Kate Yeskigian: Hello, and welcome to today’s ORPP&E webinar titled -Electronic Documentation of Written Informed Consent. I’m Kate and I’ll be your administrator today.

I’d like to go over a few reminders and housekeeping items. First, today’s session is being presented in lecture-only mode; therefore, the audience is muted. This presentation is being recorded.

Slides were emailed in advance to everyone that registered; for those that did not receive the slides, they can be accessed using the SharePoint link in the Q&A box. I’m going to pause here for a moment to allow everyone to find the Q&A box. You can find it on the lower right-hand side of your screen by clicking on the button with three dots; then click on the blue Q&A text, there you will find the SharePoint link with today’s slides.

Questions will be addressed at the end of the webinar during the question-and-answer portion. When submitting questions, please send to all panelists. Please do not use the chat feature to submit questions.

The Webex events platform does not automatically enable attendees to see comments submitted by others; however, we will share questions with the entire audience by responding to each submission with the phrase, “Thank you for your question.” You can make the Q&A box larger by undocking the box and then clicking on the corner of it, and dragging it to resize. To return to the normal view, simply double-click on the middle of your Webex event screen. Once you exit the webinar, a quick survey will pop up in the browser window. We would appreciate your feedback regarding today’s presentation to improve future webinars. If you have difficulties running the webinar, some people have had more success using Google Chrome instead of Internet Explorer.

If you experience connectivity issues our live webinar can be accessed by using the call-in number that you see in the upper right-hand corner. And with that, I will pass it along to Dr. Paska Permana, Human Research Protection Program Officer at Phoenix VA.

Paska Permana: Thank you, Kate. And good afternoon, everyone. My name is Paska Permana. I’ve been asked to organize this webinar by Dr. Molly Klote, the Director of the Office of Research Protections, Policy, and Education. I would like to thank her and Dr. Karen Jeans for their input into the webinar. And now, I will introduce the other presenters: Erica Aulik, the ORPP&E Instructional Designer; Nigel Clark, the Functional Analyst in the Identity & Access Management Team; Janet Fawcett, Research Methodologist at Phoenix VA; and April Primous, Information Technology Specialist and Project Manager of DocuSign.

So, let’s get started with the objectives of this webinar. This webinar is intended to provide a general overview of research-informed consent and documentation for IRB-approved informed consent documents and written HIPAA authorizations for research. We will describe different types of electronic documentation of written informed consent, and also the consenting processes using iMedConsent and DocuSign.

As a general overview of research informed consent, there are different types of actions regarding consent. Documentation of informed consent approved by the IRB is required for all greater than minimal risk studies in VA. Documentation of informed consent may be waived by the IRB, provided that regulatory criteria in the common rule or FDA are met; even if documentation of informed consent is waived, information must still be provided to subjects or subjects' legally authorized representatives, or LAR, in the informed consent process, but the IRB does not require subject or subjects' LAR to sign the form. We will go over this action further in Slide 9.

IRB may also allow alteration of informed consent for minimal risk studies only, where one or more of the basic elements of consent are not required by the IRB. A signed document is required unless documentation is also waived.  Please note that there are waivers of consent, but they are outside the scope of this webinar.

So, who can sign the written IRB-approved informed consent document? Well, the answer is the research subject or the subject's legally authorized representative. VHA Directive 1200.05 defines a legally authorized representative or LAR as an individual, or judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.

And who can sign the written HIPAA authorization for research? It’s either the research subject or the subject’s personal representative. A personal representative is defined in VHA Directive 1605.01 as a person who, under applicable law, has the authority to act on behalf of the individual to include privacy-related matters. Some examples of research subjects' personal representatives include court-appointed legal guardians, healthcare power of attorney, and next of kin if authorized by state law. Please note that there may be local exceptions for health care power of attorney as defined by the state law. If you plan to use personal representative signature on the HIPAA authorization for your study, please consult the privacy officer and regional counsel.

So, what about the documentation of informed consent? Well, informed consent shall be documented unless documentation is waived by the IRB, and this is done through the use of a written consent form approved by the IRB, and signed and dated by the subject or the subject’s legally authorized representative. Please note that there is no requirement for the person obtaining consent to sign the informed consent form under ORD policy. Local rules may vary.

