Don Workman: Good afternoon, thanks for taking some time. We want to go over some important changes that are being made to VA Central IRB forms. And in preparation for talking about those changes I wanted to cover some issues related to continuing review and to IRB approval. The next slide?

When the topics we're going to cover include what does Central IRB approval mean? What is continuing review approval for a multi-site project, which is different than continuing review approval for a single site project, different than the same. How is the VA Central IRB process structured? That's the part that's particularly different. What changes have been made to documentation and what is still to come? And then I'll be handing it over to my colleague, Jessica Kroll, to talk through the changes to new forms. Next slide.

What does Central IRB approval mean? It's the same as any IRB approval. The criteria for approval or in the regulations in Section 111, we refer to it as, and it includes seven criteria. And these are abbreviated. But the risks for subjects are minimized. It doesn't mean there is no risk, but the risks have been minimized through using sound research design, and when possible by combining research interventions with clinical interventions that may already be being done.

Secondly, risks for subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. It's unacceptable to put subjects at any risk if there isn't some anticipated benefit, either to the subjects enrolled or from the knowledge that we'll gain.

Third, selection of subjects was equitable. This has to do with the justice principle and the idea that the risks of benefit should be shared by the same population of people who will benefit from the research. Risks and benefits should be equitably distributed in social terms. Fourth, informed consent will be sought from each prospective subject or legally authorized representative in accordance, and to the extent required by regulation. The informed consent has to be adequate, it has to meet all of the requirements.

And five, informed consent will be documented unless documentation or informed consent have been waived. Six, where appropriate, the research plan includes adequate provisions for monitoring. And then, finally, where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data. Next slide.

In addition to the criteria for approval, IRB approval from the Central IRB means that relevant VHA policies and their requirements have been met in the research. In particular, Central PO and ISSO review and approval have been granted. And then the bullet below that, I'm sorry, it's a little bit short. It should say exceptions.

At times we actually issue a Central IRB approval before the final ISSO review approval is documented in IRBNet. Because sometimes there are delays, for instance, in the research or getting back in terms of ATO questions or other questions that have to do with ISSO review. But typically, they're all reviewed and approved before we issue the approval letter.

In addition, the informed consent document conforms not just to federal regulations but to VA-specific language requirements. The requirements for waivers of HIPAA authorization or waiver alteration of informed consent or informed consent documentation have also been met. And then, if applicable continuing review period has been assigned no less than annually, but appropriate to the degree of risk.

Continuing review is part of the IRB approval for research that is either more than minimal risk or that does not fall into the categories of research to be reviewed by expedited procedures. Generally, with the 2018 regulations continuing review is not done on expedited review research, unless the IRB determines and documents a reason for requiring it. But continuing review really isn't an opportunity for the IRB, at least annually and oftentimes sooner, to go back and ask all of those questions again about approval of the research. Does it still meet the criteria for approval? Next slide.

What is continuing review approval for a multi-site project? The regulations and policies don't articulate the requirements specific to multi-site research, but they do dictate the requirements for continuing approval. In the case of multi-site research, the Central IRB divides that into the PI project, the Principal Investigator or Study Chair. We used to use that terminology; and then the Local Site Investigators.

And the key is re-approval of the research is re-approval of the whole research project. And as number three indicates, when we re-approve the whole project that includes re-approval of the sites, their investigator for the informed consent documents. In the VA Central IRB we do have a unique structure and process. Next slide.

Some Central IRBs or IRBs that review multi-site research get simply a single application that comes in from the investigator or the sponsor to review for that study. In the VA Central IRB we get both an application that comes from the PI or Study Chair, and we also get LSI applications, which are supplemental continuing review applications that feed into the PI application itself.

We have IRBNet set up so that there are notifications that go out 90, 60, and 30 days prior to expiration of IRB approval. And if the study lapses or the approval period expires prior to re-approval, there is a final notice that goes out that instructs the research team to stop all research activities and to be in contact with the IRB Chair if there are subjects who are currently enrolled.

