Dr. Don E. Workman: For those who are watching it's my first opportunity to meet many of you. And I look forward to working with you in the months and years ahead. And getting to know each other a little better. I thought I would introduce myself just a little bit. I've been an IRB administrator for much of my career. I was in charge of the human subject protection program at St. Jude Children's Research Hospital, at the University of Illinois in Chicago and at Northwestern University before going onto Western IRB. While I was at the two Chicago affiliates, we oversaw human subjects research at the Jesse Brown VA. So I've known of VA research for some time. I also was an unaffiliated member of the VA Central IRB when it was stood up in 2007 and continued as an unaffiliated member until 2011 when I went back to work as a clinical psychologist in a research position. In January, many of you know Annette Anderson retired and the following day I started this position. And part of what we're doing is as we move into VAIRRS or IRBNet for the central IRB, is we're adopting the same program that many of you have adopted already. So that we can share a single enterprise-wide network or platform. Allowing us to look at data across a much larger institution. So it's a time of great change. It's a time of relearning things that had been familiar. And then becoming familiar with new ways of doing them. And as we do that we certainly are looking pretty well to ask questions to offer tips and suggestions given that many of you have already broken in the system or at least learned how to work with it optimally. So again, I look forward to getting your input, we look forward to getting the questions and responses at the end. And I'd like to introduce the two women who will be providing information and answering most of the questions in the Webinar. Angie Foster our VAIRRS program manager, and Christy O'Brien, VA Central IRB manager. Angie?

Angela Foster: Thank you, Don. I'll be walking you through our Webinar today. And I am going to share my screen with you. I'll be sharing this same presentation that you received beforehand.

The topics we will cover today are the Central IRB SharePoint site. A description of the VAIRRS program. How to access and register in IRBNet. The user profile and My Projects sections. The planned Central IRB submission process. Viewing the review results and how to handle a returned package and subsequent packages.

Great. What happens to the Central IRB SharePoint portal? The portal will not accept any new submissions after Friday March 12th, at 8 P.M. Eastern. There should be no submissions over the weekend unless it is a reportable event. If a reportable event needs to be submitted between Friday 8 P.M. and Monday morning, that package should be submitted to the Central IRB at VA Central IRB at VA dot gov. The SharePoint portal will remain for meeting minutes and as a reference until all study documents have been migrated to IRBNet.

I'm sorry. Give me one second. I didn't mean to stop sharing. There we go. The SharePoint portal will remain for meeting minutes and as a reference until all study documents have been migrated to IRBNet. The project data for active Central IRB studies will be uploaded into IRBNet prior to the Central IRB Go-Live. Starting Monday morning the 15th, the IRB managers will work with the study teams to migrate or upload study documents to IRBNet. We will have additional resources to assist with migrating study documents for studies with a continuing review or progress report due date on or before April 15th. For studies with no pending actions and no due date before April 15th, the study documents will be uploaded over the course of the next few months. Please work with your IRB manager if you need to submit an action before the documents are uploaded to your active study. The instructions for uploading study documents will be posted to the Central IRB SharePoint portal. And VAIRRS SharePoint portal for your reference. After March 12th, all new actions must be submitted via IRBNet. All new study actions should be submitted through your local research administration. The research office administrator will ensure that the new action is shared with the local site liaison and submit the action to Central IRB. All post approval actions including continuing reviews, amendments, reportable events, may be submitted directly to the Central IRB. This is an important process change to note. The Central IRB will only accept submissions directly from the researcher for post approval actions and for new studies only if they affiliated Medical Center has not yet gone live in IRBNet.

The proposed routing is subject to continued conversations with VA Central IRB stakeholders. All SOP changes will be communicated via email and posted to the Central IRB website. A list of all sites that have not yet gone live and this schedule Go-Live date is included at the end of the presentation.

The important planned SOP changes are highlighted for you again on this slide. No submissions to the Central IRB SharePoint after March 12th. We ask that all PIs and LSIs register in IRBNet as soon as possible so that your active study can be linked to your account. All new study applications must be submitted to your local administration if your site is active on IRBNet. All post-actions can continue to be submitted directly to the Central IRB and IRBNet.

During this presentation and going forward, you will likely hear the terms IRBNet and VAIRRS used interchangeably. VAIRRS is the VA Innovation Research and Review System. VAIRRS is the program that includes the IRBNet submission and committee management platform. The VAIRRS website, VAIRRS SharePoint portal, and the Power BI dashboards. The VAIRRS website communicates important program updates, implementation progress, and Frequently Asked Questions. The SharePoint portal has a number of helpful training resources including videos,

training energizers, and the VAIRRS toolkit which contains all preloaded forms and letter templates. The IRBNet data will drive the Power BI dashboards that will report upon metrics important to all research stakeholders.

The VA's instance of IRBNet is located at GOV dot IRBNet dot org. You may access VA's instance of IRBNet using your PIV card after your first login. You may also access your VA account from outside of the VA network using your account credentials.

If you do not have an IRBNet account, you may enroll by selecting the register now link on the GOV dot IRBNet dot org homepage. You will need to enter your name, email address, and your local research organization. Note that all VA research sites—whether the site is live in IRBNet or not—are available in the research organization dropdown field. It is critical that you register as soon as possible so that your projects can be linked to your account at the time the Central IRB shell data is uploaded.

