Karen Jeans: Hi, everybody. My name’s Karen Jeans. First of all, this is a very -- I’m going to turn on my video. I’m not going to turn on my video. I’ll turn it back off. Okay. My name is Karen Jeans. I’m the director of regulatory affairs here in ORD, and you are a group of a small, select group that has been invited -- and this is going to be part of our normal process from now on -- to where, for the TPOXX CDC study, program, we’re using different methods of informed consent, and one of those is the VA DocuSign. We developed, with the incredible assistance of IM, jointly, a tool for how to do the request and streamline those requests. But then once you get approval, what do you do? So through the incredible work of Nigel, who I’m fixing to turn this over to, and April, they have developed a job aid that you can use, that will enable you to better implement VA DocuSign for this TPOXX program.

And so, it’s a job aid, but it’s -- part of this job aid that you’re going to get to see right now from Nigel is going to be, like I said, with every new user, they get the copy of the job aid. It’s also going to be posted on the ORD CDC TPOXX website. We think it will help answer any questions, so that you can successfully use the VA DocuSign for this TPOXX program. So with that said, also, Nigel will talk very briefly -- he didn’t know specifically -- about you’ll have your VA DocuSign access turned on, in terms of your accounts. So rather than me keep talking -- again, it’s a very short time here -- is that I’m going to turn this over to Nigel.

Nigel: Hi. Thank you very much, Karen. I appreciate it. Okay. I guess I just have to ask, has the job aid been shared yet, or is --

Karen Jeans: No, it has not --

Nigel: -- it going to be shared after?

Karen Jeans: -- been shared. We were waiting until this presentation right now.

Nigel: Okay. All right. First, I have the first slide for the job aid up, but what I’m going to do is rather than go through the job aid, I am actually going to use DocuSign itself. Show you how to login, go through each step, and show you live how to actually use the tool. The job aid of course will have screenshots in there, and you can go step by step using that.

As was stated before, at the end of this meeting there will be -- I will activate your accounts, and what will happen is DocuSign will send an email, basically letting you know that an account’s been created for you by me. You’ll have a big yellow button in there to activate the account, to just open the email to kind of activate, and it will make your account active, to allow you to login. I will also send a separate email with the URL, just so you know what the URL is, and make sure you bookmark that.

What I’m going to do is I’m actually going to go straight to production. Actually, I’m going to do it from my Sandbox account. To log in to DocuSign, you don’t have to remember a username and password. You login using your email address, and you authenticate using SSO. I’m just going to log in using my VA.gov email address. On the second screen -- yours will look a little different. You’ll get a blue button that says use company login. When you click on that, it’s going to trigger SSO, so I’m just going to log in using SSO. Like I said, there’s no username, no password to remember.

Okay. All right. This is the default screen you’ll get logged into, and if you notice, it looks a bit like webmail. If you’ll note, on the navigation panel on the left, you’ll see inbox and drafts, deleted, et cetera, so it’s kind of like webmail. What we’re going to do is I’ve put the documents together in a template, and what we do is we send that out to recipients, kind of like you’re sending an email. That’s kind of the analogy. For everything I send, it will show up here in the sent box, eventually. It’ll show up here in the sent box.

To send a template out from this screen, you’re just going to click on new, and you’re going to say user template. So like I said, I’ve created templates, and at the end of the call I’ll create your accounts, and your accounts will automatically share the template. So you won’t see the hundreds and probably thousands that I see. You will see just one for now.

Once you say user template, it’s going to come up with this screen. Your template will show up under here. It says shared with me, and it will just show up right here, and it’s just going to be -- on my screen, it’s going to be -- actually, my apologies. I just realized I have to switch. I have two accounts, and some you actually may have two accounts, also. I’m just going to have to switch an account here. Okay. My apologies for that. It’s going to say user template. Nothing shows up under shared with me because no one shares anything with me, but your template will show up here. Mine shows up right in the top. This is the name of it, Monkeypox Expanded Access Study. That’s the one you’re going to select.

