Katrina Young: All right, well, thank you, everyone, for joining the VAIRRS month of February installment of the VAIRRS monthly series. Before we actually get into our presentation, I will go over some brief announcements for VAIRRS. So, next slide, please.

First, VAIRRS is making some updates to the IRB informational sheet wizard. And if you would like to review those updates, there is a draft wizard that's online on the VAIRRS SharePoint portal. And it's under the CC, the VAIRRS CCB menu option.

Second update, our mentor programs is up, and running, and well on its way. And we're still accepting applications. And you can apply via the VAIRRS SharePoint under the VAIRRS mentor program SharePoint page. And then as always, VAIRRS University is also live. If you have not visited that training resource as of yet, I highly encourage everyone to stop by VAIRRS University, and check out all of the new, and improved training resources that VAIRRS has to offer.

And if you have not already, please subscribe to the VAIRRS newsletter and program update to keep up with all important announcements, and program updates for VAIRRS. So with all that being said, I will pass it over to Jessica Kroll, and her team to start off their presentation.

Jessica Kroll: Thanks, Katrina. Next slid?

Parker Cunneen: Jessica, before you begin, you sound a little distant. So I just want to let you know, and maybe come a little closer to that microphone.

Jessica Kroll: Thanks, Parker. Is this better?

Parker Cunneen: Yeah.

Jessica Kroll: Great, so today the objectives are for the Central IRB to share the development of our quality assurance process and IRBNet. So this webinar will cover the following topics: the importance of QA, identifying opportunities for improvement, standardizing processes with the development of internal workflows, and developing a QA process in IRBNet. The next slide.

So I want to share the importance of QA as it's related to our process that we developed at the Central IRB. And that's to strengthen the quality of our IRB reviews; identify opportunities for improvement; increase standardized use of IRBNet by staff. Ensure data are entered consistently in IRBNet. To ensure data integrity in order to support Insight Reports in VAIRRS dashboards. And lastly, IRBNet implementation had required us to adopt to a number of new and different processes. The next slide.

So identify opportunities for improvement, these are the steps we took to identify where we should focus our initial QA efforts. So early on in the implementation of IRBNet, we met with staff to identify where there could be the processing inconsistencies in the system. And this provided us with some great insight as to how some staff were using IRBNet. How they were entering information in the system. And some were doing it differently. And that was specifically identified in how reviews were being documented in the Review Details section.

We also spent some time looking at IRBNet Insight Reports to, to see how we could evaluate our metrics. Specifically, we spent some time looking at the review process and project status report. And this was very insightful in giving us a big picture of the, the data, and the processing that was occurring at the Central IRB.

Lastly, we identified that there was a need for us to standardize our practices. And that was in order to be able to validate our data within the VAIRRS dashboard and within other means, so that we could really start to generate those metrics. The next slide.

So what we identified during this review was an opportunity to take a deep dive into IRBNet Review Details. So information in IRBNet Review Details is directly linked to determination letters, our minutes, IRBNet Insight Reports, VAIRRS dashboards, and even future packages that will be submitted for that project. So as we go through the next slides, I'll be providing some examples of how we develop the QA process, specifically looking at the Review Details section within IRBNet. The next slide.

So now we get to the point of standardizing processes in IRBNet. And this stems from the step where we were trying to identify opportunities for us to improve. And I would like to note that IRBNet had provided training and guidance for, for users on how to use the system, but it really is up to the IRB, or the other committee to define, and provide instruction to staff on how to document a review, or an action taken within the system.

So as we looked to standardize our processes, we started with defining some of the terms that we commonly see within the system, specifically selecting an action to document a review. So, for example, there are the terms approval with conditions versus modifications required. We have taken a step to ensure that those type of actions are defined, so that we can ensure that when those actions are being used, they're being used consistently; and that all staff and panel members have the same understanding of what that term is defined as, and how we use it at our IRB.

Next, we developed internal workflows for staff to follow when processing a submission. And this was an important step. Over time we developed a number of different workflows. Specifically, one of them was how to complete Review Details. And I'll show an example of that, and then in an upcoming slide. Next, we talked about developing checklists. And the importance of having checklists was just to ensure that staff were taking all the required steps when documenting a review in IRBNet.