After you have established our account in IRBNet you can go to your user profile to add additional affiliations. There is no limit to the number of affiliations you may have. You can also add your training records and credentials. Additional instructions on uploading your training and credentialing records are available on the VAIRRS SharePoint portal in the training energizers folder. The VAIRRS project team is currently working with TMS and CITI to automate importing the training records from both systems. We expect to have this complete in the next few months.

After logging into IRBNet you will be taken to your My Projects workspace. Where you can view all projects that have been created and projects that have been shared with you by other users. Projects can be organized using the tags feature. Tags can be created and managed using the create and manage tags link. Tags may also be applied to your personal view only, or you may make the tags viewable to anyone that has been shared on your project.

My reminders will show any new notifications in red. Notifications will be sent to you when the board has taken an action on a project, or when a project has been shared with you. An email will also be sent to your registered email address when a reminder is triggered. You can silence a reminder by selecting the red flag to the left of the IRBNet ID. Selecting the project title will take you directly to the project overview section for that project. Selecting the message type field will show a preview of the sent email.

The search options allow you to enter a search string or you may search by any of the previously created tags.

The forms and templates menu option will open the forms and templates library. From this page you can select the library for any organization to which you are affiliated and the Central IRB. The electronic wizards that must be completed are also shown on the online document wizards section at the bottom. You will have the opportunity to complete the electronic wizard once you start a new package. Which we will discuss in a moment.

Before we walk through creating and submitting a package, I wanted to discuss the relationship between a project and a package in IRBNet. The project is the approved overall study. And the packages are each action submitted for that study. For a new project submission the IRBNet ID—which is the unique identifier for every project in IRBNet—will have a suffix of dash 1. For every subsequent package that is created for that project the suffix will increment by one number. As an example, a new project is created, and the system generated IRBNet ID is assigned with a suffix of 1. The next package that is created for that project will have the same project ID and a suffix of dash 2. The numbering system continues for every subsequent package created for the project.

For the next phase of the presentation we will switch over to the IRBNet sandbox platform. While we prepare I'd like for the attendees to participate in a poll to find out how many have registered already in IRBNet and how many are actively using IRBNet. Just to reiterate, you must be registered in IRBNet to ensure your active study is appropriately linked to your user account. If you have not already registered please do so as soon as possible. And Soundia, if we could start the poll now.

So please take a few moments and answer the two questions. If you don't see both questions scroll down, there is a second question. And we'll pause for a moment while you participate.

[silence 0:14:05 – 0:14:27]

Angela Foster: And once the time elapses you still have a few more moments. We have 20 more seconds if you haven't already answered both questions you still have more time.

[silence 0:14:37 – 0:14:43]

Angela Foster: And once those 20 minutes expire, we'll have another few seconds—I'm sorry, not 20 minutes, 20 seconds. Once those 20 seconds expire, there we go. Now we have our results. So the majority that answered the poll have already registered for an account. Which is great. Those 118 that did not answer and the 103 that said they did not have an account, please go out and create your accounts as soon as possible.

Okay, and the answers are dispersed for those that are using the system. So thank you very much for responding to the survey.

The planned Central IRB submission process can be described in seven steps and is presented on this slide in a workflow diagram. If you are submitting a post-approval action the number of steps is actually reduced to just five. Again, the planned process is subject to continued conversations. The basic steps though are creating the package, completing the wizards, uploading your study documents, sharing the package, signing the package, and submitting the package. Now we'll switch over to our sandbox.

This is the Central IRB's sandbox environment. I'm currently logged in as Lindsey researcher. This is a test account. So let's go over the steps for creating a new project, uploading the study documents, submitting the package for review, and viewing the review results. The first step, step one, for an initial submission is to select the create a new project link. Which is in the left-hand menu options.

The project information page will open where you will enter your details. So I'll just enter some test information. Okay. Continue.

Step two is to complete the electronic wizards. After answering the project details you'll be taken to the designer page. This is the page where you can complete your project coversheet and IRB information sheet wizards. You'll do so by selecting start a wizard, where you'll see both wizard names. Selecting the wizard name will open the wizard. I'll start with the project coversheet. If you have previously created a wizard, you can actually clone the preexisting wizard instead of creating a new wizard from scratch. So to save time today, I am going to clone a wizard that was previously created.

And you're given the opportunity to go through and check the responses in the copied wizard to verify everything is still correct. Once you've done so, you can select save and exit. Again, for the IRB information sheet I'm going to clone an existing wizard. Verify that all the answers are still correct. And I'm just showing you the different sections of the wizard that you can jump to. And save and exit.

All right. Moving forward to step three, which is uploading your study documents. In the designer window you can select the VA Central IRB library. In the select a library field. Select the appropriate document that you wish to complete and click the download button. The blank form will be downloaded to your PC.

After completing the form and saving your changes, upload the completed form by clicking the attach document button. The file dialogue box will open. Locate the file that you wish to upload. And select open. Select the document type. And the document is now a part of the submission package.

So now I have my wizards uploaded and I have all of my study documents uploaded. And we're going to move forward with sharing the package, which is step four. As a multisite PI study, you may share your package with local site investigators participating in your study. If you are the owner or creator of the project you may share your project with any other IRBNet user. You will be prompted to select the user's organization, user's name and level of access you wish to share. So let's step through this process. I'm going to share this project. I'm selecting multisite as the sharing type. I'm going to search for the other user's organization and in this case we have a test organization. Select the organization and from here you would select the user. And this is intelligent. So once you type in the first letter it jumps there. And save.

