Karen Jeans: So hi, everybody. My name is Karen Jeans .And I am going to be your lead presenter today on this presentation, which is more like a workshop in some ways. It's a one hour presentation on checklist and tools for submission of informed consent documents to ORD-approved commercial IRBs. And in this hour we are really going to center in on some revised tools, checklist, and processes that, while we're calling it for the commercial IRBs, is actually applicable to any VA study that requires an IRB approved consent form.

And in terms of some of the content I'll be presenting, we are indeed centering again on the informed consent documents. We're not going to focus on the HIPAA authorization. So I'm going to jump right in so that we can indeed have time for questions at the end of our, this presentation.

So, we start with, why are we doing this? Why are we even discussing this issue concerning revision of tools with our ORD-approved commercial IRBs, with our submissions, specifically centering on our informed consent documents? And let's go back to 2020, when we first started to use our first commercial IRBs, which was Advarra and WCG. And this story with the COVID-19 pandemic, we've been preparing for it.

And we had discussed our procedures with our, our our IRBs that we were negotiating with. And we're always looking at adding more IRBs. So it has always been an expectation requirement they say, that study teams that were submitting to the ORD-approved commercial IRBs put in the VA specific informed consent documents when they submit their, their study, their application to the commercial IRBs.

And we've had issues going back and forth for the last three years, but have really escalated recently, with VA informed consent documents being submitted without those elements. And also the other side of it where the IRBs, some, and again it's not all, are approving some of these informed consent documents for VA without the required elements. So that, that is, that's been an issue we've been dealing with for the last three years.

And and while we're trying to get a handle on it with that revised process, because this the way that it is supposed to be working. The the site \_\_\_\_\_ [00:02:42] and receives, and they've been selected at the participating site. And they get the informed consent form. And then as part of their application they take that informed consent form. They make it theirs in terms of including any VA specific site information, and then any applicable VA specific and requirements. Now, what is supposed to have happened is the commercial IRB that gets it as part of intake.

And then if it doesn't have the required VA specific elements, it's supposed to go back, and then the study team puts it in. and it goes forward. But then at the end, the IRB, yeah, you'll hear me say this over and over again. The IRB is always responsible. Then that's why we have reliance agreements for approving an informed consent form that meets all the applicable requirements of the institution for which it's serving.

So in this case we have reliance agreements with all of our commercial IRBs. And they are indeed responsible for when they approve an informed consent document for a VA site, of ensuring that it meets the applicable requirements. That includes federal regulations as well as VA policy requirements. And that is why back in 2020, we issued our first version of this VA specific requirements for informed consent, and HIPPA authorization.

But again, we're centering on informed consent. So what has also though, came to our attention is an issue involving the revised Common Rule. And again, looking at the, the the types of studies that come to commercial IRBs, and what we are as a federal entity. Now, as everyone on this phone, this webinar knows, we are a federal agency. We apply the Common Rule to all human subjects research. That's what we do, that, we are signatory. The secretary signed it.

And so when you're looking at studies that are submitted to, by VA participating sites to our commercial IRBs, some of them are indeed sponsored by federal agencies, primarily the National Institute of Health, the NIH. And for those studies, the commercial IRBs have, usually routinely know, okay, this is, this is, sponsor is the, another federal agency.

Therefore, we must include the applicable 2018 Common Rule requirements. But by far, I mean by an overwhelming majority, we're talking 80 percent or more, most, most studies that are overseen by commercial IRBs that VA sites submit to, and we have hundreds, our industry-sponsored clinical trials. And industry is not required to follow the Common Rule. They're not a federal entity, it doesn't involve federal funds.

And so what we have found is that some of these informed consent documents for industry-sponsored studies are being approved without the required 2018 Common Rule informed consent, yeah, document elements. And again, reinforcing going back in time to 2020, it has never been an expectation or a requirement for VA sites as part of that submission to – of their sites application to the ORD-approved commercial IRB to also include the applicable Common Rule requirements.

So as a result of discussions with our commercial IRBs and some, and what we're trying to remediate, we've had discussions about changing our process to indeed put better systems in place on both sides, from our stie as a federal entity as well as also on their side, again, reinforcing that at the end of the day by regulations under the reliance agreements, the IRBs are responsible for approving an informed consent form that follows the applicable requirements.

So in terms of what we're going to be discussing today and looking at details regarding how we do it, what is going to be happening now as a result of this revised process is a slight change. You're selected participating site, a site is chosen to participate in this, this industry-sponsored clinical trial.

Now, centering on the industry again, so within that situation, the VA site does what it always does, it was always expected to. You include the applicable VA specific requirements, but you're also going to include the applicable in 2018 Common Rule requirements if they're not present.

