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Session: Launch of the Veterans Health Administration (VHA) Central Research Privacy Board (CRPB)
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Michelle Christiano: Hello everyone. Thank you for joining us for today's Webinar to launch the VA Central Research Privacy Board. As Kate indicated, I'm Michelle Christiano. I'm the ORD privacy officer, and I'm the administrator for the newly established VA Central Research Privacy Board. I'm joined today by Dr. Karen Jeans, Director of Regulatory Affairs, for the Office of Research Protections, Policy, and Education. We're really excited to bring this new service forward to you all. There's a lot of information that we want to cover with you. So we're going to jump right in and get started.

We have lots of discussion topics today, including the purpose of Central Research Privacy Board as well as the types of VA studies that are eligible to be reviewed, the review functions for the Central Research Privacy Board, as well as the Central Research Privacy Board administration. We'll provide information today on the requirements to use the Central Research Privacy Board, right from the VA facility side and the investigator side. We'll include the differences between the live VAIRRS sites and pending VAIRRS sites. And we'll complete our session today by providing a demonstration of the VAIRRS submission process. We'll have time at the end of our session for questions. So please feel free to add those to the Question and Answer boxes Kate indicated earlier.

Our first topic today lays the foundation for the Privacy Board. The HIPAA Privacy Rule limits authorities for only two types of boards or committees to grant a waiver of HIPAA authorization, or an alteration of HIPAA authorization. The two boards that have been granted this authority are Institutional Review Boards or IRBs and Privacy Boards. The Privacy Rule also permits a covered entity to rely on the documentation approval of waiver or the alteration from any qualified Board. Whether that's an IRB or a Privacy Board. As a reminder, we'd like to note that VA does not permit alterations of HIPAA authorization.

We discussed what a Privacy Board is under the HIPAA Privacy Rule. But we'd also like to clarify what the Central Research Privacy Board is not. So for example, the Central Research Privacy Board is not an Institutional Review Board. It does not grant IRB approval for any VA research activities. And the Central Research Privacy Board and an IRB cannot both grant a waiver of HIPAA authorization for the same VA research study.

There are four primary purposes of the VA Central Research Privacy Board. Our first purpose is to reduce IRB reviews that are only occurring to review and approve waivers of HIPAA authorization for VA research. Another purpose is to enhance the review efficiency for these waivers. To facilitate the review and approval for eligible multisite studies that require a waiver of HIPAA authorization. And finally, we also like to serve as a model for any VA facility that may want to create their own Privacy Board.

After reviewing the purposes of the Privacy Board, let's clearly define the authority of the Central Research Privacy Board by noting that the only authority of the Central Research Privacy Board is to review and approve waivers of HIPAA authorization only. The Central Research Privacy Board does not make exempt determinations. The Central Research Privacy Board does not approve exempt research. They do not conduct limited IRB reviews. They also do not conduct the preliminary or final privacy officer reviews.

ORD is initiating the VA Central Research Privacy Board for multiple reasons. To include some external IRBs the VA uses or relies upon such as the National Cancer Institute IRB as well as some affiliate IRBs that do not provide the reviews or approvals and waivers of HIPAA authorization. Also under the revised Common Rule there are some studies, such as those that meet criteria under exempt category 4(iii) that no longer require IRB oversight, but they may require a waiver of HIPAA authorization.

So far we've provided information on what a Privacy Board is. The authority of the Privacy Board and why ORD initiated the VA Central Research Privacy Board. So let's now get into the types of studies that are eligible for submission to the Board. There are basically three types. The first type are ORD funded, multisite exempt projects that do not require a limited IRB review. The Central Research Privacy Board has defined multisite as being three or more sites. The second type are any National Cancer Institute study overseen by the NCI IRB as the IRB does not provide the review or approval of waivers of HIPAA authorization. The third type are studies that are exempt that do not require limited IRB review that are under the oversite of the VA Central Institutional Review Board, Individual Facility Panel or IFP. You may have heard this panel previously referred to as a single site IRB. But the name has recently changed to provide additional clarity. Individual facility panel initiation is projected for Fall of this year.

Whenever there are criteria for eligibility, there are usually potential exceptions. So let's review some of those as well. The following studies may be eligible for an exception. Such as ORD funded exempt studies involving only two VA participating sites. Non-ORD multisite funded studies that are exempt, not requiring limited IRB review. ORD or non-ORD funded non-exempt studies in which the reviewing IRB is unable to review waivers of HIPAA authorization for the VA human subjects research study. Or other VA human subject studies that require a waiver of HIPAA authorization if accepted by the VA Central Research Privacy Board administrator. As the Central Research Privacy Board administrator, my contact information is provided at the end of this presentation. As well as on the Central Research Privacy Board website. We'll provide that link to you later in the presentation as well.

Now that we've identified the eligibility criteria, as well as potential exceptions of studies, let's turn our focus to the ORD management and support of the VA Central Research Privacy Board. The Board will meet monthly, or excuse me, bi-monthly with ad hoc meetings as needed. The meeting dates will be posted on the VA Central Research Privacy Board website. The Privacy Rule allows the Central Research Privacy Board to conduct their reviews of waivers of HIPAA authorizations at convened meetings or through the expedited review processes. We are supported and managed by the Office of Research and Development. There's no fee for any VA facility wishing to use the VA Central Research Privacy Board. And there's also no requirement for any VA facility to use the VA Central Research Privacy Board.

The Privacy Rule provides requirements for the composition of the membership of a Privacy Board. The VA Central Research Privacy Board is composed of three voting members. We have one non-VA voting member as required to meet the non-affiliated standard of the Privacy Rule. And we have two VA members. These members were appointed in January of 2021 and completed formal training last month, in February. Central Research Privacy Board is currently supported by one administrator, that's me as the ORD's privacy officer, and administrative support personnel.

This is the slide that I like to call the how-to slide because it provides an overview of the steps required by the VA facility and ORD to allow the VA facility to rely on the Central Research Privacy Board. Each of these five steps are discussed in detail on the following slides 14 through 20.

