facility, at the institutional level which puts it at the R&D committee level. And that is how I've sort of figured out why it would go into 1200.01 rather than 1200.05, but really the whole issue about including non-Veterans in research studies comes down to what happens if they get injured, right? So research-related injury is really at the core of this. And if a facility has to make funds available or admit people and create medical records for people, then that's really an institutional decision that has to be made. And so it's been placed under the new 1200.01 at the feet of the R&D committee and not for the IRB to decide. Because lots of times we rely on another institution's IRB or an affiliate's IRB and so this is an institutional decision. So if your institution however, if the facility center director decides nope, I want to make those decisions myself, you can always go above and beyond what the regulation requires, but as it's written the regulation only requires that decision to be made at the level of the R&D committee.

Soundia Duche: Thank you. All right, next question's about IRB of records. What is the process for requesting that ORD recognize another non-affiliated IRB to serve as an IRB of record for VA studies? And remember, this is specific for multi-site research.

Dr. Karen Jeans: Right, so this is Karen. Again, we will have that document out next week for the process to review. And those requests will be going to Dr. Klote. She has been given the authority by the CRADA to review and approve those processes. So we will have a number of different types of information that we will need as part of that request such as whether or not the request is for a series of studies, for example a block of studies. Is it for a single study? What type of format do they use? What kind of platform do they use? Do they use a cloud? We will be asking any information about where we can get their website so that we can see their history. And then we'll also be collaborating with ORO on this, but that document will be present next week. We will be announcing the release of these documents next week, so you can expect these by next week.

Soundia Duche: Thank you, Karen. All right, certificates of confidentiality. Can you clarify the new CoC policy procedure? As I understand, certificates of confidentiality will now be automatically issued for an NIH-funded project that uses identifiable, sensitive information. Will CoCs also be automatically issued for studies funded by other entities and for non-funded studies, or will investigators still have to apply for them?

Dr. Karen Jeans: This is Karen. Really, really a saga question. Short answer is yes, if the study is not NIH funded, you will need to apply for a CoC, a certificate of confidentiality. There is a requirement under 21st Century Cures for basically all federally-funded studies that are using identifiable sensitive information to have a CoC. That process has still not been worked out by HHS. So bottom line is that until that process has been worked out by HHS, Health and Human Services, your NIH studies automatically have a CoC as, they are using identifiable sensitive information [unintelligible 1:12:10] conveyed by NIH. For any other studies you will need to apply to either the NIH Institute or to FDA or any other of the few agencies that have issuing authority.

Soundia Duche: Thank you. All right, next one. Agreements. VHA Handbook 1200.05 had required that there be a written agreement that addresses such issues as the responsibilities of each party, the ownership of the data and the reuse of data when a VA investigator undertakes collaborative research with a non-VA institution. The current directive, by contrast, states that agreements regarding data use and transmission must be executed as required in VHA Handbook 1200.12. This handbook, however, does not pertain to specimens. Therefore, in some cases, for example specimens, collaborative research can now be undertaken without a written agreement? Is that what we're saying?

Dr. Karen Jeans: Well first of all, the handbook does apply to human subjects research involving biospecimens. So I do want to correct that because it would be identifiable. But let's talk about the issue of specimens first and then I want to get to the broader issue. As part of the, we keep referencing it, but I will reference it again, the imminent release of VHA Directive 1200.01 will have a requirement for material transfer agreements unless there are other agreements such as a CRADA that covers the, address the transport of biospecimens, the use of by the collaborator. And that is because we had a major issue going on within this agency about a fluidity concerning the control of biospecimens. So we are putting that in place with this national ORD policy. Now, the bigger issue is why did we take it out? And the problem is this. We are not going to put in place, in the Office of Research and Development, a policy that we cannot adhere to. We are not going to say you have to have a written agreement and then we're not clear on exactly what that agreement would look like. We're living with that in some areas right now. We are actively working with the Office of General Counsel to determine the appropriate legal agreement that should be used for these collaborative studies. We do thousands, and that is the truth of [unintelligible 1:14:37], and so we're not in a place where we can do thousands of CRADAs. So this is an issue that we will be addressing in later guidance and or later policies. But for right now, as this question has rightly stated, we have not specified [unintelligible 1:14:55] be an overall agreement. That does not mean that you do not have to have a DUA when it applies to 1200.05 [unintelligible 1:15:03-1:15:05] when required by 1200.12. If money is moving you must have a mechanism, an agreement, for the movement of money. When it comes to storing VA data on non-VA servers, you have to have an agreement as per VA 6500. We will be working, again this is as part of the list of documents that we want to work on in terms of our priority list, our plan is to issue a [unintelligible 1:15:34] or some type of diagram that again, compiles all these different ones. But the big issue, and why this is a huge issue, is like what Dr. Klote was talking about earlier about the use, about including non-Veterans in a VA research study. In terms of doing studies with our collaborative institution, and let's say we're doing a PET scan or a MRI, there are risks associated with that. And in so, do we have something that addresses liability if there's a research related injury? Who takes care of that? That's the risk that we're trying to address here with OGC on what type of agreement should we be applying to all of these different types of relationships? The issue is that there are so many different types of collaboration. One size doesn't fit all. So if you make a model agreement and you're doing, for example, a data-only study, that's going to have an entirely different take than a study involving an intervention or testing. So that is why it was left out because we do not have a firm grasp, [unintelligible 1:16:41-1:16:42] put into policy, you have to have a written agreement and we're not sure how the written agreement looks like. And so that will be coming, but for right now the policies of VHA Directive 1200.05 are as they're described.

