ORPP&E Webinar
Date: February 24, 2021
Session: ORD Policy Updates - Technical Amendments to VHA Directives 1200.01, 1200.05, and 1200.08
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Dr. C. Karen Jeans: We are going to be covering the Technical Amendments to 1200.01, 1200.05, 1200.08, with emphasis on 1200.01. We're also going to be discussing, we have discretionary hold on some three policy areas within 1200.01. And we'll discuss the relationship between those discretionary holds and the issuance of these technical amendments.

So, you know, we use this word technical amendment, and we assume everybody knows about it. And, you know, that's a wrong assumption. So, I want to take a couple of slides here to explain what is the difference between a technical amendment and what we consider to be a major revision in policy. Well, technical amendments are those revisions that do not substantially change the policy. They, you know, again they're, they can do grammar, but really, they exist to clarify, or in the case of what occurs with 1200.01 to delete something which never actually was implemented. So, it is something that, again, does not substantially change the existing policy. Now, ORD does not do technical amendments in isolation. We don't need to sit around and say, oh, by the way, we're going to do a technical amendment today. These still require a concurrence process. Now when there is major revision of policy it, and you're going to see a slide here in a second, it's a very, very structured formal process. Pre-concurrence, senior editors, formal concurrence processes, signed off by all the letter offices until it finally reaches its final signatory. So, a technical amendment, while it doesn't go through the whole formal concurrence process, every office that is impacted at the national level by that technical amendment still has to review, and still has input on the language that is actually published. And so, in the cases of this, of these technical amendments that we have executed for these three different VHA directives, Office of Research Oversight, RSD, and VHA privacy have all had input as well as legal. Now, what is interesting about a technical amendment is that there really isn't a long run in on these. You know, you don't have six or seven months to initiate. These are issues with the expectation that they'll be implemented as rapidly as possible. And indeed, many of the technical amendments are executed with the expectation, with just minor wording changes.

And so, we're going to jump into the slides themselves. And again, I'm, so in terms of this slide, I want to, again, as we're trying to reinforce the difference between a technical amendment and a major revision of policy, I wanted to give you an example. From, you know, a directive that almost everyone on this call is going to be familiar with. And that's VHA Directive 1200.05. Which is ORD's policy for the implementation of the Common Rule. And so, you know, we have had the directive that was issued, and with the recent issuance of the technical amendments that we're going to talk about today and get back to the second set of technical amendments. Now, 1200.05, it was a major revision in policy when in was issued on January 7th of 2019. We actually did very good in that, it took us about nine and a half months to get that published from the time that we sat down and said, okay, we've got to issue a new policy, a major revision to, in order to revise the policy to implement the revised common rule.

Now, last March we initiated a code of some technical amendments, including VA's use of commercial IRBs. Now it took us around four months to get those executed. So, you can, for a timeline. And in terms of the technical amendment that we're going to talk about today, these actually have taken us about six months, still a shorter time than a major revision in policy. But that slide, when you're hearing us say sometimes, well we're going to pursue a technical amendment, it's not something that's going to happen in a week or two. Usually it does take at least a couple months. And usually between four or five months, it's been more, but yeah, there have been circumstances when we can get a technical amendment issued as recently as three or four days. Which was an example with right to try notice.

So, as we start to jump into the context of this _

Kate: So, so sorry to interrupt, Karen, for audio, can you just pick up your phone?

Dr. C. Karen Jeans: Yes.

Kate: Thank you so much.

Dr. C. Karen Jeans: Okay, Kate, is that better?

Kate: That is, that's excellent, thank you.

Dr. C. Karen Jeans: Okay, thank you. All right. So, I apologize. So, in terms of this slide that you're seeing right now, it says summary of technical amendments: number. Again, the reason we're talking mainly about 1200.08 today is, I mean 1200.01, excuse me, is because the majority of the technical amendments that were executed were indeed related to 1200.01. We

issued 20 technical amendments on January 8th, 11 of those were 1200.01, six 1200.08, and three for 1200.05.

And again, the primary purpose of these recently issued technical amendments, again, you don't just flip a coin and say, okay, let's just see what we can do because we have nothing else to do today. What we have done is in terms of 1200.01, that was the primary purpose of executing technical amendments was to reverse the discretionary hold, to deal with the issues that had been put in place for over two years. And we will talk about the discretionary hold here in a little bit.

For 1200.05, as we were reviewing these and sending these to the different program offices, again, other program offices can comment, you know, there was a discussion, hey, can we make some minor clarifications to 1200.05 because of the result of COVID? There has been so many questions about, you know, is R&D committee approval required for an emergency use of a test article? You know, is it clear that, yes, you don't have to have IRB prospective approval? Can we specifically make those in clarifying statements? So, that was the primary reason that was put in.

And then in 1200.08, we needed to do some, again, some minor clarity on some sentences, but also there was a new issue of NIH guidelines with this, which was issued right after 1200.08 was published. So, this begins that alignment process.

So, we're going to start right off and jump into 1200.01. Now, what you'll see on this slide, it's what's called, what I call a quick guide. If you want to, you know, if you're, and many times many of our presentations they are then provided subsequently for your R&D committees, or to investigators, and so this is what I call a cheat sheet. If a one, one slide it says, really, what do these technical amendments do? And so, it clarified that the R&D committee reviews, designated review processes, and we're going to go through all five of these. Including this, some key areas. So, rather than read this slide I'm going to go through the five.

So, what you'll see on these next two slides, again, as part of the attachments that you received today, is a detailed listing of the exact paragraphs. So, again, I'm going to jump through these, you have these in your handouts, and jump into the actual meat of 1200.01's technical amendments, starting with those technical amendments that were issued to clarify, resolve the confusion. Is R&D committee approval required for emergency use of a test article? Over and over, and over again, you will hear us say, as very clear, that by the way, it's not VA research until it is approved by an R&D committee. Now emergency use of a test article doesn't require IRB approval prospectively, it requires notification within five working days afterwards. But what about the R&D committee? So, that is why, and then you get it's this issue of, you know,

well by the way, you know, it states in 17.85 that you can't be covered for a research related injury if it's not approved by the R&D committee. So, there was a lot of questions about this. And again, reinforcing that individuals who received test articles under FDA's regulations, including emergency use provisions, under these regulations they're still human subjects.

And so, we wanted to enter, put in a few sentences here to state, very clearly, in two different sentences, in two different paragraphs, that emergency use of test article, it's still VA research, even though it doesn't require R&D committee approval. And again, reinforcing over and over again, you do not need R&D committee approval when an emergency use of a test article is applicable to that activity under FDA's regulations.