That notification process is automated; and then we do get, as I mentioned, both the PI application. And the PI application synthesizes some of the LSI information and so that, again, the IRB can review the study as a whole.

Re-approval of the study is done at the PI level and applies to all the sites who are active and have submitted their supplemental continuing review application. And that is indicated in the PI continuing review application. In the past letters have gone out to the LSIs, local site, acknowledging the re-approval of the study, but they indicate or would appear to indicate that the supplemental application has actually been re-approved. And that's caused some question. Next slide.

We want to explain that, again, the acknowledgment of the LSI supplemental continuing review application does not mean that the LSI has not been re-approved. The re-approval is being given at the level of the PI. And in the near future we have a template that IRBNet is still working on that will list on that letter all of the sites that are re-approved with the approval of the project as a whole. That will be a little clearer documentation. It is not available yet, and we're hoping to have that from IRBNet soon.

Anyone who has, who is associated with the LSI project has access to the PI documentation. One of the things we want to touch on a little bit later is how to do that from the LSI project, so that you can access that PI re-approval letter. And then the continuing review application, as I mentioned, lists the sites and their status at the time of continuing review. Next slide.

A couple of things are still to come, one is the revised approval template that I mentioned for the PI continuing review approval. And the list will, again, make it very explicit which institutions, which facilities have been re-approved with the re-approval of this study as a whole.

We also will be distributing a memo clarifying that the PI submission approval that we're giving until that letter comes out applies to all of the sites listed as active in the continuing review application. Next slide. And with that, I'll turn it over to Jessica.

Jessica Kroll: Thanks, Don. Now we can move on to the next portion of the webinar and discuss the new project forms. Next slide, so the objectives of this section will focus on recent changes to Central IRB new project forms.

This portion of the webinar will cover the following: a general overview, a description of new project forms, process updates, and what to expect next. Next slide, so the overview; next slide. Why change our forms and process?

There are a number of reasons for this. And first, it was to better align our forms with the required IRBNet wizards, to improve the usability and to provide better instructions for researchers; and to eliminate unnecessary submission forms, reducing the number of Central IRB forms altogether. And to focus on capturing relevant information for the Central IRB to conduct an efficient and compliant review, and this was done by eliminating duplicate questions across all of our forms. Next slide.

New project forms, all of our forms have undergone some minor formatting and administrative changes. These changes include new headers, instructions, and improved fillable formatting. As I go into detail, the next slides are going to provide a summary of the significant changes that were made to each form, provide a date the form will be released for use, and the date that the new form must be used by. Lastly, we'll provide a list of all the forms that are going to be discontinued. Next slide.

This past year the Central IRB has planned to release forms in three scheduled phases. Phase 1 was the release of our continuing review forms and that took place back on June 14. Phase 2 was the release of post-approval submission forms and that was on June 28. Now we're in the last phase, phase 3, and we're releasing the remainder of our forms, which are the new project forms. And these new forms will be released tomorrow on October 25th. Next slide.

The next two slides here will list and describe new project forms that are going to be released tomorrow. In the far right column of the table there is also going to be a date of when the new form must be used by. We have made some significant changes, and as you can see here there are now two protocol templates that can be used based on the type of project. There is Form 100, the protocol template, and this will be used for projects that involve subject interactions or interventions.

Form 100 protocol template will be used for data specimen only projects, meaning the project will have no subject interaction or intervention. Overall, new sections have been added to the protocol templates to collect more comprehensive information and to focus more on the multi-site aspects of a project.

They have also been revised to incorporate elements of Form 108 as Form 108, the PI New Project application will be permanently discontinued. Lastly, the protocol templates include more detailed instructions and guidance to help the researchers write the protocol. Next slide.

There are no significant changes to Form 105 for Request for Exemption. Form 107, Co-PI in a different VA facility, this is a new form and this is replacing old forms 105a and 108a. This new form can be used for exempt and non-exempt projects. However, it is important to note that this form is only required when there is a Co-PI at a different VA facilities. When there are Co-PI's from the same VA facility there is no need to complete this form. I have on the table Form 109, Coordinating Center Supplement, and this will be a new form to replace Form 108b.

