ORPP&E Webinar
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Session: VA Central IRB Site Liaison and IRBNet Administrator Training
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Dr. Don E. Workman: Good afternoon. It's my first time meeting many of you. And I'd like to take just a few minutes to introduce myself. I look forward to getting to know you by name and certainly in person in the months or years ahead. So I've been an IRB administrator most of my adult career. And I have been responsible for the HRPP at St. Jude Children's Research Hospital University of Illinois in Chicago and North Western University. And during my tenure in those two Chicago institutions we were, our affiliated university IRBs oversaw human subjects research at Jesse Brown VA. So I'm certainly familiar with the VA world. I was on the Central IRB, the VA Central IRB from the time they stood up the IRB in 2007 until I resigned from that in 2011. I may have met some of you previously on [unintelligible name 0:00:58] which was the IRB Listserv that was eventually renamed IRB Forum. Or at one of the premier annual meetings which I attended from 2000 to 2011.

Those of you who've gone through the adoption of an electronic IRB system know that this can be a stressful and difficult time, but it's also a great time for us to work together and improve our processes. So we look forward to your input. We look forward to working with you on making this a good system for all of us. And look forward to getting some of the tips and tricks that those of you who have been using IRBNet for a while can share. So with no further ado let me turn it over to Angie Foster. Go ahead, Angie.

Lindsey Martin: You're muted, Angie.

Angela Foster: Thank you. A little mute button challenged today. Good afternoon and thank you for joining us. My name is Angela Foster and I am the VAIRRS program manager. I'll be walking you through the presentation today. And with that I'm going to stop my video to go into screen share mode.

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 Central IRB submission process, and review where you can find additional guidance and support. What happens to the Central IRB SharePoint portal? The portal will not accept any submissions after Friday March 12th at 8 PM Eastern. There should be no submissions over the weekend. Starting Monday morning at 8 AM

Eastern all actions must be submitted via IRBNet. The SharePoint portal will remain for the meeting minutes and as a reference until all study documents have been migrated to IRBNet. We will also continue to post the meeting minutes to the portal. The project data for active Central IRB studies will be uploaded into IRBNet prior to the central IRBs Go-Live. Starting Monday morning on the 15th, the IRB managers will work with the study teams to migrate or upload study documents into IRBNet. We will have additional resources to assist with migrating the study documents from SharePoint for studies within 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. After March 12th, all new actions will be submitted via IRBNet through your local Research office. The Research office administrator will ensure your action is shared with the local site liaison and submit the action to the Central IRB. This is an important process change to note. The Central IRB will only accept submissions directly from the researcher if the local Research office has not yet gone live in IRBNet. The ability to submit directly to the Central IRB will only be turned on for researchers affiliated with an institution not yet live in IRBNet. A list of sites that have not yet gone live and the scheduled Go-Live date is included at the end of the presentation.

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 platform, the VAIRRS website, VAIRRS SharePoint portal and Power BI dashboards. Our 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 VA 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 IRBNet or not—are available in the research organization dropdown field. It is important for all site liaisons to register for an account in IRBNet. Board documents will no longer be posted to SharePoint as all information is available in this system.

Again, this is an important SOP change. The board documents will no longer be posted to SharePoint. All information related to a submission will be stored in IRBNet.

At this point we would like to poll the attendees to find out how many have registered and how many are actively using this system. Just to reiterate, as a site liaison you must be registered in IRBNet to ensure you are notified of the Central IRB review results. If you have not already registered again please do so as soon as possible. And Soundia we can move to the polls now.

Soundia Duche: Open to responses to the poll.

Angela Foster: So you can- Thank you. If you take a few minutes and respond to both questions we just want to get a feel for how many of you all have already registered. And for those that have registered, how often are you using this system. So we'll take a few minutes.

[silence 0:08:11 – 0:08:28]

Angela Foster: Thank you. So are the results posted? I'm sorry I can't see the dialogue. There we go. Okay great. So the majority of you have registered but we do have a lot that did not answer. So we'll take that to mean if you didn't answer you probably have not already registered. Thank you so much for participating in the poll for those that answered.

The Central IRB submission process will change with the implementation of IRBNet. The workflow presented on this slide deck is our vision for what will occur. But we do have the opportunity to work together to improve the process. We invite those who are interested to work with us to refine the process to ensure it is beneficial and meets the need for all stakeholders. One of our goals is to provide the local site notification of a Central IRB submission prior to submitting to the Central IRB. The submission process as we have envisioned it at this point, is a six step workflow. Step one, the researcher completes the package in IRBNet and submits to the local research office. In cases where the local research office is not yet live in IRBNet the investigator will have the option to submit directly to the Central IRB.

The researchers will be instructed to include a comment alerting their gatekeeper at the local research site that the package is intended for the Central IRB. We will stress the importance of including the Central IRB comment in the notification during our training session tomorrow. However, I'm sure there will be instances where the researcher forgets to include the comment. And we will discuss other ways to identify a Central IRB submission in the next few slides. Step two, the local gatekeeper receives an email notification and an alert in the My Reminder section of IRBNet. The email notification should include a note that the submission is for the Central IRB. The My Reminder section includes your reminders for all activity in your workspace. You can select the message type field to view the reminder that was sent to your email. And in the enlarged image of the reminder you can see what the comment will look like, including the Central IRB note.