Soundia Duche: Okay, thank you. And then the last of the questions that we received in advance deal with the definition of a VA investigator and specifically contractors. And this question has come up numerous times before, but regarding contractors, we understand that a contracted clinician cannot conduct VA research and that it's not appropriate to make that person a WOC while they are also working their contract hours to allow them to have the necessary VA appointment they require. Couple of scenarios. What about a scenario where a contracted VA clinician works 20 contract hours. Could that person also receive a WOC, say through the NPC, to conduct VA research as long as it is not on their contract hours?

Dr. Karen Jeans: So the issue is that, and I hate to use this word, two words, it depends, because it does. What is the relationship between the role, the activities that this individual is doing as a contractor versus the role or activities that this individual is doing as a federal employee because of the federal ethics rules which state that you cannot use your VA employment for the benefit of your non-VA employer. So these are issues where it will depend upon the type of activities that are being done. The office that is best suited to address these questions are ethics because it is an ethics issue. ORD does not make, does not interpret the ethics rules. Now, one thing that this office will be doing, again, I know we keep saying we're doing it, but these are again a long list of activities that we're doing, is we will be meeting with the Office of General Council, both our specialty [unintelligible 1:18:41] research and the Office of General Ethics to meet and instead of each institution reaching out and overwhelming the resources that are out there for the Office of General Council, working to have a statement, a guidance that gives more parameters on how to make this differentiation. When is it something that you don't need to send to ethics, when do you do? So, that's the general guidance regarding this scenario.

Soundia Duche: So the next question [unintelligible 1:19:18] part of this list, does the term investigator apply to anyone on the study team? For example, data analyst, or is that directly only to PI's and sub-investigators?

Dr. Karen Jeans: It is a great question because it gets back to the definition of who is an investigator. And VA follows the Department of Health and Human Services in terms of what they consider to be an investigator. And the definition is very simple. It's an individual who is conducting research. Okay, that's it. So that, when you look at that and you look at it literally, you could say well, anybody who's involved on a research [unintelligible 1:19:57] is involved in the conduct of research. But, the definition is really intended for the individuals who are in a supervisory capacity. Who have primary roles for assuming responsibilities of the study in that capacity. So no, investigator does not automatically apply to everyone on the study team. And FDA issued very good guidance on supervisory roles of investigators versus study team members because even their definition is the same definition. But there is a differentiation between investigators, co-investigators or sub-investigators and then you have your study staff.

Soundia Duche: And then the last part of this question asks, if a contractor is included on a VA grant budget proposal, is it assumed that person will work on the project? And should they just not to be listed under the facility VA IRB's approval and thus also under their FWA? Or can these lower level study staff be included because they don't fall under the investigator status?

Dr. Karen Jeans: Again, a fantastic question. And we consulted with some of the service chiefs for this study, because this is really talking about the grant applications that are submitted to ORD. And in talking about this and asking the service directors okay, when do you put a contractor on there and what does it mean? When, the instructions on this are on the [unintelligible 1:21:21-1:21:22] and the budget. It's all about the budget. And what this is referencing, when a contractor is placed on these myriad applications, is giving the peer review committee and giving the program office an idea of okay, what services are going to be required to do this study? So, that's how they're looking at it. They're looking at it as okay, when you're including this person, or if it's person or if it's a type of service, what are the services are going to be used and what are the qualifications that are going to be needed for this service to be provided in support of the merit? So from the perspective of the funding agencies and the grant proposals, that is the response that they had [unintelligible 1:22:10].

