Karen James: So, hi, everybody. And first of all, my name is Karen James. I'm the Director of Regulatory Affairs here in the Office of Research, Protection, Policy and Education. I'm a little hoarse sometimes and I'm going to start off by apologizing for the delay of this workshop. We had it scheduled and I unfortunately got very sick. So, we had to schedule at a very inopportune time. We don’t like to reschedule our webinars so, again, wanted to thank you for your patience with this.

This is an hour-and-a-half webinar today. We wanted to make sure there was time for questions but we also have a variety of topics we really appreciate. The purpose of this bimonthly series is, again, not on a single topic but, again, updates that have happened that are of interest to the VA research community.

We are going to briefly talk about the TPOXX Expanded Access Program in terms of closure procedures if your site wishes to close.

We are going to be talking about consultants and investigators because we get a lot of questions about that. And so, again, when we get a lot of high volumes of questions about certain topics, that drives the agenda that goes into these bimonthly updates.

We’re also going to be talking about some common issues when making research versus non-research terminations in connection to, also, a release of a new tool, a new letter, that’s billable which we think will – we get a lot of requests for and we think will be utilized.

But a large portion of today’s workshop is going to be about commercial IRB issues and some new procedures that are going to be implemented, effective immediately, regarding submission requirements; particularly related to the informed consent and HIPAA authorizations and a number of some tables that have been updated but, more importantly, in an internal checklist that we have developed for your use to facilitate. And we’re going to be talking about that but, also, announcing another webinar – a focus webinar – that will be about those tools that we’ll discuss when we get to that agenda item.

And indeed, there is a lag time today associated with the webinar. So, I'm going to ask for everybody’s patience as we deal with some technical issues that are clearly occurring.

Okay. So, again, in terms of the TPOXX protocol, Expanded Access Program, we used to spend a large part of these bimonthly webinars talking about. And we have 81 VA facilities that are currently active in that program, Expanded Access, use of TPOXX to [stumble] tecovirimat for the treatment of mpox; 79 VA facilities, of course, relying upon CDC; two are relying upon their own.

Now, this Expanded Access protocol continues to go. It is still in existence. It is sponsored by the CDC and we have a number, again, of facilities that are in it. There have been no modifications in the protocol or informed consent document since October. The informed consent document was last revised in August by the CDC IRB and the current protocol is still Version 6.2, which was approved in October.

Now, the continuing review of that protocol under CDC’s IRB will expire in July. Now, of course, there’s always a lot of scuttlebutt in terms of what’s going on. There is no everything whatsoever that this program is going to close and so, that is one of the reasons we wanted to put this on the agenda [sound out] to say there is no indication from the CDC IRB that it will not continue. We do indeed expect it to undergo CDC IRB continued review prior to its expiration date.

However, this is not a high-volume use at most VA facilities. Luckily, monkeypox – mpox – has not had the prevalence that we, of course, saw with COVID-19. And so, many of our sites are asking; what are the correct procedures to follow according to the CDC IRB if a VA facility under the oversight of CDC – you’re one of the 79 – want to voluntarily close? Saying, “Okay, we’ve seen no activity, we don’t anticipate any activity, so, we would like to whatever our procedures and what do we do?”

So, we have contacted the CDC Office of Regulatory Affairs and what you will see on your screen is the steps they have told us to follow. This information is also going to be made available by tomorrow on ORD’s dedicated webpage for the VA’s participation in the CDC Expanded Access IRB program for TPOXX.

So, what will happen if your site wishes to, again, voluntarily close – I want to emphasize, because I do not want to – I do know things can get miscommunicated and that I do not want to say that, “ORD is saying that the program’s going to close.” That is not true. It’s just if your site wishes to close, send an email. It can be your research office, it can be the clinical provider. I would ask – ORD is requesting that it go through your resource office so that, again, everyone is aware, send an email to RegulatoryAffairs@cdc.gov to the address that is on the slide. Again, this will be made available on ORD’s website.

CDC has specifically stated they want two things addressed in that email; one being, did you include any patients under the Expanded Access Protocol? And does your pharmacy have any TPOXX onsite? And that is exactly the way they questioned it – they’ve asked it. If they have followup questions, they will indeed follow up with whoever is the requestor. We are asking that you copy ORD and ORO on the email because we also keep track of all of the VA facilities that are in the program under the CDC IRB. And the reliance agreement between ORD – the master service agreement – and CDC, as well as your own individual VA facility reliances, is for this protocol and this program only. And so, that is why we keep track of it.

So, please send it to the IRB Reliance, the single IRB exceptions box; that’s Dr. Workman, as well as to Ms. Priscilla Craig and Ms. Elizabeth Clark with the Office of Research Oversight. You will get an acknowledgement from CDC Regulatory Affairs when that email is sent by your VA facility. They will either say, “Thank you, acknowledged,” or they will say, “Oh, we have a question.”

Then, after you do that, close the program with the R&D committee, and that is the end of it. There’ll be no more actions that you’ll need to take.

So, that is the actions for your VA facility to take if you wish to voluntarily close the CDC’s Expanded Access Program, the CDC IRB, if you’re IRB of record for that site.

There are additional questions that we are seeking some clarification on from the CDC specifically related to changes in, you know, if your lead clinician leaves because there’s different interpretations that are going on. And so, we have also sent that query to CDC. Again, they have thousands of institutions that are in this program so, you can understand why there’s sometimes a lag time. When we get that information, we will send that out to you. Whenever we change anything, we send it to the liaisons or the – as part of this changing of the standard operating practice, we will also update our website.

Now, I’m going to move onto the next topic. Again, the way this format works for our webinar, if it is bimonthly, is, again, it’s different topics covered in different degrees of depth. But again, to try to reach a wide variety of people on different issues.

So, we’ve been getting a lot of questions lately here in the Office of Research – the Office of Research and Development – about investigators versus consultants. And the issue is very simple and, actually, very complex. That’s the crux of it. The two words are not interchangeable. And if you look up – try to look up – where would I find the definition of “consultant” in regulation or in policy, you will never find it. Because the word “consultant” in terms of being as part of a study does not exist. You will see the word “consultants” in terms of the word – the role of the IRB a lot of times.

But in terms of, “Hey, I'm going to be a consultant to a study; what can I and can’t I do?” you will never find it. You will have different agencies in terms of different funding agencies whether they be federal funding or they be nonfederal funding, different institutions, that will say, “Okay, for us, a consultant is someone who never does research.” In other places, “Oh, yeah, the consultant can conduct research.” We are a consulting firm and we conduct research.

So, that’s why the word itself, “consultant,” is problematic. Because depending on who you are – whether or not you’re the person giving that information as a consultant or whether or not you’re the person trying to interpret it, it has different meanings.

