Karen Jeans: Thank you, Parker. Hi everybody. As Parker said, I am Karen Jeans. I am the Director of Regulatory Affairs here at ORPP&E. Welcome to what is going to be either a monthly or bi-monthly series of updates in HRPP. This is a different type of format. It is one hour. We are combining multiple topics. There will be time for some questions and answers at the end. There will be follow-up also for those that we cannot answer. This is to try to better use your time and hopefully you will like it. Your feedback will be important regarding how we continue this series.

With that, I am going to jump right in. I am joined today by so many incredible panelists. You will hear about them at the very end. I am very grateful for their participation and for your participation. We will start off this morning. Okay. We are going to do a variety of things today. We are going to talk about a variety of a number of different topics involving the reason why we originally had this seminar. It is to discuss changes in the informed consent addendum for the NCI Central IRB. I am going to bring you up to date on the electronic portal for doing SharePoint for the proactive calling, the cold calling. I will talk about that. There is some new guidance that we issued on Monday concerning the infamous California state law applicability for separation of the written informed consent form and written HIPAA authorization. It described why that written guidance was issued. We are going to be talking about different types of questions and answers involving DocuSign and commercial IRBs. Then we are going to jump straight into a question-and-answer session.

We are going to start off with the first topic, which is recent change to the VA informed consent documentation for the NCI Central IRB. Just a very brief overview, the NCI Central IRB is one of our already approved IRBs. It oversees multi-site studies. It is specific to those sponsored by the National Cancer Institute. Currently, 46 VA facilities of our over 100 VA facilities have VA approved IRB reliance agreements with the NCI CIRB. Now 46 sounds like a lot, but they have over 2700 institutions that they have executed reliance agreements for. That comes into play when we talk about what we are going to next. It is we have a VA boilerplate informed consent form, and that is the template for all VA participating sites when they submit informed consents to the NCI Central IRB.

The issue with these boilerplates is that when policy changes, that boilerplate has to be changed as well. If there are policy changes at the national level. It is not the local level, but the national. When 1200.05 was published in 2019, there were two issues that the VA boilerplate did not have. We had very specific requirements regarding what needed to be in the informed consent. One is that you have to tell subjects they have a certificate of confidentiality if the study has one. By the way, all NCI studies have certificates of confidentiality by a default position because of 21st century \_\_\_\_\_ [00:05:09]. If you are going to put information about their participation in the medical record, the subjects have to be told, by the way you have a certificate of confidentiality, and we are going to put information about your participation in the study in the medical record.

Again, we are going back to 2019. It did not have that in that boilerplate. Unlike when you think about in the IRB and thinking about, oh that is an easy fix, it is not. Think about volume here. So, 2700 institutions use NCI Central IRB. At that time, we even had 32. It takes time whenever a boilerplate is changed. As a result of that, the NCI CIRB approved an informed consent addendum to address these two policy issues. On January 3, 2020, we issued ORD written guidance of the approval of this Department of Veterans Affairs informed consent addendum directing those VA facilities that utilize the NCI Central IRB, that for any new study – not an existing study even if you were added to a side of previous study, again it is new NCI studies that were approved after January 6, 2020. Any subject that was consented into that study had to sign the VA informed consent addendum in addition to the primary consent.

What you see here is a picture of this VA informed consent addendum. In 2020, we have been told already by the NCI CIRB that it would be at least six months before that informed consent addendum could be incorporated into the VA boilerplate. Then as we all know, the coronavirus hit. We expected delays, and they did indeed occur. Time has passed, and we began hearing from some sites. By the way, we already have it in our boilerplate. Some are going, no we do not. We have been following it with the NCI Central IRB. They have been excellent. I have to say that right now. This is again an update on the current status of the revision to the NCI CIRB VA boilerplate language, so that you can drop those of you who use the NCI CIRB the use of the VA ICF informed consent addendum.

Again, it is not ORD that determines the approval of this. This is the NCI CIRB. The boilerplate language was revised to include those two sections and also, some additional sections that the NCI CIRB identified. Number one, in addition to the confidentiality certificate issue, also who also can see the records? Adding the ORO, Office of Research Oversight and the VA Office of the Inspector General. Also, it added about the signature section. They have had some problems where some VA sites have been removing required signatures on the template. They wanted to take that opportunity to say you cannot touch the ones that are required, but you can add others. Make that clear.