However, this form is still currently under development so this will not be released until early next year. Lastly, we have the Information Sheet Wizard and this has been revised as it pertains to Central IRB multi-site projects. For a lead PI completing the wizard there have been new questions added and existing questions have been revised, ultimately to ensure that there's comprehensive project level information being captured.

For an LSI completing the wizard there were a significant number of revisions. The LSI will no longer be required to answer questions that are going to be specific to the overall project. The LSI will only be required to enter information as it pertains to their local site activity. What this means is that all project level information will be captured in the PI IRB Information Sheet Wizard. Next slide.

Here we have a listing of Central IRB forms that will be discontinued on January 2nd. This is in an effort to reduce the collection of duplicate information across multiple forms. As we all know at the Central IRB, we had a number of forms that all collected very similar information. We're hoping to reduce that redundancy and reduce the amount of issues of inconsistent information being provided, which often led to multiple rounds of revisions being needed. This table provides a description of where information from a discontinued form will now be captured. Next slide.

Now that I have provided an overview of the form changes, I would like to share some process updates and some new requirements as it pertains to those changes. The discontinuation of Form 108, so all information that was captured in Form 108, the PI New Project Application, is now going to be captured across the IRB Information Sheet Wizard, the Project Cover Sheet Wizard, the Protocol Template, and the ERDSP.

The 108 was discontinued to eliminate, as I mentioned before, the duplicate questions and the collection of very similar information across multiple Central IRB forms. With the Form 108 no longer being required, we hope that the process of completing a Central IRB submission will be more streamlined and simplified for our researchers.

With the discontinuation of Form 108, the Project Cover Sheet Wizard will now be the new source documentation when key study personnel are listed, added, or removed from a project. However, I would like to note that a new study team tracking wizard is currently under development with VAIRRS, that should be released at some point in the near future. There will be more information shared with the field regarding the new study team tracking wizard at an upcoming VAIRRS webinar. Next slide.

Existing projects with old forms, the Central IRB is not going to require projects submitted prior to January 2nd to convert old forms to new forms. For example, if a project was initially approved in 2021 with the old protocol template in a Form 108, the study team is not going to be required to update their study documents to the new protocol template.

However, I will state there is an exception to this, and that is with the IRB Information Sheet Wizard. When the Information Sheet Wizard is going to be updated, which will be tomorrow, October 25th, all projects with an existing IRB Information Sheet Wizard will be prompted and required to answer the new questions in the form the next time the form is going to be revised.

Again, as I mentioned, VAIRRS will be holding another webinar later this year where more information will be provided with the field regarding those changes. Next slide.

LSI New Project submissions, here we had made some pretty significant changes, again in an effort to reduce the amount of work for LSI study teams as they go through the Central IRB new project submission process. With that, LSIs are no longer going to be required to include PI project level information in their submission.

Form 104, the LSI New Project Supplement and the LSI's completion of an Information Sheet Wizard were revised to remove questions pertaining to PI project level information. These forms have been redesigned so that the LSI is only required to provide local context information pertaining to their site's involvement in the project.

All project level information such as study procedures, the risk level, expedited review category, et cetera, all of that will be described and approved within the PI project. With that, the PI will be responsible for ensuring that all participating local site activities, and procedures are described in the protocol, and other applicable project materials. Next slide.

I'm sure the last slide had raised some questions about how local sites are going to be able to review the LSI submission and know what the project is about if the project level information will no longer be included? And the answer to that is that they can access the PI project directly from the LSI project. Local site study teams and local site research offices have access to project level information through the PI project in IRBNet.

All project documentation like the protocol, the information sheet, determination letters, all of that can be accessed by navigating to the project overview page in IRBNet, and clicking on the lead site details hyperlink. We have uploaded some instructions to the Central IRBNet library, and the document is titled, *Instructions Multi-Site projects in IRBNet*. And we recommend reviewing that document for step-by-step instructions on how to follow these steps to access the PI project information. Next slide.