A physical or electronic copy of the informed consent must be given or made available to the person signing the form. Also, note that ORD policy does not say that the person must receive a copy of the signed informed consent form.

Documentation of consent may be obtained electronically so long as the informed consent process meets all requirements in Section 18 VHA Directive 1200.05 and VA requirements for use of electronic signatures; and the electronic process must follow the VA information security requirements.

The informed consent form may be combined with the HIPAA authorization form if the study does not involve optional banking of identifiable private information, or identifiable biospecimens; or if the study does not involve consent by subjects' legally authorized representatives. Please note that there’s an exception in the state of California, that doesn’t allow the informed consent form to be combined with HIPAA authorization.

Documentation of informed consent that is permitted under clinical procedures as described in VHA Directive 1004.01, that is, Informed Consent for Clinical Treatments and Procedures, does not apply for research. And researchers cannot sign on behalf of a VA subject or as a VA subject’s legally authorized representative on a written informed consent document approved by the IRB.

ORD is in alignment with FDA for obtaining informed consent in clinical trials as published in the FDA guidance cited here.

Now, the common rule allows for IRB to waive the documentation of consent if it finds any of the following: one, that the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or legally authorized representative will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.

Two, that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

There’s also a third criterion added in the revised common rule: that is, if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

So, what constitutes an electronic or digital signature? In conjunction with ORD, OI&T, VHA Privacy, and ORO, the Research Support Division has published a guide on electronic methods to obtain informed consent cited here as part of ORD’s toolkit on cyber security. This guide states that signatures can be obtained when a person physically marks a document, typically referred to as a wet signature, or through electronic or digital signatures such as an electronically-captured signature made on a touch device, or checking a box using a Personal Identity Verification or PIV card to generate a digital signature.

There are various ways to electronically document informed consent in VA research: including iMedConsent Web, DocuSign, and other electronic methods approved by the information system security officer for the study, such as the online platforms used in Million Veteran Program or All of Us Research Program.

So, what are the factors to consider when determining the most optimal methods for consenting? Some primary factors include the subject population for the study, who can be in-hospital or remote at the time of consenting; in-hospital subject population can be inpatient or outpatient. iMedConsent can be used for inpatient studies or outpatient studies where all study subjects will be present at the facility with CPRS access. When the subject population is remote, it is best to use DocuSign and/or mailing paper consent.

Another primary factor to consider is the study design that should take into account a consenting method that is optimal for the subject. For example, “Is recruitment best conducted at the clinic as a point of care or can the consenting process be followed with a short initial research procedure?” If so, your subject population falls under in-hospital population for whom consenting can be done using paper or iMedConsent; nevertheless, iMedConsent is not optimal if the study has a Certificate of Confidentiality.

So, now, let’s consider the characteristics of the platform. These are the main characteristics of iMedConsent, although not an all-inclusive list. iMedConsent is integrated in VistA or CPRS and, later on, Cerner, and it can pull in subject’s name et cetera from the medical record; it is compliant with 21 CFR 11, thus can be used for FDA-regulated studies.

iMedConsent web provides a Report Viewer option which will allow local iMedConsent administrators to generate reports on form usage. Both study team and research subjects need access to the VA network to use iMedConsent. The request to use iMedConsent for VA research should be made to the local facility administrator. iMedConsent needs Word documents as input and there is no cost to study team.

What about DocuSign? Instead of being integrated into the electronic health record, DocuSign utilizes its own server. A study using DocuSign requires a waiver of HIPAA authorization to disclose the name and email address of prospective subjects to DocuSign.

There are two types of DocuSign envelopes: one that is 21 CFR 11-compliant and another one that isn’t.

Different from iMedConsent, access to VA network is required only for the study team, but not the subject; and instead of being administered locally, DocuSign is administered by the Identity & Access Management or IAM Team.