Soundia Duche: Awesome, thank you.

Unidentified speaker: All right, so I know everybody's been watching the clock [unintelligible 1:22:15] been watching the clock. We got though all of the questions that were sent in in advance but the last thing we want is for people who weren't able to get their questions in in advance to feel that we're not going to give you enough time for the open Q&A. So what we're going to do is we're going to go, I know I had said we'd go till 3:45, till 3:30 and then transition to the Mini Moonshoot update. We're going to go till the 3:45 with the open Q&A session and at that point we will extend this for about 15 minutes and do the Mini Moonshoot update as well as update on education. Petrice before you go into the questions, I do have something I need to show regarding a correction that I need to draw your attention to. So I think you will need to show my screen. Yeah, thank you.

One of the questions we did get in was a great question because it was a correction. On Friday's workshop, and I think I've done this multiple times because I've used this slide before, I stated something incorrectly and so I apologize. I'm going to use this opportunity to let everybody know the correction, but we're also going to send it out to the field because I know sometimes people borrow these slides and use them. So when I went over the study-specific elements of informed consent, and I mentioned that there were three new additional elements required when research involves biospecimens, in the revised common rule there are three new additional elements, but only two apply to research involving biospecimens. And so I'm going to cross out that. This is going to be the corrected slide. There are two new additional elements required when research involves biospecimens. Additional elements seven and nine. Number eight was in there and I inadvertently just lumped them together. Number eight is not specific to research involving biospecimens. The statement whether clinically relevant research results will be disclosed to subjects, and if so under what conditions, applies more broadly and you use it as applicable. So I apologize for that but I really appreciate the person who brought this to my attention. So please make a note of that. We'll be sending this out to everybody, especially because people do borrow this slides. The regulations are clear. Number eight does not, but it was sandwiched between the two, so just want to bring that. All right, now we're ready for our open Q&A. Oh, one thing with the open Q&A session, last thing. As I mentioned, privacy was only here for half an hour so we are not going to be addressing privacy-related questions that were submitted. We have them, we can forward them on to privacy. But so Petrice, if you can skip those and just let people know that we'll be addressing those offline in consultation with privacy because they really are the best people and individuals to answer those questions.

Dr. Petrice Longenecker: Okay, sounds good. So I'm going to switch presenters to my own screen now and go through the questions.

Dr. Karen Jeans: Can I inter-, there was a question which we received which may not have made it on there that we received right prior to the conference, so I do want to address that one because it's a great question. And it's can volunteers be used to assist in the conduct of VA research?

And the answer to that is yes. But it is a situation where we follow the policies of the National Volunteer Office Handbook which is VHA Handbook 1620.01. And when you have volunteers and they are designated as such and they go through a process, you categorize those volunteers as to what they're going to do into one of four different groups. A, B, C or D. And so depending upon what they are doing, they're going to have different levels of requirements that they have to meet in order to do those responsibilities. For example, someone at an A cannot do clinical research because they don't have the level of training that is required to do so. Or even like a TB skin test which is required to interact with subjects, or if you're interacting with subjects which would be in the C category. So the bottom line is it can be done, you do have to follow the National Volunteer Handbook 1620.01, but that is something that I don't know if everybody was aware of and so I'm really glad for that question. Thank you.

Dr. Petrice Longenecker: Okay, are we ready for the first question?

Unidentified speaker: Yes we are.

Dr. Petrice Longenecker: Okay, and can you see my screen with the question?

Unidentified speaker: Yes we can.

Dr. Petrice Longenecker: Okay, great. So the first question is VA is collaborating with an academic affiliate in a human study. For VA's participation in the study, VA staff are analyzing data which has been de-identified by the affiliate. There's no overlap in study personnel between the affiliate side, which is collecting PII, and the VA side which is only analyzing de-identified data. For VA side, does our research meet the criteria for exemption category four-two if the study is approved post common rule revisions. So these are the new categories of exemption. The regulations at 45 CFR 46.104 describe this with the term secondary research, but that seem counter intuitive for a project that is collaborative. Must secondary research involve two or more studies to be applicable?

Dr. Molly Klote: Hi there, it's Molly Klote. We're jockeying to see who would answer this. So here's my take on this. What the VA side is doing is supporting research, but it's research not involving human subjects. So it wouldn't fall into any of the exempt criteria since exempt research is human subjects research right? So you have things that are not research, then things that are research not involving human subjects, then you get into human subjects research and you look at the exemptions. If they don't match that you go to the IRB. So for what is described in this scenario no exemption would apply and secondary research wouldn't apply because this is part of the primary study that's happening. This isn't being used in a secondary purpose. This is analysis happening in support of the primary study. So really the determination that should be made on the VA side is that you are involved in research not involving human subjects and that should be the determination you get. Over.