Also, I want to note if anyone’s used DocuSign before, these templates are used in CFR 11 standard. What that means is there is additional validation on the signatures used in CFR 11. Standard DocuSign, when you send a template out, the recipient will just basically click on a link. It’ll go straight into the template. They’ll fill out the information, and that’s it. The difference with CFR 11 is it does require that the recipient has a DocuSign account, so if you’re sending it to a participant and they don’t have a DocuSign account, it will actually prompt them to create one. So when they get the email note finding that you sent them a template, it will actually go to a screen asking them to create an account, and it will take the information in the envelope that you send them, and ask them to create a password.

Also, the other thing with CFR 11 is every time that they sign, they have to do w-hat they call re-attestation, which means that you have to actually log in again, enter your login information again, to validate that you’re the person at the keyboard before you sign. Also, it requires that a sign-in reason is given, and the sign-in reasons have actually been dropped down to one, so it’s evident which one needs to be picked.

Okay. In this template, there are four roles. This is the reason why we actually need to go through the session here. The typical -- I’m hearing an echo in my head. That’s why I’m kind of hesitating a bit. The typical use case is going to be person obtaining consent on the participant, but we also have roles for the LAR and the translator, because there are sign-in blocks in the template for those roles, so they’re in there. If you notice, on the left of each one -- on the right of each one. I’m sorry -- there’s a little trash can. Depending on your scenario, you will delete the role that you don’t need. For example, if I’m going to send this out, and I don’t need a translator, doesn’t need to be translated for your participant, I’m just going to delete that, so I’m just going to say delete.

Then you’re going to have to make the choice, is it going straight to the participant, or is it going to go to their legally authorized rep. Typically it’s going to go to just the participant, so you can just delete the LAR, or switch it the other way around. If you have a LAR -- if the patient isn’t able to sign for themselves, then it’ll just be you delete the patient, and they would have the LAR fill out those fields. So I’m just going to delete the LAR. I’m just going to standard scenario.

Person obtaining consent. What I’m going to do is I’m just going to send it to myself. I’m just going to change my name. I’m going to call myself -- and the name that you put here is the name that DocuSign will use. It doesn’t actually validate it, so it is important that the name that you put here has to be accurate as well. Because as I’m demoing it, you’ll see that it uses this name here to fill out the -- in the template, where it asks for the person’s full name, it'll put the full name. When it goes to sign the document, it will use the name here to sign the document. So whatever you type here is what DocuSign will actually use, so it is important that you have the name accurate and the email accurate. In this case, like I said, there’s two roles that are going to be used. Fill out everything correctly, and then all you do is send. So you just have to know person obtaining consent -- probably yourself -- participant, veteran, and I’m just going to hit send.

Okay, so now I’ve sent that template. Okay. If I go into my sent box, you can see it here, but I’m just waiting for my email. Because I sent it to myself -- I’m just going to show what the emails look like. This is an example of what the emails look like in DocuSign. Everything is very branded. These are VA colors, and we can put custom text in there. But in this example, the person obtaining consent goes up first. Like I said, from the email, you can actually click the yellow button and it’ll take you into DocuSign. But seeing as I’m already in DocuSign, and I sent it to myself, I can actually sign it from here.

I’m logged in. It takes me straight into DocuSign. It shows the template. If they’ve never used DocuSign before, there will also be a checkbox here to agree to the electronic record, the signature disclosure. Either way, there’s a yellow button to hit continue. One thing to note with DocuSign is whenever you see a yellow button, it means basically look at me, pay attention. The yellow button’s normally the action that you’re going to take, so I’m just going to hit continue.

Now it displays the template. It’s going to display the template, with the documents in the template. If you notice, there are two yellow buttons here. You have a start button, and you have a finish button. The start button will navigate you from required field to required field, so if I hit the start button, it's going to jump straight to a required field. You can also scroll through the document and read it if you want to, but I’m just going to hit start. This is asking for the physician and contact info, so I’m just going to fill that in. This is the person obtaining consent. This is the first person.

You’re going to fill this out, and then send it to your recipient. Drop the signature in there. This is the first signature that I’m going to do, and if you notice, it’s asking for a reason for signing. There’s only one reason in there. Just pick the reason and sign. Then it’s going to say authentication. It says, “CFR 11 requires you to authenticate each signature on this document.” When you hit continue, it’ll take you to a secure login page to enter your credentials. That doesn’t mean that you’ve gotten logged out. That just means it’s basically forcing you to reauthenticate before you sign, proving that you’re the one at the keyboard at the moment of signature. That’s what that’s about. And if I scroll back up, this is what the signature looks like, and it adds a lot more information than a typical DocuSign signature, because this is CFR 11.