Now, in terms of the next technical amendment, in terms of the topic area we covered, it all is related to designated review. Again, still building upon this expanded access. COVID really truly did change many of the ways and issues that we were dealing with, because now we're seeing all these different expanded access uses of test article. Treatment protocols, you know, things that, you know, they're now becoming commonplace. Unlike before. Where it was very, very periodic, very, very random. And not common. Now it's a part of our everyday language. And so, what happened here is we got some questions, and we kept thinking about this. Right now, in current ORD policy, prior to the issuance of the technical amendments, we stated that you could use a designated review process as an R&D committee. For single patient expanded protocols. For those that required prospective IRB review. Those are the non-emergency expanded access. And so, we felt very strongly in ORD that VA facilities should be given the option. That if it falls under an expanded access use, and it's non-emergency, because it's we're going to require IRB prospective approval, then those R&D committees should have the ability to use a designated review process. That they shouldn't have to convene an R&D committee, they have a choice. Again, it's about a choice. If you chose to do so, you can. But this is a choice that we wanted to be able to provide to all VA facilities.

And again, there's many different types of expanded access activities. And even though what you'll see on the screen is applying to drugs, even on medical devices, we have your non-emergency, you have your individual, you have you r small group, intermediate, and then you have your treatment. And so, there's a whole different realm that falls into expanded access, a number of different activities.

So, we went into the policy, in terms, and this is a minor tweak, again, it didn't substantially change the existing policy, to state let's expand it. Let's revise our policy. Here in ORD. For VHA Directive 1200.01. To state that designated review, by the R&D committee, can be used for any non-emergency expanded access protocol activity. Because non-emergencies all require prospective IRB approval. And again, we wanted to reinforce that concept by adding a note,

again, reinforcing over and again that emergency use of a test article does not require prospective R&D committee approval or notification. So, that is the reason why we executed that technical amendment. Again, minor. Does not substantially change current practice. And again, it is a choice.

So, then we continue to move on. And this is something, this is an area, and we're now going to talk about exempt research. 1200.01 actually went into the pre-concurrent major revision of policy even before 1200.05 hit. It took us around 19 months to get 1200.01 through approval. So, 1200.01 was going through the concurrence process even before we were able to get all the materials ready for 1200.05. And so, there was a disconnect. Right now, prior to the issuance of the technical amendments, R&D committee was required to conduct continuing review, and is required to conduct continuing review, when it's the only sole oversight committee. That's what it says in policy. But then you come along to the revised Common Rule. And the revised Common Rule eliminated the requirement for continuing review of most minimal risk non-exempt human subject research activity. That is now the regulation, unless the IRB, because those studies remain under the oversight of the IRB, they have to provide a specific written justification. So, our position in ORD, and again, this is something that many of the researchers, and research offices, they can, it is about a logic here, is if those types of activities do not require continuing review by an IRB, and again, remember they are maintained under IRB oversight, then why are we doing continuing review for exempt studies? And again, and exempt studies are still human subjects. When the R&D committee is the only oversight committee.

And so, what we did through this technical amendment, again, a minor clarification, a minor tweak, was to state that when exempt research occurs, and again, the R&D committee is the only oversight committee for that, the R&D has the ability to say, you know, we don't have to do continuing review approval. Again, remembering that just because you don't do continuing review does not mean as an R&D committee that you are yielding oversight. You don't, you still have oversight of that study. Exempt. But you are not required to conduct continuing review by virtue of this revision of ORD policy through this technical amendment. That is in paragraph 9.d.(2)(c). So, that is the, that is how that technical amendment is executed. And we think it's actually a really good one that we're hoping many of you will have been verbalized to us will choose to take of you wish. It gives you, again, a choice.

So, now we're going to get to me into the most, the more, the ones that really, I want to talk more about, and that concerns the ISSO PO reviews. When 1200.01 was issued, and originally through its major revision, it stated that all VA research, and I do use that word all, requires ISSO and PO review. And again, a lot of times when you, the policy is issued, you see something that, oh no, unintended consequences. Now a discretionary hold was put into place basically immediately. To state now hold. You know, that really was not the intent of a policy. And so,

this technical amendment, and again, we had input from the VHA privacy office, and the research support division, was intended to clarify and narrow that review. And this is the reason why. VHA Directive 1605.01, excuse me, and it actually should be 1605.03, requires privacy officers to conduct a review of human subject research protocols to ensure the privacy requirements are met. That is, it. VHA privacy, and again, our ability to tell privacy officers what to do again, we're ORD. we work closely with the VHA privacy office. You know, we do not want to do something which is over and beyond that which VHA privacy requires. VHA privacy policies do not require privacy officer reviews of all VA research. Nor was it ever ORD's intent to require it. Same thing with ISSO reviews. All VA research does not require the same level of ISSO reviews. Because all studies do not have the same type of information security requirements. Nor was it ORD's intent to require that as well. So, these technical amendments were executed to deal with this issue that had been created when 1200.01 was released.

Now, you will have in your attachments that were sent to you, prior to this call, a copy of this letter that's called the discretionary hold memorandum. It is, this one that you have with you in your attachments is dated July 29th, but it's actually one of several that were signed by the DUSH-DEAN, that puts into place a hold on the implementation of polices in 1200.01 until issues were resolved. And the discretionary hold involved policies related to the R&D COI Committee, which we're going to talk about later, as soon as we finish talking about these ISSO and PO reviews, and MPAs. And so, this discretionary hold was scheduled to end, and it is now ended on January 31st, 2021, and so this technical amendment was put into place so that it was the key steps to be able to say we don't need another discretionary hold.

So, what you're going to see in the next three slides, and this is one of the few places in this whole slide set where you're going to see the actual content that I will put in a slide set. And you also of course have these in your attachments the language that was involved. And you really have to look at these three different revisions of the technical amendments together. Because when you take them in isolation, they don't make sense. So, when it comes to 1200.01, when we amended h.(6), you know, it talks about what is the responsibilities of the, of you know, in terms of responsibilities of the facility, the responsibilities of the R&D committee, and it's responsible for ensuring the ISSO review and the PO review of studies are complete before a study is given final approval. Now the technical amendment took the ISSO review and it talked about studies that involve collection, processing, storage, and transmission of research data. And then for the privacy office review, it singled out studies using human data. So, that is the first scope of how we were trying to narrow this.

Then you take the next technical amendment, which is how are they going to do it? So, the ISSO reviews are directly connected to the tool that is used by the ISSOs to determine the level of

review, which is the enterprise research data security plan. And for the privacy officers they'd use the research protocol privacy review checklist.

And then as part of a technical amendment that strictly talked about the ISSO responsibility. It talks about the fact, and again, clarifying, not a substantial change in policy, that the ISSO is responsible for making sure that that research complies with the applicable VA information security requirements for VA research data, and also in terms of the IRB. That, you know, there is a role of the ISSO in relation to the IRB review and approval of that protocol.