Step three, the gatekeeper conducts their administrative check per the local policy. In cases where the researcher did not include a comment, the admin check process will reveal packages intended for the Central IRB.

During the admin review, the project coversheet wizard will be included with new study submissions. Section seven of the wizard includes a checkbox that identifies the Central IRB as the IRB of record.

Another great way is to use the tag function. We suggest that you globally tag all projects under the oversight of the Central IRB. If a global tag is assigned to the project in your research administration workspace, the tag will be applied to all new packages submitted for that project. This is the easiest way to tell immediately when a new package needs to be submitted to the Central IRB. The project notes is another tool that can be used to identify your projects. Just like the global tag, all new submissions for this project will share the same project notes.

The project overview section provides details of previous reviews. This section will show you if the project has been previously reviewed at the Central IRB.

Once it is determined that the package is determined for Central IRB review, the gatekeeper will share the submission with the local site liaison.

The sharing process is very straightforward. Select the share link on the submission detail page, select the site liaison from your list of users. This step does require that the local site liaison be added to your reviewer roster, and your research administration workspace. If your local site liaison is not currently included as a reviewer in your administration workspace you can submit an email to IRBNet support to have the liaison added. You would then select reviewer for access type then save.

Step five, is to submit to the Central IRB. Like the sharing step, the submission step is also straightforward. The gatekeeper will select submit the package from the project administration menu on the submission detail page. Select the VA Central IRB office in the select a board field. Select the submission type from the dropdown and click the submit button.

Once the Central IRB has completed its review and published the board document, the gatekeeper at the local administration and the site liaison will have access to review results. Open the project overview page to view the board action. Selecting the review details link will open the detail page where you can view the published board document.

After the review results are published by the Central IRB the project can then proceed forward with local reviews as applicable. And that is the six step process. I will switch now to share my screen and the IRBNet sandbox environment and step through the process with you.

I’m currently logged in, in the sandbox environment. This is a local site. And I am the administrator at that site. We see an investigator has submitted a package to us, and because the project had already been tagged the label is applied to this submission. If I go to my reminders I see where I received a submission notification of this package, and in that notification a note was included for the Central IRB. Now I will go back to the package and perform my local admin check. As part of that I’m going to take a look at the wizard that was included. Now I won't actually open it because I don't think you’ll be able to see it on the screen share, but in the wizard, the researcher has identified this project as under the oversight of the Central IRB. I can also look at the project notes section to see if there are any notes alerting me

to where this project is to be reviewed. The project overview will show me if the project has gone to the Central IRB of a previous package.

Now as the gatekeeper I am going to share my package with my site liaison. And that is the same way you would share it with any other committee member. I'm going to select Ella and grant her reviewer access. I would like to notify her. And I'll just put a little note to let her know it's a Central IRB study. And that's all it is to the sharing step. The next step is to submit the package to the Central IRB. I'm going to select submit this package so that the Central IRB is my institution. It's a new project. And submit. And the package is now off to the Central IRB for review.

So let's take a look at all submissions so I can show you what the review results would look like once a package comes back from the Central IRB. I'm going to open my reviews, and in the reviews you see where it has gone to the Central IRB, and the Central IRB has also submitted it to one of its panels for review. The panel has published a board letter which is available to me here. And I can click, view the letter by selecting the paper icon. And that is the six step process. So I will switch back now to presentation mode.

All right. So that concludes the description of the Central IRB submission process as we envision it today. In summary, please remember that the Central IRB submissions will begin in IRBNet on Monday March 15th. If you are a site liaison and you have not registered for an IRBNet account, please do so as soon as possible so that your gatekeeper can add you to the roster for Central IRB packages.

Before we open the discussion for questions, I did want to point out where you can go for help. Again the VAIRRS SharePoint portal contains training videos and energizers. The recording of this Webinar will be posted to the ORD Webinar page and loaded to the SharePoint portal. If you encounter issues while managing a Central IRB project, you may reach out to your local research office, the IRB manager responsible for your project, or you can email the VAIRRS project team at VAIRRS at VA dot gov. General questions regarding the VAIRRS program can be sent directly to me at Angela dot Foster at VA dot gov. For technical issues with IRBNet and to request updates to your roster and the administration workspace, please email IRBNet support at GOV Support at IRBNet dot org. Finally we have included useful terms to remember when working in or communicating about IRBNet. And we've also included a list of medical centers that have not yet gone live and they're planned Go-Live date.

Thank you 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, your IRB manager, and definitely reach out for help if you encounter issues. We welcome your feedback on the proposed process, and again if you are interested in working with us to refine the process you can send me an email. Thank you again and we are now open for questions.

Moderator: All right and thank you everyone who's submitted your questions so far. I'm just going to show the first question that was submitted.

Angela Foster: How will researchers be submitting their Conflict of Interest statements to the Central IRB for review? Initial review and annual review. Okay. And I think, Christy are you, can you take that question?