Now, we've been talking to the, some of the sponsors who now understand the requirements, and and they do get it. But again, and that's part of this change here. Otherwise, it goes right back to the way it's supposed to be happening. And we have had a lot of discussions with our commercial IRBs to make sure that these systems are in place, that when your study team submits that application, that submission to the commercial IRB, there is supposed to be a compliance check.

And again, if they're not there, the required elements, they're going to return it back to the study site. And it's going to come back in. It still goes to that commercial IRB after that is done. And again, the commercial IRB approves that informed consent document from the VA site with required applicable elements, both the VA specific elements, and the applicable 2018 Common Rue requirements. So that is, that is the change that is occurring.

It's all about for these industry-sponsored clinical trials in assuring and getting some assistance from the sites to say, "Okay, let's make sure the elements are there." And you may say, "Now wait a minute, I'm not a regulator." Well, what do I do? Well, I think you're going to be very pleased after this webinar, how, what what is needed to be done.

Okay. So jumping right in, again I cannot emphasize enough, at the end of, the IRB is ultimately responsible. That is the responsibility by, by, by regulation. And again, you'll hear it nine or ten more times through this. And I, and I'm doing that because I want to make sure you understand, while there is a role for the VA sites, it is always at the end of the day the IRB by regulation that's held accountable.

So when we identify this issue, we started to work with our IRBs, and find out, what could we do to make things happen better? And also, let's clear up some misunderstandings that are not only specific to use of commercial IRBs, but also in terms of the application of specific policy requirements for anybody who is submitting to an IRB for a VA study.

So we have revised the tools that we previously had in 2020, and we've created this new checklist. And we, all these tools, and they were included in your handouts today, but they're all available on ORD's website for the dedicated webpage about how VA ORD implements the single IRB cooperative research provision. But more importantly about commercial IRBs, and what, what are the current ORD-approved commercial IRBs, and the processes. So again, this is your site for all, where all these tools are located.

So we're going to jump in, and we're gonna, we're gonna to walk through these, and discuss this, and then, then open this up for questions. So in terms of what we did with the revision of a tool, because we didn't do a redline. Because it makes it unreadable. But what we did is there's five, what I call VA specific elements, and one isn't truly a VA specific element. It's related to COVID-19.

But because this came out, we started using commercial IRBs during COVID-19, we we made it part of this. Because VA OGC ruled on an issue regarding the PREP Act. So there's five specific elements that are, quote, VA specific elements: The, the VA treatment for research related injuries, costs for study participation, the consent for photographs, video, or audio recordings, CoC certificates, confidentiality, and again, the PREP Act.

And then, as part of this revised tool, we included a section that basically said, if this is industry-sponsored, keep going. And when we're talking about the 2018 requirements that are specific, that we're trying to make sure they're in there, there are only those that basically did not, are, are are unique to the Common Rule. Because industry-sponsored studies, clinical trials, are subject to FDA regulations.

So what we're centering in are those unique 2018 Common Rule elements that are not present in FDA's regulations for instance, for consent requirements. And I'm going to be showing you some tricks and, and some, some things that, please don't worry about it when you say, "How do I make sure all five of these are on there?" Well you don't necessarily have to worry about all five.

So what we're gonna do is jump straight in as for the remainder of this presentation using the checklist. And that checklist, this new checklist we devised is to be used in combination with the revised tool. It's a three-page checklist, and it is not a regulatory document. It is not something that you have to submit nor do we want you to submit it to the commercial IRBs with your submission.

It is not something you have to keep for compliance sake. It is a worksheet just like what you would do when you were doing, when you're trying to prepare an application. And and it is just to to help you, prompt you, "Okay did I do what I need to do?"

So the checklist is, again, it's located on ORD's webpage. And the checklist again is coordination with the tools, but it's, it's a prompter. And it will help you walk you through what you need to do. So we're going to go through this starting now with the checklists, and it will go into different sections. Specifically, we're centering on today, and today's presentation about the VA specific elements of informed consent in 1200.05. And then also, the Common Rule requirements that are, are are germane to this, this issue.

So we're starting out with a checklist. It's broken up into sections, again, nonregulatory, a worksheet, a tool for your use. You don't have to use it if you don't want to but, it again, it's an aid. Section one of this project, of this checklist, it's just talking about the project information. Many of your study teams have lots of studies you're submitting at one time, including Central IRB, commercial IRB, every, your affiliate IRB, NCI IRB.

So this again is just a tool that can help you, "Which study am I working on?" And so again, you don't have to fill in all the fields. But it's there. What's the name of the project? Who's the investigator? Which IRB are you dealing with?

Now as we start now this discussion of all the VA informed consent documents, the, the ICD-specific elements to be included, here's something that I want to start out first place. There were five I showed you on that slide. There are five that are in the checklist. There's five that's in the table. There's two of these VA informed consent elements that are required by VHA Directive 1200.05 that will always be applicable, always, and that is the language concerning VA treatment for research related injuries, and also the language for cost per study participation.