So, when you look at those, what does it all mean? In terms of the PO review, and what these technical amendments were designed to do, was to align 1200.01 with VHA directive 1605.03. Whatever VHA privacy requires, for privacy officer reviews, is what we require. We defer to them. So, in terms of what studies require review by a privacy officer, those studies involving human data. 1605.03 defines which studies require that, which studies require the completion of the VA form 10-250. And in terms of the 1200.01 in ISSO reviews, that is where, again, the role of that technical amendment was to state we want to reference the ERDSP as the tool that will be used to determine the level of ISO review, if any, that applies to that research protocol. And I'm going to talk a little bit more about that.

What you'll see on the next two slides is this VA form 250, that's just a snapshot of the picture, that you know, that is completed and that is referenced in VHA 1605.03, and now of course 1200.01 through this technical amendment. And then the Enterprise Research Data Security Plan, the ERDSP.

Now, and again, before we start talking about this more in depth, again, the ERDSP has been located in VAIRRS for several months. And this slide will show you the pictures where it's accessible. Now, many sites, we have around 30, I believe, that are not on VAIRRS right now.

So, how is that accessible? Well, it's accessible in our toolkit that we have in ORD, and also there is an OIS Research Support Division public document site, and that can be accessed there. But I want to get, because we have received multiple questions about the ISSO reviews. It is not the intent, and I want to go back, and I'm going to back to this slide right here, that is talking about paragraph 5 h.(6). Is the ISSO review only apply if the study involves the collection, processing, storage, and transmission. Do all four of those criteria have to be met in order to trigger an ISSO review? The answer is no. The answer is that the level of review will depend upon the answers to the questions in the ERDSP. And that's why you'll see throughout the ERDSP, there is these different areas, and like on this one you'll see on your slide, there's four questions. And it says if any of these are answered yes, the study requires the ISSO review. Well if it doesn't, then it doesn't. And then, again, there's a whole, this is a multiple page, you know,

there's multiple fields on this, and I'm not showing the entire ERDSP, but I wanted to reinforce that. So, it's all about the answers to the ERDSP.

Now, also in the amendment it talks about the ISSOs are responsible for participating in the IRB review. That does not mean that the ISSOs are required to attend IRB meetings. Nor is that ORD's intent. But as, again, many on this phone are aware, and if not, you're going to all hear it right now, is for example, preliminary ISSO review is required for any study that is submitted to an IRB. And for example, in the commercial IRBs we have an endorsement letter. Where indeed the purpose of that endorsement letter, among many other purposes, is to ensure that the preliminary PO and ISSO review is completed prior to the sending of that study to, for review to the commercial IRB. So, again, reinforcing that it's not the purpose of 1200.01 to state now your ISSO is required to sit on the IRB and attend meetings, because that is not the purpose. The participation of the ISSO is through the conduct of that review that is done.

Again, one of the big issues with 1200.01 in the beginning was what is the scope with the review? And now through this technical amendment we've now referenced this tool that's used by the ISSOs. That's called the ERDSP. So, does that mean since 1200.01 is issued that now, again, I've made a reference that there's multiple sites that are not on VAIRRS yet, and there was no policy that dictated using it, and many sites really had never heard of it before we issued the technical amendments. Does that mean you have to use it right now today? At our site, and you know, Dr. Jeans has now done this presentation, so now you have to implement it. Again, reinforcing that ORD communicates very, very often, frequently, almost every day, and again, technical amendments are never executed in isolation. RSD, the Research Support Division, is preparing to release again a bulletin on how that will provide guidance on, again, a phased transition towards all VA facilities that conduct research to use the ERDSP. So, that, again, the requirements can be met that are in this technical amendment. However, please get, if you don't get anything else out of this presentation today, I want to reinforce that until that training has been provided to the field, the VA sites are to continue to use their local procedures in your own, you know, your, the tools that have been provided to you, in their interim until the transition is complete. Transition is projected to be in April of this year, but please, that is a really important issue that this workshop today we wanted to reinforce.

We're also going to spend some time here talking about the technical amendments that resulted in the deletion of several paragraphs within the policies of 1200.01. policies that were never implemented. Again, they did not substantially change 1200.01 because they were never implemented. Again, during the formal concurrence process, a lot of times what starts is not what ends up in the final policy. And so, at the very end of the concurrence process for 1200.01 the Office of General Counsel Ethics Specialty Team and OGC put in some policies that were very important, again, because as federal employees we are responsible for complying with the

federal ethics laws regarding financial conflict of interest. And that includes any VA investigator as well. Now, there were several things that were in R&D committee. The one that was released in 2019, the major revision, it included the formation of an R&D COI committee, it was mandated. It also described the VA investigator responsibilities for filing the OGE form 450 Alternative-VA, that was the OGE form 450, which was specifically designed for VA researchers. And one of the reasons this was put in was because prior to that point there was really no policy that stated you have to do it. And so again we, you'll hear often we say, there's no such thing as form by policy. Your form is not a policy. A policy represents use of the form. And so that was why that had been put into place.

But again, it caused unintended consequences. Again, you'll see on this slide where, you know, this form had been released in 2013 by the VA Office of General Counsel Ethics Specialty Team, but again, there was no policy that accompanied that. And so, there is this, there was this huge policy gap. But as a result of 1200.01 being issued in 2019, you know, there was just not enough detail concerning how does this review occur. And so, a discretionary hold was put in place to say, you don't implement those policies, but you will continue to do what you were doing before 1200.01 came into place regarding the reporting for, and review of those forms. And yes, you are to continue using those forms.

And I have here on this slide that you'll see is just the front page of the OGE Form 50 Alternative VA. So, what we did in 1200.01, through the technical amendment, was delete these policies that had never been implemented. They were never implemented because they had been placed in discretionary hold basically from the day they were put out.

But please, and again, you will hear me say this over and over again, and one of the purposes of this webinar was to reinforce that removal of those policy sections is not to be given as permission or as a go to say, okay, you can now stop using the OGE form 450 alternative VA. That form was developed as a result of another, you know, it was either GAO or the IG, you know, again, dealing with this agency and finding out we did not have the appropriate reporting mechanisms for the agency to comply with the federal ethics laws. This form was developed and approved by the Office of Government Ethics. And so, this is the form that is to be used. Because you cannot say, because 1200.01 now deleted these policies that we can now disregard federal law. Also, ORD is reinforcing through this webinar, do not dissolve those committees you have. Some VA facilities already had financial conflict of interest committees. Everyone, almost everyone else has, again, a financial conflict of interest administrator to process, review these forms. Again, this is not permission to dissolve that. So, that is a key reason why we wanted to have this webinar today to review, to discuss this, we will also be putting in FAQs in our FAQ searchable database to reinforce as well. So, as well, so that you don't have to look at the slide set, you can just go to the FAQs. Now, the, again, the other issue

is, okay, so ORD has now taken this out of the technical amendment, so we're now back to the state we've been in. There is no policy that mandates, that describes the use of this form, OGE 450 Alternative VA, or the review. So, the Office of General Counsel Ethics Specialty Team ORD and OGC STAR have been working for the last year, and this gets complicated, where the development of a separate research financial conflict of interest directive. And so, we are hoping to get that put into a pre-concurrent process with a possible publication for next year, that is the plan. So, please know we are in the process of getting that, you know, to have a separate directive while this gap exists.