Step one, a fully executed Memorandum of Understanding or MOU must be executed between the VA facility and the Office of Research and Development before the facility can rely on the Central Research Privacy Board. Fully executed means that the signature of the VA facility medical center director and the ORD signature of Dr. Jeans, have been signed and dated on the last page of the MOU. We provided the MOU today as a handout with the presentation, but as you'll note on the slide, you can download a copy of it from the Central Research Privacy Board website. You can email the VA Central Research Privacy Board at VACRPB at VA dot gov. Once the MOU template is obtained by the site, we'll go through, and we recommend that you use the Ctrl F and Ctrl R find and replace feature to replace the name of the local VA facility throughout the document and then also to update the last page of the signature as well. We'd like to remind you that only the medical center director can sign and date the signature page.

As part of step, one we provided screenshots of the first and last page of the Memorandum of Understanding. And the direct link to the MOU document is provided at the bottom of the slide.

Step two is to identify a local site liaison or an LSL to the VA Central Research Privacy Board who serves as the primary point of contact between the VA facility and the VA Central Research Privacy Board. The local site liaison will receive copies of all VA Central Research Privacy Board approvals. And this will require an active VAIRRS account. It should be noted that a VAIRRS account must be created by all local site liaisons even if the VA facility is not currently live on VAIRRS. We also call these types of sites pending VAIRRS sites. Existing VAIRRS accounts will be

sufficient for LSLs and as such a new or duplicate account is not necessary. Upon the MOU execution, the local site liaison also has the responsibility to add the Central Research Privacy Board submission application to the VA facility VAIRRS library or designate another person to add it. And that person may be someone such as the local IRBNet site administrator.

Step three is to submit the MOU signed and dated by the medical center director to the VA Central Research Privacy Board. This can be accomplished either through the central mailbox, VACRPB at VA dot gov, directly to me Michelle Christiano at VA dot gov, or you may choose to do both. We ask that you please use the suggested text for the email subject line, as well as the email body text, so that we can rapidly identify the request. And don't forget to attach the signed and dated MOU. The next slide is an example for your convenience of the draft email.

As you'll note we have the subject line VA CRPB MOU Submission for VA XYZ. Of course you would enter your VA facility name. And then we use the text document in there to tell us who's going to be the VA facility local site liaison, and also the site VAIRRS status.

Step four provides the guidance on the updates of the VA facility Standard Operating Procedure to rely on the Central Research Privacy Board. We'd like to note that these revisions are not required to be reviewed by ORD or the Office of Research Oversight prior to execution of the VA Central Research Privacy Board Memorandum of Understanding. We do recommend that your revisions include the processes for how investigators at your facility will request use of the VA Central Research Privacy Board. And how Central Research Privacy Board determinations will then be communicated to your facility's R&D Committee, including prior to initial R&D Committee approval.

Step five is the last step of the process. The VA Central Research Privacy Board administration or designee will email the fully executed Memorandum of Understanding to the local site liaison. We will also publish the VA facilities name on the VA CRPB website and VA facilities approved to use the Central Research Privacy Board.

The key responsibilities of the Central Research Privacy Board are outlined in the MOU and they're also noted here for your convenience on the slide. They include that the Central Research Privacy Board must comply with all applicable Federal laws. As well as VA and VHA regulations and policy when making their determinations. It must provide timely written notice of their determinations. And this is usually within three days, excuse me three working days of the Central Research Privacy Board determinations. Then we will notify the VA facility of all actions related to the approval of the waiver of HIPAA authorization. Within five working days, the VA Central Research Privacy Board will notify the facility through the local site liaison, when unredacted and signed copies of the approved minutes are available. The Central Research Privacy Board will also seek feedback on the efficiency and effectiveness of our operations as part of our continuous quality improvement process.

The Central Research Privacy Board determinations during the lifecycle of a study are approve, require modifications in order to secure approval, or disapprove. Please note, that only the VA

Central Research Privacy Board, when it's at a convened meeting, can disapprove the request for an authorization. There are no continuing reviews required for VA Central Research Privacy Board determinations. And the VA Central Research Privacy Board will review and approve modifications of the waiver of HIPAA authorization throughout the life of the study, as necessary.

The most pressing question for any review process or oversight process is usually related to time length. The VA Central Research Privacy Board anticipates that most applications for waivers of authorization will be eligible for review via expedited procedures. Each submission will undergo a pre-review by the Central Research Privacy Board administration support personnel with a target of completion of five business days. At the completion of that review, the project will be assigned to either expedited or convened review pathway. The expedited review has a target of five business days, but within 10 business days and based on the availability of the Central Research Privacy reviewer for the expedited review to be complete. The convened meeting will be scheduled no later than 30 calendar days following completion of the pre-review if the project is not eligible for expedited review.

Investigators and VA facilities local site liaison will be notified via VAIRRS of any Central Research Privacy Board determinations. And that includes the approvals or required changes within three business days following the decision.

We've discussed the role and the responsibilities of the VA facility's medical center director, the local site liaison, and the research office. But we'd also like to address the role of the research compliance officer and alleged noncompliance reporting. If alleged noncompliance related to a VA Central Research Privacy Board approved waiver of authorization is found as part of a RCO regulatory audit, the audit is to be reported to the VA Central Research Privacy Board in addition to any other required groups. However, routine and for-cause RCO audits are not to be submitted to the VA Central Research Privacy Board unless there is alleged noncompliance related to VA CRPB approved waiver of authorization. No RCO informed consent audits are to be submitted to the VA Central Research Privacy Board.

Now, let's discuss the investigators' requirements when relying on the VA Central Research Privacy Board. Before the investigator can rely on the Board, the VA facility must have the executed MOU that we discussed earlier. The investigator must also have a VAIRRS account that is active. This is true, even if the investigator's VA facility is pending VAIRRS activation. If the investigator has a current VAIRRS account, that's sufficient and an additional account should not be created. There's no need for a duplicate VAIRRS account. It should also be noted that all VA facilities have been added to VAIRRS to enable those pending VAIRRS sites to submit to the VA Central Research Privacy Board.

The investigator submission process to the VA Central Research Privacy Board for waivers of HIPAA authorization requires each site to submit a separate application. Even if they are part of a multisite project. The VA Central Research Privacy Board is not based upon the lead site, local

investigator model like the VA Central Institutional Review Board, or the CIRB. And also, no paper applications will be accepted by the Central Research Privacy Board.