Again, we issued guidance on this because, what do you do now? We have told you can do it. What are your next steps? Again, it is coming straight from the NCI CIRB and the help desk, which is amazing. They have done incredible things. They have VA specialists specifically assigned to the Department of Veterans Affairs. The number one thing is you will revise your annual signatory institution worksheet to include the language in the revised NCI template. Here is the deal. Until you do revise your template so that your boilerplate reflects what is in the new boilerplate, you have to continue to use the ICF addendum to make sure that you address those two policy requirements concerning the COC. Subjects are told they have a certificate of confidentiality and that their information is going to be in the medical record.

Again, once your boilerplate language and your revision has been approved, then you update as applicable your local SOPs. You stop using your NCI CIRB VA informed consent addendum. Again, I want to reinforce what the NCI CIRB help desk has told me over and over again. Please contact them. In fact, one of the things that I want to tell you right now is we are going to have a lot of questions about this. They have been so responsive – and you are going to see these in just a second – of answering the questions that we have sent them and that we can disseminate these out.

This starts. When the VA addendum was initiated in January of 2020, it was to be used for new studies approved by the NCI CIRB after the date of January 6, 2020. Do the older studies require the addendum or the boilerplate language/ Again, the answer is no. You do not have to. You are not required to use the new boilerplate language for any studies that were approved on or prior to that January 6, 2020, date. However, it does not mean that if you want to you cannot. You can choose to do so. I see some typos there that we will correct in the one that is uploaded. That is something that both the NCI CIRB and the ORD are conveying as part of this question.

Then we get to this question. This again is something that the NCI CIRB wanted to add to the boilerplate, which was not in it prior. In the NCI CIRB boilerplate that has been issued, we updated to 4/21/2022. It is one of your attachments. It is also on a SharePoint slide that you will also have a link for as part of the references to this slide set. It talks about these optional signatures. Do VA facilities add all the optional signatures like witness, print name, legally authorized representative to the VA facility’s boilerplate if it is not in that NCI template consent form? It is the one where it states these are the signatures you cannot remove. These are your optional signatures. The answer is yes. We ask the question. Directly from the NCI CIRB, their response is yes. Signature lines can be added to your VA facility’s boilerplate, and it is used as needed in the informed consent.

This probably is one of the most important questions and why we are also having this discussion. It is because of the result of this new guidance that we issue saying hooray. The boilerplate has been revised. Some sites have come to us and said okay, what do we do? Yes, we knew that ORD and the NCI CIRB approved this VA informed consent addendum in 2020 for us to use. What if we did not do it?

This is again a policy requirement from the Office of Research and Development. It was an informed consent requirement. It is an informed consent requirement for all new NCI studies for VA subjects consented after January 6, 2020. This would indeed require reporting to the NCI CIRB because it does fall into the category of apparent serious or continuing non-compliance. It would be continuing non-compliance involving VA non-exempt human subjects research. If you have other requirements for reporting as per your institution, you will do that as well. Yes, the answer is yes. It does go to the NCI CIRB for reporting.

This is another great question. Again, as part of okay you have issued the guidance. Okay, now you have answered what happens if we did not do it. What about the deadline? What is this mission deadline to have the site’s updated boilerplate language approved? This is the new VA boilerplate language. Update them in all the NCI CIRB informed consent documents following approval of the VA facility’s revised boilerplate language. Again, from the NCI CIRB, their answer was your boilerplate language for your facility should be updated now, at the next protocol amendment, or per institutional policy if more stringent. The NCI CIRB has told us if there are additional questions either please contact them directly or also I will indeed ask you. You can put these in the question-and-answer box. We will indeed send these questions to the NCI CIRB, send these all out after the meeting after they have had a chance to respond. There are a lot of technical questions here that are associated with this. This is again the NCI CIRB’s response to this question.

Again, the whole focus of this update is again to convey information. It is not really a training session. Again, it is to keep you updated on recent changes that are going on in human research protection programs in the VA. We also want to take this opportunity to update you on the process for adding the NCI CIRB as an IRB record. Again, we have 46. Not all VA facilities of the over 100 that we conduct research can do cancer research. They may not have cancer programs. Indeed, it is not as hard as you think. If you are a program which you believe you can utilize the NCI CIRB to do that, it is not the horror that people say it is. You hear these stories. They are not accurate.