Now, as part of this discretionary hold, and I'm going to come back to this, you know, I made the reference that there's three policy areas that it put in hold, on hold. It put on hold ISSO PO reviews, the R&D COI committee, again, those are addressed through the technical amendments. But also, MTAs. And one of the reasons we put these on hold is that we knew we were updating the template.

Because 1200.01 puts into place the requirement that only applies in collaborative research. By virtue of policy. Now what is in policy versus what is recommended are two different things. But because there were major issues going on, in terms of accountability of biospecimens in research, already put into place policy, that states, and as, and I've put it in yellow, I want to single it out, for collaborative research activities a Material Transfer Agreement must be used to transfer biospecimens from VA unless the biospecimens transfers is addressed in another agreement executed between VA and the receiving institution or party, such as a CRADA, a subaward, or MOU. Please understand an MTA is for biospecimens. You cannot use a DUA, a Data Use Agreement, for the transfer of biospecimens.

Now when it comes to MTAs, again, the policy applies to collaborative research activities. Again, reinforcing MTAs are not required when another type of agreement is in place related to the collaborative research activity. And that occurs quite frequently. But that is a key issue we want to reinforce. Now, I do, I have a slide here in a second, but while ORD policy, and we, this is again an urban myth, I hear it all the time, well ORD requires the use of the VA template. No, we actually don't. There is an MTA template which is available for your use, but you don't have to use it. You can use another one if it meets the applicable requirements. However, it is highly encouraged to use the VA MTA template particularly when VA is the provider. Most of the time when VA is the recipient of the biospecimens in a collaborative research activity, or any type of activity, it again, is the provider that establishes the terms. They have their template that they use. And we are fine with that. But if you use our template, particularly when we are the provider, it simplifies the execution of the MTA. Because, again, it's a template. If you modified it, there is some type of review that's going to have to occur. And again, that's why these terms are, have been reviewed by OGC legal, tech transfer, again, ORD policy, we have the MTA

template, it was updated in July, on ORD's technology transfer website. It is a bidirectional MTA in that it can be used when VA is the provider or the recipient. These are legal agreements. MTAs are not memorandums of understanding, they are binding. And what I mean by that is, let's say in a worst case scenario someone violated the MTA. Well we now have the ability to ultimately go to the Department of Justice and say, okay, we've got a problem here because the legal agreement was not executed. And so, with that in mind, a VA PI cannot execute the MTA, cannot sign it as a signatory. There has to be someone when the VA is entering into an MTA, or any agreement by the way. Okay, DUA, CRADA, the investigator cannot sign a legal agreement binding the agency. Only the person that has been either the medical center director or whoever has been given the legal authority delegation to sign on behalf of the agency for that institution can sign these legal agreements. Many times, that authority is given to the ACOS. But that is something that also we see very commonly here in ORD and OGC.

And again, on the slide that you'll see a picture of the MTA and the location. So, when going to talk about 1200.05, the technical amendments for these, which are very, again, this is, this part of the presentation is very fast. Because these were truly, truly clarifications that are, that you're going to hear over and over again. Again, your quick guide is, bottom line, it clarifies, emergency use is under FDA's regulation and doesn't require prospective IRB approval, nor does it require R&D committee. The language in 1200.05 was changed to align it with the technical amendments in 1200.01. so that's how the two are joined together.

Again, the itemization is on this slide. Again, the technical aspects of where you'll find the exact changes and the description of it. And what you'll see is we wanted to reinforce, when it comes to emergency use versus a nonemergency expanded access use of a test article, you know, with emergency use there's no prospective IRB approval, but you are required by FDA regulations, if you are the investigator, and again, an investigator is what FDA regulations state, that's what they are, must notify the IRB five days, five working days after the administration of a test article. Again, no R&D approval, nor is there an ORD policy requiring notification. For any non-emergency expanded access to a test article, again, and classic examples is your treatment protocols, Mayo Clinic was a great example of an expanded access protocol, non-emergency, require prospective IRB approval. It also requires prospective R&D committee approval, but now through the technical amendment designated review can be used for that. It couldn't prior to the execution of the technical amendment. Because it is an expanded access protocol that required IRB approval, R&D committee can, approval can be done through a designated review process.

Now, I'm going to take this opportunity to take one minute to reinforce emergency use authorization, such as the vaccines, are not the same as expanded access use of a test article under FDA's regulations. They are not synonymous. And there's a lot of confusion about that.

So, what we've done in this presentation, and the next two slides, is basically do a cheat sheet. That gives you, again, a quick glance of the differences between expanded access, and again, this is your, like your Mayo Clinic, and this is pre, because the convalescent plasma got an EUA. But the difference is between your expanded access protocols versus the emergency use. And the bottom line is they're both investigational. That's the one thing you have to remember. Even under an EUA it's still investigational. But they come under different authorities. Expanded access use of, through a test article is under FDA's regulations under expanded access use, emergency use authorization is part of the Project BioShield Act of 2004. And so, they're totally different, one comes under the human subjects research regulations, EUAs do not. And so that is, so again, this is something that we wanted to do to reinforce that at this point.

Again, going to end this up before we do questions on 1200.08. Again, while we say there's six amendments that were executed, as part of the technical amendment set for 1200.08, they're actually quite minor, again. Because we did some minor word clarifications you'll see at your quick guide, we wanted to clarify the SRS liaison member's status, and I'll explain why in a second. Again, because a lot of questions had come in. And most importantly, because we wanted to align it with the NIH guidelines.

As part of this slide set, you'll see, again, this is part of your attachments as well, the technical itemization of the six amendments. So, this is what prompted the technical amendments. When it comes to the NIH guidelines. VHA directive 1200.08 was published in April of 2019. Again, going back to the remembering of that it takes months to get through 1200.08. I mean any, a major revision of policy. So, right as 1200.08 was getting ready to be published ORD was made aware that the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, and it's commonly called the NIH guidelines, that's the short term for it. It was being revised on April 26th, 2019. We didn't know what those revisions were going to occur, but we didn't want to stop that from coming. So, we wanted to say, okay, let's start going through those NIH guidelines and figure out what changed that we need to update in 1200.08 to bring ORD policy in alignment with the NIH guidelines that were published in 2019. And so, what we did is, for example, with the new NIH guidelines that were published in 2019, they changed entirely the concept of geographic location. And so, we removed the policy requiring a VA facility to rely upon another VA facility's IBC in the same community. That had been NIH's position prior to the new guidelines that were issued in 2019, they revised their position. They also changed their position regarding annual recertification of studies. Again, the only time ORD wants to exceed a requirement is when there is actually a legitimate reason. That is always the approach that we use in policy. And so, again, we wanted to align with NIH on this to change that language to a periodic review. I do want to say there are more technical amendments that

we will, are planning to execute in 1200.08 to align it with the NIH guidelines, so please anticipate that.