The package has now been shared and that user will have access to your package as well as a new package created in their workspace to complete. Now we'll move forward to step five which is signing the package. All packages must be signed by the researcher before submission to the Central IRB. Sign the package by selecting the sign this package link in the menu option. Excuse me. Enter your role. And select sign. You will be prompted to enter your credentials and the package is now signed. You can see the details of that signature. Certification statement as well as the date and time that the package was.

The last step in the submission process is submitting the package to your local research administration for new study applications or for post approval applications and for sites not yet active, submitting directly to the Central IRB. So we'll complete this step by selecting the submit this package menu option. Select the appropriate organization and continue. Depending on how your local research administration has their workspace configured you may have to select the administrator, or it may be automatically routed to all administrators. You would select the submission type, and we do ask that if you are submitting through your research administration that you add a note that the package is intended for the Central IRB. And this is to alert that administrator that the package needs to continue forward to the Central IRB. Once you've entered your note you select submit. And the package is immediately sent to the designated organization's workspace.

And those are all the steps that you need to go through to submit a package for the Central IRB's review. Now let's talk about how you would see the review results. You will get an alert in your email and it will trigger a reminder every time an action is taken. And when a board document is published. In viewing your reminders you can select the project title to be taken directly to the project overview where you can view the review details. The board's decision, and any published board documents. So we'll walk through that step. Here we have a notification that there was a board action. So we're going to click on the project title which takes us to the project overview page. Scrolling down to view the board that made the action we can select review details. That will open the next page where we can see the board action, the review type, the effective date, the current project status for that board, we can also view any board documents that were published by that board. Now let's go through what happens when you have a returned package. A part of the auditing function in IRBNet is to lock all packages upon submission. This prevents packages from being altered. If the administrator finds that the documents are missing from your submission package or any other deficiency, prior to board review the package may be unlocked and returned to you. You would follow— and this is an example of what an unlocked package looks like. You would get your reminder that says a package has been unlocked. You can view the whole reminder, the whole message, excuse me. You can also go directly to that submission to see that the package has been unlocked.

In order to upload additional documents you would go to your designer window, designer page. From there you would follow the exact same steps for attaching a new document. Mark revisions complete, which is an important step if you don't select mark revisions complete then the package is just going to sit. So you have to select mark my revisions complete. Once doing

so you can answer a note for the administrator and click continue. Once you do that, the package is automatically locked again. And ready to move forward in the process.

The administrator will receive notification and email that the revisions have been completed. Now that we've gone through the steps for creating a new project, let's look at the steps for creating a new package for a previously approved project. So I'll go back to my projects and the primary difference between creating a project and creating a package you see that there's no menu option available for creating a new package. In order to do so you have to open your project and then you will see the menu option to create a new package.

Select and create a new package will take you to your designer window where you can complete wizards if you need to complete a new wizard. Attach a document. Documents that were submitted as part of previous packages is also viewable and you can download or view from this dialogue. After uploading your documents you would follow all of the same steps that we previously went through. You assign the package. And you submit the package. Those two steps are exactly the same. That concludes the live demonstration.

I will switch now to the PowerPoint again. And I'm going to just quickly go through all of the steps we just did live. In summary, the primary changes to remember from this presentation are the final date for submissions to the SharePoint portal. Please register for your IRBNet account. New studies are submitted through the local research administration and post-approval actions are submitted directly to the Central IRB.

Before we open the discussion for questions, I would like to point out where you can go for help. The Central IRB forms and templates library will contain all the forms required by the Central IRB and any guidance documents. The VAIRRS SharePoint portal contains training videos and energizers. If you encounter issues while creating or managing a Central IRB project you can reach out to your local research office, the IRB manager responsible for the project, or you may email the VAIRRS project team at VAIRRS at VA dot gov. If you have any questions or comments regarding the VAIRRS program in general you can email me directly at Angela dot Foster at VA dot gov. And for technical issues while using IRBNet you can contact the IRBNet helpdesk at GOV Support at IRBNet dot org.

Finally we've included useful terms to remember when working in or communicating about in IRBNet. The list of Medical Centers that have not gone live yet and their planned Go-Live date, any questions about your local research offices' processes should be directed to that office. Thank you again for attending the Webinar today. As we go forward please remember that the system is new to most of us and we are all learning together. Please be patient and communicate with your local research office and the IRB manager responsible for your study. We welcome your feedback on the proposed process changes. Please send me an email if you're interested in working with the Central IRB in the future to refine the submission process. We're now open for questions.

Moderator: All right and thank you to everyone who has submitted questions so far. Just a reminder that you can submit questions through the Q&A box. And I'm just taking one moment to share my screen.