One of the reasons we also wanted to have this is again to reinforce the steps. If your VA facility currently does not rely upon the NCI CIRB and has an interest in doing so, your first response is number one you are going to email Dr. Workman’s group. It is ORD at the IRBRelianceandSIRBExceptions@VA.gov. That is the mailbox that will hit Dr. Workman. Then you are also going to contact the Office of Research Oversight. You are going to email Priscilla Craig and Elizabeth Clark.

What I want to reinforce is that your VA facility will be guided each step of the way. It is not that we just hand you some instructions and say go for it. There are certain things that happen. It is not just signing a piece of paper. Your facility will be required to develop local standard operating procedures. There is already a template on the ORD NCI SharePoint site. Again, we will work with you to customize those for your VA facilities.

In terms of the submission process itself and in terms of what you would go to the NCI CIRB about, there will be an institution enrollment form. If your VA facility does not have its own IRB or its local IRB, there is an additional oversight questionnaire that you will be asked to do. It starts with that process. Then it is followed by an authorization agreement that will go to the NCI CIRB.

Before you actually begin doing this, your SOPs again will be looked at by the Office of Research Oversight. We also want to take this opportunity to clarify something, which is a really good question. Let us say your VA facility decides to join the NCI CIRB. You develop SOPs. You get your authorization agreement done after the institutional enrollment form. SOPs are fluid. They change all the time. Does that mean the Office of Research Oversight has to see them every time? The answer is no. We wanted to take that opportunity to clarify that right now. In addition to the support that you get in starting from the Office of Research Oversight and the Office of Research and Development, the NCI CIRB help desk again has specialists devoted solely to the VA to help do this and help you through it so you are not alone. Again, we wanted to reinforce that as part of this Friday afternoon update. Also reinforce that we do have this SharePoint site which is solely dedicated to assisting sites and conveying information about use of the NCI CIRB.

With that said, now we are going to move to the next topic. The next topic is about proactive calling or the cold calling policies. A new portal that the ORD has developed and launched in order to facilitate VA studies that wish to seek permission to cold call subjects for recruitment. What does that mean? We have policy. This policy has existed a long time because of an event that happened related to a data breach. After the data breach, people were calling VA patients and saying they were from the VA and wanting confidential information. As a result of that event in 2008, we are in 2022, ORD has had policy that requires. By the way, if you want to try to make a call to a VA patient, a veteran, or anyone in the name of VA research and they have not previously told you in writing that by the way you can contact me by telephone. If you have nothing in writing, you have to email them by letter or in person prior to doing that phone call.

That is what we do. The only time it does not apply is when a veteran calls in response to an advertisement. There were issues with this. Particularly, we saw this as a result of Covid. We needed some flexibility, and we needed a process to recognize everything is not black and white. One solution does not fit all. Therefore, we developed in connection with the acting Undersecretary of Health a mechanism in which policy was basically said, okay we will indeed not require this cold calling prohibition to be in place if ORD has a mechanism in place to which it will define criterion uses for those studies. It is not all studies in which cold calling is indeed appropriate.

We had a webinar back on August 24, 2021. It was called Recruitment by Phone. It was always about proactive calling and this whole concept in which ORD officially announced the criteria that it would use for studies that were seeking an application, seeking to do cold calling as a recruitment for subjects in their VA studies. In that webinar, we stated that we would have a SharePoint site up within two weeks. That did not happen, but we have now gotten this portal up. Again, these applications are submitted prior to IRB approval. The requests are processed within five to ten business days.

As one of your many handouts you receive in the webinar today, you have a list of the criteria that are used. We have opened this SharePoint site. The location is on the slide that you see in front of you. It will be posted shortly on ORD’s policy and web page at the Human Research webpage. That should be up no later than Monday morning. Right now, the link is active. I can honestly tell you that because I already have three application in there. We have made this process much simpler than the paper-driven process.

What I am showing you is a screenshot right now if what the portal looks like. It lists the criteria. More importantly, it will tell you okay if you want to do a request, you click on the new button to open up an application. What we have done with the application is make it very user-friendly. You can take this. It has dropdown boxes. It will have three components. There is background information, recruitment information, and any attachments. It will tell you what to include, if anything. Most applications will not require any attachments whatsoever, but it will take you through every step of it and give you options so that you just do not have to guess what the question is. We believe this is going to be much easier and much better suited to be able to make this successful.