So right off the bat you know they'll have to be there. And the other three remaining VA specific elements are dependent upon the study. And many times they will not be required. So now we're going to walk you through these, and show you why, when they're required, and when they're not knowing upfront that the first two are going to be required. And the checklist is pretty well, once you look at the table a few times, you probably won't even have to use the table anymore. So it's, it but it is designed to be used in coordination.

So the first two are about treatment for research related injuries and cost for study participation. And also what I will also say is we're going to continue tweaking the checklist. So even today, as you know I was looking at this and thinking about this presentation, we're gonna go back in, and revise this checklist to also trigger, "always required, always required" to, again, prompt you. And so that's, again, making this a user-friendly tool.

Now, and what I'm doing here on some of these slides is pulling the language from the tables that are used in conjunction and with these checklists. In terms of the VA required element for treatment for research related injuries, we have language that we have provided to the ORD commercial IRBs. And what the they use, is they use this word exactly.

Sometimes we will get called by the commercial IRBs saying, "Well, the site changed this a little bit. Is that okay?" Yeah most of the time it is. However, if a sponsor wants to change it significantly, that is ORD's call. And so that is why we get a lot of calls from sponsors sometimes. We get calls from study sites saying, "The sponsor wants to do X," but that is the first required element is for VA specific elements that you always have in your informed consent documents that are submitted to the commercial IRBs.

The other required element that will always be present, always, is the language concerning cost for study participation, basically reinforcing, and this is one that gets very, sometimes confusing to sponsors. No VA study participant will ever by regulation be charged to participate in a research study for that which is research.

Again, if there is copayment involved as part of usual care, that's a different situation. But neither them or their insurance, if they had it, will be, will be charged. That is not language that you normally see in a sponsor's model template because again, in the non-VA world that's a different situation. So many times a sponsor requests to alter this language.

And again, we put this in the table and I'm reinforcing this to you right now. If they want to change it, they have to come to us. And I have, every time a sponsored wants to change saying that the, the patient's insurance will be billed, that is no. It will not happen. And once we explain it to them, they understand it.

But that's why I wanted to to reinforce today, it's not uncommon. Please just have them send it to us, and and we will talk with them. And we find the sponsors or, if CROs, contracted research organizations, are highly reasonable.

So we've already ruled out two of them. They have to be done, and that's why on the checklist it has a ' yes,' or a 'no.' Yes, it's going to, it, it's got to be there. But that's why you have those two up there. Now, look at the rest of them. You'll see yes, no, not applicable. And the reason for that is that they may or may not be required, it depends upon the study.

So the first thing we're gonna look at is consent for photographs, video, or audio recordings. And much of the content that we're presenting today in how we revise the tables is based upon feedback from our commercial IRBs in terms of their own questions and confusion on to how it applies. So in terms of ORD policy, this is again from VHA Directive 1200.05, we require language to be included to be conveyed to the subject when a photograph, video, or audio recording is taken exclusively for research purposes only.

When we say, "Yeah, I can do three things," you got to tell them, "What are you doing?" What photograph, video, or audio recording are you doing for research purposes only? How are you gonna – how are they going to be used? And are they leaving the VA?

That's it. That's all there is. But it's research purposes only. So one of the, what, what some of our commercial IRBs have found is that sometimes the language gets put in there even when it isn't applicable. And it's not common for a clinical trial, trial to utilize your photographs, audio, or video recording for research purposes only. Many times an industry-sponsored clinical trial will use that in connection for clinical care. Now, that is not to say that's, that is always true.

Many times, even if there's a clinical trial involving monkey pox where there are photographs taken exclusively for research purposes, and in that consent form there must be all the content which we described before. What and where are the photographs being taken? How will they be used? Are they being reviewed by someone else outside the agency, by the researchers who are doing the study? In this case it's the, the NIH and the CDC. And then, of course, they're leaving the VA. They're going to be retained by those, those groups.

So what I want to reinforce is that usually it is only at a study level that this would apply. And you would easily be able to see that in the informed consent document. Because when you get that model informed consent document, it would specify; as part of the study, we're going to take a photograph, for example, for research purposes.

If it's not associated with clinical care that's, that's a different situation. So so that's where you get into this, when does it apply? It is highly, highly unlikely that your site, not the whole study, would need to have a site specific inclusion of this VA specific requirement. And the only time that we – and we would ponder this was one of the commercial IRBs – is if you had as part of the study of you being the site where you wanted to do a taping of the consent form.

For example, a taping of the consent process, that's not required. You're still getting the written informed consent. But let's say for some odd reason, or some reason, that is one that's desired. And that would be specific to your site because it's not required by sponsor. It was not approved for the entire study. And then, so your site, site would have to submit an amendment, site-specific amendment to the IRB, and they would decide whether or not that site specific amendment would be approved.