Dr. Kristina Borror: So this is Kristina. I have another way of possibly looking at it. And I think that maybe it might depend upon some of the details, but we recommend that you ask first, is it research? We know it is. And second, does the study involve human subjects? And generally you want to look at the study overall and so it's not clear if this VA participation of the study is part of the overall study that is happening at the affiliate side too, or if they really are separable. Because if they're not separable, if it's all one study then the whole study involves human subjects and it may just be that the VA is not engaged. You come to the same outcome right? That the VA doesn't have to review it, that the IRB doesn't review it. But you wouldn't even get to the engagement question if you had determined it was exempt. And that's one of the questions. But it's not clear to me from the question whether they are separable or whether it's one big study. And when you're looking at exemptions you have to look at the whole study, not just VA's portion of it.

Unidentified speaker: For purposes of this one I think we're going to assume that it's one study.

Unidentified speaker: And since we're getting to the same outcome which is essentially there's no IRB review required and VA is not engaged in the human subjects portion of this because all they're getting is de-identified data from the affiliate, we'll have to just agree to disagree on this Kristina, or to just take this to, we'll take it offline and we'll come up with a, figure out between us an answer that we'll get back to the whole field. Thanks.

Unidentified speaker: But I think the key is, I think the nuance that we've touched on is really, exempt category four as the requester asked, is secondary research. And this would not be secondary research. VA is participating in the study, an initial research project as Dr. Klote said. So thank you.

Dr. Petrice Longenecker: Hey Soundia, I've got 3:33 on my clock, do you want to go ahead into the next portion? We've got tons of questions, we're going to have to table them for another time though.

Soundia Duche: No, no. What I mentioned was we are going to go. We're going to respect the fact that people spent time and sent in their questions. We are slated to go for 3:45, we will go for 3:45 with the open Q&A session. That's the time that presentation is supposed to end. Those who need to leave can leave at that point and then we'll spend a maximum of 10 to 15 minutes on the Mini Moonshoot update. So we'll go till 3:45 with the open Q&A.

Dr. Petrice Longenecker: Okay, sorry I must have missed that.

Soundia Duche: [Unintelligible 1:31:48].

Dr. Petrice Longenecker: Next question. Someone explain exemption category four in the pre-2018 common rule. It states, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Unidentified speaker: I guess we're not clear on what the issue\_

Unidentified speaker: I mean there's a lot of, I mean it is about being publicly available. So let's say you were doing research recording from newspapers. That's a publicly available source and you're recording individually identifiable information, but it's not private.

Unidentified speaker: Right.

Unidentified speaker: So you're not, so that's an example of a public resource. And also this is the again, the pre-2018 requirements. Again it's about when you're looking at charts, for example medical records of for example, patients with asthma, you're looking at the charts, you're reviewing the identifiable information, but you're not recording it. So that's what the second half of that means. That you may look at it, but you're not recording it in a way that it's individually identifiable.

Unidentified speaker: Right. You can't create a code.

Unidentified speaker: Right.

Unidentified speaker: You can't, if you mess up you can't go back and fix it. Lots of times when there used to be records rooms, you'd go in and they'd have a pile of 100 records and you'd take like ten a day and sit in a corner and take the information you needed out of those records without any identifiers and then hand those ten back and the next day come and get ten new ones and that's how you sort of tracked which ones you'd already done or not done because you weren't allowed to record identifiers about whose charts you'd already looked at. Over.

Unidentified speaker: Thank you.

Dr. Petrice Longenecker: Okay. On a VA informed consent form, does time of a subject's signature need to be recorded in addition to the date or is recording the date alone sufficient?

Dr. Karen Jeans: This is Karen. No. Date alone is sufficient. This isn't like consenting for a medical procedure where you have to do date and time.

Dr. Petrice Longenecker: Okay, follow-up question. Also, no witness signature needs to be obtained, recorded moving forward.

Unidentified speaker: Witness signatures.

Unidentified speaker: No requirements have changed about the witness signature.

Dr. Karen Jeans: Yeah. We took out the person obtaining\_

Unidentified speaker: Obtaining consent, yes.

Unidentified speaker: If the study is such that it requires a witness and the IRB has indicated that a witness, [unintelligible 1:34:28] that would be something that the IRB would determine and that would be part of the approval. But what we took out was specifically the signature of the individual obtaining consent which does differ from a witness, want to be clear.