Angela Foster: Okay, first question. Will data entry submissions be submitted on IRBNet as well after March 12th? All submissions to the Central IRB are to be submitted via IRBNet. Just to confirm, initial submissions to Central IRB will be entered into IRBNet and then routed through the research office. Post-approval submissions such as SAE concerns raised during the admin training yesterday will be submitted in IRBNet, but will be submitted through IRBNet directly to Central IRB by the research team, and not through the research office, correct? Yes. You are correct. This is a change from yesterday's Webinar. We revised the process based on feedback we received from the participants yesterday. So we will still need to communicate that change to the site liaisons. Thank you. If we have a local IRBNet account do we reregister for CIRBNet? No. Your existing account is the account that you keep. You do not need a new account. Does everyone on this study staffing list need to register for an IRBNet account or just PI and study coordinator, person submitting? That is—the PI and study coordinator at a minimum based on if you want to track your training and your credentials in IRBNet you would need to register for an account in order to do so. When will IRBNet be implemented for the Central IRB? All submissions will come through IRBNet starting March 15th, Monday morning 8 A.M. March 15th. When will researchers be able to affiliate their user profile accounts with the Central IRB? You do not need to affiliate your account with the Central IRB. You would only need to affiliate it if you were—you would only need to add affiliations if you were affiliated with more than one Medical Center. But everyone will have access to the Central IRB. You do not need to affiliate your account. Can I ask why packages can only be made one at a time? Since we often are waiting for documents or signatures it would be helpful to be able to make more than one package at a time. So one package for project is what I am assuming from this question, and that's really how the system is structured. I can't answer for why it was developed a certain way. But that is simply how the system is built.

Dr. Don E. Workman: So Angie let me just comment and I'm not sure what the questioner was asking for. But it often has been the case that if you don't have all the documents you don't want to put a protocol or a project forward to the IRB to review. So we typically wait until all the documents are ready and then the whole thing comes in at once. When we do piece mail review that often can drag the process out because we're still waiting for another document. And while it may seem prudent to send forward for instance just the protocol or just the application it really helps to have all the documents at once. Because you need to make sure they all line up and make sense together and we need to review them all and make sure they line up together. Over.

Angela Foster: Will current Central IRB project numbers be carried over to IRBNet project numbers? So when the packages, when the active studies are uploaded for the Central IRB they will receive an IRBNet ID, but we will have the Central IRB, the current numbering system uploaded into the board reference number. I have an active IRBNet account, how do I add Central IRB to my list of affiliates? I don't see Central IRB listed. And again, you do not have to

affiliate with the Central IRB. Everyone will have access to the Central IRB's library and be able to submit to the organization.

Dr. Don E. Workman: Angie, will that access be effective as of Monday the 15th?

Angela Foster: That is correct. They won't see it until Monday March 15th. Will the Central IRB SharePoint be available for awhile after studies have migrated to IRBNet in case there is a need to have access to study records that might not have been downloaded? Yes. The Central IRB SharePoint will remain as a reference until all study documents have been migrated from SharePoint to IRBNet. And the meeting minutes will continue to be posted on SharePoint.

Dr. Don E. Workman: And Angie, if I can just add, this was a question that was asked yesterday, the plan, the long-term plan is to eventually have all of the files that are currently in SharePoint for active and even the closed studies in IRBNet. At least for the active studies. Our goal is to have all of that available electronically at some point. It'll take some time to get there so the plan at first is to take the active studies, the things that are currently in process that you may be wanting to submit a document against and get them up and running as soon as possible with the necessary documents. Both our IRB members and you may be using SharePoint reference. The last version was available, but the next version needs to come in through IRBNet. And so our goal is to start with that. And as soon as we have the contract support in place and we anticipate that's weeks, and hopefully not too many months from now, they'll begin uploading the electronic files until eventually we have everything in one place. Over.

Angela Foster: Okay. Thanks Don. Should new IRB applications be submitted directly to IRBNet or submitted to the local research administration? So I'm not quite sure what you mean by submitted directly to IRBNet, but all new Central IRB applications should be submitted in IRBNet to your local research administration. The local workspace administrator will then submit the package to the Central IRB.

Dr. Don E. Workman: So again, if I can just comment, Angie. If it's a new project it goes directly through the administration. Our goal there is to provide the local site with as much lead time as we can. That a new project is potentially coming so that they can begin whatever processes can be done in parallel with IRB review. It's only that for new applications, not a new amendment, not a new reportable event. Those things will go directly to the Central IRB and not through research administration. So it's again, just that new project application. Over.

Angela Foster: Has Central IRB published contact information for resources for PIs? We get many, many questions about what documents are required from PIs as is. So I'll-

Christine O'Brien: Yeah, this is Christy. There will be instructions for submitting to us and what forms will be needed through IRBNet, VAIRRS. So you'll stay posted. They're coming.

Angela Foster: Is the VA project coversheet PDF, VA project coversheet 1.25.2021 PUBLIC in the VAIRRS toolbox the current version. There are three in the folder. So the three that are out

there should have dates in the name to tell you which one is current. I would really have to look at my files to see which one. I can't say if that one is the most recent. There may be one more version after that. But if it's not posted then it shouldn't—it's not in production yet. They are used to emailing us for VAIRRS questions, but we are not equipped to answer programmatic questions about Central IRB documents.

Christine O'Brien: So definitely forward any questions in regards to IRB documents to the VA Central IRB manager or staff. We can answer those for you. Going back to, if there are instructions to submit to the Central IRB using VAIRRS there will be instructions to help with that process.

Angela Foster: Will any study staff be able to sign and submit or only PI, like UF IRB?

Christine O'Brien: As of right now the PI is the one who signs the package. I believe the system allowed for whoever can designate but for signing the package it will have to be the PI.