Christine O'Brien: Yes. Hi. This is Christy O'Brien. I'm a VA Central IRB manager with the Central IRB. I believe in SharePoint, I've got to switch over to my terminology and use VAIRRS now. I believe in VAIRRS there's a section and when the investigator submits their project that we ask them to link their training credential and COI determinations. That's where those documents should be uploaded. For reviewed submission to the VA Central IRB for their submission.

Angela Foster: Thank you, and just to follow-up. The COI statement not the form, the VA form right, but the statement can be uploaded along with the other study documents. Will site liaisons get an email notifying them of Central IRB approval? So as a reviewer, I do not believe you get a reminder once the board document has been published. And the site liaisons and the process that we propose, the site liaisons would have reviewer level access.

Soundia Duche: Angie, I think there was a question above that you didn't read out, about exempt status.

Angela Foster: Oh, I'm sorry. I didn't see that. At what step would a local determination of exempt status happen?

Christine O'Brien: This is Christy, I believe there's a workflow if there's a study that's being submitted as exempt. I believe there is a workflow that will direct—and correct me if I'm wrong, as Angie said this is still a new process for us—that will direct for local determination of exempt status. There's two wizards, project- I think it's called the project coversheet as well as the IRB information sheet. That if you're saying this is an exempt project it has a separate workflow and I think it will be directed to that research administration office.

Angela Foster: That is correct. This is the IRB information wizard I believe that as I believe that asks the question if they're seeking a determination of exempt status. Who is the gatekeeper versus the administrative clerk? Does the Central IRB liaison fill one of these two roles? So that is really dependent on your local research office. The gatekeeper is a term that we use when talking about IRBNet to identify the person who manages your intake. Now who that person is locally it could be anyone in your research office. The Central IRB would not dictate that portion. So the next question is submission to the Central IRB is done by the gatekeeper. Yes. And are there any steps required by the liaison prior to doing so or is this sharing just an FYI? The sharing is to give the liaison insight so that they can view the published board documents once the review is completed. Did anyone else on the panel want to add to that?

Christine O'Brien: And this is Christy. I think also for the liaison the way we currently work, what we're hoping to address to use VAIRRS for, is that the liaison learns of information at review, submission and review to the Central IRB. If there's anything that would benefit to do prior to submitting to us, I think that's the perfect opportunity to do so. Any reviews, administrative checks that need to be done, that's the opportunity we're hoping that will be the opportunity for the liaison to take lead or to even give us feedback on that. That's what we're proposing to do with this change in flow.

Angela Foster: You did not mention the IRB information sheet. Which supposedly must also be submitted for any project submitted to either internal or external IRB. You only mentioned the project coversheet. If I did not state specifically the IRB information sheet that's an oversight on my part. I do apologize. But when the researcher completes their package they should be completing both wizards. I only highlighted the project coversheet during the demonstration to show where the person doing the admin check would be able to identify if the project is intended for the Central IRB. Our site migrated all Central IRB studies to IRBNet. Is there a way to merge this with the Central IRB migrated studies? Great question. So I actually had this discussion with IRBNet and how we would make sure that we did not have different versions of the same project floating around in the system. And the answer that I was given was that we would take this on a case by case basis. So once the Central IRB studies are uploaded into the system we can look at this, how it impacts each site. And if we can work with IRBNet and the site to make sure there's only one record, authoritative record for the project, that would be a great way to move forward. So who ever asked that question, thank you. That's a great question. Will local VAIRRS study numbers be used for studies already in the system? If not, how will this be addressed to ensure local reviews and approvals already in the system are not lost? So I'm not sure what you mean by local VAIRRS study numbers. There's the IRBNet ID which stays with the study with the submission through its lifecycle. And then there's a local board reference number that is assigned locally by the user. So we would not be overwriting any data that's already in the system with the Central IRB studies. If I think I understand what you're asking and it kind of relates to the previous question wherein we're going to work with IRBNet to ensure there are not multiple records for a study. Or for a submission. Does the VA Central IRB have a Read Me First document in an IRBNet library that can be accessed by all VA's using Central IRB. Great question. So I'll let Christy answer that because I know that she's working on some cheat sheets right now.

Christine O'Brien: Yes. And I like, the idea of a Read Me First, which you mentioned. Put another task on my list to do. But I am trying to develop kind of like little cheat sheets to help with the flow of working with the Central IRB in VAIRRS and how to submit stuff, submissions to us. So stay tuned, and possibly stay tuned for Read Me First document as well.

Angela Foster: Where do you register for an IRBNet account? You register at GOV dot IRBNet dot org. And you select the register now link and then you can create your account. Please confirm you will not show any studies as active upon Central IRB approval since active status is determined once all local approvals are obtained. So the board actions and the project status would apply only to the VA Central IRB workspace. So once they approve a project it will be

marked active, but it will only be marked active in their workspace. As far as what you see at the local site, you would see that the action was approved, but it would have no bearing on how- or have no bearing on the project status for you locally. Since the national privacy officer and national ISSO seem to review most, all VA Central IRB studies, can these be skipped in the local admin pre-preview stage?