Unidentified speaker: Yeah.

Unidentified speaker: And witnesses sometimes are required if the person can't physically sign their name or all they can do is nod and then somebody witnesses that. But those are decisions made by the IRB about having a witness. But not routinely.

Dr. Petrice Longenecker: Okay, the next question is about preparatory to research. You may want to table this, just let me know. [Unintelligible 1:35:05] how does this affect access preparatory to research? And that's kind of what the privacy does?

Dr. Karen Jeans: Well it actually doesn't because the privacy rule didn't change.

Dr. Petrice Longenecker: Okay.

Dr. Karen Jeans: So the common rule has nothing to do with HIPAA, so it does not affect preparatory to research activities and the policies that's described in the privacy policies. Good question.

Dr. Petrice Longenecker: Okay, next question. Sorry, I'm going on two screens here. What are some regulatory suggestions for enrolling subjects that have the capacity to decide to participate or not but are not physically able to sign their name and also for patients who may be blind?

Unidentified speaker: So FDA has issued guidance as an agency regarding the issue when individuals are not physically able to sign in terms of, and those are considered by the IRB. And in terms of for patients who may be blind, just because they're blind does not mean that they cannot consent and do a mark or a signature.

Unidentified speaker: Same with deaf. Same with, I mean there's lots of different ways. We had double amputees at Walter Reed, double arm amputees who signed with their mouth. You know, you put the pen in their mouth and they sign their consent forms with their mouths. So it doesn't mean they lack capacity just because they can't sign for themselves.

Dr. Petrice Longenecker: Next question. Are there amendments under exempt categories 2(iii), 3c, seven or eight, that change privacy, confidentiality or broad consent? Would it require the R&D committee to return the study to the IRB to conduct a limited IRB review to make sure the project still qualifies for exempt?

Unidentified speaker: So this goes back to that question we had earlier, or the statement I made earlier. So for categories two, three and 3c, the only two things you have to check are the privacy and confidentiality. For seven and eight, you have to do those two things plus you have to apply a few other standards. And there is a form that we have which is the limited IRB review checklist in the forms and templates that are on the SharePoint site that we're going to be sending out to everybody or releasing to everybody, that look at every single requirement that has to be met. And category seven has the most because under category seven, that's where you establish a repository. For that one you have to go through all of the components of the broad consent document. Under category eight, you do privacy, confidentiality and then ensure that the broad consent was adequate that the specimens were collected under and that the investigator does not intend to return results to people under which the original repository was collected. There's a couple of other things, but there is no need, as we talked about earlier, to send something back to the IRB if it's transitioned from an expedited study to an exempt study. At this point you don't have to get that IRB review again because you already looked at those items for categories two, three and 3c. There is no study right now, until Monday, that would be qualified under category seven or eight because those exempt categories don't exist because broad consent doesn't exist until Monday.

Unidentified speaker: I think however, though, they may be specifically asking about post-January 21st, they've approved an exemption, it's now followed and overseen by the R&D committee and there's been a change. An amendments been submitted [unintelligible 1:39:18]\_

Unidentified speaker: Oh, I see.

Unidentified speaker: \_privacy and confidentiality which is one of the things that the limited IRB review [unintelligible 1:39:23-1:39:25].

Unidentified speaker: Oh, absolutely. Yeah. So in that case if you've got a study that, so it got originally reviewed under the limited IRB review under the exemption, it no longer gets continuing review by the IRB. It now shifts to the R&D committee or whatever the committee is that your institution that has to review them. But it's now overseen by the R&D committee. If the investigator submits an amendment to one of those projects that changes something about the privacy, the confidentiality, the repository, how it's being managed or the broad consent, then those may in fact have to go back to the IRB to be re-reviewed to ensure that they still fall within the specifications to stay under limited IRB review or even to say really under their exempt category.

Unidentified speaker: Right.

Unidentified speaker: Thank you. So will the revised 1200.01 allow for an expedited review mechanism? There will be a designed review process for certain activities. The answer is yes.

Unidentified speaker: Too fast for you Petrice.

Dr. Petrice Longenecker: Okay. Can ORD provide what is recommended for R&D committee to review for studies that need continuing review under R&D committee oversight?

Dr. Karen Jeans: So, this is Karen again. The answer is yes. As part of the revision of 1200.01 we did include specific criteria for those studies. Excellent question. Thank you.