The request to use DocuSign for your research should be made to ORD. For studies funded by sponsors outside of VA, please make sure that your sponsor will not require the use of their electronic signature platform prior to requesting DocuSign use. Reimbursement to ORD may be required for studies funded by non-VA sponsors. DocuSign can take Word documents or PDF files; and currently, there’s no cost to study team.

Both platforms, iMedConsent and DocuSign, will need the study team to provide IRB-approved informed consent form and approved HIPAA authorization form.

Let’s talk a little bit more about the platforms. Earlier this year, iMedConsent transitioned from iMedConsent Legacy to iMedCosent Web. General information and training on iMedConsent Web is provided in these hyperlinks provided on the slide. A general SOP to use iMedConsent for research may be provided upon request.

So, how to start using iMedConsent for VA research? First, the study team needs to identify the local iMedConsent administrator; for example, Clinical Application Coordinator. There’s a link here that points to an Excel file listing the facility iMedConsent administrators; if you can’t open the link in this slide when you’re connected through VPN, just copy the link and paste it in a browser or connect directly to the VA network, for example, using Citrix. There should also be a local administrative process connecting the study team, IRB administrator, and iMedConsent administrator for study initiation and also for amendments.

Now, I’m going to turn over the presentation to Janet who will provide a demo on how to use iMedConsent.

Janet Fawcett: Thank you very much, Paska. And this, to start with, is just a screenshot of a test patient in CPRS just to save the switching backwards and forwards; and once you have the patient open in CPRS, iMedConsent Web is located in the Tools menu; and click on that and it takes you to iMedConsent Web in Internet Explorer.

And I will now share my screen and give you a quick demo on how to complete consent in iMedConsent Web; and you should be able to see my screen now which shows iMedConsent for the web. Once you go in, you do authenticate with the PIV card, and then you’re faced with the first screen. The tabs at the top, if they’re not here, it may just have one tab that says tabs and a plus sign. If you hit the plus sign, you should be able to see the current tabs.

If you go to Browse, this is basically all the consents for the VA. Now, in Phoenix, we store our consents down in a folder called ZResearch Consents, and these are our current studies that actually use iMedConsent to recruit patients. If you go to the study that’s important--I’m kind of clicking on this one right now--and highlight the consent that you need--if you have a study that has more than one consent, just be particularly careful which consent you choose; and then if you go to the Start button, it comes up with this screen which is kind of the opening screen asking you for information.

This particular study can use a surrogate for signing if the patient is not able to. Not all studies have this option available, so for this one we’ll just put “N/A” for now, and then type the name of the person obtaining consent. We’ll choose me and hit Add. If the person obtaining consent is not here, you are allowed to type the name in this box, and you will also give a copy of this document to the patient.

You now want to go down either to generate document in the bottom corner here or hit Document tab, and that will produce the consent in this window, and you can go through this consent now with the patient. And it may be easier for the patient, at least, to read a paper copy at the same time rather than peering over your shoulder or looking to see the screen; and at this stage, you can actually say Print to get a copy of the consent; this, obviously, will not be signed but you have to note that it will have PII on the document because the name of the patient is automatically put in the document, the last four, date of birth, and also today’s date.

The last one, the social is not mandated on ICF, but that is a local policy in Phoenix that we have it on that.

So, you go through this consent with the patient; and once they’ve agreed that they want to participate, and then you’re going to go sign the document. If you hit the signature tab and then you have the signature boxes that are available. The first one, Participant, if you hit Sign, and then they can sign either with the mouse or preferably with an e-signature pad that’s attached to the computer, and hit Save. We’re not going to use the surrogate this time, and you also--the signature of the person obtaining consent, again, this is not required by Directive 1200.05, that is a local policy. So, we hit that for Save. And then once everybody has signed, you can hit save and that sends it to the patient record in CPRS, the little green banner comes across the bottom saying it’s been saved successfully.

So, then, if I could just go back to the slide deck, again, I just have screenshots of the CPRS. You see the... this is obviously one I did earlier this week, but you get the study note, it’s automatically attached to the consent. This is the wording down here and you see the image is to--the consent is sent straight to VistA imaging.

So, again, VistA imaging is located in the Tools menu. I did not do a screenshot of this imaging, but the consent including the signatures is in there, that is available and you can print from there if you need to, but it’s available for auditing purposes and it’s in the patient record.