The investigator submission process to the VA Central Research Privacy Board for waivers of HIPAA authorization is done via VAIRRS with required support documents that will be reviewed on the next two slides. The VAIRRS status of the VA facility drives the next steps. Most VA facilities are now live. And as such their investigators submit to their local VA facility research office, who in turn submit to the VA Central Research Privacy Board. The pending VAIRRS sites have the ability to submit directly to the VA Central Research Privacy Board. And these steps are provided on the next few slides.

All site's packages must include the IRB approval letter, or the exempt determination which must also include the exempt category or categories, the date of the determination, or the person or committee or group who made that determination.

VAIRRS live sites follow the local process as defined by the VA facility. The additional step for VA Central Research Privacy Board submission is the completion of the CRPB application for submission, which is to be included with the initial submission to the IRB or the exemption determination official committee. The inclusion of the form will notify the VA facility research office of the investigator's intent to rely on the Central Research Privacy Board. The VA facility research office submits the package to the VA Central Research Privacy Board, Washington DC in the dropdown box that we'll show you in just a moment during the demonstration. If necessary, the VA facility research office, in VAIRRS, can submit a package to multiple boards for review.

The VAIRRS system allows the use of all project documents so that the Central Research Privacy Board reviewers and support staff will have access to documents in previous submissions and packages. VAIRRS live sites do not submit an additional package if their initial submission package contained the CRPB submission application. We'll transition between the VAIRRS live site requirements and the VAIRRS pending sites requirements with the next slide.

Investigators at VAIRRS pending sites create a new project. And they complete the initial screens in VAIRRS along with completing two wizards that are listed here. The project cover sheet, and the IRB information sheet. The wizards in VAIRRS are smart forms or dynamic forms that change depending on the responses that the investigator provides.

Investigators at VAIRRS pending sites submit these documents as noted below, as applicable, based on their study type as part of their overall submission package. The Central Research Privacy Board application for submission will be provided to each VA facility by the Central Research Privacy Board administrator at the time the signed MOU is provided back to the institution. There will also be provided instructions to add the CRPB application for submission to the VA facility library in VAIRRS. The form will be available via the forms and templates tab and should be submitted with the protocol and informed consent form, or information sheet as applicable.

Investigators at VAIRRS pending sites will submit these documents as applicable based on their study type as part of their overall submission package. This should include the HIPAA authorization as applicable, which is also known as form 10-0493. The application for waiver of authorization, data collection tools, recruitment materials and scripts as applicable.

Investigators at VAIRRS pending sites submit their submissions for the Central Research Privacy Board directly to the VA Central Research Privacy Board. Once their site becomes active in VAIRRS they will need to follow their local facility requirements.

Both VAIRRS status boards, whether they're active or pending, will submit to the same VA Central Research Privacy Board. We've noted it here for you and also put there at the bottom so you can see a little bit better, sometimes the fonts are a little small on the sides.

There are basically two VAIRRS sites. There's the live site and there's also the training environment or the sandbox. And there are multiple roles throughout VAIRRS. Both in the live site and in the training environment. We're going to use the training and Sandbox site for our demonstration today. A couple of things before we go into that, for those of you who have not yet registered in VAIRRS, you will go to the live site to register in VAIRRS.

If you have already registered in VAIRRS and you're still entering your username and password, we'd like to encourage you to select prefer to login with your PIV card. As noted by the blue arrow. This will allow you to link your PIV card to the VAIRRS login and prevent you from having to enter your username and password each time you enter the live site.

I'm going to transition now. I'm going to stop sharing this for just a moment and pull up the training environment site for VAIRRS. So if you can give just a moment. [silence 0:24:07 – 0:24:26] There we go.

Moderator: And Michelle, we can see your screen.

Michelle Christiano: Thank you for confirming, Kate. I appreciate that. So today we're logging into the training environment. We're going to login the first role as a VAMC researcher. We've entered our username and our password and clicked login. We have several test projects that have already been loaded into our site today. So for the purposes of the demonstration we're going to create a new project from the research perspective.

There are a few things that you'll need to do to complete your project information. One of the things I'd like to remind everyone is as you enter information into these screens here, this is how your project will be identified from this point forward. So any typographical errors or if you meant to capitalize something and you didn't, it will live in perpetuity from here. It can be changed at one point, but just to kind of let you know upfront that that may be there.

Going through each tab as we go through the system. We've identified our research institution; those can be changed depending on who you have access to within the system by pressing the down arrow. Anything with a red asterisks of course is a required field like every other webform. You can fill out keywords if you choose to do so to help you. Or if your local site has an internal reference number or a nickname for the project then you can enter that here under internal reference number. Once you complete the required fields, you can click continue. This will then bring up the designer. There are two steps noted here. Step one is where you'll download any blank forms, document templates or reference materials that will help you as the researcher to assemble your package. So things that are already loaded into the system, such as the Central Research Privacy Board submission application.

So we're going to go here and select that. Today it's only showing the 103 waiver. So you can download whatever document you need from the library directly to your desktop or your shared drive, which ever prefer. You will then save that so that you can make any changes that you would like to make or need to make based on this specific type.

The second step for you to do is to start a wizard. That's on the lower left corner of your screen. And as you'll notice there are two wizards that you can do. The VA project cover sheet is the very bottom one and the VA IRB information sheet is the top. I always like to start with the cover sheet.

One of the things that VAIRRS allows you to do is to create a clone of one of your existing wizards. So if you traditionally have the same research team members or the same process that you follow, sometimes it's easier to select clone. For this demonstration we're only going to create a new wizard from scratch. So we'll select that and click continue.

The jump feature once you start completing the wizard will allow you to jump to certain sections in there. Since we're only on the introduction there's only one section available to us. It's a reminder here that anything marked with an asterisk must be answered.

The concise project summary, we're just going to use a space filler at this point, but you would put information in here, a brief description about your project. You would also provide the significance in the next text box and then you'll select next. I don't know if you remember a moment ago from when I said that the jump to feature allows you to jump to sections that have already been completed. If you'll notice we now have three sections here. If we needed to go back to project summary we could select that and hit jump. Or we could select previous and go back.