What you will see on the next slide is a list of the criteria. Again, we are not going to go through every one of these. The bottom line is that in doing proactive calling, what ORD values number one is it has to be a non-exempt study. It cannot be an exempt study whatsoever. The biggest issue that I want to reinforce is that you have to justify it. Why is it that cold calling is needed rather than contacting the subject in person, by email, or by letter prior to a cold call? That is the most important aspect of this application that you will see. Again, the SharePoint makes it where you have to address every question, and there are nine different criteria. That is what we have done. Again, the SharePoint site is live. We will be looking forward to getting your feedback and what you think about it. We will move on now to the next update.

This is an interesting topic. This is about related to applicability of state law to a federal agency. This is about, as you will see on the slide, California state law applicability for separation of the written IRB approved informed consent document and written HIPAA authorization for VA research. This last Monday when I sent an update out, it went across again all the VA research community. The Office of Research and Development and the VA Office of the General Counsel Specialty Team Advising Research issued a guidance titled *Frequently Asked Question.* It is exactly what I just said, California state law applicability. The question is the key one. Must VA separate the written IRB approved consent and written HIPAA authorization for research and language into separate documents requiring two separate signatures, the latter of which the authorization is required to be in at least 14 size font for purposes of VA research conducted at VA sites in California.

The answer is no. For this purpose, the VA is not required. You have flexibility. This is all part of the California Confidentiality of Medical Information Act, CMIA. That is why that was very important guidance that we needed to issue because there is always an origin of why these guidance documents are issued. We have to go back to the past. Again, remember federal laws apply at VA facilities or federal agency. When it comes to whether or not VA will adhere, apply a state law at the federal agency, we have to look to whether or not there is a basis to apply the state law. When I say we, I mean the Office of General Counsel. ORD does not determine whether or not a state law applies. We are policy. We are not lawyers. That is why this guidance came from ORD on behalf of the common rule, but from the Office of General Counsel regarding the applicability.

The reason this one comes into play is because of the common rule language. It specifically states this policy does not affect any state or local laws or regulations, including tribal law passed by the official governing body of an American Indian or Alaska Native trial that may otherwise be applicable and that provide additional protections for human subjects. That is the key part – that last part. Does that state in this situation law provide additional protections for human subjects?

In the past, the agency has interpreted this law and deferred to it. By deferring means that we recognize it. That indeed we would indeed separate it. Now the Office of General Counsel has re-evaluated this policy. The May 9, 2022 guidance which states there is flexibility that VA does not have to adhere to the CMIA is now in effect. That is how the origin of this guidance came into play. In terms of what you have to do, you do not have to do anything. No action is required for ongoing VA research. Again, it goes into flexibility. For those new studies, you have flexibility in whether or not you want to separate or not.

Moving onto the next topic, DocuSign. What we are going to talk about here is some updates in DocuSign and some dispelling of some urban myths. DocuSign has been very successfully executed across the VA. It is used for a number of studies. Originally, there were restraints on it. This question has come up over and over again. Can my study apply for use of VA DocuSign if the total number of subjects to be entered into the study is less than 100? The answer is yes. There is no longer a minimum requirement. In the beginning, we had a very limited number. We being the Office of Research and Development, that could use for studies. They are research studies wanting to use it. Now we do not have that restriction, but it takes manpower to use DocuSign and set it up.

Priority is given to those studies that require more than 100 envelopes, but we have more than several numerous studies that have less than 100 studies than those that use DocuSign. Again, it is clarifying that point. If you do only, let us say you ask for 100 and you actually need 150. You just modify your original request. It does not mean you start a whole new application. You do not want to ask for more than what you need. That is another critical part when you are asking for use of DocuSign.

These are all true or false questions. These are four different statements. One is that you have to have a special program in order for the person that you are sending it to or the prospective subject. Again, they have not been consented into the study. They have not been consented into the study. They have not signed a written authorization yet. They have to have special application that you as a VA investigator or VA study team does not matter about VA. You can use the university’s DocuSign. It is DocuSign. You cannot use a DocuSign application portal until you have IRB approval. The use of VA DocuSign only is for VA funded studies.