Paska Permana: Thank you, Janet. So, now, we will go over the process for using DocuSign for VA research. Erica will show us how to start this process using the links provided here, followed by April and Nigel, who will provide a demo on how to use DocuSign. Erica?

Erica Aulik: Thanks, Paska. I am going to start sharing my screen. Now, in the slides and in the Q&A box, I have the link to our DocuSign request, and just so you can kind of get an overview of how it looks to orientate yourself, I have a... I’m going to zoom in so that you can see a little closer.

So, basically, on the left, it gives you a little bit of background information of all the things that Paska has described to you in the policy, kind of technical portion of the talk, and then it has, in red, a warning. VA’s contracted with DocuSign just to make sure we have the right people using it. If you need help, here is the email address for people to help; and then finally, you get down here to the actual request form. All you have to do--and there’s an instruction in green here--click the new button to open a new form. Now, you are only going to see your own submissions, you are not going to see everyone who has submitted in the past. So, you when you get here, there will be nothing under here unless if you submitted something, you want to create a new item, and use the scroll bar to answer all the questions. Now, this is kind of the tricky thing because you have the scroll bar here on the form and you have your scroll bar here, and Internet Explorer or Google Chrome, whatever you’re using.

This is the biggest thing that confuses people; otherwise, it’s a very simple form. You just basically fill out the information; and you pretty much have to fill out everything. If there’s a star in front of it, that means it’s a required field.

You see how my scroll bar ended; it’s because I really have this enlarged quite a bit; you may have to go over and use that other scroll bar as well. When you’re done, you just hit Save and that’s it. What will happen then is that you will get an email saying, “Hey, we got your requesting. Hang tight, we’re going to check it out.” And then it’ll tell you, “We’ll get back to you in a few days,” and the turnaround time is really quite quick.

And then in the email, it’ll direct you here to the post-approval instructions, and it tells you the steps that you need to go through after you have been approved. And really, this section, it tells you what your next steps are; it tells you who to ask for help, where to get more help if you need more help. There are more links and there are SOPs and training materials at the bottom.

I have not heard a lot of feedback of people having issues with registering the actual steps to registering.  So, I mean you should be good to go; it should be an intuitive process. And, of course, if you have questions about content or any specific issues to your facility, you would click this link here for the help and that’s about it.

Again, I put the link in the chat and it’s also in the Slide deck for your later reference. Okay, Paska.

Paska Permana: Thank you, Erica. I’m going to share the screen for April.

April Primous: Hi. Good afternoon. This is April Primous. Thank you, Paska. So, I just want to go over real quick before I show a little demo on how to request our services. I want to show the process of what we’re talking through today. So, the first thing--and what Erica alluded to or mentioned as well--is the first step after you’ve got come from the ORD request portal. So, this is our handoff from that group to our group in IAM for DocuSign requests. And so, the first step is to request the service through e-Signature playbook page.

Once you get that request--and I’m going to show you how to do that here in a second-- then our team is going to set up an initial meeting with your POCs of the study team so that we can talk through the process of what you’ve requested, and just ensure that everybody’s on the same page on what we’re going to do next. The next step is we’re going to use that email that Erica also showed you, is you’re going to send--and we’re going to tell you this in that initial meeting--you’re going to send us your IRB-approved forms; and typically, this is going to be done within two to three weeks of when you need to use the DocuSign service. And the service is an envelope, so the envelope contains whatever documents that need to be sent to a study participant.

Once our team has gotten their documents, then we’ll have a technical analyst who will also show you the process, who would take that form--we can get it in Word or PDF form--and they’ll create a template in DocuSign with those forms. And then what we do typically is most of the study teams have a workflow that is similar, and so we’ll set that up. If there is another workflow that needs to happen, then we’ll work with you to fix that for you.

Once we’ve gotten those documents set up in DocuSign, you’ll receive another email; this email is to set up the training for those teams. We haven’t completed an overall training that you can go to as you need, so what we’ve been doing initially is meeting with each individual team and showing you your documents, how to go through DocuSign, how to send the forms, what happens when it comes back; and then we provide those training slides, which is actually also a reference document in Erica’s presentation, it’s there as well. But we provide that after we do the training.