Angela Foster: Okay. And I think this is the same, does a package need to be signed by all study team members or only the PI similar to the current Central IRB forms?

Christine O'Brien: The package would, yeah signed by the PI. It can be forwarded or what's the word, submitted by a designated study staff. But again the package would have to be signed by the PI.

Angela Foster: What exactly is a wizard? Great question. A wizard is an electronic form, an electronic questionnaire. It is logic based so it routes you based on your answers to the questions. It routes you in different pathways. Right now we have an affiliate pathway. We will have a Central IRB pathway coming and this is for the IRB information sheet. The project coversheet is really just about your study team and your project details, the IRB of record, and project characteristics. And it applies to all projects whether it's an IRB project or not. Does everyone have to build their own wizards or will there be frequently used packets for CRs or amendments. No. You cannot build your own wizard. The wizards are built by ORPP&E. If this is asking about a wizard for CR and amendments, so yes there is a wizard coming for CR and amendments. Right now we have a wizard just the two wizards for the coversheet and the IRB application. But we do have more wizards coming. A CR closure. And a reportable event also. Good afternoon, local research department at VA Caribbean Healthcare System San Juan are using IRBNet. How will the PI from the CSP study will have access to IRBNet to review all registered study events?

Christine O'Brien: I believe are we asking the PI will have access to view actions taken, you know submissions, they will still be able to view their package for the life of the study. I'm not exactly clear what's being asked. But the PI will have access to the study documents, see event amendments in the total life of the study.

Angela Foster: If you are not a primary site on a multisite Central IRB, would you create a separate package to get approval for the local site? For instance, if the primary site is the Hines VA and you are at the Milwaukee VA, how would you submit the Milwaukee application. I think that's what that means. So when the primary site at the Hines VA that PI when he creates his package, or her package, they would share the package in the multisite share mode with you at Milwaukee. What you'll see at Milwaukee is a brand-new package sitting in your My Projects space that will be a work in progress, it will not be a completed package. When you open that package you will be able to see everything that's in the PI's package, and you will also be able to upload your own documents, complete your own wizards, and submit it through your Milwaukee research administration. Can you clarify how a coordinator could prepare the documents but then the PI would sign? Also is the PI required only to sign an individual document or the package? Is there a difference? Okay. So we've got three questions here. The first question is to clarify how a coordinator could prepare the documents, but the PI would sign. The first thing the PI would do would be to share the package with the coordinator. And this is using the share mode, not the multisite, but sharing. That coordinator would then have access to the package and be able to complete the wizards if necessary, upload additional documents, and then the PI would take over and sign the package using the PI's account and then the package could be submitted. Is the PI required only to sign an individual document or the package? Is there a difference? Yes. The individual document still requires whatever signatures are required today; nothing is changing with the individual documents. The package itself must also be signed to comply with the auditing feature. So the difference is the individual documents and PDF or a Word document, if it requires a signature today it still requires a signature after IRBNet. So the local site, Milwaukee will distinguish what documents are important from the package. If some, if one of the other panelists can answer because I don't really understand that question.

Christine O'Brien: I'm not clear as well, but Milwaukee if it's a local site will have to submit their own documents for review and approval. Is that, I hope that's—I feel bad we're not answering the question.

Dr. Don E. Workman: Yeah, so this is Don. I mean maybe that the-

Moderator: I'm so sorry. This one came, this was a follow-up on the previous question. I can go back to it. It was just clarifying about this.

Dr. Don E. Workman: Just as a comment, there's oftentimes confusion about what the central site or the primary site submits and then what the local site submits. So in this case the local site does not need to submit all the documents that are submitted with the primary site. They only submit the documents that are needed for the local site investigator and the local site application.

Christine O'Brien: Correct. Yes. Thanks Don. So in the same way we do now, the local site will only submit their site specific documents. They do not resubmit information that was

submitted and reviewed and approved on the PISC level. This will be just a local site application if you think of the same way we're doing now, except through VAIRRS.

Angela Foster: Okay. Is there a projected date of automation of uploading TMS and CITI training certificates into IRBNet. So we are working on having this completed in the next few months. There are technical challenges to both systems that have to be resolved. But we are actively engaged with EES for the TMS system and with Dr. Huang for the CITI system. After a PISC amendment is approved, how would LSI updates be submitted to Central IRB? Can the PISC coordinator still submit on behalf of the local sites?

Christine O'Brien: So that's going to be a slightly different process because each, so if the PISC coordinator is shared on the local site package that can be a process that can be worked out with that study team. But it will be an individual package submission from that local site in VAIRRS.

Angela Foster: If an amendment has been approved by Central IRB will those documents be available to the local research committees through VAIRRS? So all of the published board documents would be available to anyone who has access to the app. Will RCOs be able to have access to the study records for auditing purposes? Great question. So individual sites would work with your administrator to gain access to do your auditing. But we are looking into some type of system-wide at least a suggested process granting to RCOs access to more IRBNet records. So to answer the question in short, you would have to work with your local IRBNet administrators so that you could get access to the workspace. If a site that is coordinating a multisite study is not yet live, the PISC site, but the specific operating sites are live, LSIs, can the PISC participate in IRBNet activities and help the LSI submissions for those sites? Yes. So if your site is not yet active then you would be able to submit directly to the Central IRB. You can still go out and create your account, you can affiliate with that site, you can do everything except submit to that site. For new PISC or LSI studies, should researchers include both Central IRB documents and local SRSRDC documents in the same package?