So, when it comes to this issue though, that has nothing to do with SRS memberships. Why did ORD execute an amendment? Well there was, there's confusion in the wording. Again, language is so highly interpretable. No matter what you do. Language can be misinterpreted. And so, we had a statement in 1200.08 that was issued in 2019 that stated that ex-officio members, and they're talking about of SRS, must include a liaison member from the VA facility's R&D committee. And then it had parentheses after it, non-voting. And ORD was getting multiple questions about whether the intent of that policy was that the ex-officio member for SRS, can they be voting or not voting because of the phrasing of the non-voting phrase? Bottom line, it didn't make sense.

And so, what we did is revise that policy to clarify that the liaison member to the SRS from the R&D committee is a non-voting member of SRS. It's an ex-officio role. So, that was the clarification that was put into play.

So, and so with that said, one of the reasons that, you know, again, I've gone very fast, is we wanted to have plenty of time to address the questions related to these technical amendments. Again, remembering that technical amendments do not substantially change existing policy. They are their primary intent is to clarify existing policy or remove policy that's never been implemented. ORD does not make that decision whether or not something is technical in nature. And so that is what's happening. And we will expect additional technical amendments in the future, but we are looking at major revisions in 1200.01 and 1200.05.

And so, with that said, what you have here is a number of, at the end of the slide set, a number of different links to references that are related to this webinar today, but at this point, I think we're ready to open this up to questions.

[Silence 47:41-48:07]

Kate: So, sorry, I was speaking on mute. All right just hold on one moment as I share my screen. And thank you to everyone who's already submitted questions.

[Silence 48:16-48:41]

Dr. C. Karen Jeans: And oh, also this is Karen, I wanted to also say that I am, I want to, we have a number of different panelists on the call today, from both RSD, the Office of Research

Oversight, the Office of Research and Development, so I am very grateful for their participation today in this panel as we look at your questions.

[Silence 49:01-49:13]

Kate: And so, Karen, can you see the first question?

Unknown speaker: Yeah, can you read it out for her please?

Kate: Yep. So, it says slide 16/17, RDC elimination of CR, question: Are RDC oversight projects still required to have a 365 CR, even without RDC approval? If so, is the study expired if the PI is late on their 365 CR report?

Dr. C. Karen Jeans: So, thank you. So, in terms of R&D oversight projects, so of course all studies, you know, any VA study, except for emergency use by the way, requires R&D committee approval. So, I'm assuming the question is about for those studies that do not, that in which the R&D committee is the only oversight committee. Because all R&D projects, studies under R&D committee are not required to have continuing review. Only those studies as stated in policy that are not under another committee or subcommittee's approval for research require continuing review by the R&D committee. And so, the technical amendment, of course, was executed to state that exempt studies, which are usually only being overseen by the R&D committee, do not require continuing review. That is a choice the VA facilities can make. So, that is the policy position of R&D. Now let's say that your R&D committee does indeed require continuing review. So, if the R&D committee requires continuing review for, let's say for continue, for studies that present. It says it's going to require this as part of local policy. Then if it doesn't, so if it does require it then if the study does not obtain continuing review required by the R&D committee then it would not be in compliance with your local policies. So, is the study expired if the PI is late on their 365 CR report? Well the study has not made its continuing review requirements under R&D committee. When the R&DC requires continuing review. That is what has happened. Now ORD does not have a position regarding what exactly, you know, if the study does not meet R&D continuing review what are the actions that R&D committee could make? That is up, we leave that to local VA facility because it's not like an IRB. But yeah, the study, bottom line is the study would not meet its requirements for R&D committee approval. And it does have to get back into approval status. Next question.

Soundia: Hi Karen, this is Soundia, I'm going to take over reading them so, that Kate can focus on adding the questions that keep coming in. So, this is regarding the ERDSP. The question is, for section nine of the ERDSP, PIs with partial offsite waivers are answering no to the question about transferring data to an external entity because the PI didn't transfer it externally. Instead

they created it externally. Should this question be revised to also ask if the data is created externally? Can you relay this question to the OIS RSD please?

Terry Peters: Hey, this is Terry Peters from Research Support Division. Yeah, that's a very good question there. And yes, yeah, it should be answered no, you know, if we're creating it offsite and storing it offsite, you know, that's still, you know, we were, it's outside the VA, right? So, yeah, that should be corrected. We will clarify that in the ERDSP guide, as well as we'll also bring that up in the training as well.

Soundia: Great, thank you, Terry. Next question, Kate? If a site developed an exemption subcommittee can we also remove the requirement for annual review for exempt studies? That's the first question, Karen.

Dr. C. Karen Jeans: So, when it comes to the exemption, so in terms of can we also remove the requirement for annual review for exempt studies, I'm assuming that question is related to the exemption subcommittee. I mean the bottom line is that there is no requirement as of now, unless the VA facility chooses to do so, to do continuing review for exempt studies. So, if you developed, you being the VA facility, developed an exemption subcommittee, and your exemption subcommittee had as part of its policies and procedures that it required an annual review, then again, it can be removed since it's not even required, it wasn't required before. Even then. So, yes, it could be removed. Absolutely.

Soundia: Thank you, Karen. Next question, Is ISSO and PO review still required on exempt and expedited reviews with these new changes, correct?

Dr. C. Karen Jeans: PO reviews, excellent question, again, PO reviews are required, as per 1605.03. These are human subjects research activities. You know, any study that is, in terms of, and I'm going to defer to Mr. Peters as well, but again, the level of ISSO review is going to be dictated by the responses on the ERDSP, but those studies still will require review as well, and I will defer to Mr. Peters for additional comments on that.

Terry Peters: Yes, thank you, Karen. Yes, the ISSO review is required on exempt studies. But because, you know, we're still collecting, processing, storing data, right? So, yeah, that review is still required. And again, you know, as far as the ISSO review that's required, you know, it's going to be, that will be conditional on the conditions, right? As of how you answer those conditions. So, but yeah, but it is required for exempt studies.

Soundia: Thanks, Terry. Next question? Perfect. Must the OGE form 450 alt VA be returned to the investigator after the COI administrator reviewed and signed it?

Dr. C. Karen Jeans: Well, most of the, I mean in terms of the actual, we don't have a policy statement, we, and so I'm actually going to find out from OGC, this is one of the reasons we actually had to resolve the initial policy, normally the OGE 450 alternative VA is returned to the investigator after the review as been signed, so they will have a copy of the form. However, because I do want to clear this with OGC I am going to ask to get a formal position from OGC ethics, since this is not something that, this is again, this is not a policy issue for ORD, and get an answer to that concerning OGC's ethics formal position on the return of the completed OGE form 50 after it is reviewed by the COI administrator. So, I will get back to you on that answer and get the position from OGC STAR. I mean OGC ethics.