What we typically do after that is we ask for those study teams to test in the Sandbox or in the testing environment, just test how you’re going to send it this way that you get a little bit more comfortable with DocuSign and how it works. And this is an environment that you can go into, and if you mess up or something happens, it’s no issue.

Once you’re done testing in that environment, then you’re going to email the group email again and let us know that you’re ready to go into production you’re ready to go ahead and send these documents to study participants to get consent. When you let us know you’re ready, we will set you up in the production environment, you’ll get an email that shows the URL that you will use for that environment. And so, so one of the things that you’ll want to ensure is that when you’re requesting envelopes--so, typically, if you have 100 study participants that you want to consent to, you may ask for a hundred envelopes because that one is a one-for-one, all those documents are all compiled in one envelope. However, what you may want to do--and what I know Dr. Klote's team does, is they will add a few more envelopes to that request, and that’s because you may have a study participant that doesn’t sign the form. If they don’t sign it that’s an envelope that’s used, so you’re going to need another one if you’re still trying to get 100 study participants. So, that’s something that you would want to take into consideration.

So, now, I’ll go ahead and share my screen so that I can show you just the process that we ask you to take in order to request our service.

Unfortunately, this particular process is used by all of the IAM team; and so, you would have to kind of go through the process. And I’m not seeing my screen, but if you can just let me know if you can see it?

Paska Permana: Yes, we can see it.

April Primous: Awesome. Thank you. So, you can see my web page in IAM eSig playbook. So, when you click on the link to the eSig playbook, it’s going to take you to the SharePoint site that we have; and what you would have seen from the previous presentation that Erica sent or provided, she has a screenshot of the bottom of our page, and it talks about where to submit or where to request our services.

Currently, it’s at the bottom of the page, but we’re going to be working on trying to make this link at the top so you don’t have to scroll to the bottom. A lot of our customers who are not part of ORD typically like to figure out which portion of DocuSign they want to use; but with your group, you’re going to go directly to requesting this service. As well, we have a step-by-step Word document that can help you through this process so that you don’t have to try to figure it out on your own.

So, once you click on that link, it’s going to take you to the next page that’s the IT request portal. So, part of the process, because we use the Jira intake tool that VA provides. Every person that wants to request will have to have a max.gov account; and if you look to the left, it says, “Registering with max.gov,” and that’s going to be the first step. And when you look at the step-by-step guide, we talk you through that. So, you would click on the Registering with max.gov first, so that you can have access to then request our services, and that’s going to be in the Make a New Request link. So, once you click on that link, it’ll take you to our request portal. And then what you would want to type is “DocuSign” or “eSig”. So, if you look down here at the links provided, it’s the electronic signature. So, that’s what DocuSign is for and you would click on that link.

So, for your request title, you will typically use the study name that you used when you requested services or envelopes and DocuSign use through ORD request portal, the ORPP&E request portal; and that way, we can track your request through that title. And then you would go through and ask for “Use this Service.”

One of the things that we added with this new process--and it’s been in use for about six month--is we ask you for that envelope number. And so, that number is going to be what you requested and was approved for on that previous SharePoint site through ORD.

The next thing is the date is optional; this is really just so we try to keep within certain timelines, we typically do try to get study teams into production within two weeks, that there is a lot that goes into that, and it means that if you have your IRB-approved forms, you’re ready to consent, and then you’ve done all your testing. So, if everything is perfect, then we can do it within two weeks. If not, we work with you during that timeframe; and it may be that you forgot to ask for us to move you into production and you’re ready to go live that day or the next day. We can work with your team, we’ve had one or two out of the hundreds that we’ve had requested do that and were able to get them into production in the timeline that they needed.

And then once you’re done entering all of your information into the next boxes and you hit “Create”, you’re going to get what we call a service request number, it’s probably going to have a couple more letters in front of it. But it’s going to have a number, and that’s the number that we use to track your project.