But again, it's going to be, it's almost, and then there's no instance I can think of that that I – and we've talked to the commercial IRBs. Has this ever happened with the VA site or even a non-VA site? And the answer has always been no. So that's an example of how it's highly unlikely that there would ever be a site-specific amendment.

So that \_\_\_\_\_ [00:23:31] is consent for photographs, audio recordings. Next is about certificates of confidentiality. VA has, ORD policy has two specific requirements regarding language in the informed consent document that is to be included if the study has a CoC. One is to tell them it has a CoC. The second is, if there is going to be information about your participation and the subject in the medical record, you got to tell them, "By the way your participation in this study is going to be included in the medical record." That's it.

Now, any NIH sponsored study that is submitted to an ORD commercial IRB will have a certificate of confidentiality, and that is by virtue of the 21st Century Cures Act. So you will always see in that consent document a statement that it has a CoC. That is, that is standard.

What you may not find is whether or not that consent says information will be included in the medical record. How do you make that determination? It's very simple. If the study involves a drug or medical device, there is going to be something in the medical record. That is the easiest way to ascertain it.

And so that is, again, a, an easy way to figure out whether or not you need to put a statement in the informed consent document, if the study has a CoC. It is not common for an industry-sponsored clinical trial to have their certificate of confidentiality, however, it does happen. And we have in these seen, we have indeed seen that with some of our industry-sponsored clinical trials to see, depending upon what is being studied.

So while it's not common, it can occur. So how do you know? If your site is in one of those industry-sponsored clinical trials, and you can't figure it out, you being the site, whether or not it has a CoC? It's not in that informed consent document that you're being asked to review, and modify, and put in the VA specific elements. Don't worry about it. You don't need to call the sponsor, and you don't need to call whoever the commercial IRB isn't.

Because all you're doing is doing it, what is given to you. Again, at the end of the day, it's the responsibility of the reviewing IRB to make that, to make sure the VA required elements are there. They have the same list that you are given. And so my take home story on this is, again, don't, you don't have to do a lot of research.

If it's not there and you don't see it, there is a system in place to catch it. And also because this question has been asked to all three of our commercial IRBs by different sites, your site individually cannot choose to apply for a CoC for it to cover your site only. CoCs are for entire studies. And so it would have to be a sponsor or whoever is the overall study PI of the study, and it won't be VA.

So again, reinforcing, if you're a participating site, you cannot ask FDA, or put in an application into NIH to cover your site's participation. And that's a sponsor issue. And again, this is from the table, basically everything that I just talked about concerning the type of language, and the two different parts of CoC, informed consent language that ORD policy requires if the study has a certificate of confidentiality.

So then we're moving to the PREP Act, last of the five. Now, the PREP Act is not specifically addressed nor would it be appropriate for me to put in 1200.05. It's not an ORD policy requirement. It's a, it's a requirement that was originated as part of the COVID-19 response, the, the countermeasures, and the protections to, to prevent liability. And that someone will pay if you're, you're getting a countermeasure during COVID-19.

And so VA Office of General Counsel gave us a ORD language that we gave to our commercial IRBs to be included, if that study involved a COVID-19 countermeasure, which is a drug, or a device, or a vaccine. Now, as many of you know on the news, the public health emergency is due to be ended in May.

And what we're seeing right now from sponsors who are starting up studies right now, our industry sponsors, is that many of them will include both the language from the PREP Act, if it involves a COVID-19 countermeasure as well as the language for VA's research related injury. So that both are covered from when the PREP Act ends.

Now, the PREP Act's coverage doesn't automatically end when the president declares the COVID-19 public health emergency over. It will continue for those applicable federal agreements that are in place; for example, it may extend all the way to October. The bottom line take home message is, if your sponsor wants to include both languages, and if you're doing an industry-sponsored clinical trial with, with the COVID-19, countermeasure, or even an NIH; I mean federal or not. It is okay. It is perfectly fine because again, it is acceptable if it's approved by the IRB.

So now, that's, that's really reviewing right now what we were doing before in terms of VA specific elements. What the process that went through when studies were submitted to the commercial IRBs in terms of what, and what was supposed to be in there, or thinking that needs to happen. And that's why we created this checklist to, kind of, prompt the, the decision making that goes, and also the table.

But also, now as a result of this issue that we found, where again, the industry-sponsored clinical trials usually do not have the Common Rule requirements because the sponsors don't follow the Common Rule, nor are they required to. But the IRB of record for a federal entity has to. That we, we and we being ORD discussing it with our commercial IRBs, have come up with, again, checks and balances to remediate the issue.

So there are five 2018 Common Rule requirements that are specific to the Common Rule not found in FDA regulations that this checklist ask study to review. Up front again, I want to say, the majority of these elements are those that you actually don't have to, what I call search and destroy or search and seek. Because at the end of the day it is up to the IRB to determine whether or not they have to be in the consent form because they're additional elements?