Soundia: Perfect. Thanks, Karen. Now for studies that no longer require continuing review, do the investigators still need to submit the OGE form 450 alt VA annually?

Dr. C. Karen Jeans: Yes. Yeah, I'm really glad this, this is one of the reasons, again, there are so many issues. When the OGE 450 alt was developed back in 2013 the revised Common Rule wasn't, didn't exist. And so, one of the reasons, again, this policy was pulled is that position of OGC ethics when this form was developed was when it stated it would occur at continuing review it would be annual. And so, you know, the what OGC ethics has informed ORD is that indeed that form is to be completed annually. So, yes, it still needs to be submitted annually.

Soundia: And just to add to that, folks, we know that some of the FAQs will need to be adjusted, and we plan to do that, so we'll be pulling some of the FAQs to edit them accordingly. Again, in the revised [unintelligible acronym 58:10] technical amendment. So, the next question is, if R&D committee no longer has to do continuing reviews of IRB exempt studies but they still have oversight, how does that oversight occur?

Dr. C. Karen Jeans: So, a good analogy is this one, how does the IRB still have oversight of the studies that don't require a continuing review? So, just because you don't have oversight doesn't mean, I mean that you don't have a continuing review doesn't mean you don't have oversight. Now, ORD does not define how an R&D committee, just as it does not define how an IRB continues to have the oversight in terms to verify that the study is still going on, that the study is still meeting its requirements. Some R&D Committees, and we actually, you know, we have not issued a formal position on this, but you may again want to do similar to what we have recommended on the IRB side that you check-in to what, and we call it a check-in, you know, annually, biannually, depending on the study. You know, hey, are you still doing the study? You know, please be reminded, this continues to require R&D oversight. You know, if you are modifying the protocol you must, you know, this is what must occur. You must submit this to the R&D committee prior to implementation. In terms of reminding investigators when it's not a study undergoing continuing review you still have to meet those obligations for

submitting to the R&D committee any modifications, any events that require reporting to the R&D committee. So, that is one mechanism that can occur when you don't have that yearly check-in is some type of communication through the continuing review process have some type of communication go out to the study, again, what we've seen on the IRB side is many IRBs are still doing some type of, quote, check-in to say, hey, by the way, you don't require continuing review but we just want to verify. Again, we don't have a policy that requires that, but these, again, in answer to that question, these are some steps that we think are good ideas that are at your discretion that you can implement.

Soundia: Great. Thanks, Karen. Next slide please. So, can we stop requiring continuing reviews for exempt studies effective immediately? And so, the point we just raised, Karen, does ORD plan to provide a project status update form in VAIRRS for those studies under R&D's committee oversight that no longer require a continuing review?

Dr. C. Karen Jeans: So, the first part of the question, can you start effective immediately? You can do that effective as soon as you change your SOPs. Because, again, you want your, again, you're held to what you do. And so, if your SOPs, your local SOPs state you're doing continuing review, revise your SOP first. So, that, again, your practice is consistent with your policy. Again, we will be making any changes in VAIRRS that are necessary to align the VAIRRS processes, any forms, wizards, in alignment with the technical amendments that have been issued for 1200.01.

Soundia: Thanks, Karen. Next question please. So, these are two about MTA. Is an MTA required for transfer of specimens between VA facilities?

Dr. C. Karen Jeans: No, we, no, no, it is, in terms of policy requirement for collaborative research, VA to VA is not collaborative research as defined in 1200.01. It is collaborative, by the way. You know, when we work with other, our colleagues with other VA investigators, it's absolutely. But in terms of the policy requirement, it's when VA is transferring to a non-VA entity as part of a collaborative research entity. Activity. Such as your academic affiliate. Or university. Now, a lot of times, in terms of what you'll see from ORD policy versus what is practiced, you will see as part of accountability MTAs executed between facilities. Because it's the way to account for the biospecimens. Particularly when you're dealing with biospecimen repositories. The name of the game is accountability. But that is up to the holder of those biospecimens. But policy only requires an MTA for 1200.01, an MTA for collaborative research activities biospecimens from VA to the non-VA entity when another agreement is not in place.

Soundia: Thanks, Karen. So, the next question I think relates to your point about whether a PI can sign the form independent of the institution, the MTA, or any agreement. Question asked

is, if a PI does sign it does that automatically dismiss it as a legal document? That is it no longer is legally affected from it.

Dr. C. Karen Jeans: Oh, it's still a legal document. That's a really great question. The MTA itself is a legal document. The issue is that it's not executed. Because the MTA can only be executed between those entities that are legally authorized to enter into an agreement. So, it's like if I sign it. I've signed it, but it doesn't mean that it has been legally executed. And so that's the issue when you have individuals who sign it who are not legally authorized on behalf of the agency, or the institution for this place, the VA facility to sign the agreement. It's not an executed agreement.

Soundia: Thank you, Karen. Sticking with this MTA topic right now, are live animals considered biospecimens? On occasion animals are transferred to collaborative institutions from one VA approved protocol to another institution approved protocol. I think there's some of those asking what forms or what documents does an MTA use for that, is something else used?

Dr. C. Karen Jeans: There's different types of agreements that can be used. This is where you get into that issue, is what is the authority VA is using to send those biospecimens over? We use MTAs a great deal for mice. When we are transferring mice between VA and the non-VA entity, particularly our universities. And so that's going to be the issue, again, I'm going to ask is, when you, you know, do we consider a mouse a live animal to be a biospecimen? Yeah, it is. I mean it's a biological creature. But a lot of times there are different types of mechanisms that are used. But again, ORD is reinforcing, there has to be something that states, you know, it can be accounting for okay, what did we transfer over there and what is the document to show that we transferred it over there? And I will get with, as with the VMU and also follow-up on that question to see what type of documents they advise that they have, they would use.

Soundia: Thank you. Next set of questions, Kate? Okay. Is ISSO review required for animal research projects even for projects that are off site? There have been email the past week regarding this, but it still seems to be a little unclear if it's a requirement for project approval.

Terry Peters: Hey, this is Terry Peters, with Research Support Division. Yes, so, well let me reply that yes. For animal research projects, again, you know, the ISSO review will be dependent on how the questions are answered in the ERDSP. So, you know, you have those research study conditions up top, you know, if any of those were marked yes, right? Then an ISSO review is required. And the form alerts you of this too. It actually pops up a message. And then also as you're completing that ERDSP there are also embedded questions that if they are answered a certain way will also trigger the ISSO review. But again, it just depends on how the ERDSP is completed. You know, like if you got an animal study, and you're going to be transmitting or

transferring data outside of the VA, then that's going to trigger an ISSO review. So, but again, you know, it's dependent on how you answer the, how you complete the ERDSP.

Soundia: Thanks, Terry. And then following that, is animal research under USDA categories D and E considered non-sensitive if there are no photos or videos collected?

Dujuan Williams: Hey, I'll take that one, Terry.