Christine O'Brien: So currently for Central IRB review projects, it is a central review by the PO and ISSO. So there really- I don't think there should be a local review, I'm not sure of what the local facilities do. But for Central IRB projects submitting to us, there will still be a central review by the national privacy officer and ISSO.

Dr. Don E. Workman: Christy could we add if I'm correct the MOU also allows for the local site to especially have a look at the ISSO issues because there may be local issues that need to be taken into account.

Christine O'Brien: Correct. So of course. Exactly. Yes.

Angela Foster: What activates happen during administrative review? Training, assuring COIs submitted, other. That is really a process that should be outlined or developed locally. Again the Central IRB has its own standards for an admin review that's conducted for the Central IRB. But for your local research administration workspaces we just ask that you determine if it's to be routed to the Central IRB. Any other requirements for administrative review would be determined locally. And that is really the same answer for the second question. What should we be checking for in the administrative check? Again, for the Central IRB purposes, all that we need you to check for is to find out if the package is to be routed to the Central IRB. If there are other requirements locally then we ask that you meet those requirements as well, but the Central IRB does not determine what steps or what needs to take place for your local administrative review. After the Central IRB approves the local package, does the investigator submit a new package with all material required for local approvals? No. That same package that was submitted to the Central IRB can also be submitted to your local R&DC or SRS. You can route the same package to multiple boards. It does not need to be a new package for every board. When will your SOPs be updated to reflect the IRBNet changes so we can update our own processes for working with Central IRB? Christy?

Dr. Don E. Workman: Well I'll jump on that one.

Angela Foster: Okay.

Dr. Don E. Workman: The current plan is to have the revised SOPs published online the day that we open for IRBNet submissions. So it will be March 15th.

Angela Foster: So are you saying the COI statement must be used or something similar? There should be a COI findings. The Central IRB I do believe, and I'll let Christy clarify, but I do believe

the Central IRB has its own requirement for what they accept for the Conflict of Interest statement.

Christine O'Brien: Yes, so we, if there are no findings- we do accept a statement from the facility or the COI committee saying there are no findings after review of the COI, at the review of the COI submission. So that is what we would be asking to be submitted or uploaded into that section when the investigators submit their package for review. It's asking to link their training credentials and COI statement.

Angela Foster: And I'll just skip to the third question since it's related. Can we submit form OGE 450? No. That form, we are asking that you not upload the OGE 450 VA into IRBNet. You would only upload the finding statement, or the COI statement. Do you envision PISC applications to be processed differently than LSI applications?

Christine O'Brien: Yes. Similar as they are processed now. PISC application would be submitted and reviewed prior to any local site applications to be reviewed and approved.

Angela Foster: Will the site be creating a project for each existing Central IRB submission or will the historical data be captured by the Central IRB and be made available for the study team? The Central IRB will be uploading the most recent review data for all of their active projects. And the active approved study documents, excuse me. I'll let Dr. Workman talk about the plans for the historical documents.

Dr. Don E. Workman: Thanks, Angie. So the plan is to begin populating VAIRRS or IRBNet with the current recent active study information. And then we will be having contract support to backfill the files so that eventually all of the files for active studies will be, all of the packets, all of the previous files will be in there. And previous studies that are currently closed will eventually be added as well. So that's a fairly long-term project but our attempt is to start working with the current documents that are in play and begin backfilling as soon as we can have resources to do that.

Angela Foster: Thanks Don. And I believe this next question is a repeat. Will local VAIRRS study numbers be used for studies already in the system? If not how will this be addressed to ensure local reviews and approvals already in the system are not lost? And again, with the Central IRB data upload it will not overwrite any data that is existing in the system already. If we find that there is an issue reconciling the records we will work with IRBNet to ensure there's one record for the study. But again, no data would be overwritten, no data would be lost. The Central IRB's projects would be uploaded to their workspace initially and will have no bearing on you locally. Can a study continue the review process without local SRS approval? Now that question I cannot answer and I invite any other panelists to input, but I have no insight into the local SRS process.

Christine O'Brien: Will the study- so this is Christy I would say that you would just follow your current local practice in regards to when the local SRS approval is conducted or when, if and when the study can continue.

Angela Foster: Mm-hmm.

Christine O'Brien: I'm not familiar with a local requirement.

Angela Foster: And I think the second question is asking the same thing. Should sites submit Central IRB packages through local SRSB before submitting to the Central IRB and submit to the R&DC following Central IRB approval.

Christine O'Brien: So again, I apologize, I'm assuming maybe it's a safety review board. But I'm not familiar with SRSB panel. But following your local practices and I am understanding for our studies currently as we are now with our current reviews, approved packages, approved documents should be submitted to RDC for review. I believe that's the current practice; I think that should still be followed. But again, follow your local policy.