If you'll remember earlier, one of the things that we said is an eligibility criteria for submission to the Central Research Privacy Board is that the study must be funded by ORD. So here we're going to go ahead and select yes for funding. And then we'll select next.

We'll select our funding source code here. I'm just going to pull cooperative studies and we'll say this is not a Merit Award. Again, we do have all of these required things to do. So we'll need

to make sure that those are completed properly as we go forward. If you don't complete one, it will stop you at this process point and ask you to go back and complete it. You'll select your funding date based on the information provided to you by your funding source, as well as your anticipated funding. We're only having one funding source for our demo today, so we're going to go ahead and select next.

On the contracts and agreements page, we're going to select no at this time. And we're going to select next. And again, we're going to complete the information for our investigator. And we're going to select with a conflict of interest. One of the things that you can do with VAIRRS that was not allowed on several other systems is that we can save and exit. It will hold our place and when you log back in, it will take you back to the screen that you were on. We're going to go ahead and select next. We're not going to add any additional personnel this time due to the time constraints that we have this afternoon. If you only have one person on your project you'll click this red X, and that screen goes away. And then we'll select next.

For the purposes of our project today we're going to do data from living individuals, and not select any others. We're not seeking a determination request at this time although you may be for your project. You'll need to go through each one individually. The predominant ones that you should see would of course be exemptions. And again, it must be a multisite study. As noted in our eligibility criteria earlier.

For this one, we're going to say now, it's now a cooperative nonexempt study. And the IRB of record type, we're going to say it's the PI's VA Medical Center IRB. And no other IRBs will do this. And we're almost to the end of this wizard. And if you'll notice I'm just going to refer you back up to the jump to section. If you made an error on any of these sections all you have to do is click on them and go right back to where you were. And once you completed that you can then go back to the previous forms.

We're back on additional IRBs. As we noted earlier there are no other IRBs of record reviewing the study, so we're going to put next and that completes the wizard. That's our first wizard, which is the project cover sheet. You can preview it in a PDF if you choose to do so. It takes just a moment for it to load. And this gives you a summary of all the information that you entered onto that wizard.

Some people choose to save those, you certainly do not have to. We're gonna click save and exit. And now under step two in our documents in this package you'll see that we have completed the VA project cover sheet. We can start the additional wizard of the IRB information sheet at this time. And again remember earlier, you can create a new one from scratch or clone one of your existing. For this project we're going to create a new one.

And again, you'll notice you have the same jump to feature, save, and exit, and preview that you had on the other wizard.

We're not going to be submitting to a non-VA IRB. If you were using the National Cancer Institute IRB you would select yes here. Again it must be a multisite project. And we're not a local site investigator submitting to the Central IRB. For this project we're going to choose minimal risk. You'll be able to as the PI assessment make your own determination based on the information provided in the definition above. Of course the IRB will always make your final assessment of new risk level. So for this one, we're just going to go ahead and ask for IRB expedited review. Because remember, this is the IRB cover sheet. And we'll select four as our expedited category.

You can select more than one expedited category on the previous page. If there is a lead site you can enter it. Remember for the Central Research Privacy Board we do not use the lead site model that the Central IRB does. It's up to you as you go through this. I would recommend if you are using the Central IRB to enter the lead site information here.

For this page we're going to select no coordinating center just in the interest of time. And also that this is not a clinical trial. And no sites outside of the United States, and data will not originate from outside the States. And we will not send it outside the United States.

For this project we're going to say that we have no special populations that require special considerations. And we'll scroll down and select next.

And in the interest of time today, we're going to ignore this part here much like we did for the initial investigators. Ah, it's not allowing me to do that today. I'll need to report that. So we'll just fill in information here as needed. We're only going to use adults and we're asking for a waiver or alteration of informed consent. We will also ask that a waiver of authorization will be requested. Remember, if you're asking for a waiver of authorization for the project and you ask for a waiver of informed consent, those are usually triggers that go through the reviewers minds as they look at those.

Under check all that apply for HIPAA authorization, we're going to say that a waiver of HIPAA authorization is being sought. And we're also going to say that we'll be using these records to identify potential subjects for recruitment or for screening purposes. Notice that there's no asterisk here for the number of records that will be accessed but we're going to complete this as 100 just for a task. And will say that 50 are needed to meet the objectives. And again we're going to select next.

Remember you can use the jump to if you need to go back and change anything as well. The recruitment strategy information will be based on the individual project that you're doing. We are going to say letters to potential subjects in this and select next.

We are not targeting a specific race or group or gender. So we'll select no. Now remember, each of these will be dependent on the type of project that you're submitting to either your IRB of record, or to your exempt determination official or committee. So your responses will probably change.

Participants will not receive compensation due to time constraints for our demonstration. We are not going to be establishing a data repository—but we will perhaps use data from a data repository.

So again, we'll select next. Our project does not, or our project does involve, excuse me, does not involve the usual standard of care as we're doing basically a chart review for this project. And we're not obtaining a certificate of confidentiality.

This form is now complete. And again you can do a preview of this form should you choose to do so. But as I said earlier some people like to save these. It doesn't matter if you do or don't. It will be contained in your IRBNet project document.

So you can see what you selected on each one. And then we're going to hit save and exit. And now you'll see that both of your wizards are showing up under your documents in this package.

We also would like to attach a new document for this submission. And that's based on the completion, excuse me, the completion of the Central Research Privacy Board application.

We can change our document type here so that we can identify the type of document that we're submitting for review. And then once we're complete we have our documents attached through here if you need to make any changes or perhaps delete a document. So for this one, I uploaded the IRBNet information sheet. If I wanted to add or change this, all I would have to do is select delete this document, or revise it as needed.

So now at this point we've completed our library, or excuse me, our submission package for this. We can also add other documents such as our protocol and you would just do that as you attach any document to perhaps an email. You would add your informed consent. You would add other documents such as your data collection tool. Basically the documents that we outlined during the slides that are also noted on the Central Research Privacy Board website. At this point we're going to sign this package because each package must be signed.

Okay. First time I've had that happen. So we're going to ignore signing the package and click submit this package. If you'll notice here for ours it's going to go to the VA research administration for our institution. This is for individual sites that are active in VAIRRS. If you were not yet active in VAIRRS you would be able to search for the Central Research Privacy Board.