Terry Peters: Okay, Dujuan.

Dujuan Williams: And good afternoon everyone, this is Dujuan Williams from OIS research support division as well. Based on our collaboration and input from the ORD animal research program they're subject matter experts and DC VMO office, we've provided clarity in that if you have research data under that specific category that does not involve pictures and/or video the data would not be considered sensitive. It would in fact be considered non-sensitive from a data classification perspective. But we will address that in specific use cases in the upcoming role-based training as well.

Soundia: Thanks, Dujuan. Next question, Kate? Keeping on the topic of ERDSP, if the ERDSP indicates that no ISSO review is required, who is responsible for reviewing the ERDSP and comparing it with the protocol and other materials to make sure the investigator's responses are accurate? In our experience, investigators often answer the ERDSP questions inaccurately or incompletely. So, even when the form says an ISSO review is not required, our ISSO finds that there are information security issues requiring ISSO review.

Terry Peters: Hey, this is Terry Peters again. Yeah, so you know, the PI, you know, the researchers responsible for properly completing the ERDSP, in those cases where we don't have an ISSO reviewing the ERDSP we're currently working on a process where those studies that are not being reviewed by the ISSO will be audited monthly to ensure that the ERDSP is being properly completed, as well as to ensure that the study conditions as well are appropriately answered. And so that's a process we're working on that we hope to have out here soon.

Soundia: Great. Thank you. Question is, I've heard some VA R&D committees are asking their members to complete an extensive financial conflict of interest disclosure as a new requirement for R&DC members. Is this required? And if so, what is driving this change in expectations or requirements?

Dr. C. Karen Jeans: This is Karen, I'll take this. So, ORD has been aware that the Office of General Counsel Ethics Specialty Team has informed some VA facilities that R&D committee members,

and we've recently also found, we've also heard perhaps some RCOs, that all are being informed that they are required to file the OGE 450, which is very different than the alt 450 VA, as a result of their position. ORD has communicated with OGC ethics asking how this falls within the federal ethics laws, and that is the reason OGC ethics is communicating this is that they're, they feel this is just their position that these positions require an OG 450. We have asked, and we are seeking clarification from the Office of General Counsel Ethics Specialty Team. And that's, so we are waiting additional information from OGC ethics.

Soundia: Thank you, Karen. Next question is back to our ERDSP. Do you know if we need to have Adobe Pro to fill out the form?

Terry Peters: No, you don't. Just, you know, Adobe reader will work just fine for it.

Soundia: Thanks, Terry. Onto the next _

Terry Peters: Or, or, or you, and then, then there's, I'm sorry, then there's another variation of Adobe, but they will work with it, so.

Soundia: Great. Thank you. Does the SRS liaison, who is an ex-officio member, have to be a voting member of the R&D committee?

Dr. C. Karen Jeans: That is ORD's intent. Because again, many times the ex-officio members of the R&D committee are again, by virtue of position, for example, privacy officers. And so, you know, again, we, you know, that would not be the appropriate liaison for SRS. So, and because I'm picking on privacy officers because Michelle Christiano works for me, who is awesome by the way, and so again, our intent when we wrote that policy was that it be a voting member of the R&D committee.

Soundia: Thank you, Karen. Next question, Kate. Okay. Can the SRS use an R&D committee member who is a voting SRS member instead of an ex-officio liaison? Think you just answered that. Do you have anything more to say about that, Karen? I think you just answered that question. Yeah, so.

Dr. C. Karen Jeans: I, I, I, yeah, I'm not sure what the, the, I'm, I'm, I don't understand the question, so I'm going to have to _

Soundia: Yeah.

Dr. C. Karen Jeans: _ follow-up on that. So, I don't _

Soundia: Okay.

Dr. C. Karen Jeans: _ because it's asking different things.

Soundia: We'll leave that one for, yeah.

Dr. C. Karen Jeans: Let's go to the next one, and we've answered the, the _

Soundia: Yeah.

Dr. C. Karen Jeans: _ the second question already.

Soundia: Yes. All right. Okay, and here we go again, yep, can we move on?

Dr. C. Karen Jeans: Okay, and we've, we've, we've answered this question, yes.

Soundia: Kate, next one, thanks. All right. I've found the answers the study team puts on the VA form 10-250 usually includes at least wrong information almost every time. Unless the PO works with them on filling it out. The PI portion of the ERDSP is longer. If the ISSO is not doing at least some review of every study, who catches whether ISSO review is actually required? And I think, Terry, you mentioned your upcoming plans on how you're going to do that with your monthly audit?

Terry Peters: Yes, yes, correct, yeah, the audit process will be _

Soundia: Okay.

Terry Peters: _ put in place to look at those, you know, studies not reviewed by the ISSO to ensure they're, properly completed and everything.

Soundia: Excellent. Thank you. Next question? Can you please specifically define collaborative research?

Dr. C. Karen Jeans: Again, I mean it's a, in terms of a, it's a research activity, as defined as between an institution and a VA institution for purpose of policy in 1200.01 in which the VA institution and a non-VA institution are involved in the conduct of that research activity. And that is why the, and that specific scenario is what elicits the policy requirements regarding collaborative research.

Soundia: Thank you. For studies determined to be research but not human subjects research, is the PO review needed? I believe that ISSO review would still be needed.

Dr. C. Karen Jeans: So, in terms of, this is Karen again, for reference for the, in terms of the VA form 10-250, the VA form 10-250 addresses human subjects research activities. Now in terms of, you know, and so that's when we're talking about PO review. Now does it not mean that the PO may be needed to determine whether or not if it's, for example, you know, a deidentified dataset, is it indeed deidentified? That is a different type of PO input than the requirements in 1605.03 regarding completion of the form of the VA form 10-250.

Soundia: Terry, do you have anything to add about non-human subjects research and whether ISSO review would still need, be needed?

Terry Peters: Yes, the ISO review would still be, well, again, when this non-human research, right? It all depends on how you respond to the questions.

Soundia: Mm-hmm.

Terry Peters: in the ERDSP, right?

Soundia: Okay.

Terry Peters: So.

Soundia: Okay. Good. And I think the next question is the point Terry has made a few times, you know, is ISSO review still required after the study has been approved at the IRB? Is it fair to say depends on how the form is filled out?

Terry Peters: Yeah, so a couple things on this one here. So, you know, the ISO of course is required to at least do a preliminary review before the study is submitted to the IRB. So, if the ISO has done a preliminary review, and that review goes to the IRB, and of course the ISO needs to do a final review once that study comes back from the IRB. Now, if the ISSO has done a final review, before it goes to the IRB, the ISO is not required to review it again unless there's been some major changes made by the IRB, right, that affects the information security of that study. Otherwise, no. That ISO would not need just do another review once it's been approved.

Soundia: Thanks for clarifying that. Next question, Kate. Can the SRS use the R&D committee coordinator as the ex-officio liaison member if the R&D committee coordinator regularly attends both SRS and R&D committee meetings?