Here is a screenshot from the project overview page of an LSI project. Any site that has had a project shared with them through the multi-site function is automatically given access to not only the lead PI project, but to other participating sites. Local sites may want to use this function to access the PI protocol or the PI Information Sheet Wizard to review that project level information.

An example of this would be when a local site might want to access the PI initial approval letter or to get access to the latest PI continuing review approval letter. You would follow these steps as they're outlined in that reference document that's in our library, and it will show you exactly how to get there. Next slide.

LSI site-specific differences or changes, so there is a new requirement in place when an LSI is going to be documenting a site-specific difference or request a site-specific change at the time of an LSI new project submission or an LSI amendment submission.

In these instances the lead PI must provide a memo or an e-mail with concurrence of the site-specific differences as well as indication that this will not be implemented across all participating local sites. And then that memo can be uploaded to the IRBNet package for Central IRB review. And the reason for this new requirement is to ensure that the PI is made aware of any changes that are being proposed or requested at the local site level. Next slide.

As this is a new requirement I would like to share an example of the scenario when PI concurrence would be required for an LSI site-specific change. In this example the LSI is planning to submit an amendment to the Central IRB requesting approval to use a revised recruitment flyer at their local facility. The LSI redesigned a recruitment flyer that was approved as a MODEL document under the PI project, and they're going to be adding new images, and new content, which is all in addition to their local contact information. In this scenario the PI would provide a memo concurring with the LSI change to the MODEL recruitment flyer, and indicate that this change is site-specific, and that it's not going to be implemented across any of the other participating local sites.

I would like to note that when the PI is assessing and providing concurrence of this change, that if the PI is planning to actually incorporate that change that the LSI made into the PI MODEL recruitment flyer or other MODEL documents for other sites to use, then the PI should not provide concurrence for the LSI change. But rather they should submit that change as a PI amendment. By submitting it as a PI amendment is what would allow not only that site but other local sites to use that recruitment flyer. Next slide.

While still on this topic it is important to note that some local site-specific differences or changes must be approved at the PI level and cannot be approved in an LSI submission. An example would be if the LSI is requesting or planning site-specific differences to the study design, study procedures, or activities that are not currently approved under the PI project, then the PI must first update their project via an amendment prior to the local site beginning procedures or activities that are not yet approved.

Some examples could be if the local site is requesting revisions to the project's waiver of informed consent or if the local site is using a specific local data source. Ultimately, the PI is responsible for ensuring that all local participating site activities, and procedures are described in the PI protocol, and in the other PI project materials. Next slide.

PI oversight, this is a reminder that the PI team does have a responsibility to review LSI new project packages prior to the LSI submitting to the Central IRB. And this is to ensure that the site is following the currently approved protocol and using the correct MODEL documents. This allows for a more efficient review process with the Central IRB and can reduce the need to unlock the LSI packages for corrections.

The Central IRB does recommend that when the PI is also going to serve as an LSI that they have the PI submit their LSI new project first in order to serve as a MODEL LSI applications for any of the other sites that plan to submit following that. This can really help streamline the submission process for other LSI new project packages. Next slide.

PI project documentation, this is a reminder that PI project documents must stay up to date and always reflect what the project is currently approved for. When an approved project is submitting an amendment it's a reminder just to double check and make sure that all applicable documents are being updated, if they're being impacted by that proposed change. Next slide.

What's next? Here are some tips. Next slide, please? Thank you. Here are some tips for preparing for these upcoming changes. First, continue to always download forms directly from our IRBNet library when they're needed. And this is just to ensure that you're grabbing the most current version.

The Central IRB is going to continue to provide communications to the field as we go through this process, so keep an eye out for e-mails. We'll be posting updates in the VAIRRS newsletter and we'll be also posting information on our website over the next few months.

We will also be updating our researcher guidance and instructions that should be completed by January 2nd. And that will be available in our IRBNet library. We would also like to remind study teams to use version control in IRBNet to maintain revision history of any existing documents. And if there are any questions about a new process, please always feel free to contact the Central IRB manager that is responsible for your project or a Central IRB administrator.