Unidentified speaker: So this is the question. Does the key info section on the informed consent have to be on one page? And the answer is, no. It's whatever amount of room it takes to communicate that key information. I think the spirit of the new common rule was that it be short so that you're not doubling the size of your informed consent document. I think that's why they used the term key information. So you're really trying to give somebody an overview of what the study's going to entail, but you would like to condense it as much as possible while still presenting that key information.

Unidentified speaker: It does have to be upfront.

Unidentified speaker: Yes.

Unidentified speaker: [Unintelligible 1:42:02] start on page one.

Unidentified speaker: That is correct.

Unidentified speaker: [Unintelligible 1:42:04] Yeah.

Unidentified speaker: You don't want it to be a ten page key information document.

[Pause 1:42:09-1:42:16]

Unidentified speaker: That's fine.

Unidentified speaker: Okay. University of Kentucky permits appendixes to be attached behind the main consent document and are referenced in the consent document. Example tables, prohibited meds etc. Might we do the same? [Unintelligible 1:42:32].

Unidentified speaker: So I, yeah. So I think the trick to this is how are you accounting for these appendixes to ensure that they're attached to the consent form? So the easiest way to do it is to embed it because when you do your page counts you say, this is page 17 of 18 or whatever it is to make sure that they received all of those pages. So that's really the trickiest part to this, but there's no prohibition to putting pictures, to doing all sorts of things as part of the informed consent. Because again, it is a process that has to get documented in most cases and so how you choose to document it, you can use your imagination in a lot of cases, although you cannot change the HIPAA language if you're embedding it in the consent form. But there's lots of way to do this, so absolutely. But again, just make sure that you are somehow capturing that you're giving them all of these attachments or addendums that you put on it. It's all still part of the informed consent form.

Unidentified speaker: That's correct.

Unidentified speaker: Not a separate document. Right.

Dr. Petrice Longenecker: Okay. I've got 3:46 on the clock. We have five questions left unanswered.

Unidentified speaker: Okay. We will get back to those questions. We're going to proceed with the update on the Mini Moonshoot. I'm going to display it on my screen. Petrice? Okay, perfect. Thank you.

Dr. Molly Klote: So I'm going to actually start by talking a little bit more about the bigger Moon Shoot before we talk about the Mini Moonshoot. But the bigger Moon Shoot is really an initiative that we put forward to get us to January 20, 2020. And it's on the next slide is sort of the picture. And these are all the things that really need to happen in order for us to move forward as an institution to really be seen as a leader in multi-site research review by the time the single IRB review mandate shoe drops, right? So there's some cultural changes that have to happen. We've got to look at how do we start looking to rely on one another rather than only on our affiliates. How do we define very clearly as we move to maybe someday relying on a commercial IRB, what are institutional responsibilities separate from the IRB's responsibilities? And this is really hardest in institutions that have an institutional review board where the IRB is sort of the go-to committee for anything that happens in research within the institution. For institutions that don't have their IRB, they've been dealing with this paradigm for a long time because the IRB doesn't want to hear everything about everything that's going on in your institution. And so it's really some cultural change we have to make, specifically in the institutions that house an IRB. But there's a lot of other things that are going on. We're going to distribute some regulatory knowledge across the VA through the regional regulatory support network. We're building a VA electronic determination aid which is going to take a lot of workload off of IRB chairs and IRB members right now who are making exempt determinations or writing letters for quality improvement projects that are trying to get published that say you don't need IRB review. We're going to look at getting an exception to policy to try to do at least one study with a commercial IRB this year so that we can figure out what we have to do to play in this arena and what sort of policies or guidances we're going to need to develop for that. We're taking a look at some of the IRBs across the VA that have capacity because we've got other VAs that would love to rely on an internal VA IRB. Maybe right now they're partnered with sort of a high-power IRB and they don't feel like they may have the same voice that they would like to have if they were partnered with someone who had a little more capacity or interest in them. So we're taking a look at that. We're taking a hard look at the Central IRB's processes, especially on initial review and how we might be able to streamline and harmonize that with some of way other IRBs might do multi-site review. I think we've grown out of the idea that we can only have one IRB that does really confident big multi-site review within the VA, and maybe that means we just add panels to it. Maybe that means we empower other IRBs to take on a similar role with similar practices, SOPs, templates, forms, that sort of thing. We've got legislative language changes to make with research-related injury if we're going to look at streamlining potentially the R&DC process. Of the eleven VAs that I've gotten out to be able to visit, having this sort of one-size-fits-all R&D committee structure, it may be better suited to make that the responsibility of the R&D, what are committee now, a more functional requirement and perhaps let the institutions decide whether that should be a coordinator position, whether that should be a two-person little group, or it really needs to be a committee as we currently have it built. But really nothing is off the table at this point. We're looking at the [unintelligible 1:48:54] system to see what the true feasibility is of getting that stood up in time for this January 20th, 2020 initiative.