Then we went on to provide regular training and education on those internal workflows, and those checklists that we developed, and we used our weekly team meetings as an opportunity to select a workflow, go through it, collect feedback from staff, and ensure that the instructions were, were easily followed.

Then, after providing those resources, and the training, and education, we allowed for a time, we allowed time for staff to learn and implement those new workflows before we wanted to begin the QA process. Next slide.

So here's an example of an internal workflow that was created to provide guidance on how to document review in Review Details. So, this is something we created specifically for the Central IRB. However, it's definitely a document that we're happy to share with the field, if it's something you want to take and adopt to your own process.

As mentioned before, this guidance document is important because the, the information that is being entered into review details is directly linked to those determination letters, minutes, reports, and dashboards. So we really wanted to make sure that we had a clear step by step process that staff could follow when entering information into that section of, of IRBNet.

So this specific workflow we created has three different workflows. One is when to enter information, what to enter. And then the third is incident explanation of those terms. So as I had mentioned, we wanted to define the terms within IRBNet. And that's what we had done in this document. The next slide.

So this is an example of the first workflow. And you can see in the table here, it follows the order of which items get entered into review details. And this, again, is just an example of how we defined some of this information at the Central IRB. So for example, projects expiration, when to enter into update, so that would be an initial review, continuing review, or a closure. And we did that for all of the, the options within the review details. Next slide.

So workflow 2 provides very detailed instructions on how to enter review details for a specific submission type and review type. So what we did here was we created a color coded system to indicate when, and what should be completed in the review details. And we did this for all the types of submission packages that we process. Next slide.

And this is a close up of one of those examples. So for this instance, here we have continuing review. And this is a snapshot of what continuing review details could look like for an expedited item or a full committee. So in this instance, we have used the color coding to identify what information needs to be entered. What information should be left alone, or what information should be updated.

And here we also include specific notes based on the type of submission. In this one here we call out that when entering review details, it's important that there is only an expiration date, or a next report due date. You never want to have both because in the system that can trigger multiple notifications to the study team, and could be confusing. So for our process here, we call out that only one or the other should be entered. The next slide.

And this third Workflow that we've developed goes back to defining those terms within the system. So this is where we listed out all of the actions that are in the dropdown menu in IRBNet that that can be selected when processing a package. And it was important to define these terms, not only for our staff, but they're also the same terms that board members use when selecting a recommendation when they document their review in an IRBNet. So as you can see here, we have defined when to use these type of actions, and then the definition of, of that action. Next slide.

So now, we're going to get into the development of the QA process. So at the Central IRB we identified our area of opportunity for improvement, and that was really focusing on review details. So we developed a plan where we defined our objectives and our goals. We identified content to be reviewed and determined the frequency.

Once we did that, then we moved on to the development of tools. And this is where we decided to utilize existing IRBNet Insight Reports. But also develop a QA checklist created within an Excel template. Then for evaluation, we determined a percentage of compliance while reviewing within the tools. We developed a mechanisms to report a summary of findings, and a process to address any type of corrective actions that would need to be taken following the review. Next slide.

So within our plan, we came up with an area of focus. So as mentioned, that focus was on review details. And we decided to include a couple of other submission detail items while we would be inside the IRBNet package. We also make clear that this effort is truly an operational review of processes in IRBNet, not a regulatory review.

And reviewing the data and the processing of submission packages was made according to the Central IRB internal workflows that were developed. So as we were creating the tools, and the checklists, and defining our area of focus, we really aligned that with what we had developed, and outlined in our IRBNet internal workflow for the review details.

For the frequency we determined that we will QA on a quarterly basis, and include every panel meeting. For content selection, we decided to focus on expedited items reported on full board agenda. And we would make a random selection of those submission packages, including 20 percent of each submission type. The next slide.

So for the tools, we used IRBNet Insight Reports to randomly select those submission packages. And this is where I would say the IRBNet Insight Reports provide a lot of information. So this is where we had to really drill down, and do some filtering, specifically to get to the agenda needs, and expedited items in order to make that selection of packages.

Then we created a Q&A checklist using an Excel spreadsheet. So this checklist covered all areas of review details. So all of those elements where information can be entered were listed in the QA checklist. And we plan to use that to verify any missing or incorrect data, and to also identify a percentage of compliance, and to report on the summary of findings.