The only one that is, that really, you really have to center on is the first one, key information presented up front. And so we're going to start with that. Again, as part of this checklist it, it walks you through these are the, the five 2018 Common Rule requirements. And again looking at the slide, you're gonna see a yes or no for the first one; key information presented up front. And then you're gonna see yes, no, or not applicable for the rest.

And so we're going to walk through each of these. So the first one, and again this is a must. Every informed consent form that is under the Common Rule with VA is gonna have it, the information presented up front. The informed consent must begin with a concise and focused presentation of that information which is most likely to assist a prospective subject.

You say, why do I want to participate or why do I not? Now, what is interesting is that the Common Rule ORD policy, if you look for guidance, but particularly in terms of policy and regulation, both are silent in terms of what constitutes key information. And that is to give latitude to the IRB. They, at the end of the day make that determination, and they justify it.

So when it comes to the checklist, and the checklist includes in terms of that, what you saw previously, again, going back two slides, you'll see note. There are five list of topics that would generally satisfy the requirements. Now, that's not in the reg itself. But this is again as a guidance on what, what is, and what was the, what was the thinking behind this? But at the end of the day, it is the IRB that makes that determination.

Now, we've had several sponsors who when we tell them, "By the way this consent form needs key information," they themselves will decide what they want to put in the key information instead of letting the site do it, which is fine. So, again, at the end of day, it's the IRB that makes the determination of what constitutes adequate key information. The original belief of the Common Rule agencies when we did this, and VA being one of the Common Rule, is that this would be not more than a page. It would be one or two paragraphs.

Of course, some of us have seen key information that are three or four pages long. That was not the intents of key information up front to be three or four pages. So again, because there is not strict regulation or policy defining exactly what it is, that's why you see that variability. You'll see that variability in the IRBs. But again, the regulation is just about, it must begin with presentation of key information that is most likely to assist a prospective subject, or \_\_\_\_\_ [00:33:59] or, and understanding why they would or would not participate in the research.

Now, that always must be present. But now we go to the others, and this is where there is, if if you're not sure about it, it's okay. Because at the end the day, it's up to the reviewing IRB of record. So in regards to the next one, which is about biospecimens or an identifiable information. Common Rule put in a requirement that you got to have one or the other statements.

If you're have identifiable data or identify in the biospecimens, there has to be a statement, one or the other, at those could, the identifiers could be stripped. And they could be used for future research without your consent, or no, they won't be used anymore.

Now, there is a lot of, of ambiguity sometimes in this when you're looking at this from a consent form, and evaluating, and deciding whether or not it needs to be there or not. Because the Common Rule doesn't require it to be verbatim. And so in terms of study teams looking at this when you're preparing your application, again, if you're not sure, don't worry about it. Just go ahead and put, don't put it in there, or put it in there.

But at the end of the day it's going to be the IRB that will decide whether or not it's applicable or not. So again, trying to make sure that you're not spending a lot of time; if you're not sure, it's NA, just let the, let the reviewing IRB figure it out. You're gonna hear me say this over again three more times.

Because the next additional element of informed consent, and that's where the IRB of record determines if it's applicable, is about whether or not the subject's biospecimens, identifiable or not, can be used for commercial profit? And whether the subject will or will not share in that commercial profit?

So again, one of the things I do when I'm trying to look at whether or not I need to put it in the consent form is I do a word search really fast of the informed consent document, and look up for the word commercial, or commercialization. Nine times out of ten when I see that word I need to put that statement in the informed consent if it's an industry-sponsored study. So that's again where, a tip that you can use. But again, if you're not sure, you can leave it out. Again, it's up to the IRB to determine whether or not it's applicable.

Next one, you're gonna hear this two more times, return of research results to subjects. The revised Common Rule now requires that, if it's applicable, again, it's additional element of informed consents, that there is a statement regarding whether those research results are clinically relevant results, are going to be given back to the subjects.

Such as, you're doing a study involving an MRI and there may be a finding there that should be important to the clinical care of the subject who is also a patient. Is that, or is that not going to be returned to the subject? Now, that's a hard evaluation for maybe a study team to make. It has to be made by the IRB. So again, if you're unsure of it just move on, and the IRB determines whether or not it's applicable.

And then the last one is whether or not the, the research involves whole genome sequencing? In terms of the additional elements of informed consent, to me this is the easiest because you can do a word search. And you'll looking up, either one of two things. WGS, which stands for whole genome sequencing, or you look up for the words 'whole genome sequencing.'

And most of the time, 99.9 percent of the times, if you see those words in the informed consent form, you're gonna see the words also, "We will be doing whole genome sequencing on your biospecimens." So therefore, if that statement is there, and you see the words, 'whole genome sequencing,' it most of the time, if you see it in the consent form, you don't have to include any other statements.