I would like to note that during this transition to new forms we are willing to work with study teams and to be flexible in accommodating for any submissions that are in progress during this time. The next slide…. That was the last slide and we can move on to questions.

All right. Can you define key personnel? What is an LSI? Currently, we do not have a formal definition of key personnel, but we are following the guidance document that is provided by ORD that describes key personnel as anyone in the role of an investigator or someone that is named in the submission document, so named in the protocol or other project materials.

An LSI is a Local Site Investigator. An LSI is an individual that is responsible for delivering the project at a participating site of a multi-site project. The next question is, does this include change of LSI and addition removal of Co-I? I'm not quite sure what that is pertaining to, but if you would like to put that question back into chat with a little bit more context, we can answer that question following the webinar.

Don Workman: Jessica, if I could just jump in?

Jessica Kroll: Yes.

Don Workman: The examples that you used where you referred to a Co-I as a co-investigator, a co-PI. And I may be mistaking the question, but there is a distinction between the co-PI and the co-investigator. We have a number of different terms that are used, somewhat interchangeably like a co-investigator, LS, Local Site Investigator, or sub-investigator.

And we don't need to confuse people but we try to use the terminology that's consistent with, again, the guidance document. It's the document from 2013 that's in the ORPP&E guidance. Over.

Jessica Kroll: Thanks, Don. What type of packages, if not all of them, are project and/or information cover sheets required for? Information Sheet and a Project Cover Sheet Wizard are required for a PI new project submission and an LSI new project submission. Outside of a new project submission, they may need to be submitted at the time of an amendment if any of the content within those forms is affected by that amendment.

Regarding Form 107, is this only intended to allow for the lead PI, lead site PI, or is there an option for this to be utilized for single site LSI collaborating with another site for recruitment? From a Central IRB perspective we are only using that form in the case of a PI. When it comes to LSIs, co-LSIs should be at the same facility.

If there were co-LSIs at different facilities that would require both of those LSIs to submit individual LSI applications. If it's something that you're interested in utilizing for single sites, you can take the form and model it as appropriate for your facility.

We submitted an amendment to Central IRB for approval of an additional study coordinator. Amendment was approved. We were told if a study coordinator obtains informed consent from a subject, then the study coordinator should be considered key personnel even though the study coordinator is not listed on any subject facing materials.

I would recommend sending an e-mail to, you can send it to me offline. And I would like to look through that, and see how that amendment was processed. It's difficult to say without understanding the full context of the submission.

How will removal of overall project information from the IRB Information Sheet affect dashboard reporting for those elements of local site studies? Angie, would you be able to speak to this?

Angela Foster: Sure, Jessica. The dashboard team has already started working on revising the dashboards to align with the questions in the revised IRB Information Sheet. Starting next week, once we get our first extract under the new structure you'll see changes to how your data is reported on the dashboard. As always, if you find any issues or have any suggestions, please reach out to us at VAIRRS at VA dot gov. And if we need to address anything at the site level, we will certainly do that. Thank you.

Jessica Kroll: Does an LSI site need to submit an amendment form in addition to cover sheet when there are new staff, or is a site update memo with cover sheet okay? What about staff departures? If there is an addition of key personnel, then the Central IRB requires that to be submitted as an amendment and would require the cover sheet to be updated with those key personnel.

For staff departures, that process is managed with your local facility. The only time the Central IRB would process a staff departure or staff removal is if it was the Local Site Investigator or the PI, and there was a replacement of oversight for the project. Next question.

For 1200.01 Directive, RDC does not review Central IRB amendments. With the exception of studies with SRS components, the recent change of non-key personnel are no longer required to be submitted to Central IRB for approval. How does this work considering local sites are not the IRB of record and the study oversight is by Central IRB, not our local IRB or RDC? This is not only the 1200.01 Directive, but also local policy. How should the study team proceed?

I would recommend reaching out to us offline and we can have that discussion. Typically, local sites have been able to process non-key personnel changes locally. It is difficult for the Central IRB to dictate how that would occur at a local facility. But, Don, I don't know if you have anything you would like to add as it pertains to 1200.01 in regards to this question?