Christine O'Brien: What we're looking for are the CRIB documents for our review. But there's information that we need from the SRS review, so we can take those in the package. I hope I answered that question.

Angela Foster: Yeah I think it's-

Christine O'Brien: What you're looking for.

Angela Foster: You know, kind of like a discussion we had yesterday. If it's a new study how would that same package be submitted to the Central IRB as well as the SRS and the RDC. And yesterday we gave that same guidance that yes, it's the same package.

Christine O'Brien: Correct. Yes.

Angela Foster: Will we be submitting continuing review documents to IRBNet and if so will it begin March 15th as well? Yes. Will the Central IRB studies already be entered into IRBNet and then we just need to add packages for subsequent actions? Or do we need to add the legacy documents into VAIRRS ourselves? So the active studies will be loaded into IRBNet. They will be available to you to submit subsequent actions. And the Central IRB will have the resources to upload the initial approved documents as well as the historical documents over the next several months. When cloning documents, will the program verify the form versions are the most up to date forms? So when you clone a wizard the recipient of that, the recipient receiving board does not have insight as to whether or not it's a cloned document. They would only see the output which is the final PDF. So the only person, or the only individual that would know if it's cloned or not is the individual that created it or cloned it at that time. So. Can the study coordinator sign the submission? And this is a repeat that Christy answered that the PI must sign. The coordinator can submit but the PI must sign the submission. Hello, I am a project manager who often helps study chairs and local site investigators with their submissions. Will I still have that ability? Or will they need to do their own submissions and sign off on their own submissions? You can still help. You would need an IRBNet account. And that PI or LSI would share the package with you and then you would have access to help them compile the documents. They would still need to sign the package and in order to submit you would need full access to the package. How should we handle Central IRB applications that do not need annual review? Do we need to enter them into the system?

Christine O'Brien: I believe all of our projects would be entered in the VAIRRS IRBNet. I don't know if you're saying annual review or continuing review, but there's still a process if there's a study that is going through annual view, we would still need, we have a process the way our current forms- The same request that we have for annual review process then all studies will be in the IRBNet system. Whether you need annual review or not.

Dr. Don E. Workman: So Christy, I think the question was asking for those that have the status update, the annual status update that don't need to go to a convening board, et cetera, that would all still go in VAIRRS. Correct?

Christine O'Brien: Correct. Yes. There will be- Our forms will still have a request for a form to be completed for the status update.

Angela Foster: Who should we contact if we do not see our study listed? So you would not see the study until Monday March 15th. If at that time you are registered in IRBNet and the study is not linked to your account, then you would reach out to your IRB manager or you could email the VAIRRS at VA dot gov email address.

Dr. Don E. Workman: Angie, I just want to add the comment. The whole reason for kind of freezing the system at 8 P.M. on Friday is so that there can be a process that IRBNet goes through that adds the shell, and I'm using words I don't necessarily understand, adds the shell for all of the studies and all of the sites that we currently have in our system. And so we don't want to move that needle so to speak between Friday at 8 P.M. and Monday at I believe it

would be 8 A.M. even though I think your slides said P.M. I probably wrote that wrong. It's only to allow that to happen. So all of this should appear like magic on Monday morning and we're all eager to see whether it does and what happens in there. So bear with us. But that's the reason for the delay. And that's why you won't be able to see these things until presumably when we log in on Monday morning. Excuse me.

Angela Foster: For multiple packages, for instance an amendment awaiting new CRADA and ICF receiving approval responses as well as a second or third package with perhaps a more urgent protocol deviation or some such. Right now the PI can only sign and submit one. So I think this is—okay if you have an approved project, and you want to create multiple packages, you have a package that's pending review, and you cannot create a new package because that current package is pending review. I think that's the scenario that's being painted here. What happens if you have a more urgent package that needs to go through? That's a great question. And to be honest I don't have a direct answer for you because that's a system capability that will not allow you to create a new package. So I would ask if you could please send this—well actually, we'll follow-up after the call. But if you would like you could send this to me in email at Angela dot Foster and I'd be happy to discuss offline. But I don't have an answer for that right now. Will sites on multisite studies, i.e. CSPCC studies be responsible to upload all their own documents? CSP project managers and national study coordinators will not be involved with uploads.

Christine O'Brien: So this goes back to again the same assistance that you currently have with uploading or what you currently give with uploading and getting a package or project ready for submission to the IRB can still occur. You just have to be shared on the project and given the access. And you are able to submit an IRB. Certain packages will have to be signed by the investigator similar to forms that need to be signed by the investigator before submitting to the IRB. But you can still provide that guidance of that assistance in uploading, getting packages ready for IRB submission. Just got to ensure that your permissions are set up for that task.

Angela Foster: If the coordinating center has been handling the application submissions for a PISC, will the PISC now have to do themselves from the local site IRBNet? So I believe this is asking if the LSI will have to do their own application in IRBNet. And the answer is yes. If you want to add anything Christy.