Because it's saying that they're going to be doing whole genome sequencing, and that is the the requirement of the Common Rule. Again, if you're not sure, again it's up to the reviewing IRB to determine whether it's applicable. So when it comes to these Common Rule requirements, and I've, ORD is saying you now have to include the applicable 2018 Common Rule requirements.

What I have to reinforce over and over to you is it's about key information. That is the single most important thing that you've got to make sure is in those informed consent documents that are submitted to the commercial IRBs, or it will be returned back to you. The others are again, as we've walked through this, they are debatable depending upon what's in the informed consent document, what's in the protocol. And there may be information that you don't have access to. And again, at the end of the day, it's up to the IRB to make that determination.

Now, the last thing we're going to talk about, very briefly, and we're not gonna spend a lot of time on this, because really, our focus is about informed consent documents. We did revise the tool for the the HIPAA authorization because we separate it. And the biggest issues we're having with our commercial IBSs about when to use a standalone HIPAA authorization versus when it can be combined.

That's the first issue. And the second is whether or not the standalone HIPAA authorization must be submitted to the commercial IRB. So what we have done in the tool, as well as the checklist, is we put in the checklist that you don't have to submit the standalone. We've also again clarified in the tool when a, when the HIPAA authorization can be combined with the informed consent document.

And so we split up the tool to make it easier to, to read and also to be able to be utilized. Again, like, I want to reinforce all three of our commercial IRBs have told us, have told ORD, "You don't need to submit the standalone HIPAA authorization when that is what is required to be used." And the reason for that is because IRBs are not responsible for reviewing or approving it.

Now, they have to review the combined document because they are required by regulation to approve the informed consent document. Now, again, it's the job of the covered entity to make sure that the authorization language is correct, and that it does indeed, that any disclosures and use made within the agency are in compliance with the applicable privacy regulations, and laws. But that is, that is the rationale is that is applicable in this situation. You don't submit the standalone HIPAA authorization.

Now, not a tool, but I'll change in process. And this will not be implemented until the end of May. Is that we have as a requirement, and this is also started back in 2021, I believe because we were having a lot of the issues. Actually, it may be of '20, with – when we started using commercial IRBs, we had a lot of studies that were submitted where sites were either not actually a selected site. That happened around 75 times in three months.

Or, more importantly, we would have studies that were submitted without a privacy review, or an information security review, and then they had to be revised. The IRB, for example, would approve a waiver of HIPAA authorization for research for, for recruitment purposes, a partial waiver. And yet, the appropriate content may have not been there. And so it had to go back.

And so as a result of this when we started using the commercial IRBs, a process we put in place with the endorsement letter to say, to make sure that those reviews were done. But really, the primary reason was because studies were being submitted in which the VA facility was not selected or participating as a participating site; and also, sites were submitting, study teams were submitting to the commercial IRBs, and the research office didn't know about it.

So again, to increase that communication to make sure the research office was aware of what's going on, this mechanism was put in place. At again, as a result of the changing processes that are occurring to get to, to to try to increase our compliance, and and also facilitate the approvals, and the processing that is involved with both side, study teams as well as the IRBs. We have added a line in those endorsement letters that says the VA investigator has included the applicable language and Common Rule requirements.

Now, it does not mean, by the way, that we expect the research office to go into VAIRRS, or, or look in the platforms, and see whether or not that has actually happened? That's not the intent. It is the intent, but when the study team says, "This is ready for a submission, here, y'all, I'm ready for you to sign the endorsement letter," that they have, they have done what they needed to do. Which is why we're walking through this today. But again, reinforcing because that has been asked since we've introduced us two weeks ago, whether or not it was supposed to be a research office responsibility to do the check? No that is not, that is not.

So please, please, please know that. And again, the the, right now, if you're using the old endorsement letter, that's okay. Again, we want to lead in on this one. So it will be roughly another six weeks before we do a hard stop on you got to use the revised endorsement letter. And again, that template is available on our website.

And we're also going to be making changes again, trying to make this as user friendly as possible so that it's readily accessible at all times. Again, I want to reinforce that we're going to be making tweaks to all of these tools as a result of feedback from you. I can tell you right now, the first generation of these tools even for the checklist, from the time that we sent it for review for commercial IRBs until the product that you see today, it was radically changed to the time of, of ten days.

So again, my advice for you is come back often to the checklist, to the, to the the websites for any updates. Again, and we will send out a notice when we're updating those checklists of tools so that you'll know, hey, by the way, there is a new tool that we can look at. Our our, we revised it.

Let's see how they revised it. So in terms of, again, ending this webinar and opening up this for questions, we created this new checklist that is to be used with these revised tools to facilitate study teams who are submitting informed consent documents as part of their applications to the commercial IRBs. The checklists themselves are not required to be submitted.