And again, as I put on this slide, the confusion arises, and why we’re bringing this up, is that it gets an issue when you have someone – “you” being like a VA facility – who is trying to review a study and looking at it, and you have someone listed as a consultant. And your institution is trying to figure out, “Wait, should they be part of the study, too? Okay, we’re going to put them on the study team because they’re ‘a consultant.’” Or, “Oh, no, they never conduct research. So, it’s a consultant so, we’re not going to put them here.”

So, that is where that word itself, the label, is problematic. But in VA in terms of what we see normally in this agency, consultants are not traditionally involved in research. Consultants are indeed – it’s like – and I’ll use the analogy of an IRB, which is a rough analogy but it’s kind of worked for this, is where, you know, when you add a consultant to the IRB, they are not part of that IRB voting membership. They are consulting on an issue, relevant, that is being asked by the Institutional Review Board.

And so, that is how, in terms of conceptually, what you will traditionally see both within the VA and outside the VA, what a consultant is. And again, where you get into this issue of consultant and trying to figure out what they are is indeed; what are they indeed doing?

And so, we’ve gotten a lot of questions in the last month related to consultants and again, it’s dealing with that label. So, we have two poll questions that we want to ask. And also, please know that the answers to these when we release the slides on the ORPP&E cyber webinar website, the answers are on those slides that can be downloaded.

So, the first is – this is a true-or-false question – and the question is; if a consultant is to be listed as an author on a research publication, the person must be part of the study team. The consultant must be part of the study team. And so, Parker, are you going to open the poll?

Parker: Yup, that is open. We’re getting answers coming in. [Pause]

And here we go. Here are your results.

Karen James: Okay. So, based on the poll results, 48 individuals said yes; if they are listed as an author, they are indeed a member of the study team. And 105 of you said false; no, that is not true. They can be listed as an author on a research publication and still be part of the study team. Thank you, Parker.

Parker: And one sec, I'm bringing up the second poll. Go ahead.

Karen James: No, so, let me give the answer. So, the answer is – in terms of the answer is – and again, the lag time, a little bit of lag time here.

Parker: Nothing’s going to show up on our end.

Karen James: Okay. Again, we’re have a little problem with WebEx. There it is. The answer is false; having author status on a publication of manuscript does not automatically make that individual part of the study team, and vice versa.

So, the label, just because you’re a consultant, does not make that person a member of the study team. I’ll use myself as an example. If, as many of you on this call are more part of Research Offices, many of your sites participated in the Mayo Clinic Convalescent Plasma Protocol for COVID-19. There are many of us – and ORD itself – who were listed as – we were listed as authors but we consulted on that protocol as regulatory specialists; for example, in my office. That did not mean we were part of the study team.

So, that’s a concrete example of why just being a – just putting yourself as an author does not make yourself one of the study team, okay?

So, now, we’re going to the next question. This is a “yes or no” question and this is again talking about whether or not the consultant would – is required to complete training in ORD ethical protections.

So, in this situation, you have a member of the study team who is reviewing a study stating that a consultant from another VA facility will provide advice to the study [sound out] methods to analyze the study [sound out] as far as study planning. The consultant is not interacting with any subjects nor will have access to the study data. However, that individual is a consultant on that VA study and they are from a VA facility.

So, yes or no; is that consultant from the VA facility – another VA facility – required to complete ORD training and ethical principles of human subjects protections? And I think, Parker, you’re ready to open the poll.

Parker: Yeah, and we already have a bunch of responses. You can see some of the results there.

Karen James: Is the poll closed?

Parker: Yup. Oh, yeah, you should be able to see the responses.

Karen James: Okay, alright. So, the answer is – so, this was – so, 16 of you answered yes and 43 of you answered no. And so, the answer is – and again, technology is great and wonderful and if gives me a chance to talk some. And as we’re moving forward to this next slide on a beautiful day in Arkansas. I can tell some great stories here as I'm moving along. Appreciate your patience.

Okay, okay. So, the answer’s no. And I mean, most of you who responded said no. Because in that situation, they’re providing advice to the study on \_\_\_\_\_ [00:18:11] but they’re not analyzing data. They’re not playing a substantial role in the conduct of the research because they’re not conducting the research. They are consultants. And you’ll hear that word, and that’s why we try to, you know, hear that word. But however, they’re a consultant.

However, does it change the status, that word? They are not doing anything that makes them part of that study. ORD-required training in ethical principles of human subjects protections is for those individuals who are VA employees, by the way, who are conducting human subjects research, not advising. And so, that is why the answer is no.

So, the bottom line, again, the take-home message for this it’s always about not looking at the label; is evaluate what that individual is doing. And this is going to lead into the next section on a different topic where you have to get into the details a lot of times. Because just putting out on it, saying, “Okay, I'm a consultant. Okay, I'm only going to be doing some advising,” that alone, if you told me that and asked me as ORD to make a determination whether or not that person is or is not doing an activity that would be involved in conducting human research, that’s not enough. I'm going to be following up that question if you presented that to me. “What do you mean by advising?” “Well, I'm going to be working with the data.” “What do you mean with the data?” “Well, I'm going to be working with the manuscript.” “What do you mean, working the manuscript? Are you going to be reviewing the manuscript for publication? Are you going to be analyzing the data itself?”

So, that’s why getting into the devil of the details is important when you have those types of scenarios. It’s important for any type of scenario. And that’s why it leads right into this issue of looking at, you know, what are some of the common issues when one is trying to make research versus non-research terminations.

And again, it’s like it is possessed today as we see what is going on with the lag time here. Always interesting; again, in VA Research, we’re very innovative. We manage to deal with situations as we go in terms of any challenges that come before us. So, as you’re looking at great picture; yes, no, maybe, perhaps, you know, yes, no, maybe it will advance to the next slide eventually.

So, okay. So, you know, as everyone on this call knows, whether or not you’re from a research office, you’re an investigator, if you’re an RCO, if you’re a Chair, whatever your role is; anyone who tells you that making research and non-research determinations are easy, that’s not quite accurate in almost every one of our opinions. If we did a poll question, I don’t know if any of us could say that it’s easy. And that is because no matter how you write something, in regulation policy guidance, you can never ever be 100% clear. And there is such activity within the definition of research under the common rule. That is a given. And it goes back to like when we were talking about consultants and investigators. If you don’t get enough information, you can’t make the right determination. Or if you don’t have the information, if you’re trying to provide that to somebody, you can’t do it.

So, that’s where you get into issues. That’s where – you know, why VAEDA was introduced; to try to standardize these questions so that the person who’s answering the questions self-report as well as evaluating the determination; this gives you clues and triggers onto what is the type of information you need in order to make that determination.