But then back to the Mini Moonshoot. So the Mini Moonshoot was the first thing that was on our plate to try to help jump start you guys because we knew we were delayed in getting the regulations out and so we really wanted to do something to show our interest in supporting all of you in getting ready for the new requirements next Monday. But it was also part of an idea of potentially supporting standardization and harmonization, not that we mandated you adopt these form, you can adapt them. But it gives us a starting point. It gives us that initial crystal that we might grow a larger system around to really support reliance on each other. Because when you get down to relying on each other, it comes down to trust. It comes down to understanding the other institution's policies and procedures so that you feel good about relying on them. The good news is, under the new common rule that, well under the old common rule, if you relied on another institution's IRB and that IRB made a mistake, your institution was held responsible. So there wasn't a whole lot of benefit to relying on another institution's IRB from the point of view of the institution. For the investigator there was, but the institution still had all that liability. Under the 2018 requirements, the new common rule, if an IRB makes a mistake and an institution relied on that IRB in good faith, the institution is not held responsible for the decision of the IRB. So if the IRB makes a bad risk determination call, the institution is not held responsible for that, as long as you relied in good faith. So those are some of the changes that are happening on the grand scale. Dr. Ramoni and Dr. Clancy have been briefed on the whole Moonshoot initiative. They're incredibly supportive of it. They're helping me work my way through the VA system on a lot of these issues which is tricky, but fun. And are we going to get there by January 20th, 2020? That is the goal. We got those documents out on 21 December so we're a little shy of a year away of making this goal, but we're going to do everything in our power to get as much done on that Moonshoot so that we've got a safe landing.

Unidentified speaker: Do you want to comment about the documents?

Dr. Molly Klote: Oh right. So the documents that are going to be released on Thursday. I believe it's Thursday. We're going to do our very best to release the final on Thursday are, and it's up on the screen right now. So there are four SOPs. Well, there's an HRPP document that again, has a lot of details, a lot of things that your program can look at. And really the goal of this was to show you what's required. We went through these documents and removed a lot of things that were super regulatory. That were way above and beyond what was required and tried to par them back to what was required. Specifically within the HRPP document, there are some decisions that your institution gets to make. Whether or not you will adopt broad consent at an institutional level, which has implications when you're going to do multi-site things. And all of these decisions you make will have implications when you engage in multi-site research. But it will be important that you decide within your culture at your facility what you're going to accept. The idea, maybe your medical center director doesn't want any non-Veterans in studies where they could get hurt. Where it's going to be an interventional trial. You guys get to make those sort of decisions and then build the process around them. But that's in there. You've got four SOPs. You've got a number of forms for both the IRB and for the HRPP and then you've got letters and documentation, certification letters. You've got a whole bunch of algorithms in there of what are the FDA requirements for drug studies, device studies, supplement studies. There's all the viseos for the exemptions as well as things to consider when you transition a study. And then, some very generous people from across the VA donated to us their safety training manuals and other items for you to consider as you look at your own internal forms and templates. We're not putting these out there as perfect or necessarily a, this is the gold standard. We're just saying these have been offered up and we wanted to make sure that we shared them. So under the other category, number four, which is appendix 11, the responsibility matrix, what we did there was we went through the new 1200.05 and the new 1200.01 and pulled out every responsibility and who it was assigned to and then sorted them by the physician so that you can see the scope of what is responsible [unintelligible 1:54:55] operate your HRPP. And it's from everything from the Under Secretary of Health all the way down, not down to, but to the investigator. This is not a pyramidal structure. But across to what are the investigators responsibilities. And so that all, but hopefully these will be of value to your institutions when you get them. And with that I'm done.

Soundia Duche: Thank you Dr. Klote. All right. We're just going to spend the last few minutes, I'm just going to brief people on what our plans are for web-based training in 2019. We'll be talking in the future about whether we'll be able do some face-to-face training. But for web-based training one thing I just want to let people know, back in, I want to say it was late-October, early-November we were actually able to purchase GoToWebinar and so that was huge because that means unlike all last year, 2018, where we were restricted to only one training a month and so we had to jam-pack all content into one training a month, we now have the platform and we can do as many trainings as we want and so you're going to see us ramp up training. What that also means is, since we just recently took this over, we benefited greatly from having Heidi who was with HSR&D, for years assist us with trainings. And as you know, the trainings were flawless. She did a wonderful job. Well, we're learning how to manage the platform ourselves and so we did have some technical challenges last year. We hope to improve. We're learning little tricks and troubleshooting things we need to do. But bear with us. We apologize for some of the technical glitches towards the end of last year. We can't promise you won't experience any others, but we are working hard and every session we learn new things that we need to do, new things that we need to have in place to make sure the training goes smoothly.