Again, as part of this, the issue with the industry-sponsored clinical trials who do not consistently, because they're not required to put the 2018 requirements into their model consent forms, we are indeed requesting that the, the VA submitting sites make sure that those elements are in there while focusing on the key information presenting up front. But again, reinforcing that the IRB is responsible for their reapproval of informed consent documents.

And one thing, that Dr. Workman is on the phone call with me today, the panel today along with Ms. Christiano. Is what I really need, and I'm requesting from you is as these issues, as any issues are coming up with commercial IRBs, please let us know. And please, let your liaison know. That is the most important also in terms of what, if you get anything out of this presentation today. We can fix it. We can address it. We are on the phone constantly with them in meetings dealing with issues. And as we all know, no IRB is perfect, y'all.

That's the truth. And so, we we want to be able to address your needs. Because if something's not working for you, we need to know it. And so with that, again, we appreciate your attendance today, this afternoon. A recording again will be, will be available in our archives within a week. You can send questions to our regulatory box.

Again, the presentation has the webpage where you can find all the documents that were included in your handouts today. And with that, I'm gonna stop sharing, and I'm going to open this up for questions. Thank you very much.

Okay, we have our first question. So is the way the external IRBs handle the consent with extra language required by VA and inclusion of the 2018 Common Rule, that that extra language is a site specific language like inclusion of the actual name and contact information of the PI? That is this extra language does not appear in consents at other non-VA sites.

You are correct that in terms of the VA specific requirements for informed consent, those really four, PREP Act is, is a unique issue. Those are indeed VA specific requirements you're not gonna find in a non-VA consent that VA is going to pay for your, or for any cost associated with research-related interests. So so that is, that is accurate.

In terms of the 2018 Common Rule requirements, you're not gonna find that language in other non-federal sites unless the sponsor chooses to apply the Common Rule to all this research. I have never worked with a sponsor, industry sponsor that has chosen to apply the Common Rule to all of its research. And so it's a rarity that you would find the Common Rule requirements in there such as key information presented up front. Thank you, the next question?

Do all of these elements apply to FDA studies that do not use the 2018 Common Rule? For the VA specific elements, no matter if it's an FDA regulated study or not, if it's a VA human subjects study, human, if it's human subjects research, it requires an informed consent. The VA specific elements of informed consent are going to apply. That is ORD policy. And so for FDA studies, FDA again, it doesn't follow the Common Rule.

But again, it applies, I mean, those requirement. It studies that FDA regulated, and that's why this is, this is issue with the industry-sponsored clinical trials. They apply FDA regulators, regulations because their studies are FDA regulated. But for VA, since we are a federal entity, we have to apply the Common Rule. And because we are a VA entity, you also have VA specific requirements of informed consent as required by ORD policy Directive 1200.05. So that's how the applying occurs. Thank you.

Great questions, this is a, this is a, I'm really glad whoever asked this question. Every question is important, but this, this is, this is one that we've gone back and forth with. Who writes the Key information page for an industry-sponsored study. It seems like the sponsor should do it, or does the VA PI need to write it?

A great question, we have had it both ways. This, and this is again where we're going to be tweaking the, the information on the, the table. I have dealt with six sponsors on this issue in the last three weeks. With three of those sponsors when we told them that key information had to be presented up front, they or their CRO get it. And they did that because they knew there was more than one VA in the study.

So that would make sense, standardized key information. Every site should have different key information. In three of those studies VA, there was only one VA site participating. And so what they had in those three situations with the VA, and study team wrote the key information, and had it reviewed by the sponsor. And, of course, later on it would be, of course, reviewed by the IRB of record.

So that is where my advice here is on this, please check with your sponsor if it's not already present, and say, "We are VA. We must include key information at front." Do you want me to include it? Or do you want, or do you want to include it? And again, if there is any questions, please direct them to the regulatory box.

We will, we respond immediately to their questions, and we will help them, and and address any questions. And again they have understood this every time we've talked to them. No problems whatsoever, everybody just wants to do what's right. Next question?

Who do you recommend should be reviewing and confirming all of those elements have been addressed in a consent form prior to submission to a commercial IRB? This process is not based upon a confirmatory measure. We're creating this checklist as a tool for study teams. And as you can see based upon the presentation today, a lot of these elements, particularly and when it comes to the Common Rule, it's an evaluation of the IRB.

So so in terms of what we are asking from ORD is we're not expecting your research office to do it. Now, if we have a problem, and we hear from the commercial IRBs that X site is not putting in key information up front for all the industry-sponsored clinical trials that are being submitted, that endorsement letter when it gets into effect is saying the study team did it. We're gonna go back to your research office.