Don Workman: Yes, no, I think your answer was fine. The issue we have as a Central IRB is we're linked to the 108 facilities. We have to be careful not to try and stipulate processes that would be unique to a facility. It's just the set piece, send an e-mail to us, and we'll be happy to look into this, offer whatever feedback we can. Over.

Jessica Kroll: Will there be a template provided for the e-mail memo to use for the PI concurrence for the site specific changes? We don't have a specific template, but as part of our new forms we do have a memo template now, I believe that is Form 140 available in our library. And you could utilize that memo template.

Please clarify, there will be site specific sections in the main PI protocol and ICF documents? There won't be site specific sections in the consent forms. But the main PI protocol template has been revised so that it can identify if any of the sites are doing something specific or different than the other sites. That will be able to be described in the protocol template as well as in the LSI IRB Information Sheet Wizard. There will be a question in the wizard that asks if there is any specific site differences.

What is the role of local R&D in oversight of exempt study or limited study reviews at LSIs when it comes to amendments to the site's activities? I will defer this question to a later time. The Central IRB is working on some new guidance as it pertains to exempt research and that will be shared at an update in the near future.

Regarding submission of PI concurrence memo for an LSI amendment, is this required for an LSI amendment to add or remove an investigator? No, that would not be required because it's just documenting personnel. It's not documenting the site specific change from what's currently approved at the PI level. Think about PI MODEL documents, anything described in the protocol, things like that, so this will not affect staff.

Please confirm that LSIs will or will not submit an IRB Information Sheet Wizard. Yes, LSIs are required to submit an IRB Information Sheet Wizard. But as I mentioned today, the content within that document has been significantly reduced, and now is focusing on local site specific information.

Will Central IRB eventually define what key personnel is? Yes, we hope to do that in the near future.

Don Workman: And let me mention, Jessica, if I could just add? I did put at one point in the chat the link to the guidance document we have referred to. And again, it does, it has a section that refers to key personnel. As somebody else noted in the chat, there are numerous definitions out there. And if you even look at the NIH guidance, and NIH actually began, for instance, the education requirements for key research personnel in the section that talks about the continuing education of human subject protections, key personnel is defined differently than it is in the grant application section.

It's a general term. It's a term of art, it's used different ways in different places. And I'm not sure it's helpful to add another definition to what are already a bunch of definitions, but we'll certainly take this into consideration. Thanks, over.

Jessica Kroll: What changes are –?

Don Workman: Jessica, did you want to add something in terms of in terms of key personnel?

Jessica Kroll: No, that was all, thanks, Don.

Don Workman: Yes. I think Karen wanted to add something.

Jessica Kroll: Right.

Karen Jeans: This is Karen Jean, sorry. I'm with the, again, Regulatory Affairs with ORD. In terms of the definition of key personnel from an ORD policy perspective, what has been stated is we don't have a definition. It's not a regulatory term. But basically in terms of what we consider to be key personnel, are those individuals as part of a research study.

And whether it's human subjects, whether it's animal, or whether it's basic lab, those individuals who are directly involved in the conduct of the study for human subjects, those individuals who are directly involved in the study procedures, or in the cases of, of course, accessing information, accessing and analyzing, obtaining that individually identifiable information, if it's PHI.

In terms of, we're talking about an IRB process, that is, what you're asking is, what does the IRB wish to consider as key personnel in terms of listing on the protocol? And again, that's an IRB process. And you'll see that differ, as Dr. Workman has said, across different IRBs. It's not just a – because it's not a defined terms.

In terms of ORD, we have a guidance document that was published in 2010 that is regarding when do key study personnel need to be submitted to the IRB for approval in terms of revised protocols for non-exempt research? And that's when we have that person who is named in the protocol, no matter what they are, if they're like a study coordinator and they're named in the informed consent document, you change them, and their name. That has to go to the IRB, but also any investigator and any principal investigator.

But again, I want to say something, that there was an earlier question about R&D. Again, we're talking about IRB processes. And if you're bringing on people into a protocol, the IRB is not responsible for making sure they have all the requirements in terms of credentialing, privileging, if that's true, their education requirement. That's a research office process.