The answer to all of these is no. False. Every one of these is false. DocuSign does not require any special program like \_\_\_\_\_ [00:30:11] or RMS where you have to have Microsoft Outlook. You can use this. As long as your recipient can have email, they can use DocuSign. You cannot use the university as a VA, the university instance of DocuSign. That has not been cleared or approved, and that is not appropriate. That is not acceptable for a VA research study.

You also have to get IRB approval before you implement use of DocuSign. It does not mean that you cannot apply and get approved by the way prior to IRB application and IRB approval. In terms of the use of VA DocuSign, it does not matter if you are funded by industry, or you are funded by the VA. Funding does not come into the determination.

We have also gotten a lot of questions regarding DocuSign because people want to know why you have to get a waiver of HIPAA authorization. Why is that part of the IRB application? Here is the reason why. The contract for DocuSign is held by LINT, and it is managed by the VI Identity Access Management Office, IAM. While there is a contract indeed between a W DocuSign and OINT VHA, we as a healthcare agency must have legal authority to be able to provide that PHI, protected health information to both OINT and its contractor, Adobe DocuSign. While we have a contract, we also need to have a waiver of HIPAA authorization.

Again, the subjects are not going to sign it until they get the written HIPAA authorization. That is why we have to have approval of a waiver of HIPAA authorization issued by an IRB or a privacy board before you can actually implement DocuSign. Indeed, that waiver of HIPAA authorization for research must include VA OINT and its contractor Adobe DocuSign as entities to which the research team will disclose. We are hoping to do a targeted DocuSign presentation just for the VHA privacy officers to discuss the different aspects or the privacy aspects associated with DocuSign.

Then I want to switch lastly before we open it up for questions and answers to commercial IRBs. There are a lot of different questions and issues going on with VA use of commercial, and they are also called independent IRBs. We have been successful with our use, but there are issues. That is one of the reasons we are talking about this today. We are in 2022. It has been two years since ORD policy and 1200.05 was revised to permit use of commercial IRBs that have been specially designated ORD-approved for multi-site research. Again, there are overarching agreements between the Office of Research and Development in each of the current three ORD approved commercial IRBs, Advarra, WCG, and Sterling.

Then we are common rule agency. Every VA facility that wishes to use a commercial IRB must enter into a reliance agreement. There had been numerous issues associated with use of the commercial IRBs. We have been working through all of them. There are also common themes and common questions. What you are seeing next are a mix of questions that are coming from the different various commercial IRBs and also from all of you. By far, this is like every single one. There are continuing issues concerning the informed consent language in terms of the process of how does it get in. Who does what? It has been confusing to the sites. It has been confusing to the commercial IRBs. It is like there is a language mix going on. There is a table as one of your attachments which the commercial IRBs have been provided. Again, it is a table of VA-specific informed consent and HIPAA authorization requirements.

The problem that is happening is that a template. VA has come on as an additional site. The parent protocol has been issued. The model informed consent form has been approved by the respective commercial IRBs. When that template is sent to your site because you are now a participating site, it will not have the VA-specific language in there. It will not have the HIPAA authorization language if the two can be combined. It is your responsibility – your being the VA site study team to put that language in before it goes back. We still to this day are having sagas going back said she said. That is what is supposed to happen.

What happens is if each of these people – each of the IRBs Sterling, WCG, and Adverra, they have a quality assurance department. After your site, as that language they have a quality assurance person who will check it. They will ask you questions if you do not put it in. You may say, if they have a quality assurance department, why do we have to do it? This is the way it works. This is the agreement that was made. This is what they also wish to happen as well. That is the way it has to happen.

Here is the issue. If you put it in, and then when it is approved by the respective commercial IRB it is not there, you go back and you tell them. Hey, by the way, this language is not there. We also want to be informed as well. Everybody makes mistakes, by the way. We all do. Again, our volume is low compared to their total EN in terms of their total population. When there are issues involving this process, we work with it. We talk to them. We correct it. It does not get to go unnoticed. This process, you put the language in. They check it. If it does not come back with the language in, please let us know because we need to correct this.