Christine O'Brien: Yes. The same, so the PI will still have to submit or have assistance if there's assistance from the coordinating center to upload a document and then assign. And the coordinators can still assist in handling in submitting to the Central IRB. In regards to the local site, I don't know if they're asking about the local site applications? So it will be the same way the local site investigator will again create the document or have the assistance at the site coordinator. The same way it's happening currently, they will still have to sign the package themselves, but they will still be able to still have the assistance of their staff with submitting to the Central IRB.

Soundia Duche: Say, Christy, this is Soundia, I think I understand what the question's getting at. If right now the coordinating center has been the one handling the submissions to the Central IRB, but now you're requiring that they go through the local research office, can the coordinating center still submit, or do they have to go through the research office to upload the items into IRBNet on behalf of the PISC?

Christine O'Brien: Oh. Thank you Soundia. So the way that we're proposing our workflow is that the coordinating center can submit I believe on the behalf—we'd have to see that workflow—but submit on behalf of the PI to the local research center. For the PISC application, or for the investigator application for new projects. So I believe that can still occur. We'll gladly take feedback on that proposed change. And we will circle back if there's any change to that.

Angela Foster: To answer the question earlier that starts with the multiple packages. A PI can only have one draft package at a time, but the PI can have multiple pending packages that have been submitted at the same time. If multiple packages need to be submitted at once, for example an amendment and a deviation, then the PI submits one package at a time. As soon as the first package, the amendment is submitted, the PI is free to create a second package, the deviation, and submit it right away. So that, thank you to whoever submitted that correction. So when we talked earlier about the technical restraint of multiple packages that was incorrect according to this contributor. That you cannot have- You can have multiple pending packages that have been submitted for review. So once you have a package and that package has been submitted to a board you can go back in that same project and create another new package and submit that package as well. So you would essentially have two packages at two different boards, or maybe even at the same board for two different actions. What is the difference between IRBNet versus CIRB? So the IRBNet is a software application, it's a platform to submit and manage your committee functions. The Central IRB is a body, Don you go ahead. If you want to add.

Dr. Don E. Workman: Sure. I think the question would be what's the different between IRBNet and VAIRRS. And VAIRRS is a VA program that includes IRBNet. The IRBNet has been deployed in 70 sites already through VA and VAIRRS is going to be another instance of IRBNet that includes the Central IRB as well as all of the VA's that are using IRBNet. We'll eventually all be using a single, online program and we'll just have access to different parts of the data. But to go back to a question earlier, entities like ORO if they want to audit will be able to audit any of our projects using a single platform. So it makes a lot of things more convenient, more transparent, and allows us to share best practices. So for instance the last comment was informing us of somebody's experience in submissions. So hopefully the goal is for us to be one enterprise using one system. And we'll be able to share best practices and create reports out of the system that make all of us, give all of us the ability to do our jobs better. So.

Angela Foster: Thank you, Don. Okay, the next question. Do projects that are being submitted to a local IRB also need to be submitted to the Central IRB?

Christine O'Brien: No. If the local IRB is the IRB of record for that project it does not need to be submitted to us. And the same, we only receive projects that we have oversight over. If the Central IRB is the IRB of record it should not need to be submitted to the local IRB for review.

Angela Foster: All right. For already approved active studies, Central IRB studies, when an LSI is ready to submit their first action in IRBNet. For example continuing review for their Central IRB study, do you want the LSI to create a new project in IRBNet? Or should they create a new package within the existing project that the local research office shared with them when IRBNet was launched at the local site? So this is a case where we may have to reconcile the records. But apart from that, you would be creating your package for the approved study. You would not need to create a new project for a continuing review package. If we have a current project, not new, with multiple sites and some of those sites have already implemented IRBNet and others have not, how do we link them moving forward? So you can't—the site that's not live yet won't have a record in the system. So there's nothing that you could do until that site comes onboard with IRBNet. As far as linking the record to the local research administration. The LSI can still create an account, can still affiliate with that Medical Center, can still create a project, and can still be shared on a multisite project. When you say research administration, you mean our local research office? If we do not use IRBNet currently we bypass the local research office and go directly to Central IRB for new applications, correct? When I say research administration, research administration is the intake workspace in IRBNet. So if you are not using IRBNet then you would not have a research administration workspace. Which is why we are permitting researchers from affiliated sites not yet lined to submit directly to the Central IRB. Because they would not be able to submit to their local research administration. Where can we find instructions for getting an IRBNet account set up? Well there's an energizer that's on the VAIRRS SharePoint portal that walks you through all the steps for creating a new account. Once all studies are uploaded and a new submission is created for the first time on an existing study, will the amendment start as dash 1 or dash 2? Well that's all dependent on if there are any actions, other actions that come before that amendment. But if the amendment is the very first action after studies have been uploaded, then that amendment should be package dash 2.

Dr. Don E. Workman: So Angie, just to clarify, the numbering of the package is separate from the numbering of the amendment. So for instance if the first amendment is amendment number 16 in a study that's been going on for a few years, the package may be number dash 1. But that doesn't mean that it's amendment 1, it's whatever amendment would be numbered in the documentation.

Angela Foster: Our local research administration requires COIs to be sent via encrypted email and not via IRBNet. Does the same pertain to Central IRB submission?

Christine O'Brien: So what we would request similar would be the COI form not be uploaded to the package or submission in IRBNet. We would like the final determination review or statement; COI statement can be uploaded in the training credentials location. I think Angie showed in the demo. So that is what we would request the, but we would not request the COI form—forgot the number—uploaded to the training documents.