Angela Foster: If there are corrections that need to be made by the submitting staff, who handles the back and forth communication? Will it be the liaison reaching out to the study team? Or will it go back to the gatekeeper to handle? Who is responsible for accuracy of the submission? The gatekeeper or the Central IRB liaison? So the Central IRB will conduct their own review, both administrative and scientific as they do now. If the Central IRB determines the package is deficient and they unlock the package and return it to the researcher, that notification goes directly to the researcher, it does not have to go through the gatekeeper or the site liaison. And once the researcher modifies the package by uploading whatever documents were missing and marks the package as complete or the revisions as complete, then the Central IRB manager is notified that the package has been updated. But that communication does not go through the local gatekeeper or through the local site liaison. And I think I did address the portion of who is responsible for accuracy of the submission, if there is anything to add, Christy or Don please do so.

Christine O'Brien: No, you're correct. So we'll still do, when it's submitted to us we'll still do our review and if there's additional information that's requested we will contact the study team.

Angela Foster: For those sites which are already using IRBNet and already have their LSI documents in IRBNet along with completed VA coversheet and IRB information sheet, will the migration of the VA Central IRB documents replace the locally completed VA coversheet? No. When the Central IRB uploads their project data it will be in their workspace. It will not have any bearing on you locally. If a PISC will also be an LSI will you still require two separate applications?

Christine O'Brien: At this time, yes, but we are and have been thinking of practice of reducing or removing that second step. But at this time, yes.

Angela Foster: Is there any issue if you already have an IRBNet account at another institution? No, that is not an issue. You can have multiple affiliations to one account. You just go to your user profile and select add an affiliation and then you would be affiliated with both sites. It seems you are putting quite a bit of work, quite a bit of new work expectations on the local site liaison and local site. Is that correct? We are asking the local site to perform the one step of forwarding it to the Central IRB. We are not asking any additional steps of the local site liaison instead of having the information sent to you or emailed to you. You would or instead of you going out into the SharePoint portal you would simply go to IRBNet. But if you feel that, oh go ahead Don.

Dr. Don E. Workman: So I was just going to say, this is Don. We're certainly open to feedback if people have thoughts about that. Feel free to write to us, not just in the chat but the attempt is to make the information available at the site at an earlier time. So that whatever site preparations may be needed there's time for those. It's not intended to give additional work to anybody, but more of a heads up earlier in the process so that you have an idea what's coming down the pike and potentially we have local investigators getting information as well. So again that's the intention behind it is simply to provide people with information earlier. Not to actually give them any more work to do.

Angela Foster: If the local research office is submitting projects to Central IRB or the PIs, will both the PIs and local office get notifications regarding Central IRB status board actions? So the PI would definitely get notifications. I cannot say for certain if the research administration, administrator would also get notification. I don't think that you will, but we have not tested that one feature in our scenarios. So I can definitely follow-up and answer that question afterwards. I'll actually go out and do a test case and see if the local administrator gets a notification. Will there be a review checklist for use to complete to ensure all applicable VA Central IRB forms have been submitted?

Christine O'Brien: This is Christy, I have in the workspace somewhat of a checklist. So stay tuned. It will be in the forms or that library section just to confirm the bare minimum requirements have been submitted and uploaded.

Angela Foster: Will document changes made during review by the Central IRB reflect in the package still in the local workspace? That's a great question. So if the package is returned to the researcher, and the researcher updates the documents in the package, whoever has access to that package would then see the updated package. Will sites still receive a request for local site comments on new projects? Will that be done via IRBNet as well? And I will ask Christy or Don to help answer that one.

Christine O'Brien: And they're referring to the 15 day comment period?

Angela Foster: I do, yes.

Christine O'Brien: As of now I believe so, but that's what we will like communication from you with. Does that communication, is that still needed, does that still work as the site liaison or being pulled in earlier in the process. Maybe consider that review happened ahead of time before coming to the VA Central IRB for review. That's where we'll like feedback on that process.

Dr. Don E. Workman: Yeah, this is Don. I think the intention again in having communication earlier, having the information is that there's more than a 15 day period then to look at that and have opportunity for comment about the protocol.

Angela Foster: Will there be a Central IRB library that the research team can use for forms? Yes. The Central IRB will have a standard library of forms that you can download and complete. Will you be developing, making available in ORPP&E official FCOI finding statement template to be used locally? So we do have a template of the findings statement that I believe is on the SharePoint portal. And if not I can certainly post a copy. We do not have it in IRBNet only because it's a Conflict of Interest statement and we're trying to keep at a minimum the number of documents that we have in our standup library that are related to Conflicts of Interest. In our experience, working with commercial IRBs it has been problematic to have one single package that contains the external IRB document and the local i.e. SRS, RDC documents. Once the commercial IRB approves then we cannot unlock the package to- and I'm not sure what the end of that question or if that's a statement or- But if you've had experience, this is another opportunity for you to work with us and share the issues that you've encountered when dealing with the commercial IRBs and maybe we can use your lessons learned in refining our process. So I'm sorry I couldn't answer the question but hopefully that will help. Will we still have access to the main site's documents such as Central IRB approval letters. There is content in these documents that are important for regulatory purposes and this info is not available in the local documents. So the way that a multisite study is structured in IRBNet the local sites do have access to the PI site's documents. And the published board letters too. So you would as an LSI have access to the PI's documents. Since IRBNet meets the criteria for electronic signature, will signature blocks be removed from ORPP&E IRBNet forms that do not specifically require signatures? Waivers being an exception and must be signed. I'm assuming that must be signed. So we are not working on this now to remove the signature blocks. We do accept recommendations for the VAIRRS change control board to review suggestions to changes to the library. So if this is something you would like the board to consider I would ask that you email me directly, Angela dot Foster and put this suggestion in your email, and I'll make sure that the board has a chance to review. Will the VA Central IRB be using IRBNet's continuing review reminders? Christy?