There are still continuing issues with the endorsement letter. The endorsement letter was put in because we had in the beginning, well actually the whole first year and even to this day, we still have sites that are submitting their applications to one or all three of the respective commercial IRBs. They are not a study site. They are a study site, but the information security and privacy reviews have not been done. They are the first ones or the initial ones. This endorsement letter was put into place to prevent rework by the commercial IRBs, but also to do a quality check to make sure that they are not approving studies that they are not authorized for.

We really want you to copy the commercial IRB liaison on all of these. Again, they need to know what is going on. I told someone earlier this week, when you as a study coordinator or principal investigator are accepted to say I am going to use for example Adverra, your first call I would strongly suggest is to contact your VA facility commercial IRB liaison. Say hey, I am doing this. Is there anything I need to know? That is the first call.

This is an evolving issue of confusion because it is not an all. It is not a none. It is a depend situation. My study, for example, has a commercial IRB review. Does that mean that there is going to be a centralized privacy officer and information security review, or does it mean that my local one has to do it? First of all, there is clarification. Even Adverra had contacted me earlier this week because they had gotten a question asking, why did not their ISSO and PO do the reviews? They are going, we do not do it. That is not part of our business. We are an IRB.

The commercial IRBs do not do these functions, but you have seen many of you throughout these two years that some studies have a central review and some do not. The central privacy review as done by IRB’s privacy officer who works for me who is Miss Michelle Christiano. The ISSO review is done by the research and operational technology cyber security division, formerly known as IRD the research security division.

There are several reasons why some studies will and will not have it. If the study goes through the partnered research program, which is run by Miss Chrissa Karoff, that is where these industry sponsored studies come through that office to where it is coordinated there to streamline the process. We see whether or not, we being the Office of Research and Development and ROTCD, whether or not we can support doing those reviews for those programs. If a central ISSO and PO review is going to be done, you hear where I am going, it is going to be done. Your site is going to be notified. Your investigator is going to be notified. Your research office is going to be notified so that we do not have central reviews going on and local reviews being done.

Then there are others. There are also studies that are not. They are not sponsored by industry. Again, they are going through the commercial IRBs. The partnered research program, those all are industry sponsored clinical trials. You may have these studies going through the National Institute of Health, the NIH. Again, the VA is conducting them, and they have chosen a commercial IRB. Again, not all but some of these will have a centralized PO, privacy officer and information security officer review. Again, it is the same thing. Your research office, your investigators are going to be told as soon as the decision is made that a central PO and ISSO is going to be done.

Many people ask, why can they not all be done for the commercial IRB studies or whenever commercial IRB is used? Sometimes only one VA site is in a study. It is also an issue of bandwidth. Again, as we are trying to figure out better ways to support VA sites, yes. When there is more than one site it makes sense to have a central review. We are looking at bandwidth. That is something we are working on. That is the process that you will know so that there is not duplicate review.

Another very often asked very good question is concerning the annual reports that are to be sent by the commercial IRBs to ORD. They are part of the master agreement. Again, as part of your – your being the VA facility annual review, you have that information about the commercial IRB because the evaluation of the commercial IRB is based upon the relationship and the MOU. Are they meeting the terms of the MOU? It is not about the review of the minutes.

How do you get that? You contact us. You email that box. Dr. Workman takes those reports. We do not post those publicly. That is not something that we really need to do on the public-facing website. These are for the VA sites, but those events are then made available to you. Then when does my VA facility need to contact ORD? When it comes to these issues involving commercial IRDs. Anytime. Right now literally before this call, a major issue it could be or maybe a minor issue. We do not know. It was brought to our attention. We do not know how to fix it unless you tell us. Dr. Workman and I are going to be reaching out to that applicable IRB that we were contacted about to follow up on that. We asked them. Would we be contacted so that we can indeed convey the information that needs to be conveyed. If we need to issue something out formally we can do that to all sites. That way we do know what is going on. What is going on at that commercial IRB might affect the other commercial IRBs. We also want you, when you email us to say you are a VA investigator or you are a VA study coordinator, please include your VA facility’s commercial IRB liaison on that. Your liaison needs to know everything that is going on when you are having issues. That is why we really want to be able to include that person on everything so they will know.