And then, we also go back to the ORD SharePoint site because we have access to view everybody’s requests so that we can verify, “Yes, they have been approved,” what they have been approved for and then that way, we know, we can proceed to do the first step or the second step, which is to set up that first initial meeting with you with the study teams.

And so, with that, I’m going to send it over to Nigel Clark. He is our technical analyst and he’s the one that does all of the magic on DocuSign. Nigel?

Nigel Clarke: Thanks, April. So, I’m going to begin straight from DocuSign, so this is assuming all the steps have been followed, the request has been submitted, proof document sent. And I have a demo template, so I’m just going to show logging into DocuSign. And as Paska had said before as VA senders, so people sending do need to get--they do need to have access to the VA network, and I’ll show you why.

So, you log in with your va.gov email address as your ID, and then it’s going to trigger SSL--and it didn’t for me because I guess I was just logged in. You’ll trigger SSL, you log in with your PIV and pin, and you get to DocuSign. DocuSign.com is an external site, and so what I’m going to do is I’m just going to send the template out and then go through each step.

So, I’m going to go New User Template, and I’m going to pick the template that I created; and when we create templates for you, we actually segregate all of the templates. So, we don’t... I see all of them, and that’s why you’ve seen all of them here, but I put them in groups, and I put your user accounts in groups. So, when you log in, you’ll only see your templates, so only the studies that you’re associated with, you don’t see anyone else’s studies.

So, you pick the template say Add Selected, and you don't see anyone else's studies. So, you pick the template and say Add Selected. And the templates are custom-created based on use case. So, this use case that I have here is the most vanilla you can have, this is just a participant sign-in a document; the typical use case is participant and person obtaining consent. For sake of simplicity, I stripped out the person obtaining consent, just have one person. The workflow can be as simple or as complex as the study team wants. So, typically, we don’t code it for LAR. If LAR is requested--legally authorized representative--I’ll do that; we can have multiple templates like I’ve had templates where we’ll have... like for an Alzheimer’s study, we'll have a participant, and then a participant partner consent form, and then using the HIPAA form to build out different templates. So, you can have multiple templates for multiple scenarios, or if you have templates based on location, we can do that also; and as Paska alluded, there are some rules in California where the templates are different. We have the ICF and HIPAA separated, so we can do have a template specific for those team members for whatever state.

Also, in addition to that, there will be CFR 11, which adds all those use cases, but adds these CFR 11 features on top.

So, in this case, I’m going to add the participant’s name. So, I’m just going to send it to myself; and like I said, if it’s person obtaining consent, right now, I just have participant; and if I had a person obtaining consent, it’d be right behind it and I normally do it in order, so it’s one and then a 2. So, it goes to the participant first, they fill it out, then the person obtaining consent gets notified, and it comes back. So, I’m just going to send this out; and what happens is... so, the participant gets an email that looks like this--and this is a customized template--so, what I’ve done is I’ve put a custom subject in, custom text, and this is what I call my demo study. So, formatted email, put contact information et cetera in there, and they’re just going to click the yellow button. So, they get this email, they’re going to click this yellow button; and just for simplicity’s sake, they click this button and it will take them straight into DocuSign, and straight to this page.

And also, just to note, the contents as an email body, will show up here. So, if there is anything that they need to reference, they can actually go back to the email reference; it shows in the header; and also to note the email and DocuSign, we’ve customized it fully with VA logos, VA colors. This is actually VA blue and VA gold as opposed to DocuSign’s colors. So, we’ve tried to make it as--we’ve branded as much to VA as we possibly could.

So, they get this page and it shows the ICF in the background blacked out. To continue, click the yellow button--everything in the DocuSign is about the yellow buttons--and it will fill out the name from the envelope, put today’s date in. Like I said, this is a sample template. In the test environment, it shows this big red stamp, that it’s just a demonstration document only. You only use your templates when it gets to production, so here, you’re just playing around. You send it to your personal email just to see how it’s going to act for the participant; and then play around, get familiarity with it, and then request to move to production.