And once it's loaded into your site you'll be able to submit directly to them. So for this one, for a VAIRRS active site, we're going to submit directly to our research administration office so that they can review in accordance with the local facility SOP. And then submit to the VA Central Research Privacy Board.

You can indicate a new project and if you have any additional comments that you'd like to be included in the notification. Maybe you're looking at something as a funding, a deadline is close. Or you need to give them a heads up that maybe some of the research team will be out of the office during their normal schedule times, you can use the comments feature here to do that.

It now says that your package has been successfully submitted for review. It was submitted by the researcher to the administrator. You can go back to the project overview so that you can see everything that you submitted. And you can tell where the project currently is. So for example the project has now been submitted to the Lake Wobegon research administration. It's a new project and it's pending review. If there were any details they would show up here, at the site, or the research administration site had already started their review.

We're going to log out now from the researcher's point of view. And we'll log back in as the site administrator. And now you'll see as the administrator that the project that we submitted just a few moments ago during the demo, is now showing up in the site administrator's package. They'll go ahead and select this project, where they'll go in and conduct their review. For purposes of this review today we're going to do it as simply as possible. And basically we're just going to say that this project is ready to go and we'll be submitting it to the Central Research Privacy Board.

As you'll notice here it's already showing up. And this is the same as noted on your slide. And you'll click continue. And this is from the administrator perspective. The difference for the VAIRRS active sites, this is where this site research office administrator or their IRBNet administrator or their staff will submit to the Central Research Privacy Board. If you're not at a VAIRRS active site, if you're at a VAIRRS pending site, you as the investigator will be able to select VA Central Research Privacy Board yourself and it will not go to your local research facility office.

Again we can go back to the project overview. And now you'll see that it changed from being just at Lake Wobegon and now has been submitted to the Central Research Privacy Board. This is one of the best features in my opinion about IRB VAIRRS because it allows you to see where your packages are and what the details are for those. At this point we'll log out from the site administrator's perspective. And we'll login to the Privacy Board.

And you can see that this project now shows up at this Central Research Privacy Board. So project overview again will show you where the submission packages have gone to. And the current status of the project. And that concludes the VAIRRS demo for today.

I'm going to stop sharing the slides at this point. Or excuse me the training site at this point. And switch back to slides.

Here's the contact information. So this shared Central Research Privacy Board email box which includes myself as well as other support staff and the Central Research Privacy Board members.

As well as Dr. Jeans and others. Everyone on that list gets information that is submitted to the VA Central Research Privacy Board. This is where you can submit the MOU, if you have any questions about how to use the site, or if you have any questions that relate to the Privacy Board itself. My contact information is here as well.

We've added some important links for you to have as a resource. So the VA Central Research Privacy Board website is available at this link. The site is live. The Memorandum of Understanding, meeting dates, and other information is included on this site. We encourage you to go there or perhaps mark it as a bookmark or a favorite. The VAIRRS live site is noted for you as well as the VAIRRS training site. We've also included some important links for VAIRRS web based training by role. As well as VAIRRS training energizers. This site is a fantastic resource to you for training your members as well as an individual learning how to use the system. The recording for this session and the handouts will be available on ORPP&E's education and training website within about a week. And then we also have provided the link to the ORPP&E posted webinars so that we can go back and view any that you may need to do. And with that I believe it's time for questions.

Soundia Duche: Wonderful. Thank you so much Michelle for this great presentation.

Michelle Christiano: Thank you.

Kate Yeksigian: And thank you to everyone who's already submitted questions. Just as a reminder you can submit a question through the Question and Answer box located on the righthand side of your screen.

Soundia Duche: Great. Thanks Kate. So our first question is, is this expedited review primarily for exempt studies?

Michelle Christiano: It's actually not. And Karen, Dr. Jeans, please correct me if I say anything inappropriate here or unclear. The expedited pathway is for projects that are eligible for that as defined by the Privacy Rule. It's a little bit different than the way the common rule defines expedited versus convened Board. So expedited projects for the IRB will be those that are minimal risk for the project itself. Whereas for the Central Research Privacy Board, the Privacy Rule identifies those as the minimal risk to the privacy of the individual.

Dr. Karen Jeans: Yes, this is Karen. Michelle is exactly right. It's a totally different concept than minimal risk in terms of the common rule or even FDA regulations. It is all about what is considered to be minimal risk to the privacy of the individuals who are the subject of the PHI for which the use or disclosure is being sought. So when you're thinking about what is minimal risk in reference to privacy and that use and disclosure of PHI, and you're talking about a waiver of authorization, one has to think about, okay where is the data going to be used? Where is that PHI residing? Is it staying within the organization? Is it going outside the organization? Because when you're doing that with a waiver, is that truly a minimal risk activity? Taking out even the privacy act issues. So that's when you're thinking about the issue of what is minimal risk to

privacy. One way to think about this, is in terms of where is the PHI being used and by whom. And so that's the type of criteria one uses. And that doesn't apply primarily to exempt studies. It can apply to any study. Because that's the way HIPAA is written. Thank you.

Soundia Duche: Great. Thank you Karen. Next question. Since most exempt studies undergo designated review, and HIPAA waiver is granted by the designated reviewer who is a member of our local IRB, I was curious about the makeup of the Privacy Board. Why is a non-VA member needed? Also what type of exempt studies would need to go to the full Privacy Board?

Michelle Christiano: That's a great question. As a former IRB person, I asked this question when the HIPAA Privacy Rule was initiated. The requirement for a non-VA member is very similar to the requirement for a non-affiliated member on the IRB. For the Privacy Rule they've actually designated that out and they do say non-affiliated. That of course means not paid by the institution, not receiving compensation of any kind, those types of things. So a non-VA member is needed so that there's no, in my opinion the way that I've always read that is so that there's kind of a fresh perspective on it. And that there's no potential conflict of interest in regards to the activities taken by the Central Research Privacy Board. Karen, did you have anything to add to that or Stephanie?