And that's where we may need to be putting in a mechanism. Okay because of this issue that has been identified there needs to be a, we're going to need to assign someone to do that. But that's, that's not what this, that's not what this is set up to do. We're not asking for the RCO, or the research office, or the commercial IRB, and liaison to be a confirmation. It is the study team has done this.

Again and as this evolves, we may have to put in a mechanism. I'm hoping we don't. But we think the tool is going to be enough. And we're gonna start off with that. So so we're, we're not sending out the confirmation process from the, from the research office. Thank you.

If there is language about consent for photo/videos in the informed consent document, would we still require the study to utilize form VA Form 10-3203? The answer is no as long as the consent contains the elements that are in ORD policy. The VA Form 10-3203 was required. I'm saying was required by ORD policy previously, because there was not this requirement that we have currently in policy about what must be included in the consent form when a photograph, video on a audio recorded is taken for research purposes only.

So working with VA \_\_\_\_\_ [00:55:03] privacy, we, this is, this is why in, in ORD policy we're able to put this in the consent in lieu of the 3203. Now, if you want to use a 3203, that's fine, but it's not, it's not required if you do what is required by ORD policy when these photographs, audios, and videos are taken for research purposes only. So that is the answer to the question. The next question?

In regard to CoCs, are NIH sponsors specifically NIH sponsored? Or do they include sponsored studies from child agencies like NCI and such? For any NCI study it is going to have a CoC in terms of, that DHHS is covering them. And in any NCI study will have, we should, is covered by a CoC. And in the NCI they call it a privacy permit.

And I know that because we, if, for those of you who are doing the NCI studies, you will remember the issues we had with using that language because Veterans were complaining to us, and bringing issues to ORD about, they didn't know what a privacy permit is. They thought that it was a permit that expired. And so the, the NIH includes all three institutes. The next question.

What if a VA site is looking at an already approved commercial IRB consent and you notice that some VA specific language is missing? What needs to be done? We are indeed going to be addressing that in a separate communication there. And I want to reinforce right now, you do not need to stop enrollment, do not. There is nothing that you need to do right now in terms of saying you need to submit something.

We are aware that there are, there are, there are probably several studies from multiple sites that are going to need to be remediated. And so we are working with, particularly from, from Advarra, and we have communicated with Advarra about this. There is going to be a communication about what specifically to do and how to do it. So that is an orderly, basically how to do it without – in an orderly fashion so that you will know exactly what needs to be done, how to do it.

And we can basically keep track of them both in, both the commercial IRBs and the ORD. So for right now, do not do anything. Please know that there will be a communication coming later this week or on Monday morning. You are going to get this, the research community is going to get an update from our office, basically reiterating what we're talking about today, including when the new endorsement letter will be required to be used, which is May 31st.

But also, telling sites, there is going to be a communication that's coming in the next two, few weeks about studies that are currently approved in terms of remediating those. So for right now that will be addressed. Please know that we will, we do recognize that has happened, and we will be dealing with that. The next question.

If the consent form has a combined HIPAA authorization but VA requires a standalone HIPAA authorization for the study, does the HIPAA language in the consent need to be removed? Yes. That's what we normally do. I know, Michelle, \_\_\_\_\_ [00:58:51] I'm gonna – Michelle, would you like to comment on this?

Michelle Christiano: Hi, Karen. I just want to reinforce what you just said. It does need to be removed because nine times out of ten there'll be information that's either inconsistent between the language that's in the consent form that's combined with the HIPAA authorization, or that's a little bit different than what we have on the VA Form 10-0493. My recommendation is always to remove it from the combined informed consent, if a standalone 10-0493 is required.

Karen Jeans: Thank you, Michelle. And I, I know we're almost out of time. This would be the last question. The next question, okay. Is there a possibility? Yes. Is there a possibility of creating a VAIRRS library to put these tools in similar to how the VA Central IRB has their own VAIRRS library that makes it easy to access updated documents? Absolutely yes, that is one of the reasons why we are going to be issuing the update is how we get, so that we can put these in the VAIRRS library. So that you don't have to go to a website, you can go to VAIRRS.

And so this was brought up two weeks ago. I'm very glad to have this question. We are following through with this. So yes, that is going to happen. And so I know this is, this was set up for one hour, so I'm, I'm not, I want to respect everybody's time.

We are going to take the questions that were not answered, and we will be reviewing those again, and issuing more documents, and guidance, and to, just to address your issues. And so again, I want to thank you for joining us this afternoon. And Ryan, if, do I need to hand it off to you or to close? I'm sorry, we'll \_\_\_\_\_ [01:00:37].

Ryan Sohizad: No you're fine. Just real a quick thank you to everybody. And please make sure to fill out the survey at the end of the webinar. Greatly appreciated, thank you.

Karen Jeans: Thank you so much, everybody. And thank you for, for working with us through this process. We appreciate it, and have a great afternoon.

[END OF TAPE]