We did test the QA checklist first before implementing. And we did a dry run of entering information, and that was really to ensure that the summary output, and the percentage of compliance was calculating, and running correctly. Next slide.

So IRBNet Insight Reports, I wanted to talk a little bit about how we were able to utilize this for our process. So specifically, we focused on the review process report. And as I had mentioned, they do provide a lot of data. So I, I do recommend if utilizing these reports, maybe considering developing a macro, or just become familiar with doing a number of filtering, and sorting in order to, to drill down, and to be able to get the data that you need in order to utilize that report.

But the report itself does provide a great snapshot of information. And it's an easy way to do a quick review and identify if there is any missing data points in the report, so that you could go back and, and verify against IRBNet. Next slide.

So here is a overview snapshot of the QA checklists that we have developed. So it's very tiny and I'm sure it's probably not easy to read. But I am going to go through it, and some of the next slides, we'll, we'll zoom in on some of the content. So what we developed was a, a smart checklist template in Excel. And it covers each of the sections that data gets entered into review details.

And then it's also organized by submission type. So in that top section, it covers just general requirements. Then as you go down the spreadsheet, it covers each different type of submissions, so amendment, closures, reportable events, et cetera.

When the person is doing the QA, I would like to note that it's important that they do have a general understanding of the internal workflows, and understand what review details need to be entered for specific types of submissions. The next slide.

So here is a closer look at some of the data entered into the, the checklist. So as you go through and compare those against the package in IRBNet, you can select a 'yes,' or a 'no,' and I will color code in green or red or gray for not applicable. And then across the line it'll total all the yeses, no’s, not applicable, and then give a percentage of compliance. Next slide.

So, here's a closer look. This is specific to the top part of the checklist that focuses on submission details. So as I had mentioned, we are looking at review details. But since we were in the package at the same time, we included three additional elements, and that was just to take a look whether or not packages were appropriately tagged? The letter was created and published, and therefore documents were published? Next slide.

And here's a closer look at the review details from the checklist. And again, here you can see the yeses and the nos. for this example the, the package on the second column had a 'no' entered for initial approval date. And that's something that would be required, if it were a new project that was approved. Next slide.

And this is what that would look like. If you were looking at review details while making that no selection, you would identify that initial approval date was blank. And you can make that 'no' selection on the checklist. Next slide.

So for the evaluation, so after we completed our QA for that quarter, we took a look back at the percentage of compliance. So during our first run, we we chose these numbers to start out with; which green 100 percent, everything is great. Yellow 76 to 99 percent would mean that there is still some issues occurring. And that we need to continue training and education. And then anything that came up red or below, 75 percent; that's something we would focus on for the next round of QA, and definitely include specific training, and education on those items.

So with our QA checklist, it was great that we had built-in formulas to summarize those findings. And then it was also very helpful to be able to take those findings and generate them into, like, a graph or a chart. At the end of each quarter we did take those findings in aggregate and share them with the staff, and work with administrators to develop any corrective actions that needed to be taken in order to correct issues of missing data, for instance.

As mentioned, we continue to do training and education, continued to create, and develop new internal workflows that we've shared with staff. And we compared results over each quarter. So over time we started with that percentage of compliance. But as we compare results over each quarter, and we're noticing definite improvements, we would change those numbers.

So we would go from 100 percent at green. And then from yellow, change that to 90 to 99 percent. And then anything 89 percent and lower would be red. So we were able to see some source of improvement and adjust as we went. Next slide.

So here is a, a snapshot of a summary of findings. So this would be a separate tab on the Excel spreadsheet and that checklist. And it would compile the findings across all reviews done for that quarter. The next slide.

And here's a closer look at that. So this is the percentage of compliance for that top section where we would be looking at submission details, providing us with some confidence that those tests are being completed accurately. And then the next slide.

This is a sample of the review details. And this is where we would be able to see those percentage of compliance and, and be able to identify where – were those issues still occurring? Or what do we really need to ramp up our training on? So for this illustrative example we could see initial approval dates are being answered accurately at 67 percent. So that would definitely be an area we would focus on. The next slide.