Dr. Karen Jeans: So I'll start, and then I'd like to defer to Stephanie. Because the HIPAA Privacy Rule is specific in terms of what is the composition of the Privacy Boards? And unlike the common rule which specifies a specific number of five, the HIPAA Privacy Rule specifies two that can be part of the covered entity, but also one member, excuse me, I said that wrong. At least one member of the Privacy Board, according to HIPAA, and there has to be two members total, has to be an independent member. And that is the terminology that is used in HIPAA. That is not affiliated with the covered entity. That it using or, disclosing the PHI in connection with the research project. Is not affiliated with the entity conducting or sponsoring the research. As well as related to any person who is affiliated with the entities conducting or supporting the research. So the reason why there's a non-VA member is because there has to be an independent member as required by the HIPAA Privacy Rule.

Stephania Griffin: And Karen, this is Stephanie Griffin, I have nothing to add because you've stated it quite clearly.

Dr. Karen Jeans: Thank you.

Michelle Christiano: Now the second part of that question. Can we go back for just a moment, Soundia. I want to make sure that we answer that question. What type of exempt study would need to go to the full Privacy Board? Off the top of my head I truly cannot think of one. But I would caution it to say based on Dr. Jeans guidance a few moments ago, we always need to remember why things are coming to the Central Research Privacy Board. And that is because we're looking at the privacy of the individual for the use or the disclosure. So perhaps we're looking at data related to alcohol or drug abuse. Or maybe we're looking at things related to potential crimes of the past or something like that. Those may be things that require an

additional review that require a convened board, or the full Privacy Board to go forward. And as a reminder all disapprovals will require the full Privacy Board [inaudible 0:53:55].

Dr. Karen Jeans: And this is Karen. I just want to add, it's not just exempt studies that are coming to the Privacy Board. While absolutely there is no question that one of the reasons we formed the Privacy Board is because with the revision of the common rule which is not by the way, the exempt categories are not reflected in FDA's regulations. But a huge number of studies that previously required IRB review and approval under the expedited categories of the pre-2018 requirements now can be exempt. There's all these studies that, mainly category 4(iii) which no longer go to the IRB. They don't even require a limited IRB review. And so now those all will need some type of, they would have to have a waiver of authorization within VA because we are a covered entity and to meet that criteria. And so the issue is do you utilize an IRB for that sole function, or do you indeed constitute a board that that's their specialty. And so one of the reasons we're trying to streamline operations here and make this more effective is for that reason. Is to be able to enable that. But also we have the NCI studies. We do a large number of NCI studies here in the organization. The NCI IRB does not approve waivers of authorization. We also have issues, and these are just choices. Many of our VAs do not have their own IRBs. Their primary IRB as a record are affiliates. And so some of our universities are saying okay, it's an exempt study but you know we really don't want to do the waiver of authorization solely for that study whenever it doesn't even require IRB review and approval. So these are different types of options that are occurring right now in our organization to which a Privacy Board is the more efficient and logical way to do this. Thank you.

Soundia Duche: Great. Thank you Karen. For existing studies that initially used the VA CIRB as a Privacy Board for review of a HIPAA authorization waiver, and now need to amend the waiver, will that study stay under the CIRB? Or need to submit to the CRPB?

Michelle Christiano: This is Michelle, that is a great question. My understanding of it currently is that if the waiver was originally issued by the Central IRB it will stay with the Central IRB.

Dr. Karen Jeans: Yes. This is Karen, I'm gonna jump in here. Again, when it comes to the studies that the Central IRB oversees. So let's say they've reviewed that HIPAA authorization because it's a clinical trial, or again it's under Central IRB oversight. What you will never have happen, and I'm really glad whoever asked this question, is you have a study that's going to the Central IRB. Now if it's going to the Central IRB and it needs a waiver of authorization, it is not going to go to the Privacy Board. Because the IRB as part of it's review and approval of the research under the common rule and if it's FDA regulated under FDA regulations, they are also going to do the review and evaluation for the waiver of HIPAA authorization. They wouldn't separate it. So that will never happen where they would separate. If the Central IRB is the IRB of record for the study, then if the waiver of authorization is required, then they will be the review board that will be responsible for it. Thank you.

Soundia Duche: Great. Next question. Is there a user manual for using this application that would have instructions?

Michelle Christiano: Soundia, I'll presume from this question that we're talking about the VAIRRS application. And there are several training manuals and instructions that are available via the VAIRRS SharePoint page under the important link slides that we added. Angela Foster is also on the call today, so Angie would you like to follow-up with anything on that?

Angela Foster: Thanks Michelle, I was actually going to say the same thing. That the VAIRRS SharePoint portal, which was shown, the link shown earlier, has a host of resources. There's recorded training webinars. There are training energizers. And there are also a few sites that have offered their information, their training documents that they used locally.

Soundia Duche: Great. Thank you. What is the threshold for the determination of multisite study? Is it three or more participating VA sites? Or five or more participating VA sites? Can you please point me to any policy reference for the threshold determination.

Michelle Christiano: So for the Central Research Privacy Board that threshold is established at the Standard Operation Procedure for the Central Research Privacy Board. Which is available on our website. And our definition for that is three or more participating VA sites for multisite studies.

Dr. Karen Jeans: So this is Karen, I'm gonna jump in. So it's not a policy issue for this. This was initially set up as Michelle stated for three or more based upon what is the perceived capacity of this Board to take on the studies. And so that's where that came from in terms of operational use. It's not a policy determination. But that's where also when Michelle was talking about exceptions, while that is what we're looking at in terms of three or more. If there is a two site study, you are more than welcome to come in and request an exception. And Michelle will look at that. But the reason, and it goes back, and some of us are old here, and I'm talking about myself, where when the Central IRB started years ago, if some of you remember we opened it up without a numerator. It was any multisite study. And it quickly reached capacity within a few months. And then we had to do some alterations. And so we got into, and that was years ago when that happened. We see that happened back then. So right now we're saying, okay, let's start with a number of three. But again, if you have a multisite study and it has two, please as Michelle stated, contact Michelle and if we have the capacity we'll indeed be able to accept it. But again, also something we want to reiterate here, this should be coming through the research office. So if an investigator wants to ask, hey can the Central Research Privacy Board look at this two site study, please clear it through your research office first. Because I guarantee you when you contact, if you're an investigator and contact Michelle, Michelle's gonna go back to the research office and say hey we got this request. And we're going to see whether or not we can do this or not. Is this acceptable to you? So just some helpful hints. Because this is a pilot program. This is a new Privacy Board and so we're gonna learn along the way. So we appreciate your patience as we're learning. But this is a great question. So we really appreciate this and let's take the next question. Thank you.