So, I’m just going to hit the button and it’s going to jump from required field to required field, and put logic in here. So, depending on which option you pick, it will select the initial; and I’m going to sign electronically, the middle initial is optional. Last four of SSN, and it’s going to request the birth date. And that will copy across all headers, and then I sign. And now, I’m going to finish.

So, what happens now is both the sender and the participant will get an email stating that the document’s been signed and completed; and from the completion email, which looks similar to the initial email, there’s a button in there that will allow them to go back to DocuSign and download a finished copy of the ICF.

So, I’m going to go to my sent. So, this is the template that was sent; it shows us Completed; and if I click on this, it shows that the participant signed it, date and time assigned it; these two documents here are documents--these are the ICF and HIPAA in PDF formats, so I can click on each one and view them, they’re completed, and I could download from here. But I do recommend using the download button here, and it downloads everything as a package, plus it also downloads an optional file from DocuSign, which shows the audit log for the electronic signature.

So, that way, you save all of the documents locally. This is right now, it’s on the DocuSign cloud; each person’s box is private, I do recommend saving it locally for each person.

So, that’s a basic overview. Like I said, it's all customized templates and that’s a very brief overview of what we do. Thank you. So, I’ll turn it over now to Paska.

Paska Permana: Thank you very much, April and also, Nigel. I am now going to move on to the next slide.

Now that we have shown you how to use iMedConsent and DocuSign, let’s have a fun poll. So, let’s say that your study will randomize patients hospitalized with severe COVID-19 symptoms who may be intubated to receive an investigational product or a placebo. What consenting method could be applicable for this study? And please check all that apply. The options are Paper, iMedConsent, DocuSign, or the study team can request Waiver of Documentation of Informed Consent, perhaps.

Kate, please take it over.

Kate Yeskigian: Alright. And as Paska mentioned, please select all that apply, and then click on the gray Submit button in the lower right-hand corner. We’re giving everyone about a minute to answer this question; and thank you to everyone who’s already answered it.

We’ll give you about ten more seconds and then we’ll show the results.

Paska Permana: Thank you, Kate. And I see that some say paper, some say iMedConsent; some say DocuSign, and I think there may be some are saying Request Waiver of Documentation of Informed Consent. And some do not answer.

Alright. What's the answer? So, actually both paper and iMedConsent could be applicable and, perhaps, most appropriate for this study. The paper should always be available just in case iMedConsent server goes down or if the local VA facility doesn’t have the computers on wheels for the potential research participants to access.

Now, DocuSign, which is Option C, may be appropriate if the study team need to obtain consent from the potential subject's LAR and personal representative for HIPAA authorization outside of the VA facility, for example, when the local VA facility prohibits visitors. But this study is not eligible for a Request of Waiver of Documentation of Informed Consent.

Alright. This is the end of our presentation. The recording of this webinar will be available on this website in approximately one week; and this is a list of references used in this webinar as well as contact information on the topics covered in this webinar. So, now, let’s see if there are any questions that we can answer before the end of this hour.

Thank you very much for all panelists and also for the audience.

Kate Yeskigian: Alright. We’ll go into the question-and-answer portion.

Paska Permana: So, the first question is, “Did I understand that it was said that the PIV certificate signature is acceptable for viewing employees' signatures?” It is acceptable, and I’m assuming... it depends on the platform, right? The iMedConsent platform uses its own signature block; and for DocuSign, it also has a separate signature block. Does anybody else on the panel want to chime in?

Nigel Clarke: That is correct. DocuSign uses its own electronic signature. We can enable PIV and we are talking about doing that for employees; but currently, it’s just using its own signature.

Paul Tompkins: iMedConsent web requires a handwritten digitally-captured signature. So, the IRB certificate signature is not available for iMedConsent Web; it has to be physically signed.

Paska Permana: Thank you both. Next question: “Does iMedConsent require Internet Explorer or does it also work with Edge and Chrome? If it requires, is there a plan to manage how Microsoft is ending support to IE at the end of the year?” iMedConsent is integrated into VistA and CPRS; so, I think this question is perhaps a good point.