The reason I wanted to jump in, and I am grateful to be allowed to jump in, is remember, there is a difference between an IRB, and again, what's required from a research office standpoint of bringing on new people that are added to a protocol in terms of, for example, making sure they have their training before they come into a protocol. Thank you.

Jessica Kroll: Thanks, Karen. All right. What changes are being made for continuing review? I see on IRBNet, there are new forms. There were a number of significant changes that were made for continuing review process and our forms. I would recommend going back and listening to the webinar from June 14th – June 13th. And then also on the Central IRB website, we have a document that describes the summary of changes for continuing review. And you can also reference that material there.

What is the difference between LSI approval date and LSI verification date? I believe this is pertaining to the consent form. I think the LSI approval date is the date that the document is approved. And then the verification date is the date that the document is stamped. But I will admit, I don't think I have the exact definition off-hand, but I would be happy to provide a more specific explanation of this following the webinar. Sorry, I don't have an exact answer for this one.

Can you clarify whether HIPAA authorizations approved for a project is required to have a privacy officer approval stamp? I can't speak to that. At the Central IRB we put a Central IRB approval stamp, and we also have a privacy compliance review that gets completed. But if you have any other questions I'd recommend reaching out to the central privacy officer to address that.

Co-LSIs need to be at the same facility or can they be at different facilities under the FWA, under the same FWA? I think you can reach out to the Central IRB and provide a little bit more context to that. If it's the same FWA, it sounds like that would be the case, but I wouldn't want to answer that question without more context.

Is there an infographic available to share with the team with an overview of IRBNet? Angie, would you like to share where IRBNet training materials and resources can be accessed?

Angela Foster: Certainly, Jessica, thank you. All of the IRBNet training materials are located on the VAIRRS SharePoint under the VAIRRS University. From there, you can go in a role-based pathway, whether that be a study team member or an administrator, and view the work instructions, the videos, previous webinars, anything and everything that we have curated that's relevant to your role. And again, that is available on the VAIRRS SharePoint under the VAIRRS University. Thank you.

Jessica Kroll: Thanks, Angie. Do you have a definition of a VA project and the distinction between protocol and project? There is no specific definition, and I do know that they are used loosely, and interchangeably. Protocol is typically the document that describes all the study procedures, and activities, and everything that's going to be occurring; and project is typically referred to the overall. No, there is no specific definition for either of those at this moment.

Can you confirm we do not need to submit to the Central IRB or update the cover sheet when staff depart unless the study is the PI or LSI? Correct, so staff removals do not need to be directly submitted to the Central IRB for review unless it's the responsible investigator, the PI or the LSI. And that's just to ensure that there's a transition of oversight for the research.

Don Workman: And that looks like the last ones that have been approved. As a general note, I want to mention to folks, I've seen a couple questions about the recording or slides, as a reminder, all of the ORPP&E slides are going to be available on our Webinar Archive page. I will copy that link in the chat, but if you do a simple Google search of VA ORPP&E Webinar Archive, it will be your first result.

And we typically have the recordings and slides up within 48 hours of the presentation itself. You'll be able to find the slides you've seen today, if you didn't already receive them, as well as the recording, and eventually a transcript as well.

Jessica Kroll: All right. Thank you, \_\_\_\_\_ [00:53:00].

Don Workman: Could I just ask one question for clarification? If study staff leave the institution, leave a facility, does that information get updated at continuing review, if there is a continuing review for the study?

Jessica Kroll: If, I'm sorry, Don, if an investigator –?

Don Workman: No, if the study staff, non-key personnel.

Jessica Kroll: No.

Don Workman: Okay. Thank you.

Jessica Kroll: All right. Thank you all for joining today.

Parker Cunneen: Thank you, Jessica, and Don, and all of our presenters. And just a reminder to folks, if you have a minute or two as you sign off, please do take a second to fill out that survey. We greatly appreciate it. Thanks and have a great afternoon.

[END OF TAPE]