Next required field is asking for the location address, so I’m just going to make one up here. Okay. If you notice, when I filled out this field here, the yellow button the left-hand side went away. That means there are no more required fields for this person to fill out. The only yellow button that’s remaining is the finish button. Let me just show you this real quick here. This field not entered. Yellow button comes back. But if I try to hit finish, it won’t let me finish until the required field is entered. Put that back in, yellow button on the left goes away. So I’m going to finish.

What’s going to happen now is I’ve finished as the person obtaining consent, filling out those fields, and DocuSign will now send an email, similar to the one that you saw before, to your participant, letting them know that -- and I’ll wait until it comes in -- letting them know that there’s a document for them to sign. The email just came. This is what they’re going to get, and they’re going to -- they’re going to get this. They have a different DocuSign view from you, so they’re going to get this. They’re going to click on this yellow button here, and it’s going to take them to log in to DocuSign. Like I said, if they don’t have a DocuSign account, it will prompt them to create one. It will actually say, “Okay. This is your name. This is your email address. Create a password,” and it will create the account for them, and then they’ll go in and continue. So I’m just going to pretend that I’m the participant. I’m not going to click on the button, because I sent it to myself. I’m just going to sign it from here.

Okay. They’re going to come back in here. This, what I’m showing you is what we call a sign-in ceremony. Each person that has to sign has to go through a sign-in ceremony, so it’s all very similar. It looks just like what it did the last time, but everyone has different fields, different signature blocks, et cetera. When I hit the start button, it’s now going to go to the participant field. If you notice, it put the participant name in there, and that’s from what you put on the envelope when you sent it. Put the sign in date on there. Asks you this question about samples. Yes, no? I’m going to say yes. Why not? And when I click to sign, because of CFR 11, it’s going to go through the same authentication process. We’re going to have to give a sign-in reason, have you reviewed and approved this document. I’m going to hit sign, and it’s going to say it’s going to have to authenticate the signature again, so I’m going to hit continue. Going to have to reauthenticate. And in their case, because they’re not in the VA, it will actually ask them for their username and password each time, so hopefully they have autofill turned on and they’ll remember that.

Back onto the 5345. You can see the address that was entered previously by the person obtaining consent. It’s put the person’s name in there, reversed it, last name, first name. If you need a middle initial -- this is optional. Not everyone has one. Date of birth. You have to type their date of birth, in MM/DD/YYYY. It does say it here. Also, if you don’t put it in that format, if you notice, the text turns red. It asks them for their mailing address, so put that in. Hit next. It does take the information and it fills out the other like fields, so they don’t have to enter it over and over again. I’m just going to sign. Once again, with every signature with CFR 11, it’s going to ask them for a reason. Have to authenticate to get in. And in their case, like I said, it’s going to be username and password. It drops the signature in there.

Like I said, if you notice on the left-hand side, there are no more -- the yellow button is gone. That means all required fields are entered, so the only thing left to do is finish. Now your participant’s going to finish. I also just want to put -- let me do this, as well. This field here, this date of birth field here is linked to this date of birth field here, so if I mess this up, which I did before, you almost get messed up in both places. This yellow button shows back up here to say there’s a problem, so if I try to finish, it won’t let me finish. Of course, they can close their browser, and it’ll cause a problem, but hopefully they’ll realize that it’s pointing them to this field here. I’m going to finish.

Now, what’s going to happen is both roles that are in the consent have been filled. The person obtaining consent has filled their part out, the participants filled their part out. There was no LAR. There was no translator. If they were in there -- if there was a translator in there, for example, then it would go off to the translator to authenticate and go through their sign-in role, but because we deleted that role because there was no translator, it’s just going to be the person obtaining consent, and the participant.

Now, DocuSign -- and let me see if that email’s come in -- okay. When sign-in is completed -- because if you look at the status here, it shows it’s completed -- DocuSign sends a completion email. That will be your notification that the participant’s finished sign-in. If you get a completion email, it will show document’s been completed. For your participant, if they want a copy of the document, you don’t have to download the document and send it to them. They can actually click this link here, and it will take them back into DocuSign, and they can print, or preferably download the document, and they can have a copy for themselves that way. You don’t have to send it to them. That’s just an FYI.