And of course, there’s always the issue where you may have different reviewing groups have different opinions and come up with different issues. And that has been well-documented in the literature. There’s been lots of studies that happen in which you have one group that’s given a study that they say it’s exempt research. That other group will say, “It’s not human subjects.” And so, you can’t take that subjectivity out of everything. A part of it is because of the definitions within – the wording within the definition of research under the common rule itself.

Now, you know, again – and I’m not going to read this because the key issue is what I’ve highlighted in yellow on your screen. Research is a systematic investigation, you know, in terms of highlighted design to develop or contribute to generalizable knowledge. It has to meet those two conditions with living human subjects if it’s human subjects research.

The problem is this issue of developing or contributing to generalizable knowledge. What does that mean? That is using the hiccup – the pain point, issue point – of why it’s difficult to make the determinations.

You know, we try to break it up, and we try to break it up into, again, a systematic investigation is basically something that is planned. But as we all know, quality assurance is a great example. You can have systematic investigations and it still be a non-research activity. Because systematic methods is a component of many activities that are not research. What truly is the trigger for those systematic investigations to push it into the research realm when we’re involving human subjects is whether or not it develops or contributes to generalizable knowledge. It expands the knowledge base of a scientific discipline or other scholarly field of study. And you look at those words and those are very sometimes hard to differentiate based on what is presented to you.

So, we have VAEDA and VAEDA is a tool and in a reference list at the end of this presentation, there is a link to VAEDA. But in terms of giving you some common issues, in terms of trying to break it down and making it - how do you look at this – here are five questions when my office is asked to assist a site and looking at, “Hey, is this a human subjects research activity?” You know, when you’re looking at – I’m looking at the first thing is; is it producing new knowledge? You know, when you’re talking about develops or contributes to generalizable knowledge, it’s; is it new? Are we producing something that is brand new, that is not already known?

The next question that I'm always looking at is; how are the results going to be used? If I have an activity that is presented as a non-research activity but it states in that write-up, “If the results are positive, we’re going to use this to conduct a research study,” that is a pilot study, what I just said. That’s the definition of a pilot.

And so, it’s; how is it going to be used? It’s going to be used to improve practice, for example, in my division at this VA facility. Or is it, indeed, “Well, I'm going to use it to generate data for a research study, a grant?” So, these are questions that I look at when I'm trying to break that definition apart and trying to figure it out.

In terms of funding – and I'm going to skip to that one before I come back to students – how is it funded? Now, in terms of funding agencies, there are some activities – if it is funded as research, it will always be research. Within the Office of Research and Development, for example, we have to separate pots of funding. We have research funding and we have non-research funding. Our non-research funding is for query.

And so, for example, CSR&D – Clinical Sciences, Research, and Development Service – if they fund a project as research, it will always be research. It cannot be anything but that. So, that is why, also, that’s of the questions.

And then, students. Now, in terms of, you know, we can – the next bimonthly is going to have a whole section about student research because student research has a lot of issues with it when it comes to VA facilities coming to ORD about, “What do I do with this?” And part of it is because of the wide types of information you may or may not be getting when someone comes to your research office and says, “Okay, I'm a student. I'm with the affiliate that you have an academic affiliation with. And I want to do this project. I need IRB approval,” but it’s not research or the vice versa. “I'm doing a capstone.”

And one of the issues, what I always ask when it comes to students is, for example, “Is it a dissertation?” And I’ll get a letter and I get – my office gets around 1,200 requests a year from students who are asking to conduct research in the agency. And they’ll say, “I just need your permission. I need a letter of support from the Department of Veterans Affairs to conduct research in your agency.” And my first question is always, “Well, is it research?” And many times, it’s, “Well, no, I’m a PhD student. I'm doing a dissertation but it’s not research.” If it’s dissertation, it’s research. Or it will be my – you know, you’ll have a situation where, “I'm doing it, I’m doing the student research activity, I have it approved as research at my university, but it’s really not research.”

And so, this is where we get into these complicated issues concerning when is something research versus it not? And if someone says it’s research at another institution and your VA facility looks at it and it doesn’t meet the definition of human subjects research, you can’t call it research when it isn’t just because somebody else did. And that’s where we get into the difference between the institutions.

In the next bimonthly webinar, we’re going to spend around – one of the areas of focus is going to be all the issues concerning student research and the scenarios we deal with on a daily basis. But this is one of the key questions whenever you get a student who is asking to conduct an activity and they’re not sure if it’s research or not. The first question I ask is, “Why are you doing it? Is it a Master’s thesis? Is it a dissertation? Is it a capstone?” And so, these are some of the questions that come into play.

Case studies, of course, are one of the highest-volume areas of questions we receive in VA, and my offices receives because there’s a lot of confusion about case studies because they’re called “studies.” But a case study of one or two individuals is not a human subject study. Case study, case reports, are retrospective analysis.

And a case study, depending on how many cases or what it’s involving, can be research or it can be non-research. And throughout the years, there’s always been this saga about; what is the number? What is the number that makes something tip into if you’re looking at – if you’re a clinical provider and you’re coming to your research office right now and you’re going, “Okay, I want to do a case study and it involves two people – two of my patients. And of course, no PHI is going to be in that case report but do I need to submit this to the IRB?” You know, again, you will never find it in federal regulations; it’s not there. It’s not in policy. It’s not in guidance even. We haven’t updated – you know, put new guidance out.

But our general position is that if more than three cases are involved in the analytical activity, someone comes to your office – your research office – and says, “You know, I'm doing a case study involving five patients. Do I need to submit this to the IRB?” For example, if it’s retrospective, it could be exempt under 4.3. We’re going to say yes, because more times than not, that is not just an activity. That does not involve research. Why are you doing it with five cases unless you were trying to answer a question? You’re trying to generate new knowledge.

So, when our general guidance, I think there was more than three cases involved, that activity should be submitted to the group or entity that is looking at making research versus non-research determinations. Because more times than not, it is usually going to be a human subjects research activity.

Now, we published – it used to be an oral directive – but in 2019, we converted it to an ORD program guide called “VHA Operations Activities That May Constitute Research.” And this is basically a – it’s not a directive but it is a group of procedures, examples, that helps, we hope, everyone in the VA research community and it’s also used outside of VHA and with VA, as well, in terms of looking at; when is something research versus not? And particularly for the reason that many, many, many program offices outside of ORD are non-research program offices – that’s their primary mission – do a lot of publications and manuscripts. And so, they’re looking at it, their groups, and whether or not that activity is a non-research activity when they’re looking at, “By the way, we need a manuscript. We want to publish on this when we do this activity.”