Paul Tompkins: That's a good point. We do have to transition away from Internet Explorer, and we’re moving toward that right now. Internet Explorer is going to be completely deprecated from the VA in June of next year; I don’t think this is going to happen by the end of this year. We have plans to work toward transition, either make it acceptable and usable using these current signature paths with Edge or transitioning and purchasing new electronic signature pads across the enterprise.

Paska Permana: Thank you for the clarification, Paul. So, I hope that is clear. So, next question. “I heard that iMedConsent requires the consent in Word, but all these sites are using IRBNet, which provides the stamped IRB-approved consent in PDF form only. How is the PI to provide the stamped approved consent in the Word?” I’ll pass this along to Janet.

Janet Fawcett: Yes. Thank you, Paska. Yes, that was an issue to start with; but basically, what we do in Phoenix is I work with the IRB coordinator, and she provides the Word version of the document to me, and I’m the one basically, who uploads into iMedConsent for Phoenix, so it may be different other sites. It basically works with your IRB coordinator to get the right format.

Paska Permana: Thank you, Janet. Next question, please. “Is IRB approval for DocuSign required prior to submitting this DocuSign request? Or can we submit the DocuSign request and then submit an IRB amendment for DocuSign use afterwards if the request is approved?” I would ask Erica to answer this. Erica?

Erica Aulik: I’m going to defer to Karen because I just build the site; I don’t actually take care of any content on the site. Dr. Jeans, take it away.

Karen Jeans: Oh, you’re so cute. Well, I’m going to be honest, I do not approve the DocuSign request, but this is one of those, but we will get back to you because I do not know the approval process in terms of what is required upfront; however, I want to answer the second part because... “Can we submit the DocuSign request and then submit an IRB amendment for DocuSign use afterwards?” That’s always true. That is always, always true. I do believe that is true.

I will, however, find out definitively by getting into the DocuSign portal myself and talking to Dr. Klote, and we will get you an answer immediately to this, and I will have that to you by tomorrow. So, we will follow up with that. So, I appreciate the question. Thank you.

Paska Permana: Thank you. Next question, please? “For documentation of informed consent, what was the exception in California?” I believe the exception is that the state of California does not allow the combination of informed consent form and HIPAA authorization, meaning the two forms cannot be combined into one. Dr. Jeans, do you want to speak more about that?

Karen Jeans: Absolutely. Thank you. There are state laws that are applicable to California; and it does not allow, as Dr. Permana said, to combine the two. And VA does indeed recognize that and that is why, for the first studies involving California, those consent forms are never combined with the HIPAA authorization. Thank you.

Paska Permana: Thank you, Dr. Jeans. Next question. “Will it be possible to review this training later?” Yes, this webinar is recorded and I think the recording will be provided in a notification later on, I believe in about one week. It will be posted on the ORPP&E website.

Next question. “Will we be able to test out DocuSign before we have the researchers use it?” I assume “we” meaning non-investigators and that means research administrators? That’s my assumption. And I will let April answer this question, including Nigel.

April Primous: Hi, Paska. We typically don’t put people in DocuSign unless it’s for a specific use case, because we don’t have test templates in there. But DocuSign has training links that you could use or view at your leisure on the DocuSign site. But yeah, right now, we haven’t put anybody in to DocuSign unless it has been for a specific request.

Paska Permana: Thank you, April. Our next question, please. “Are there any exceptions to the 100 ppt minimum for DocuSign for smaller studies?” Maybe Dr. Klote and Dr. Jeans, can you respond to this question?

Karen Jeans: I’ll respond. Absolutely. There are, indeed, exceptions. I mean we have a guide and is what our goal was, especially when we started out when we had a limited number of envelopes; but there are indeed exceptions, so please do not let that minimum number stop you from asking for it. And I’m really glad the person who asked that question has done that. So, yes, there are exceptions. Thank you.

Paska Permana: Thank you, Dr. Jeans. Thank you to everybody on the panel, as I said, and also for the questions that the audience has posed.

Kate, please take it away.

Kate Yeskigian: Alright. Thank you, again, to everyone for attending; thank you to our panelists, and thank you to everyone who asked questions. As a reminder, the slides and a recording of this presentation will be available in the SharePoint link we shared, and the recording will be available by the end of the day.

Thanks, again.