So for you, it’s completed, but you just want to make sure that it gets saved in the right place. The completed documents are stored on DocuSign’s cloud. We want to make sure this is saved to a shared VA location. If your team has a shared VA location -- you know, SharePoint, ShareDrive, whatever -- you want to download and save it there. Because just like how this looks kind of like email, it is your private inbox. When you log in and send a consent, it’s sent from your private box. Just like how you send an email, you log in there. You can’t ask your coworker to go in there and get your email, so you have to actually download it and save it to a shared location. Every time you get a completed consent, you want to make sure you save it off into a shared location.

I’ve opened the envelope, and you can see the names of the person obtaining consent, the name of the participant. It shows the date and the time they signed it. These are actually, the documents here -- I can actually click on these, and it will open as a PDF, but what I really want to pay attention to is this download button here. Let me click the download button, and it gives me additional options. When I click on that, it says download all three files, but you’re going to say there’s only two files. What DocuSign does, it adds a certificate of completion, so I’ll download everything and show you what that looks like. You have the option of downloading this file separately, or you can combine them into one file. I will just download them separately.

I’m just going to download. This is typically where you’re going to want to save this off to your shared drive, so I’m just going to save it. When I open this, it’s going to show you the informed consent, the VA form, the 5345, and the certificate of completion, called a summary. I’m just going to open one of these, because you know what these look like already. I just want to open one of these, just to show you what a completed document looks like. It’s going to open in Adobe, because it is a PDF. It downloads as a PDF, and Adobe does recognize the signature’s in there, applied by DocuSign. Any moment now. While it’s opening --

April: We do have below, questions, I saw as well.

Nigel: Okay. Let me just finish this part, and then I’m almost done. This is what the completed document looks like. This red stamp in the top will not be in your documents. I just did this in a test platform. Yours will be in production, and it won’t have this red stamp here. Demonstration document only. This is just from the test platform. You can see everything that was filled out, and I just want to show you that the signature is in place. It does overlap, because DocuSign signatures for CFR 11 is so massive. It does show it’s valid, this is a valid signature, so Adobe does recognize the signature’s in there.

Let me just show you this one last thing, and then I’ll take questions. I’m just going to open the certificate of completion. I do like to show you this for CFR 11 in particular, because what this does, it shows an audit trail for your template. It shows you who got, when, and where. It shows some information about the document itself. Eight pages. Three signatures are in there. It shows the roles. There’s Nigel, consent. That’s what the signature looks like. It shows the sign-in reason that that person signed with. It shows the time and the date that it was sent to them, when they viewed the template, and when they signed the template. Then it shows the next one who interacted with the document. Same information, as much information as possible, even the IP address that they signed it from. It shows when it was sent to them, when they viewed it, and when they signed it. Like I said, you don’t have to download this document, but it is a nice to have, and of course you have the 5345 and the ICF form that you’re going to save off.

All right. Do I have any questions? Let me see.

April: I saw questions come in, but I don’t see them at the moment.

Nigel: Okay, because mine’s minimized here. I’m not seeing anything.

April: Okay. It says, “What if recipient or LAR does not have an email?” That’s one of the questions, Nigel.

Nigel: Oh. Unfortunately, they would have to have an email, because it does rely on email for delivery for DocuSign. They’d either have to probably create a Gmail account, or I guess the only other --

April: Do it in person.

Nigel: -- option would be a paper copy. Yeah.

April: Uh-huh. Then the second question that I see is, “Can I set this up to be sent to my PI who will be obtaining the consent, or is this just done by the person who is obtaining the consent?”

Nigel: You can send it to the PI, but -- let me see. It would still originate from your box, so it would come back to your box. So I would probably say it probably should be originated by the person who’s going to own the envelope.

April: Karen or Michelle, did y’all have any other questions for us, or do you think that there’s anything that you want to add? Questions?

Karen Jeans: \_\_\_\_\_ [00:28:24].

Parker: \_\_\_\_\_ [00:28:25].

Karen Jeans: Yeah. Okay. Parker?