And that is why as part of this program guide, part of it includes a form because most publications require someone other than the author to make an attestation that the activity is not a research activity, if that is how it’s being presented.

And so, one of the things that we did as part of – you know, today, this will be posted on ORD’s website but it was also included as one of the tools – one of the attachments for this webinar – is create a fillable version of a sample form that is included in the program guide that allows the person – the program office, for example, that is reviewing that manuscript or reviewing that activity – to say, “No, this is not a research activity,” because that’s exactly what it is not, “and this type of form of documentation can be submitted, uploaded with the manuscript.” And we do thousands of non-research manuscripts in this organization. And so, this is, again, a tool that we think will also be very useful to everybody.

So, the last portion before we open up for questions is going to be talking about changes in some of our practices and procedures for our commercial IRBs specifically related to submission requirements. And our three current ORD-approved commercial IRBs are WCG, Sterling, and Advarra.

There’s three things we included in the attachments with this webinar today that represent some changes that we’re going to be talking about. We have updated the tables of our VA-specific informed consent requirements for VA, and I'm going to be talking to you why it now includes the common rule elements. Select ones, not all of them, that we’re going to be asking you to evaluate when the study that you’re submitting to the commercial IRB is industry-funded.

We have updated the endorsement letter, and I will explain in just a second why we did it and how it’s changed.

We’re also compiling a new checklist that we never had previously. It is targeted for study teams. It can help for QA. We used a wide variety of individuals in terms of preparing informed consent documents and combined consent authorization documents.

And I also want to point out while these are targeted for commercial IRBs, these are useful for any type of study in terms of looking at, you know; here's the VA-specific requirements. Here’s common – the key 2018 Common Rule requirements. Here’s a checklist and why the rationale are there. And you’ll understand more in just a second.

So, why are we doing this? Now, if you look at the reliance agreement that was executed between your VA facility and any of the commercial IRBs that you’re relying upon, it will include in there that the IRB is responsible for reviewing according to the VA. That means for VA-specific requirements, they have to be there. Okay.

However, the expectation has always been that VA puts them in first. The reviewing IRB is responsible for ensuring that they’re there. But in terms of that initial step, the submitting study team is responsible for putting those specific VA informed consent requirements into the consent form, which is sent to them by, you know, by a sponsor of it it’s by whatever entity. But that has always been the expectation that was to be enforced.

However, what has now been added, because of a new wrinkle, is the common rule changed, the 2018 requirements. You’ve all heard about it. If you haven’t, you’re hearing about it today. That is required – not supposed to be – required to be included in any VA informed consent document. We are a common rule agency. We codify the common rule as 38 CFR Part 16.

However, when you think about the studies that are coming to a commercial IRB, in VA, we may have all 81 VAs in a commercial IRB study but that study may involve 900 sites. The majority of studies that are reviewed by any of our commercial IRBs are industry-sponsored.

There are some that are indeed federal in terms of NIH – the National Institute of Health. But by far, the majority are industry. And VA is the only federal entity that is participating among the hundreds of non-federal entities.

So, that consent form usually will not contain the applicable 2018 requirements. Now, the good news is that most of the common rule requirements are also reflected in FDA regulations and that’s why the consents don’t vary a lot. But there are some unique 2018 common rule requirements specific to those agencies such as the VA which are required to follow the common rule.

And so, because studies sponsored by industry, unlike studies sponsored by the NIH, do not routinely include the 2018 common rule requirements. We – and this is, you know, the Office of Research and Development – have been working with our commercial IRBs to come up with a way to improve the process but, also, to deal with this issue so that we; number one, we want to streamline operations, we want to make it better not only for the VA-specific requirements but, also, for this issue of now including the common rule requirements.

So, we have, as part of this workshop today, we have released updates of our tools and checklists. And we have taken one of the prior tools and split it up and then, we’ve developed a new checklist. And so, I’m going to briefly talk about all these but, also – and you’ll see a slide later – we’re going to be announcing a presentation, a workshop, in two weeks. The registration and information will go out tomorrow in which we will spend the entire time of that workshop going in depth through these tools using scenarios so that you can better understand each – how the old tools were revised but how to implement it better. And again, it not only benefits, you know, if you’re submitting to a commercial IRB; it’s understanding how the requirements apply regardless of any type of study that is nonexempt research.

These tools that you had included in your packet today are already posted on ORD’s website at the revised page that you’re seeing on your screen. So, you know, they are already up and running.

In terms of going through each of the tools, we created a tool that’s separated from the prior tool, where it will – it’s called the “VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using an Independent Commercial IRB.” And there are five VA-specific elements that we’re calling it. Now, the PREP act is not specific to VA; it’s part of COVID-19, the public health emergency. But within each of these sections, what we did is we took it and we expanded on it to provide clarifying information. We got feedback from our commercial IRBs in this revision. So, this is not just what ORD thought. We’ve also worked with some your VA study teams, as well as some of your research offices, to make it more transparent.

Again, all of these VA-specific requirements are not necessarily applicable to every study. For example, we know that every study doesn’t have a COC. And so, we have taken that tool and provided more expansion and more clarifying information.

And we have in this tool, if the study is industry-funded, then, please also look at this. And there are five different, again, unique common rule elements that are not present in the FDA regulations that we’re going to be asking you to evaluate for when you as study teams in your research offices submitting it forward, that they look at to see; is this needed or not? Even within this, the IRB is going to be the group that will decide whether or not that is present. That’s why we’re having this workshop in two weeks; to go through these and explain. If you don’t know what to do with some of these, that’s okay. Because ultimately – and I want to reinforce this right now – it is up to the reviewing IRB to approve a consent form that meets the VA requirements. That is in the reliance agreement. And that is why it’s the responsibility of any IRB that – if reviewing for VA.

So, that is the bottom line. But again, we can make this easier and more transparent. What we’re trying to do is, again, trying to waste your time. We don’t want to waste your time, excuse me. Because when you have to go back and forth, that is a waste of your time. And as we all know, nobody has enough time. We want to be able to facilitate the compliance with what is required by this agency.

And also, we feel these tools are great training and education instruments; that they expand further, including content that we get into ORD. It’s great. We get feedback from, for example, our commercial IRBs. We don’t understand this. Why is this happening? Well, those are probably questions you may have, as well.

So, again, it’s a teaching instrument. While it was designed for commercial IRBs, it can be used for any type of study.