Soundia Duche: For VAIRRS live sites, should new projects submit the CRPB application as part of their local submission? Or create a new package just for the CRPB?

Michelle Christiano: I would recommend that they submit the CRPB application as part of their local submission. First it would notify their local site research office that they would like to use the Central Research Privacy Board. And it provides a complete documentation package not only for the research office, but also for the IRB or the exempt determination official or committee that's looking at it. And it allows the Central Research Privacy Board once it's submitted to us to also have that information in there as part of that initial submission. I don't recommend creating a new package just for the Central Research Privacy Board. No.

Soundia Duche: Great, thanks Michelle. Does a HIPAA waiver approved by a commercial IRB suffice or do we need a VA specific HIPAA waiver?

Dr. Karen Jeans: This is Karen, I'll take this one. Again, a great question. In terms of any of the ORD approved commercial independent IRBs. Which is Advarra, WIRB, Sterling. As part of the master service agreements that we executed in terms of accepting those, one of the agreements that we made is that not only can they review and approve research according to VA requirements in terms of the common rule and FDA regulations as well as 1200.05, and also follow the requirements of 1058.03, but also they have to be able to approve HIPAA Waivers of Authorization according to the HIPAA rule. And so if Advarra, WIRB, or Sterling approves a waiver of authorization for the study, it does not mean that it needs to be reviewed again. It goes back to one of those slides that Michelle stated. There can only be one. It's like that infamous movie from the Highlander for some of us. You know there can only be one. So that's what happens here. So when the commercial IRB approves the waiver of authorization because it met the criteria, and it has to be documented as required by HIPAA, there cannot be another HIPAA waiver of authorization approved by another Privacy Board or another IRB. Thank you.

Soundia Duche: All right. What are the key things the Privacy Board member is looking at when reviewing and providing or approving a HIPAA waiver? Do you use some type of review or checklist? Can that be shared?

Michelle Christiano: So the application for HIPAA waiver, or waiver of authorization, page four, is the primary document that the reviewers will use for the Central Research Privacy Board when looking at the waivers of authorization. That's already available on the VAIRRS site. We'd be happy to provide it if anyone needs it individually. And it's also on the Central Research Privacy Board website. And the link is provided on these slides.

Soundia Duche: Great, thank you Michelle. Are Advarra and WIRB external IRBs not performing review or approval of waivers of HIPAA authorization? As mentioned on slide seven.

Dr. Karen Jeans: So this is Karen. Again all of our ORD approved commercial IRBs are approving waivers of authorization for VA studies that are submitted to them. So if there's a misinterpretation, we'll look at slide seven to make sure that it's not, that it's clear. But I want

to reiterate very clearly that ORD's approved, commercial independent IRBs, indeed approve waivers of authorization for VA studies. That is part of the master service agreements that ORD executed with each of these. Thank you.

Soundia Duche: Great. Thanks for that clarification Karen. If we have a robust Privacy Officer process locally, do we have to use the Central Privacy Officer process? It looks like the decision-making process is given to the PI. But what if the research administration doesn't think the study should go to the Central PO process? Can we say no, even if the PI requests it?

Michelle Christiano: So I'd like to clarify just a couple things on this question. So by PO process locally, are we talking about the Privacy Officer process, because the Central Research Privacy Board is not taking the place of the Privacy Officer preliminary or initial review, or their final review. If the site has a robust process for reviewing and approving waivers of HIPAA authorization, they do not have to use the Central Research Privacy Board. That's actually covered in one of the slides at the beginning where we talked about what the Central Research Privacy Board does not do. It's not required for use. And the decision-making process, just to build on what Karen said a few minutes ago, it's not up to the PI to make that decision. It's up to the PI to decide they would like to use it and then to work with their research office at their facility and identify that this is a potential reviewer for them. And then to follow-up with it internally with their own SOPs at the research office facility local. And then if the affiliate decides that they want to keep their research privacy reviews for waivers of HIPAA authorization locally, then they're certainly supported in doing that.

Soundia Duche: Great, thank you Michelle. All right so this is a comment just to say that there is no issue with slide seven, they were just referencing a question that was answered earlier by Karen. Thank you for that. Can you please clarify slide eight. Are the cases listed there as exceptions instances that can be reviewed by the CRPB or cannot be reviewed by the CRPB?

Michelle Christiano: Yes. Those are actually exceptions that can be reviewed by the Central Research Privacy Board.

Soundia Duche: Great. Thank you. If PIs say their NCI CIRB cancer study does not involve recruitment, and if the study is offered as one option but not recruited for it, and doesn't need a HIPAA authorization waiver for recruitment, then should we now submit to the new VA CRPB for these NCI studies?

Michelle Christiano: I don't know if I've ever seen that before. My experience with the NCI CIRB at my previous institution is that there's usually an inner screening for recruitment where you go in and you look at the medical records of the individual to ensure they meet the inclusion, exclusion criteria or you have a screening consent that you have then completed along with the HIPAA authorization. They're asking I think about recruitment itself versus identifying potential subjects for this study. And I think I would actually need additional information so that I could answer this question appropriately.