Christine O'Brien: Yes, within the system, yes.

Angela Foster: Okay. Okay. To follow-up on a previous question you answered, if the locally required documents are included in a package that will be forwarded to the Central IRB, is the Central IRB willing to sift through all of our local documents to find the ones they need? Would it help to have a naming convention for study documents so it's obvious to the Central IRB

which are the Central IRB documents, such as labeling them Central IRB at the beginning of the title? For example in a recently approved Central IRB study, we had 10 locally required documents.

Christine O'Brien: I'm not exactly following the examples.

Angela Foster: So I think they're saying like in a package you know there's 20 documents in the package, but the Central IRB only needs 10 of those documents. Would you consider that an extra burden to have to sift through those remaining 10 documents that you may not need to determine which documents in the package are for the Central IRB. And if that, if you do think that might be an issue might it make sense to create a naming convention for the Central IRB documents?

Christine O'Brien: I believe we have a naming convention, but we can look how our documents are labeled and how we review submissions come in and we do want to make sure that the documents coming into us are clear and the ones that are needed for review. And not have an extra burden on anyone's plate.

Dr. Don E. Workman: Angie, would this be addressed with the use of the tabs to define what different documents are?

Angela Foster: So the tags are applied to the package they are not applied to the individual documents. They can select a document type; in fact, you have to select a document type once you upload a document. And that can possibly be used as a reference when sifting through to determine what documents are for the Central IRB. How will site liaisons be able to access minutes and expedited listings from the Central IRB? So for the foreseeable future, we will continue to post the minutes onto the SharePoint portal. The only way site liaisons will receive all pertinent board notification would be for them to have study level access rather than reviewer access in the research space. Okay. So the site liaisons with reviewer access will be able to see the published board document from the Central IRB. Not quite sure if you're talking about the published board document or just the notification that the document has been published. If you're referring to the notification, then yes they would need a higher level of access. Will completed PO and ISSO reviews be posted in the board document section?

Christine O'Brien: Yes, we would make sure those are posted like similar to what we do in SharePoint we would post their final certifications. As part of the board documents.

Dr. Don E. Workman: Just to clarify that would be the central PO and ISSO reviews.

Christine O'Brien: Correct, yes, central.

Angela Foster: Back to previous question about changes to a current study. Once someone saves the updated package will all the changes be annotated? No. The changes are not annotated. So if a package is unlocked and returned to the researcher to upload an additional

form or change the content of an originally included form and they do so, then that new document would be present in the package but there's nothing, there's no labels or tags for the documents to show what has been changed. In order to receive notifications of board actions, the study would need to be shared with the administrator with full read and or write access to the study. Okay thank you. And that was going back to whether or not the site liaison would be notified once the board document has been published. Who is responsible for forwarding, submitting deviations, SAEs, and other reportable events to the Central IRB? Is the local research office also required to forward submit these time critical submissions for the PIs? Yes. All submissions will be submitted through the local research office and IRBNet regardless of the submission type. So whether it's a new study or an SAE or continuing review it will come through the local research administration workspace where you would then submit it to the Central IRB. When our site receives a request for local site comments from the Central IRB, the local reviewer is unfamiliar with research. What kind of feedback is expected? Should there be a wider range of local reviewers?

Christine O'Brien: So the local reviewer, the local designee, and the local site liaison are identified by the local facility. The VA Central IRB does not have a role or really a say who's assigned that role. So the person who is providing comment or reviewing should have some understanding of research. So but what we're looking for more is just a local context, a local comment how this local facility can and will be able to conduct the study, if there's any local or State issues that, or even facility issues that were not considered by the PISC or even the board during a review. That's the feedback I think the board is looking for. So I hope that helps. I know we get that question a lot during that local period - what comments are expected to be provided. But again the local site liaison and local designee are identified at the local facility. Central IRB does not select those people for those roles.

Angela Foster: Would it be more helpful to label local documents, i.e. CAVHS form, VHSO form. And this is also related to the documents. You can use the three colored stars to indicate Central IRB documents. But Central IRB needs to direct this otherwise everyone will use a different colored star. Exactly. Both of those comments are helpful. Thank you. And regarding the stars, if the Central IRB did decide to use that, that would be published in the revised SOPs. Why are the local site gatekeepers forwarding local RDC review documents to the VA Central IRB? So I'm not quite sure how to answer this question. The way that we have envisioned it is the researcher would submit all of the Central IRB, required Central IRB documents in their package. That package would go to the local gatekeeper, and then the local gatekeeper would submit it to the Central IRB. I'm not sure what the author means by the gatekeepers forwarding the RDC review documents to the VA Central IRB. And I'm sorry I couldn't answer that. But you could certainly follow-up afterwards.