In regards to the – we separated the tool. We made it separate to where instead of combining previously the informed consent and HIPAA authorization tools in terms of this is what’s required, we split the HIPAA authorization component into its own separate tool so that we could provide clarifying information. And the key issue that I want to relay today, and we have worked – Dr. Workman went to all three of our commercial IRBs – Advarra, WCG, and Sterling – and clarified with them that if the study is using a standalone HIPAA authorization – and in VA, that’s VA Form 10-0493, don’t submit the standalone HIPAA authorization. An IRB is not required to review and approve a standalone HIPAA authorization. It never has been.

Now, some IRBs will say, “Okay, as part of the common rule, we are required to review and approve anything that is given to a subject.” Well, OCR does not require it and has issue guidance. FDA has issue guidance on this, as well. Common rule agencies, we also have that position, as well.

So, in terms of, again, simplifying and not introducing some, you know, some confusion that has happened among even our own commercial IRBs, do not submit the standalone HIPAA authorization. If you do, they may just turn it back. But they won’t do anything with it. They’re not going to review it, they’re not going to stamp; it, they’re not going to approve it.

Now, when you look at these tools that we included – and again, these are available on the ORD website – you’re going to say, “Okay, there’s several pages.” Because we wanted to make it – again, when you’re doing a revision, you want to make it meaningful. And these are not little. I mean, they’re expansive. And that was the purpose of it.

But we also wanted to say, “Okay, let’s pull it together. Let’s condense this into an easy, two-page checklist that the study teams can use when they’re doing their submissions and say, ‘Okay, let’s look at this and make sure that we’ve done this before we tell our – you know, the research office who’s going to submit the endorsement letter – okay, we’ve checked to make sure that we’ve done this.’”

A new tool has been developed called a Checklist for VA Facilities using independent commercial IRBs and it’s called Inclusion and Required Language Into the Informed Consents and Combine Informed Consent HIPAA Authorizations.

Now, it’s not necessarily a standalone tool. You will need the other tables until you practice more with it. But indeed, it’s pretty self-explanatory and it's a really – the commercial IRBs have already looked at it and given their feedback and they think it’s very good. And it’s very user-friendly, which is what our objective is.

But the whole test is; is it user-friendly to you? And that’s why we’re going to be seeking feedback from you.

But this is an internal checklist tool. It is not to be submitted with your submissions. It is to facilitate the completion of getting this stuff, these elements, into the informed consent documents, into the authorization documents, when it must be combined so, it can be submitted to the applicable commercial IRB.

You know, again, this has been posted. This, again, is a two-page form. And within the form, it has an area for the VA-specific informed consent requirements. Again, as you’ll see, everything’s not necessarily applicable. It depends on the study. Again, if the study doesn’t involve taking a photograph, audio, or video for research purposes only, you’re not going to have language in there about doing a photograph in. It would be very rare that a participating site would ever be doing that independent of the protocol.

So, again, in two weeks when we do our workshop, we’re going to go through this step by step by step. But it’s very user-friendly and we’ll go through it using cases at this time. But that is – this is how, even now, you can walk through it and it’s very – it was designed to be very organic.

The same way with the key information presented upfront. Again, most of our studies are indeed industry-funded that go to commercial IRBs. So, many times, you will not see that information. We already have implemented this. We have sponsors who’ve already contacted us within the Office of Research and Development. And ladies and gentlemen, they understand. They’re not going, “Oh, no, we’re going to drop the VA sites.” But okay, because again, they want to be compliant.

And so, a lot of times, if more than one VA facility is involved, the sponsor is going to, once they find out about it, they’re going to supply that information for you to use. Other times, if you’re the only VA site participating, then, you’re going to put that in. And we can help you with that.

And so, this tool – this is not only in the table but, also, in the checklist – you know, talks about the five topics that are generally included as part of that key information. And this is, again, what all of our commercial IRBs use. This is, again, not coming from ORD policy; this is part of the regulation of the common rule.

So, again, many of these are not necessarily applicable to every study. And some of these, when we’re talking about the 2018 requirements, you won’t know. You know, you’re not going to be sure. You’re not going to be sure whether or not the research results are going to be returned to the subject. So, if you leave it out there, it doesn’t mean that they’re going to return it back. Because ultimately, it’s up to the IRB to determine whether or not that requirement, that additional element of informed consent is present.

And as you can see, there’s only, you know, five of these and then, there’s, again, the other ones for VA informed consent. We are going to, again, go through these. But one of the reasons that we’re discussing this is because we also are trying to do reminders to put this in the endorsement letter.

Even before why we’re having this workshop – why we’re doing this workshop in two weeks, we’ve had lots of issues. We’ve heard from study teams that have had issues going back and forth with some of our commercial IRBs. “We thought they were supposed to put the informed consent on this, yeah, you know, for VA-specific.” This has been going on; we’ve been using commercial IRBs for three years now. So, there’s just been some problems going back with communication.

And so, again, both sides are trying to work together and that is how we do. We come together and figure out what are strategies to help introduce efficiency so that it’s also transparent. So, as part of the endorsement letter, it now includes a statement that, again, it’s a check. By the way, has the VA investigator who’s going to submit that study included the VA-specific-required language that’s applicable and the common rule elements, you know, when it’s industry-funded? That’s it.

And so, that’s all we did with the change of the endorsement letter. I know that some of your sites may not use the endorsement letter, the specific template that we have now uploaded on ORD’s website. So, yeah, you can use variations in that letter but it’s got to contain the content because that is indeed what the commercial IRBs are going to be looking for.

And so, that is the change that has been made in the endorsement letter. And in terms of the commercial IRBs, again, reinforcing; they are responsible, at the end of the day, for ensuring those informed consent documents contain the required content. That is an IRB responsibility.

And so, this is – again, there’s what we’re doing on our side in VA but at the end of the day, it’s the IRB that is responsible.

And so, again, we will be sending out an announcement tomorrow, Thursday, with registration links for a workshop. It will be on April 19th from 2:30 to 3:30 Eastern Time. And we’re going to be doing a detailed review, step by step, of each of these using a case. Because it’s much easier, as you know, looking at how to do it when you actually have an actual study than talking about it theoretically.

And so, that is what will be happening in two weeks. And again, depending upon how that goes, we may do another one.

So, again, we’re going to do everything we can here in ORD to make this a seamless process, address the issues. There’s other issues that we’re addressing with the commercial IRBs to resolve any and everything we do. Nothing is perfect; we all know that. But when we know we can address some questions upfront, we’re going to do so. And so, this is something that you’ll be seeing tomorrow with the registration information for this.

Also, just some additional points of information. ORD has now – is now providing an optional training course through CITI, the platform, for IBC members. And it is an optional course, for example, it is not required by ORD but it is something that we wanted to offer in response to requests that ORD has received. And Mr. John Balog, who is ORD’s National Biosafety and Biosecurity Research Officer, has been working and has developed a curriculum of twelve different CITI modules, which are covering different topics on, you know, recombinant synthetic nucleic acid molecules, common hazards, you know, hazard vindication strategies, file safety. There’s no charge at all. And the facilities can make this optional, obviously, training course available to your site by submitting a request by email. That request needs to come from the ACOS or AO, and send it to Dr. Alice Wong.