Again, we wanted to allow 15 minutes for these questions and answers. This is a different type of format of a webinar. Again, it is not going through something step-by-step, but trying in a very concise and tight way to go through a variety of topics to be able to give you a burst of these are things that are going on. To prompt your questions, we are making changes to processes and guidance documents. Again, what we are talking about reflects the changes and clarifications. This is a different method that we are doing in this one-hour burst. We will see if this is something that you would like. If you like it we will continue this, again on a monthly or bi-monthly basis.

As with any of our webinars, these are recorded. They are posted within, as Parker said, within I think two to five days. Parker can correct me. This is my contact information. I do ask that you email the regulatory box rather than me directly. It is only because it is easier to categorize questions and triage those. With that said, I have a number of different references. Again, all these documents if they are not available, we are in the process of updating the website. If they are not on by this afternoon, they will be up and running by Monday.

I am joined here again by a number of esteemed people, including representatives from the Office of Research Oversight and my incredible experts on the NCI CIRB, Sara Shiller, Stephanie Ferguson, Michelle Christiano, and Central IRB Jessica Nole. With that, Parker we are ready whenever you are.

Okay, so this is the first question. After our site has updated its NCI CIRB boilerplate language, do we still need to use the consent addendum when new subjects are enrolled in subjects that today require the addendum? The answer is no. Once you update your NCI CIRB boilerplate language and that language is ready for implementation for use, you stop using the addendum. You do not need both.

Next question? Did I hear Karen Jeans say that recruitment contact can be made by email? I thought email could not be used for recruitment. You cannot put in PHI. If you think about what you are sending, if you send DocuSign and you send that envelope through DocuSign and they return that, they return that by email. There is a draft guidance document on ORD’s website. We have never finalized that, but it is in effect. It does represent. It can be used because it is current in terms of its practices. It is talking about what you can put in email when you notify someone and say hey, do I want to be in a study? The problem is you cannot put something in email saying, can I recruit you to be in a cancer study? that is sensitive. You cannot do that without encryption. That is when you talk about that situation. If you defer to that guidance, you will see examples of what is and is not appropriate if you are trying to use email for recruitment. In terms of the email, it is talking about the statements of when you have something come back from DocuSign. They send it back by email. Next question?

In California, if we are working with an academic affiliate and the informed consent form is used at both institutions, are we using the academic affiliate as the IRB of record? Then the state law applies, and we need to use separate HIPAA and informed consent forms. As OGC has stated, again that guidance clearly states you have flexibility. You as a VA facility are not required to separate the informed consent document and HIPAA authorization into two separate documents. This is as long as again there are other issues from the options points. We are not talking about the vial banking of PHI. When you have identifiable vial specimens and identifiable data as optional components for banking, that is a separate issue. In terms of your classic consent form you have flexibility. Again, we do not have to follow that CMIA. You have flexibility. It is your choice. You have flexibility as a VA and as a federal agency for this. Next question?

Okay, NCI CIRB question number four. It appears our revised boilerplate language has been submitted and is still pending approval. We need clarification on when we need to update each consent. The answer provided for number four, which is from the NCI CIRB, is boilerplate language should be updated now at the next protocol amendment. Should each consent be updated as soon as we have approval of the new signatory institution worksheet, or at the time of the next protocol amendment? I am going to be very honest here. This is a question I do not know the answer to. Unless I hear something else different from my panelists, this is a question that we are going to send to the NCI CIRB right after this as part of the questions we will send back. Then we will publish this as soon as we get these back. Thank you for this question. Next question.

If flexible in the interpretation of the California issues, we can decide local policy and keep them separate documents. You are correct in terms of this specific state law issue CMIA. You have flexibility. You are correct. Next question.

DocuSign number in a year or in a calendar year or fiscal year? We go by fiscal year. Thank you. Thank you for asking that question. By the way, every year the contract is for every 12 months. You may be asked to update. We will let you know when that contract period ends if you need to do an update to your application. We will always let you know, but it is fiscal year.

Okay. Who sets our policies for use of DocuSign, Adobe sign, et cetera? It is contract. I mean, the contract in terms of the agencies used is by the contract. In terms of our policies, that can be interpreted different ways. The IRB must approve any type of recruitment method. If you are using DocuSign, that comes out of regulation in terms of an IRB approval criteria. In terms if you have local policy that you wish to set regarding DocuSign, that is fine. I mean, you can do that. In terms of the Office of Research and Development, we are issuing guidance. We are updating the standard operating policy and procedure on how to use it in terms of implementation. I hope that answers your question. Next question.