Dr. C. Karen Jeans: that is not the intent of the policy. But since we are getting so many questions about this, let me, we will look back at this issue and issue an FAQ specifically on this issue.

Soundia: Perfect. Thanks, Karen. Our next question, Kate? It is clear that the ISSO and PO review is required for initial applications, but for the exempt studies at continuing review are the PO and ISSO review required then, even if the studies do not require reviews at the R&D committee?

Dr. C. Karen Jeans: So, this is Karen. If there's no continuing review about the R&D committee there's going to be no continuing review by the PO and ISSO review. I mean as a PO, because it doesn't exist.

Soundia: Right.

Dr. C. Karen Jeans: But the bottom line is if, you know, it's just like with [unintelligible 01:18:11] if something changes in the life of that protocol, such as a modification, that would prompt the requirement for a PO ISSO review that would occur, but no, just because the, if there's no continuing review for the study by the R&D committee then there's not going to be a separate PO and ISSO review. By virtue of secondary policies. So, it won't exist.

Soundia: We're going to skip the next question, as Karen mentioned we'll be generating an FAQ that addresses, we'll take into consideration all these different iterations of the liaison and the SRS. Is that fair?

Dr. C. Karen Jeans: Yes.

Soundia: Okay. Next question about VHA directive 1200.01, paragraph 9.d.(1), (d) states at approval, the R&D committee must set the time frame for continuing review. The time frame may not exceed 365 days. Since this is stated in 1200.01 than does this mean R&D committee must do a continued review annually every 365 days for R&D committee only oversight studies?

Dr. C. Karen Jeans: For those, unless it is exempt research. So, it will, so that is exactly what this question states. So, continuing review for those studies that are under R&D committee oversight only, except for exempt research activities, would be required to have it every 365 days. Or no later than.

Soundia: Perfect. Thank you, Karen. For the ERDSP header, under type of study field, it doesn't allow the PIs to choose both bench and animal research. Should the form be revised? Or is the PI expected to complete two forms?

Terry Peters: Hey, this is Terry Peters again. No, you shouldn't have to complete two forms. So, just to clarify what we're talking about bench we're talking like the studies basic laboratory and animal as well? That's the part I'm not sure about. But what I can do on this one here, we will follow-up with a [unintelligible 01:20:27] _

Soundia: Yes.

Terry Peters: _ on this one.

Soundia: The submitter does say yes.

Terry Peters: So, it's both bench and animal. Yes, so we can _

Soundia: Okay.

Terry Peters: _ revise the form to allow for that entry. And that's a good one to bring up. Thank you.

Soundia: Thank you, next question, Kate. Think about five more minutes, folks. Okay, we have investigators with non-VA grants using our VMU, is the ERDSP still required?

Terry Peters: So, in that one, I mean is it a VA research study? Or are they just using our VMU for, say an affiliate is using it for their study?

Dr. C. Karen Jeans: And this is Karen, I absolutely agree. I mean the question is, is it when we have investigators if they're doing _

Terry Peters: Right.

Dr. C. Karen Jeans: _ VA research that's what elicits the issue.

Soundia: I don't see anything popping up in the chat box _

Terry Peters: Okay.

Soundia: _ from the submitter, so.

Terry Peters: Right. Yeah, so it's _

Soundia: We'll go on.

Terry Peters: And even studies, you know, if the studies go, is being, you know, if it's animal and it's being approved by the R&D committee, right? Then an ERDSP would be required. Because it's VA research.

Soundia: Okay. We'll move onto the next question. Oh, submitter says not VA research. I'm sorry. Affiliate using it for their study.

Terry Peters: Yeah, it wouldn't be required, yeah.

Soundia: Okay. Perfect. Is local ISSO review required or is there an acceptable alternative to local ISSO review when the local ISO is either not available or not responsive?

Terry Peters: So, for that question there, you know, if you're localized so it's not available or not responsive, you know, the facility should reach out to the supervisory, their supervisor for, on the issue for them to have someone else conduct the review for that ISO. However, that being said, if you've got a study that is critical it gets approved right now, right, you've got some funding deadlines, some IRB deadlines, and you're kind of in a bind, and you can't necessarily reach out to the supervisor, please feel free to reach out to us at RSD and we will be glad to assist you with getting someone to review that study. You know, we don't want you in a spot where you're sitting out there and you can't get it reviewed and you got all these deadlines going on. So, you know, if you can't reach out to the supervisor, reach out to us and then we'll be glad to assist you.

Soundia: Okay, the next question is what is the definition of an investigator who is required to file the OGE financial conflict of interest form annually? And I believe that should be on the form.

Dr. C. Karen Jeans: Yeah, it is. If you are _

Soundia: Okay.

Dr. C. Karen Jeans: _ a VA investigator, you know, if for example, this is collaborative research project, the non-VA investigator does not file that. Do that. It is the VA investigator, whether you are the PI, co-PI, sub investigator, if you are listed as a VA investigator for that study, that individual is required to file the OGE 450 alt VA research financial conflict of interest statement. Both, you know, before the study is approved and also annually.

Soundia: Okay. Thank you, Karen. Okay, next question, Kate. And we only have two more minutes and we're going to be winding down our questions. So, we'll allow Karen to do a

closure in about one minute. I think this is the same question, Kate. Okay. Does the new DUA directive that was just released impact any of the technical amendments 1200.01 and 1200.05?

Dr. C. Karen Jeans: The new DUA directive and ORD, I'm, whoever asked this, I'm really glad, again, because the ORD put out an update earlier this week concerning the discretionary hold that is going to be put on the part of 1080.01 as the technical amendment is being issued. But the DUA directive 1080.01 actually has no impact on 1200.01 or 1200.05.

Soundia: Great. And this will be our last question. If a local PO is not responsive to complete the review is there an alternative? And I don't know if we have anyone to answer that from Privacy.

Dr. C. Karen Jeans: I don't, yeah, you know, all I can do is I can bring that forward to VHA privacy since this is a privacy office issue that we will bring to them. Also, I do want to address one question quickly that's in the chat box, you know, are research personnel required to complete the COI 450 alt VA or are just PI, co-PI, sub I's? All research personnel are not required, it is only the VA investigators that are indeed PIs, co-PIs, subs, co, it's not others besides those individuals.

Soundia: Perfect. All right, and with that, Karen, we are at the, and that's all the time for questions. And I think that's the end of the questions that we received. Good job.

Dr. C. Karen Jeans: Well great. Well then, I will make a quick statement to say thank you so much again for attending this webinar, we know it was rescheduled twice, so again, appreciate your patience and also your excellent questions that you've asked today. We will follow-up on these questions that we have written down to follow it with the applicable program offices. Again, we like generating FAQs in our searchable database because it makes it more readily available to everyone. With that, I really want to thank everybody and hope everyone has a great afternoon.

[ END OF AUDIO ]