Now, all of the information I just said; you don’t have to go to this slide and wait for it. We already have a webpage up about this course and it’s under Optional Training Course for VA IBC Members. You can also find a link to it on ORD’s Biosafety and Biosecurity webpage. If you go to that page, you can also find it there. And if you have any questions about this course, please send those to ORD’s Biosafety mailbox and Mr. Balog can answer those questions for you. And so, we think this is going to be very, very beneficial.

Also, yeah, last week, we sent out a Notice of Registration. We are going to be launching a new app – application – starting next week called FindPro. And some of you have already had some experience with it as part of our testing groups. This is an application – you know, when I first came to the agency twenty years ago, the big question was, you know, “Where can I find everything at one spot? You know, where can I press one link?”

That’s the goal of FindPro. “Where can I go to one source, one application, and be able to search multiple documents, VA policies, and so, VA directives, VA handbooks?”

And so, FindPro is an application which is designed to do that. There is going to be the initial launch on April 13th at 3:00 Eastern. We will be repeating that launch on April 14th noon on Eastern. And just like with other things we’ve done, we’re going to be doing office hours after we do the initial launch to facilitate the – you know, to get feedback to see how people are using it. It’s a new application.

So, we’re really excited about using it and launching it to everybody. We think it’s really going to help with, again, trying to find documents in a timely manner. Again, the whole goal is to make life easier.

And that’s what we’re trying to do with all of this. We’re working on guidance and tools continually. We listen to your feedback. And particularly, when it comes to the commercial IRBs, we know there’s lots of issues. You know, we are high-volume. It is amazing the hundreds – not tens – hundreds of studies that VA does with our commercial IRBs. It has just skyrocketed. The numbers increase exponentially every year. And with that, there’s also introduction of new issues that we actively have to work to resolve.

So, that is why we are continually working with our commercial IRBs, as well as other IRBs. But why it’s such a focus.

So, as with all ORPP&E webinars, a recording of this session will be available about in a week. Our archive is always – with any of our past archives. The Regulatory box is the best way to ask questions related to content for policy, ORD policy issues. And again, if you have any questions about research biosafety, as well as the VA IBC member optional CITI training course, please email Mr. Balog at the Biosafety mailbox. But also, you can find him through \_\_\_\_\_ [00:59:35], as well.

And then, so, I have a list of references at the end of this webinar presentation. And so, with that, I'm going to turn this over, stop sharing on my end, Parker, and so that we can start doing questions and answers. Thank you very much. [Pause]

Alright. The question is; Sorry if this was covered in the first few minutes. But if a site decides to keep the CDC tecovirimat TPOXX EAP – Expanded Access Program – open, is there anything that will need to be done in the near future? Great question. The answer is great, no. You don’t have to do anything in the near future. It will proceed just as you’re doing. And we will continue here in ORD to update that webpage. Please go to it to – as we find out additional information that would help all sites who are participating. Thank you for your question.

Okay. In poll question 2 – and I'm going to bring up my – I actually have it online, as well, on my separate computer here. Okay, poll question 2 was about the training requirements. This is the consultant who, yeah, that he is doing statistical – you know, he’s going to provide advice on statistical methods to analyze the data and he’s not interacting with subjects nor will he have access to the data. Alright. And the question is; Would the person acting as a consultant need R&D approval for the work they do if done on VA time?”

And the answer is no. Because they’re not conducting research. They are acting as a consult. They are not doing anything that requires them to have R&D committee approval because they’re not conducting research whatsoever.

Next question? Thank you. The question? We have people listed as collaborators on a project who are not here at the VA. And so, we run into gray areas as far as if we need to add them in IRBNet and go through the process of getting training, appointments, etc. Sometimes it looks like they are doing more consultant work than investigators but they call them “collaborators.” I guess the activity versus label thing might be the answer for me.

Great question. Okay. I really love this because this gets into the issue of collaborative research. Okay.

So, we do so much research that involves non-VA, and a lot of it. I mean, we have close affiliations with our academic affiliates and it’s collaborative. And a lot of times, you will see in a protocol, “Well, they’re my collaborator.”

Now, we deal with this issue a lot in ORD where someone is listed as a collaborator at the university but they get listed on the VA study. But they’re not actually part of the VA study; they are collaborators. The site is going to be open at the university.

But because they’re being listed on the VA, the belief is that they have to go through training, appointments, etc. No. When you are a non-VA collaborator, that means exactly that. Usually, you’re an investigator. You’re a part of – you may be a statistician. And sometimes they are doing consulting work.

But those individuals, when they are not part of the VA study team conducting research, do not get – they are not involved in getting training and appointment in VA because they’re not VA employees conducting research.

And you know, Dr. Workman’s on the phone right now. He’s part of our panel today. And I believe I’d like to ask a question just for my – so, for in terms of VA Central IRB. Because on the VA Central IRB applications, if a study team stated they were working with a collaborator, and let’s say that collaborator is at the Department of Energy, then, those individuals would not be listed on the VA Central IRB’s application. Isn’t that correct, Don?

Dr. Workman: Yeah, I think it goes, Karen, to what you had said before. Rather than the label, the question is what they do. And if it’s somebody who’s, for instance, consulting on how to write your program, the data, or something again where it’s not engaging them in the research, then, both the individual is not going to need R&D approval.

Karen James: Thank you.

Parker: And Don, just so you know, we’re having a little trouble hearing you. It may help to move closer to the mic.

Dr. Workman: It was in my ears, sorry. It goes, as Karen said before, it goes to what they’re doing as opposed to the label. Over.

Karen James: Thank you. And that is – and the reason this is – I'm really glad this was brought up because a lot of times, there feels like there needs to be a need to put everybody in IRBNet. You know, and that causes confusion when they’re not part of the VA study team. Next question, please. Thank you.

If a consultant is a statistician and reviewing and analyzing de-identified data, what training do they need, if any? So, if they are a consultant and they are reviewing and analyzing de-identified VA data, they are involved in the conduct of research. They are a member of the study team.

So, the question becomes; is this person doing it at VA? Are they a VA employee? Because if this is a VA statistician, then, they are going to be a VA person conducting research. If they are at the university, then again, based upon this answer, they are indeed involved in the conduct of research and whatever the university requires.

But this is not – in terms of a consultant, this is someone who is doing a research activity. They are involved in the conduct of research because they are analyzing data. Next question?