Please go over the DocuSign and HIPAA interaction again. Provide written guidance on this topic or make it a top point to cover in a future presentation. We will do that. Again, as an update yes. Again, we are going over this fairly fast in terms of this is the rationale. We can indeed spend more time on this in a future presentation. The written slide does indeed convey what is required. We can expand on that in a separate frequently asked question. We can issue that. Again, we will put that down as a response to get this done as part of this webinar. Thank you for that comment. Next question.

If the HIPAA is imbedded in the ICF combined ICF with HIPAA authorization, do commercial IRBs approve the document? The commercial IRBs indeed approve the combined document. Again, remember under HIPAA. It is the responsibility of the covered entity to ensure the authorization language is correct. That is why indeed in that table they are provided that table of information. They do not approve that authorization per se. That is still the responsibility of the covered entity of VHA. Next question.

For pre-phone calling, a prospective subject as part of recruitment, is this applicable to subjects with highly sensitive conditions such as HIV, drug users, mental health, alcoholics, et cetera? It can be. The answer is yes. When you look at the criteria, any of these are potentially life-threatening situations. Absolutely. The answer is yes. Next question.

I need another question for my panelists here. Does the R&D committee need the commercial IRBs evaluation to assess as part of the annual review of the subcommittee, and evaluate compared to the memorandum of understanding? Yes. That is exactly why that annual report needs to be available to you. You are indeed correct. Next question.

Off topic, do you have any information on the revision of 1212 repositories? It is a major haul, yes. There is going to be a major. There is. There is the process of a major rewrite of 1212. Yes, I mean that is again we can discuss that in the next update. Thank you for that. I will note that for the next update. Next question .

Can RCOs be included in the PO review of the updates to DocuSign? I will discuss this will VHA privacy. What I would like to do is a separate session. A lot of times again we gear it toward the audience. We were having a detailed session. I can discuss. Dr. Bore is here on the call, whether or not she will entertain that I can do a targeted session just for the RCOs.

Dr. Bore: That would be wonderful.

Karen Jeans: Thank you Dr. Bore, okay. That is the answer to that question. Next question. When will the draft guidance be finalized? That is a good question. If we are talking about the email guides that I was talking about earlier, it has been in a pending pattern for quite some time. Again, the information in it is indeed current. Every time we get ready to finalize, there is something new that needs to be added. I cannot answer that question. I honestly cannot answer when it will be. I hope it. I said that six months ago. Until that, it is current in terms of what you can and cannot do. Next question.

 This may be a slight tangent. Our VA users are university affiliates IRB for review. This affiliate will not serve as a single IRB for studies subject to single IRB they also will not give up responsibility for local oversight. They continue to charge us review fees with the rationale that they are still responsible for local oversight of the study. Are they truly responsible of this, or should these responsibilities be relinquished to the single IRB? There can only be one regulatory IRB for a study. You may have another IRB involved, but they do not make the regulatory decisions. I would like you follow up with me afterwards on that if you would. Next question.

 Is there an annual report available from the NCI CIRB? I do not know the answer to that, by the way. Priscilla, do you know the answer to that one?

Priscilla: I think they do an annual self-assessment for those that use the IRB, but I will verify that to be sure. We can put that out with the rest of the questions. I think they do.

Karen Jeans: Thank you. Thank you for asking that question. Next question. Can DocuSign be used for the HIPAA authorization only if a waiver of documentation is the consent process? You can use. If the study has a waiver of documentation of informed consent and you need a HIPAA of authorization, yes you could. Okay.

This is great timing. Thank you Brandon for posting those questions. We are finishing right on time. Again, this is a different type of format. We hope that you have enjoyed this type of format as we see how this goals and we will plan the next one. We will indeed be following up on every single question. Every question that you have, we will follow up within the next two weeks and send these out to you. Some of these require feedback from the NCI CIRB, so I really thank you for that. I want to thank my panelists. Thank you Parker and Brandon. I hope you all have a wonderful weekend.

Parker: All right. Thank you Karen. Thank you all for attending. If you could take a moment to fill out the survey after the fact, that would be much appreciated. Thank you. Everyone have a great weekend.