Dr. Don E. Workman: Yeah. And again I may not understand any more better than you do, but the RD Committee reviews I believe subsequent to the IRB approval. So if the intention wasn't for the gatekeeper to be forwarding RDC review documents back to us, it's more to initiate the process so that individuals at the local site have time and awareness of planned projects in their location.

Moderator: It looks like we have one more question that's been submitted that I can copy.

Angela Foster: Okay.

Dr. Don E. Workman: So if I may jump in too, there was a question that was asked previously that I think just got missed. It was if our site is not yet gone live, what are the steps for submission to Central IRB?

Angela Foster: So if your site has not yet gone live, the researcher would submit directly to the Central IRB. IRBNet has configured or will configure the system so that every site that has not yet gone live, the researchers affiliated with that site would have the option of submitting directly to the Central IRB. If your site is already live, that option would be turned off and you would only—well you would not be able to submit directly. The only one that could submit directly would be the research office. Are you saying that the research coordinators on each project are not responsible for submitting to the Central IRB? So I think that something may have been misunderstood. Whoever is submitting, whether it's the research coordinator or the researcher, instead of submitting it to the Central IRB you would be submitting it to your local research administration. That's the only difference. And then that local research administration would submit to the Central IRB.

Moderator: And we have a few more.

Dr. Don E. Workman: Yeah this is a Don, all the responsibilities of the coordinator and the research team, remain on the researcher and the research team, it's just being triaged through the gatekeeper to inform the institution at the earliest possible moment this project is moving forward. So that people have time and visibility on the information. It doesn't take responsibility from the research coordinators or the researcher and put it anywhere else.

Moderator: And there's been a few more questions submitted.

Angela Foster: If Central IRB requires changes to a submission after the study team makes revisions, will the new package come back through the local site gatekeeper or will it go back directly to the VA Central IRB? If the Central IRB unlocks a package and returns it to the researcher, once the researcher has made those adjustments the package then goes back to the Central IRB. It does not go through the gatekeeper. Forcing the research office to submit a PI's reportable events could result in violations of 1058.01 reporting requirements. Shouldn't the PI be responsible? We do not have excess staff to monitor all IRBNet submissions on an ongoing basis. Okay. That's a great point. And I think it's certainly something we should take under advisement while we are refining this process.

Dr. Don E. Workman: Yeah. Absolutely. We certainly don't want a system that creates those kinds of violations. So thank you for pointing that out. Grateful, we'll need to keep that in mind.

Angela Foster: How will you be handling studies with a central coordinating center where all documents are submitted by the LSI to the PISCs? And I will have to ask Christy or Don to weigh in on this one.

Christine O'Brien: So the studies that have central coordinating centers, they have to be shared on the package. Whether it be the LSI or the PISC. They can be involved in assisting the investigators in completing their information. But with VAIRRS it does not- the PISC is aware and can have I think visibility of the submission package going forward. But is not routed through the PISC to be submitted to the VA Central IRB. So it'll be a little slight change in I believe the process from what we can see with how VAIRRS is setup.

Angela Foster: You have stated that VAIRRS should be one package for a new study containing all Central IRB documents along with locally required documents. This is complicated for both Central IRB and local committees. Have you considered having only Central IRB documents in the pa- I'm gonna assume the P is for the package. So I would say that prior to today, no we had not considered it. But just based on the feedback we're receiving, I'm sure that this is something we would take under advisement as well. Do site liaisons need to affiliate their IRBNet user profiles with VA Central IRB? If so when will we be able to do that? And at this time, no. You do not need to affiliate with the Central IRB, you only need to be affiliated with your local site. PI submits a new study and is assigned 1234567-1. That includes paperwork for all the necessary subcommittee reviews. Is the gatekeeper supposed to forward package 1234567-1 to Central IRB or do you envision a new package only for VA Central IRB review? Which would be 1234567-2. The current workflow is that the package 1234567-1 would be forwarded to Central IRB for review. There would not be a second package. Will the local site be responsible for forwarding items like continuing reviews, amendments, et cetera, that we currently do not process? And the answer is yes. All submissions that are coming from the researcher to the Central IRB will come through the local research site and need to be forwarded to the Central IRB. Sorry to go back to before, can other approvals like SRS IBC happen before or can it happen after VA Central IRB approval? So I'll just say that there is a workflow diagram that's out on the SharePoint portal that I believe the IBC is happening before it goes to the IRB. But that is just a suggested workflow. Again we don't dictate the order of events locally. And with that I'll ask if any of the other panelists want to weigh in.

Soundia Duche: This is Soundia, Angie, I concur with what you stated. There's no ORD policy requirement that states an order of review. So there's no requirement that you can only review SRS after Central IRB approval, or IRB approval. Locally you may have your requirements, but from an ORD policy perspective there is not a requirement for the order of review. It's just that the R&D Committee does do the final review. And even that can happen initially before. But they do have to give the final approval.