Parker: I’m seeing one in here, so I’m going to just read it for you. Attendees, I’ve put in a request to see if you guys can unmute yourselves, if you’d like to just ask. If it’s not letting you, please do just put your questions in the chat, and we’ll read them for you. Let me read this. It’s a little bit longer, a comment and question. “This is complex, and has numerous steps which could be accidentally addressed incorrectly. Additionally, this assumes that the obtainer of consent has enough knowledge of the DocuSign system to troubleshoot remotely any issues using it that the study participant may encounter, which we do not. Is there a step-by-step instruction guide for the \_\_\_\_\_ [00:29:13] process, that can be used by the person obtaining the consent?”

April: Yes. The job aid, the PowerPoint slide that we created to help with this. I think Nigel would attest, and I think Karen would attest to this, too, it sounds cumbersome, but once you get into it, you’ll see that it is a little bit easier to do, once you’ve actually done one.

Karen Jeans: Yeah. This is Karen. April’s entirely correct. I had never used VA DocuSign before, and I literally went through this tool. You keep hearing us say the job aid. The job aid is a PowerPoint presentation which takes you step by step by step through it, because you’re exactly correct. When you’re hearing it like this, it’s absolutely overwhelming. And so, again, our office has recognized that, and we indeed have developed this wonderful job aid, which will do exactly what you’re talking about.

We have successfully been able to use VA DocuSign, of course, outside of these EAPs, Expanded Access Programs, in a number of VA studies, and been very successful. As you’ve already figured out, the onus is on your end. That’s where it’s the hardest part. It’s not for the recipients. The recipients do not have any issues at all. And so, it comes to them very easily. That’s exactly the purpose of the job aid, to do exactly what you’ve just said. Because there are indeed steps, and that job aid will take you through it. And Nigel, please correct me if I’m wrong, but if I’m correct, as soon as this is over -- because a lot of people could not be at this who have requested VA DocuSign accounts for the TPOXX EAP, Expanded Access Program. They automatically, they’re going to get their accounts turned on, but they’re all going to be sent this job aid. This job aid, again, it’s going to be posted on the CDC ORD, the website, so that it’s accessible to anybody and everybody who wishes to use it. But that will happen immediately following this Webex.

Nigel: That’s correct. The list of names that I had given you, I’m actually -- I have a file that I have to upload, and it will create the accounts, and it will send the notifications out. It may take a couple of minutes after the meeting to get done, but it’ll be shortly after that the accounts will be created.

Karen Jeans: And you’ll get the aid. Nigel, just make sure that I’m not saying anything that’s wrong, that they’ll also get -- that you’re going to send them the aid.

Nigel: Yes.

Karen Jeans: Okay.

Nigel: Well, if you have it uploaded, if you send me the link, I can send it with the additional information that I’m going to send out, or I can attach it. But I know it’s like three mg, also, so I could do it either way. If you have it uploaded somewhere, I can send them the link, or I can just attach it to the email.

Karen Jeans: Yes. We were going to wait -- they’re going to upload it immediately after this meeting.

Nigel: Okay.

Karen Jeans: Any other --

Parker: I don’t see any more questions in the chat at the moment.

Karen Jeans: What we want to know is if you are indeed having issues, if you cannot follow that job aid, if it is not helpful, please give us feedback on that, so we can modify it. If you see, when you’re trying to follow it, that it doesn’t -- well, this was confusing, let us know, so that we can fix it. But we have tested it on both of us who do not use this a lot, and it’s been very, very helpful. So again, any feedback is welcome feedback, negative or positive. We welcome it.

If there’s nothing else, then, again, knowing how busy all of you are, we really are very grateful that you’ve came to this. But again, we wanted to get this, offer this first to you, as the individuals who’ve requested access to VA DocuSign for the CDC TPOXX Expanded Access Program. Again, immediately after this, you’ll have your accounts activated. You will get the tool. I’ll be sending out something shortly about -- probably before the end of the week, announcing to the field where this is located at. But we hope that this is helpful, because it really works well, once you get over the -- once you read the instructions, we think it’ll be very clear to you. So thank you all for participating in this webinar today, and I want to thank Nigel and April for all the work they did in getting this tool made. It’s been tremendous.

Nigel: Thank you.

April: Thank you.

Karen Jeans: Okay. Well, I hope everybody has a great afternoon. Thank you so much.

Nigel: Thank you. You, too.

April: Bye.

Nigel: Bye-bye.