We're working on revising the webpage to include a calendar of upcoming training. Our hope is to get that out in the next week or two. And the goal will be to post upcoming training on the calendar approximately two months out. We will still announce training in the same way we do, where we send it out a week before, but this way with a calendar you'll be able to go and see what's upcoming. Unlike last year where we published up front the whole year's training, we did that because we were largely focused on core issues related to the revised common rule. Our hope is, and especially as we get past this first quarter of 2019, to be able to expand and broaden the training really to be able to address a lot of the other topics that you guys are hungry for and we know we need to get to. And so we're not able to publish all of our training for the whole year out this year, but our goal will be to be able to put that on the calendar. You should get used to going to the calendar. We'll publicize when that's available. And then you'll be able to see training one or two months out. We have always been having monthly Cyberseminars on the third Tuesday of each month and we plan on continuing that at a minimum. We've always introduced the concept of the workshop. Our goal and thinking is we'll be doing that about once a month as well, at a minimum on the first Friday of each month. The workshops were a direct response to comments we received from you all at the end of the survey. Many people felt, like today, our Cyberseminars are long and somehow we don't seem to get away from that because we have a lot of content, you all have a lot of questions. The workshops are targeted on a very specific topic and they're one hour in length. It's supposed to be brief. You asked for brief. This is our attempt to give you a different format. That said, we're also getting comments from you guys that the workshops are too short. So bear with us. We're going to revisit things around June. We're going to proceed as we've been doing. Keep putting in your comments. We are reading them, but we'll revisit things in June and see if we need to tweak things a bit further. But give us some time, send in your comments and we're taking it all into account.

In terms of what we're going to be focusing on coming up. All of our training, I have a proposed plan that I'm going to be discussing with Karen and Dr. Klote for the whole year's training. I'm not going to publish that because I don't want to over-promise and under-deliver, but just broadly speaking our goals are to have about two to three town hall Q&A sessions throughout the course of the year, maybe over four months just like this where you're able to ask questions to privacy, ORPP&E, ORO representatives. We really want to be able to focus on some beginner sessions focused on people new to the review responsibilities [unintelligible 1:59:34] both the R&D committee and the IRB. So hopefully you'll start seeing some of those focusing on things like meeting minutes, intro to FDA regulations, those types of things. We know some of our folks who have been in research for a long time are hungry for more advanced topics and we also hope to address that. Some of the things people have asked to hear about are VINCI and right to try, so we're going to see how we can get those to you and find some speakers both in-house and external. My thinking is that we'll be hosting hopefully one or two what I'm going to call multi-part series on topics such as expanded access and collaborative research. We know you all have been asking for information on collaborative research. That is not something that can be handled in one session and so when we get to that we're thinking it might be just a month or three weeks, we go week by week in all the different aspects. And of course we'll have to bring in other experts. So if you all know anybody, send them our way. We're going to continue covering our core topics. Again, our topics that I structured the training around, that is awaiting approval from Dr. Klote and Karen are based on the topics you all have suggested in the surveys. So please respond to the survey at the end of the training because I pulled everything, I reviewed all of the responses we got. And that is what we based our training on. And then lastly we hope to also host one to two sessions specifically geared at study teams and maybe more. We realize that we have not really been able to focus on you all this past year and we apologize for that. The needs were just too great with the revised common rule and getting our IRBs and R&D committees up to speed. Anytime we release a new handbook, R&D committee handbook that's coming out, we'll be having training on that too. So there's going to be a lot of training this coming year. And this is just web-based training. We'll talk later on and as the year goes on to see what else we may have in store for you for education and training.

But thank you so much for bearing with us. We know, another two-hour training. But, hopefully we got to all of the questions that were submitted in advance. Apologize that we couldn't get to some of those that were submitted online. We will respond to you offline. Everyone have a great evening and thank you so much. Thank you Petrice for moderating. Thank you Lucinda for watching and moderating as well. Thank you to all our presenters, Kristina, Stephanie who's not with us, Karen and Dr. Klote. [Unintelligible 2:01:58-2:02:00]. Thank you.

Unidentified speaker: Thank you Soundia.

[ END OF AUDIO ]