Angela Foster: Thank you Soundia. If VA Central IRB approves the package conditionally, approval with modifications, the PI will likely need to submit a new package to address the modifications because the package will not be unlocked after IRB review. Correct. Would this package come through the local—I'm assuming that's local research administration, and yes,

that would be a new package for the project. And that new project would follow the same pathway as all the other packages in that it would come through the research administration and then from there be submitted to the Central IRB. Our researchers have the ability to submit to the local research office and to WIRB. Is it not possible to let the researchers submit directly to the Central IRB instead of routing through the research office? That is certainly possible. The workflow as we've presented it today was to provide the local research office early notification of a Central IRB study. But it's not a technical constraint that the package be routed through the local research office.

Moderator: That looks like all of the questions that have been submitted so far. But Angie, there have been a few questions about the training tomorrow if you just want to do a quick plug.

Angela Foster: Sure. Tomorrow's training will be for the researchers and study teams. It will not be the same content. Some of the slides, the opening slides will be the same, but the body of the presentation will be how do you create a package, submitting the package, uploading study documents, how do you handle a returned package, those topics that are relevant to the researcher. Okay. I see we have a new question. Following up on the earlier question regarding order of subcommittee reviews, can multiple subcommittee reviews be conducted at the same time. For example Central IRB and SRS. Or do they need to be done one after the other?

Soundia Duche: Yes, ORD policies-

Dr. Don E. Workman: So this is Don.

Soundia Duche: I'm sorry. Go ahead, Don. Go ahead.

Dr. Don E. Workman: Go ahead. So part of the motivation in taking the opportunity to make process changes with a new system, is that if we give the information to the local site earlier it allows for things like parallel reviews rather than sequential reviews. And there may be some efficiencies that you can pick up from that. We're also trying to shorten our overall time to approval without any [unintelligible 1:17:29] hampering the quality of the review and the content of the review. So again, I would check your local SOPs. Soundia I think was going to comment again on the central policy, which I'd appreciate hearing again. And then you may consider the ways of doing things differently to again maximize your efficiency. Soundia?

Soundia Duche: No, nothing else, Dr. Workman, that's perfect.

Moderator: And again I think we have about nine minutes left if anyone wants to submit some last minute questions. I do have also another question about the Q&A. And just a reminder to everyone that this session is being recorded. And that we will send out the information. Oh, and we have another new question.

Dr. Don E. Workman: While we're waiting for that one, just take a moment and thank the audience for the questions. These are very helpful, very thought provoking. And we appreciate your feedback. Because again we're all entering into the system together under one VA and we want to make sure that we can maximize how we all use IRBNet to our own advantage. Thank you all.

Angela Foster: So there's another question. We were under the impression parallel reviews were not possible in VAIRRS. So if you mean technically possible, they are definitely technically possible. You can route a package to more than one board at a time. It does not have to be one at a time. How are the RCS 10 requirements going to be met? Destruction, six years after study closure. And I think we will have to take that question offline.

Moderator: I've got eight minutes left. If there are any last minute questions. And then I also got a question about the recording for tomorrow's training if people are unable to attend. Soundia, they're able to access the recording through that SharePoint link, is that correct?

Soundia Duche: We've always posted the recordings to the Webinar, our Webinar webpage. And we promise to do that about a week, within a week of the training. If you've registered for the training you will get an email whether you attend or not alerting you that the recording is up. Or you can always go visit our Webinar webpage to see if it's there.

Moderator: And then I also have the question. If the invite has been sent for tomorrow's Webinar.

Angela Foster: Yes. The invite has been sent. There have been about two email messages referencing tomorrow's training. And there'll be another reminder that goes out this evening or early in the morning tomorrow.

Soundia Duche: And Angie, I did put just now in the chat for everybody I put the registration link for tomorrow's Webinar.

Angela Foster: Oh.

Soundia Duche: For anybody who's on, who didn't get it.

Angela Foster: Okay. Thank you.

Soundia Duche: Mm-hmm. I just posted it.

Angela Foster: Thank you. Mm-hmm.

Moderator: And we have another question.

Angela Foster: But isn't the problem with parallel submission, is if different boards require changes in having to unlock the package for one board when still under review by another board. Which we were previously told in VAIRRS training was not possible once submitted. That is correct. Once you submit a package to the board, the package should not be unlocked.

Soundia Duche: But—this is Soundia—just playing devil's advocate, that does not mean one could not incorporate said changes later on. Correct, Angie? So let's say you got changes from the SRS but it's still under review by the CIRB, once those changes are made could you not as an investigator incorporate that at some point during the review process of the CIRB?

Christine O'Brien: This is Christy, that is correct. So it doesn't say you know not to do the parallel submission because those changes can be implemented. Or incorporated with the other board at a later time during that review.

Moderator: Again there's five minutes left in our time; in case anyone has any last minute questions. All right, I'm not seeing anything else. Oh. Wait. And for Kelly, this might be our last question.

Angela Foster: Will Central IRB approvals all be published as board documents so local site reviewers can see them as well? Yes. All of the board actions will have a published board document.

Dr. Don E. Workman: Absolutely, thank you.

Angela Foster: Yes. Thank you all for your feedback and please reach out if you're interested in working with the Central IRB.

[END OF AUDIO]