Okay. If someone is assisting with data analysis but not conducting the research, do they have to be listed as trial personnel? That is when I'm going to ask the question. I can’t actually answer that question based upon that alone. I'm going to follow up and say, “Please define how you mean ‘assisting.’”

So, that alone, that’s a good example where you’ve got to have enough information to make the determination. So, that’s where I would need additional information, clarification, in order to answer that question. Next question?

If some [sound out] …

Parker: Sorry about that. It double-skipped. Let me make sure we’re on the – this should be the right one.

Karen James: Okay. Do contractors who participate in the research need to be listed on the VA project cover sheet in our protocol? Okay, we have contractors who are supporting research. But in terms of – we normally do not list contractors unless you’re talking about a contract organization. Like, for example, I may have in the protocol that Westat is going to be doing the surveys for this project. So, the answer is going to be; it depends on how you’re defining “contract.” Are you talking about contract organizations in terms of, you know, are we going to have – you know, all the blood is going to be analyzed by Quest Laboratories. Or are we talking about individuals?

So, the answer to that is going to depend upon what you mean by “contractors.” But normally, we do not list individual people in a project sheet in our protocol for purposes of this question. Next question?

Is a program evaluation and implementation project required of all interns? For example, when a survey will be conducted as interested in surveying outpatient mental health clinicians regarding potential group therapy interventions to implement in the women’s health clinic, required to get an official, not-research determination. This is a required program training element for the interns.

If the program requires the interns to obtain that requirement, that is the requirement of the program. I mean, that’s not an ORD policy question. So, for example, if this is coming through Office of Academic Affiliations, if this is coming through whatever is the – who is overseeing the interns, that is a question for them. That is not a policy issue for us that we could address. Next question?

Define how or when manuscript writing is or is not conducting research activity. That is not mentioned nor clarified in 1221-DI. No, it’s not, you’re exactly right. Because manuscript writing in itself is exactly that; it’s like what I'm going to do when I write a presentation. Is that or is that not a research activity? The issue is; what are you doing with it?

You know, if I'm involved in writing a manuscript describing how VA implemented COVID-19 human subject protections, that’s not conducting a research activity. I'm writing a narrative about what VA did.

But if I'm conducting a research activity and I'm taking data and I'm – you know, I conducted a research activity and then, I am writing that up, you know, that’s different. I mean, the issue, it’s not about the manuscript writing. The issue is what was associated with the activity.

So, the writing of something isn’t necessarily research. It’s the precursor to it. What are you doing with it? Are you analyzing data? You know, how did you obtain the information to do the activity?

So, if you want to follow up – I think there’s a specific question that’s probably associated with this so, you’re free to – please contact me through the Regulatory box, I’ll follow up with you. Thank you. Next question?

Will these new checklists be added into IRBNet and the CIRB Library of \_\_\_\_\_ [01:11:09] Researchers? Great question. You know, the original – the tables were always available, or developed in 2020, the first version of this for commercial IRBs. And these are given also to the commercial IRBs. And so, we will look at that.

In terms of the checklist, the checklist, again, is an internal QA tool. If people think that would be beneficial to have as part of the library, we can certainly look at doing that if that would be a better way to – an additional way. We will always have it on the website. But if that is an additional mechanism that would make it easier to access and use, we can certainly look at that.

So, I appreciate – I'm going to put that on my little star list right now. Appreciate that question for us to also – again, we’re always looking at ways to make things easier to be used. So, thank you. Next question?

Can an individual still be considered a consultant if they are going to receive PHI VA data information? Okay. And then; how does the lot versus contractor badge factor in?

Okay, I'm not going to talk about HR because that’s a separate issue that would take me the next ten minutes to talk about.

But let’s talk about this first one because that’s really staying on – that’s – because the second is about what I'm going to be asking what’s in the contract and a lot of other questions that are unrelated to, I think, the question.

Can an individual still be considered a consultant if they’re going to receive PHI VA data information? I'm going to go back to talking about the label consultant. Different groups use that word, “consultant,” differently. The issue that I really want to reinforce is when you’re looking at that word, “consultant,” if they’re to receive PHI to basically look at data and they’re going to be – you know, again, they’re receiving it. They’re receiving something for – you know, if you’re receiving and analyzing, using that data for research, that’s a research activity under the common rule.

So, you may label yourself a consultant but my question is; okay, who is covering them for the research? So, because they’re acting as a person who is conducting research.

In some organizations – again, I want to reinforce this – you will see where the word, “consultant,” is used, they can indeed conduct research. And that’s why that word is so dangerous in some ways because the issue is; okay, you have a consultant who’s going to receive and analyze and use VA PHI data as part of this activity. Okay, so, they’re conducting research.

Now, is this person VA? You know, yeah, as the VA person, then, the employee conducting research, it’s going to require the applicable research approvals. Next question?

VHA directive 1400.05 requires health professional training project to be approved by VA IRB, although these projects may be QI and basically, not IRB, not human subject research. Our local interpretation is that a tracking number would be sufficient to satisfy the – this is OAA, Office of Academic Requirements for this approval. Can you provide guidance interpretation on students in QI in HSR? If this is concerning VHA directive 1400.05, I would need to follow up with the Office of Academic Affairs because ORD cannot interpret that.

However, what I will do as part of a followup action, is contact OAA and send them this question because this is under their authority. Next question?

Do these new consent requirements apply to the NCICIRB approved studies? I ask because the NCICIRB does not look at the final consent. They kind of just approve the local site, trusting PIs to incorporate VA-approved text. That leaves it up to us locally to doublecheck it was done correctly.

With the NCI IRB, there is a template and the boilerplate template that is used and approved. So, those requirements are already present in the approved VA consent boilerplate for your specific site. ORD, ORO, NCI, since the beginning of the relationship between the NCI IRB and VHA, because of the way they work, we have a specific VA template and that language is incorporated in the boilerplate. So, and NCI is a \_\_\_\_\_ [01:16:20] agency.

So, what you’re seeing for what we’re talking about today has already been done and negotiated with the NCI IRB. Next question.

Do any of these tools or updates also apply to when the VA facility uses the academic affiliate for their IRB? I think, well, the answer is yes. I mean, the VA-specific requirements apply regardless of whether or not it’s a commercial IRB, a VA IRB, or as an academic affiliate IRB if they’re reviewing VA research.

Now, there’s some unique elements. For example, the commercial IRBs have told us, “Don’t submit the standalone HIPAA authorization. We don’t want to see it.” Now, you’ll see many IRBs that want that submitted. They may not do anything with it but they do want it submitted. So, that’s something that is unique to commercial IRBs.