Dr. Karen Jeans: I'd also like to jump in here, this is Karen. So in some of the NCI studies it's absolutely true that there is no recruitment through the EHR. Your oncologist is seeing a patient, and they you know say oh by the way you know… this is how you recruit. You have these you know this condition; I'd like to see about putting you in this study. And so there's not a recruitment going through the screening of the medical records. And so this question, and I'm taking it literally, it doesn't need a HIPAA authorization waiver for recruitment. So if it doesn't need a HIPAA authorization waiver for recruitment because that's not a mechanism that's being used, stop right there. It doesn't go anywhere else for a waiver of authorization because it's not applicable to the study. But let's say, take the next step. That yes indeed, your investigator, your oncologist states, oh by the way, you know what? I do need to, before the patient comes in, I do want to see if I can screen for you know this. And I am going to need a waiver of HIPAA authorization. You have choices. You know again, the Central Research Privacy Board can be used for those. If your research office, again your VA facility would have to enter into an MOU to utilize the VA CRPB. Or you can use the mechanism that your quote "currently using". For those studies in which only a waiver of authorization is required. Whether that be through your own IRB if you have an internal IRB at your VA facility, or if you're using another IRB. For example you're using your academic affiliate. So there's different options here depending on that. But if it doesn't need a waiver now for recruitment, you don't need to submit to the Central Research Privacy Board for a waiver of authorization when it's not even applicable. But again, first and foremost, your VA facility has to agree to want to enter into a relationship with the Privacy Board here at Central Office before that ever starts. So thank you for that question.

Soundia Duche: All right. Next question please. If not using the CRPB, does the convened IRB need to approve the waiver of HIPAA authorization for a minimal risk study in order to have a non-VA affiliated member be part of the review? And I think what we're talking of here is the differentiation between the composition of the board versus the reviewer.

Michelle Christiano: Soundia, this is Michelle. I have to go back and review the requirements for the IRB when they're taking on the additional duties of the Privacy Board before I could definitively answer that. Karen, do you have any input on that?

Dr. Karen Jeans: Well again, it goes, I do. You know I can't help myself sometimes. So it goes back again to use your analogy of your own IRBs. Again under the Privacy Rule you've got a quote an IRB quote Privacy Board. They both have compositions that are required. One is under the common rule, FDA. One is under, you know HIPAA in terms of their composition. However, HIPAA has granted authority for either of these groups, both of these groups to approve waivers of authorization as long as the criteria are met as determined and documented by the IRB or by the Privacy Board and then the documentation must meet the privacy rules requirements. So when it comes to again, under both an IRB and under a Privacy Board, under HIPAA an expedited review process can be used for both. And so again, when it comes to who can be the expedited reviewer, again under a composition of IRB they also have a non-affiliated member just like your Privacy Board. So your expedited, you have expedited reviewers on a IRB who can also approve waivers of authorization. Voting members just as you do on a Privacy Board. Again a voting member as long as the board itself is composed according to the

applicable requirements under an IRB, common rule/FDA such as VA where we do FDA regulated research. And also under the Privacy Board here is constituted according to the HIPAA privacy rule. And if that doesn't answer your question pleases follow-up with me. Thank you.

Soundia Duche: Thanks for clarifying that Karen.

Kate Yeksigian: And we've come to the end of our submitted questions. I'll also note that we have 12 minutes left in case someone wants to submit a question last minute.

Soundia Duche: And if not, maybe we can hear any parting words from Michelle or Karen.

Michelle Christiano: I would just like to thank everyone for their time and attention today. And as Karen said earlier, this is a pilot. We'll be learning together as we go through this and I'm just really excited to launch the Privacy Board.

Dr. Molly Klote: Yeah. And this is Molly Klote. So I just want to say a huge thank you to Karen, Michelle, of course Soundia and the team who put on the Webinars. But really Karen and Michelle have worked very hard to bring this Privacy Board to reality. And I just can't thank them enough for helping to launch this. So thanks.

Kate Yeksigian: And all right, we have two more questions.

Soundia Duche: All right. Can you clarify again please, what would constitute exempt research protocols not requiring limited IRB review using the VA Central IRB Individual Facility Panel, when that panel is initiated?

Michelle Christiano: That's quite a mouthful, isn't it Soundia? [laughs]

Soundia Duche: Yeah. I think we're talking here about the VA Central IRB's new panel. I don't think we're talking about the Central Research Privacy Board here. And if that's the case we may need to hold that question and submit it to the Central IRB. Am I wrong? Are they talking about the CRPB here?

Michelle Christiano: I believe they're also talking about that panel, but Karen, what do you think?

Soundia Duche: She says this was on slide eight. Slide eight if you can refer to that.

Dr. Karen Jeans: But- Yeah this is, that slide was dealing with what is the initial target of the studies that the CRPB is really focused on. Why it was originally constituted. And so when we're looking at in terms of these groups of studies and it goes back to you know what are exempt if they go, if exempt requires limited IRB review then the IRB that's conducting that limited IRB review, should also be doing the waiver of authorization. But for example, for retrospective

chart review studies, exempt category 4(iii), those studies do not require a limited IRB review. So that's an example of an exempt research protocol in which a waiver of authorization is going to be required if it's conducted here in VA as a covered entity. But it would never go to a limited IRB review because that is not part of the exempt category. Thank you.

Soundia Duche: Thank you. That's helpful for myself as well. And the second question is, why don't we have full privacy from central instead of one to review HIPAA waivers? Why don't we have full privacy from central instead of one to review HIPAA waivers? I'm not sure what the question is asking if they're saying privacy review. Full privacy review?

Dr. Karen Jeans: So this is Karen. I think that's exactly what the question is. And I think it's a very—and that's a question that we've been asked many times. Is for some studies under the Central IRB for example, for all studies under the Central IRB, part of the agreement is that the reviews for those studies that are under the Central IRB purview, undergo Central Privacy Officer review and they undergo Central ISSO review. Now as a result of the pandemic, we've had a subset of studies particularly related to the COVID studies, the vaccine studies, in which a subset were done with a Central Privacy Officer review. And so many times we have heard here in ORD why can't the entire set of studies that are particularly multisite come to ORD so that all those studies can have a Central Privacy Review here in Central Office. And the answer is capacity. It's purely that. If we had the capacity to do it, we could. And are we looking at expanding our ability to do Central Privacy Reviews for multisite studies that are not under the purview of the Central IRB? Absolutely. Absolutely. And very glad this question was asked. But it's purely an issue of capacity. So thank you.

Soundia Duche: Great, thank you Karen. Is that it Kate?

Kate Yeksigian: Yes, that's it.

Soundia Duche: All right. Well thank you everybody for attending. Thank you our panelists again. And for all the other people who are also assisting in answering questions for today's Webinar. I hope everyone has a wonderful weekend. Happy Easter, Happy Passover. Take care.

[END OF AUDIO]