Dr. Don E. Workman: Right. So if I'm correct, we don't want the OGE 450 that, the long form that gives the detailed information about somebody's financial status. We don't want that in there. What we'd like is for the R&D Committee's Conflict of Interest determination. Which I believe is just a letter that could be put in instead. Over.

Angela Foster: I missed the answer to the question about who needs to register in IRBNet. PI, LSI, study coordinators, anyone else? So whether or not anyone else on the study team registers is really determined by the PI and LSI. It depends if you have any other roles that are helping you complete your package. It's all up to you. But at a minimum I would ask that the PI and the LSI and the study coordinator is going to be submitting on their behalf, then they would also need to be registered. As a national study coordinator for a multisite CSP study, I prepare all of the CIRB documents for all of our 46 local sites and the PI applications. Will I still be able to do this, or will each site now have to prepare and submit their own documents? Yes. You can still assist. You would need an account in IRBNet, and you would need to be shared on that package. But once you are shared you would have access and be able to help with the documents. So PIs are the only one who can create a package and then share it with the study coordinators? Can a study coordinator create a package and submit it to the PI? Yes. The study coordinator can create a package and you can transfer ownership of that package to the PI. And that function is in the share page. You can select transfer ownership and actually the PI would then own the package. For those who submit at the chair level, only half of the local site, is that still something that can be done? Or all LSIs responsible for submitting?

Christine O'Brien: So again, if you are, your role is to assist in submitting the LSI information, that can still occur. You would just have to ensure that you are shared and have the rights to do so for the LSI applications.

Angela Foster: Will SMART conduct audits via IRBNet now? Excuse me. Not to my knowledge. If any organization is going to conduct an audit and using IRBNet then that facility would be aware of it. And if it's at a national level then we would inform all of our users that that audit was going to take place. If an amendment is submitted by the PISC prior to March 12th, will the subsequent local site updates need to be submitted to Central IRB through IRBNet?

Christine O'Brien: Yes. If it's after March 12th the updates would have to come through IRBNet.

Dr. Don E. Workman: And Angie, if I can just go back to the last one. One of the questions that people might have is for instance if somebody comes into audit our local IRB operations that are in IRBNet. Will they in essence be auditing the whole system? So will they be looking at applications from another VA facility or for the Central IRB, or would it only be that they would come in and look at my local IRB files, so to speak? [silence 1:21:14 – 1:21:26] I was hoping you would answer that Angie. I'm assuming that they only see the local files, so the audits would be done just like they're done now. On the local, the files and paperwork, not on the whole system at once. Unless there's some, there's a national audit, that would be very different.

Angela Foster: That's correct. And I was on mute. My apologies. If it's going to be something that's conducted locally at your center, then access would have to be granted locally. If it's at a national level, let's say you know RSD or something of that nature, then it would alert all of our users or notify all of our users that that activity was going to occur. Who will have privilege to share a project to somebody? Will it be only the person who initially created a new project, the owner, on the IRBNet? Or persons who were given full privilege by the owner will also be able to share the project with other users? So the second question is correct. If the individual is shared with full privileges they can also share the project or package. Previously, many coordinating centers for studies submitted documents i.e. CR on behalf of the study sites. Will this still be possible or will sites now need to submit on their own after the coordinating center review?

Christine O'Brien: So, ensuring that the coordinating center representative have the rights or have been shared on the packages that they're assisting with on the local site level. They can still submit to the Central IRB for review. Just ensuring that they have access to the package and the LSI only has to sign those packages though, but the CIRB submission can be submitted by the coordinating center representatives.

Angela Foster: FYI, if a researcher needs to create an additional package, but they already have a work in progress draft package, they can contact their local affairs administrator who can create another package for them. Thank you, [inaudible 1:24:23] the author for letting us know. Thank you. Can a national study coordinator create a site package and send it to the site for sign off? Or does it have to be the other way? I.e. site creates package and provides access to NSC? So I believe this is along the same lines of an individual creating a package and then transferring ownership of that package to the PI. That is possible. Do all packages need to be signed by the PI or just the initial submission?

Christine O'Brien: As of right now, the PI will have to sign all packages. In addition to the initial submission.

Dr. Don E. Workman: So assigning in the system, which is Title 21 Part 11 compliant, you mean in essence the sending, like you send an email, of the final package, is that correct?

Christine O'Brien: Correct. So if I'm understanding the signing of the package they type in your credentials that the investigator is signing the documents and then submission can be done by the assistant or coordinator on their behalf.

Moderator: I'm sorry, it is 4:29 so I think this is just all the time we have. So as for this one last question.

Angela Foster: Are there any plans to add more document type label options in IRBNet? At least locally we are using IRBNet and having to use the other option quite a bit, even for common IRB and R&D documents. So we have given IRBNet our feedback regarding the label options. Because this is a SaaS which is Software as a Service, you cannot request changes to the

software, but we can certainly give them our feedback, as far as you know, what is meeting our needs and what isn't. So as of now, we don't have any plans for additional label document type label options. But that is not to say that IRBNet won't release additional options in the future.

Moderator: All right, thank you so much for all of those questions. Just a reminder that this session was recorded. And the recording will be available eventually. Thank you everyone again for your participation and we hope everyone has a great day.

[END OF AUDIO]