But in terms of the requirements and when something does or does not apply or considerations, the content I think you’ll find in these revised tools and the checklist can actually be modified or basically used as is to any VA study that requires an informed consent document. Next question?

Parker: And this has two parts, the one on the next slide.

Karen James: Okay. Part One. A VA research protocol plans to use a VA to non-VA service contract to collect, process, or analyze VA data. So, basically, we’re talking about doing MRI scans over at the – let’s say VA MRI scans at the university. What is the preferred option that DUA concerns are addressed with this protocol?

What are the DUA concerns? If you’re operating a service contract and you’re doing a service contract, the service – a service using a – not to collect, process, or analyze VA data. Okay, this is talking about – okay, MRI scans. What is the preferred option – a non-VA service – okay, I'm going to need a lot more information in order to address this. This is a data – yeah, I would need a lot more because I don’t know what’s involved.

Because also, fee-for-service – because when you’re talking about service contract, I'm going to start asking about the contract itself. Because I mean, normally, if you’re doing a service contract, do not execute separate DUAs. But there’s additional – a lot of content here that’s not present. So, I would need followup on this to be able to answer this appropriately. Next question?

Regarding industry-sponsored studies and the common rule; is there a one-pager for the industry consent? If so, who writes it? Will that one-pager just be for the VA sites or would the commercial IRBs start using it as part of consents for all sites?

In terms of a one-pager, I’m not sure. But that is [interruption] …

Dr. Workman: It’s Don. My guess is that that’s referring to the key information.

Karen James: Okay. It depends. It’s like when the sponsor found out – we’ve had – since we’ve implemented, we’ve had three sponsors contact us. And in all three of these situations, once the sponsor found out that, you know, again, the common rule requirements apply, all of them say, “Oh, okay, great.” All three of those sponsors, they were the ones that initiated it. And the reason was exactly is what I think your email is stating; they want to be able to standardize it in case they add another VA site. In all three of those circumstances, at the time when they started, there was only one VA site.

However, even yesterday, I was contacted by a VA site where the sponsor had decided they wanted the VA site to go ahead and include the language and then, have it reviewed by sponsor. Then, sponsor would then have it available if they added another VA site. So, it depends upon the specific scenario. Next question? Okay?

Okay, good question. If we have studies that have already received commercial IRB approval for the ICF, should we expect that the commercial IRB would have already checked for these specific required VA elements?

That is indeed what the reliance agreement requires is that that is indeed – was expected and is expected. And so, you know, there are quality assurance mechanisms in each of our commercial IRBs and so, you are indeed correct that that should have already been checked for these VA-specific-required elements. The answer is yes. Next question?

Okay. Regarding what was said about if a separate HIPAA authorization, which would be reviewed by the local VA privacy officer; should study team led sponsor know about the use of that HIPAA authorization? Seems like they would want to know, wouldn’t they? Since it’s part of the study.

What you do is – and as most of you know who are working with a lot of commercial IRBs – many industry-sponsored clinical trials will include authorization language within the model consent form. Now, VA cannot use a combined authorization if the study involves an LAR by VA or if there’s optional banking.

So, you are already correct; it’s always about communication, you’re correct. So, if you’re going to have to take out that authorization language because it can’t be combined, you’ve got to tell the sponsor. And of course, if you’re using the combined authorization language, it has to be the VA language. So, again, you’re going to have to tell the sponsor.

I believe in communicating with the sponsor on everything when I'm a study team member to make sure they’re aware of what I'm doing. Because – and usually, I'm working with the CRO.

So, yes, study team should be communicating with sponsors. And as most of the study teams, what’s usually standard practice with sponsors is that normally, sponsors review the informed consent document if it’s combined with the HIPAA authorization prior to allowing the informed consent document to be released for submission. That is what is the practice on many sponsors. Again, it may vary among sponsors.

But sponsors or CROs will communicate whether or not when you get that document, the model consent form, whether or not they have to review any changes prior to submission. Again, because ORD receives a lot of questions and negotiates with a lot of sponsors sometimes on some of the language. Because they want to use language, particularly when it comes to, you know, “You or your insurance will be billed.” In VA, a subject’s insurance will never be billed for a research-related cost. Next question?

Is a privacy board to review the 10.0483 that is being used for a study review by the commercial IRB? No. No. A privacy board under HIPAA has one function under the HIPAA privacy rule. And Michelle Christiano is on my panel today. And so, Michelle, you know, feel free to jump in after I get all my spiel. So, because Michelle ran the Central Research Privacy Board.

And so, there’s only one authority that is running under HIPPA privacy rule for privacy board, and that is to be able to approve layers of authorizations for research if the criteria are met.

Michelle Christiano: That’s right, Karen.

Karen James: Okay. Thank you, Michelle. It’s up to the covered entity to ensure that the authorization language that is used allows for the appropriate uses by covered entity, as well as also, the disclosures.

And so, a privacy board actually has no role under the HIPAA privacy rule for doing it. And as was alluded within the previous question, the privacy officers – this is where those initial and final privacy reviews were involved – look at the 10.0493. And Michelle, in terms of what you do for the Central IRB when you use a 10.0493, if the study requires it, that is also what you do, as well, don’t you?

Michelle Christiano: Correct. But [interruption] at the local facility, it’s documented with their 10C50 and then, for the Central IRB, we document our review, as well.

Karen James: Thank you, Michelle. Last question, Parker. Are we allowed to use the combined ICF HIPAA authorization? And if we do, do we still have to submit the separate HIPAA locally?

Okay, and this is where I'm going to refer you to that new tool that we just released today. That’s part of this attachment; it’s also on the website. And again, this is cleared through VHA prior so, please understand that VA already does not interpret privacy.

You are allowed to combine the ICF and HIPAA authorization unless the study involves an LAR VA Portnet when VA’s connecting it. Or there’s optional banking of the identifiable banking of vial specimens and/or data. If there’s mandatory banking, it’s fine.

And so, that is the issue. And so, that is what is allowed to be done. Now, you shouldn’t be doing – you shouldn’t be, if you’re going to use a combined HIPAA authorization, also, use a 10.0493. It’s one of the other; it's not doing both. So, that’s the answer to your question.

And Parker, that is all – I think I know we were out of time. Again, and I want to express my appreciation to everyone today who is on the call. Again, we will be announcing that followup workshop in two weeks and again, I want to thank you for spending your afternoon with us and allowing us to work on these things that will make it easier to conduct research in the agency and, also, address your questions. So, thank you so much.

Parker: And I just want to jump in. There were a couple of questions that didn’t get answered regarding suggested followup topics or things that folks would like to know in more detail. Please do put those in the post-webinar survey. That is going to be most helpful for our panelists in thinking about future webinars and what information you all need following up.