And as mentioned, having that information summarized in the Excel spreadsheet just allows an opportunity to be able to present that data into to various graphs and in charts. And this is the type of data that we would share with, with staff after completion of that QA for that quarter. Next slide.

So the outcomes of QA, really, we, we did see a reduction in inconsistencies and errors in IRBNet. We started with a focus on review details and expanded to other areas. It was an opportunity, excuse me, to really create a beneficial use of IRBNet Insight Reports. And we standardized a lot of processes and created internal workflows that supported the measurement of the staff performance \_\_\_\_\_ [00:27:17 to 00:27:20].

It became a mechanism to evaluate the performance of the IRB. And it fostered a system of accountability within the team. And lastly, it did create a sense of confidence in our data to support metrics and reporting specifically in our VAIRRS dashboards. The next slide.

All right. And that is the overview of how the Central IRB created a QA process of our operations within IRBNet. So we can open it up to questions. Thank you.

Parker Cunneen: Fantastic, thank you. And just to our audience here, I want to remind everyone. Your, your Q&A box is going to be in the right-hand portion of your screen. Feel free to add any questions you may have; we're going to try to keep them on topic today. Not IRB questions, generally, and make sure they are addressed to all panelists.

Jessica Kroll: Okay so the first question, what is the difference between QA, and QI, and between operational review versus regulatory review? So, well, what we are doing is we are ensuring that the way information is being entered in the system is being entered correctly. So that is an operational review.

Regulatory review would be what I would consider maybe going in, and looking at the category that a project was expedited under, and verifying whether or not that was the appropriate category for that project to be approved on there. So there is no regulatory component, it's strictly operational in terms of we created a workflow, and steps for information to be entered into the system. And we're making sure that that information is being entered according to those, to those steps, and to those workflows. The next question.

Who in your group performs the quality assurance review? Is it a member of the Central IRB? No. It's a staff member, and it's someone who is fully trained on our workflows according to our staff. So it's, it's definitely not a Central IRB member. They have an understanding from conducting reviews, but they don't have the same understanding as it relates to a staff member processing, processing a submission that they reviewed. The next question.

Who is responsible for QA Qi? Did you hire more staff for this or a panel manager? So we're, it's one of our existing staff. We did not hire more staff for this process. And we could share more information following this meeting, if you have questions on, on how much time it takes or how much effort is needed to conduct this.

I think it’s; it can vary based on your needs, but it's not a full-time position. It's definitely something that can be done throughout time, a couple of hours a week, maybe. Let's see. I don't know if you want to jump on it and talk about that piece?

Parker Cunneen: And Lindsey, if you're speaking, you, you may be muted right now.

Lindsey Martin: Can you hear me now?

Parker Cunneen: Yep.

Lindsey: Okay, in terms of the time required for the QA, I think it's just, get the time implementing the checklist, and just coming up with our process to do the QA was a little time consuming. But in terms of reviewing the 20 percent of expedited actions per meeting, it just depends on the level or the workflow for that meeting.

Jessica Kroll: Thanks, Lindsey, next question. Is the low number per risk level assigned compliance maybe because of exemptions, and the lack of risk level appropriate for them in the system? No, we actually account for exempt projects. So our process, if the project is exempt we do not assign a risk level. And that is explained in our workflows.

So following our workflows, we would know to not evaluate, or to check 'no,' if it was an exempt project that didn't have a risk level. So that's, that, it was a completely separate issue, not related to exempt. The next question.

Why is approved with conditions even an option to use, but every directive says different? Is Mods required appropriate term? And I would say that's, that's up to you, and your facility, and the local processor as defined by your SOPs. We followed our definition in our SOPs, and we defined it in that way.

But I think that's one of the, the issues we came across with entering information in Review Details, is there's a lot of different interpretation of terms. So that's why it's really important for you at your facility to define these terms as you would like to utilize them, and make sure that something that's understood by all staff and general members.

Don Workman: Jessica, this is Don, if I could just add a comment? There are different terms that are used. We talk, IRBNet has approved with conditions. And many of the IRBs will use a term like approval pending minor modifications. So it's a, a relatively common category to use, it doesn't mean that the project is actually approved to start. It means that there are some minor changes that need to come back for expedited review of it.

Jessica Kroll: Thanks Don. The next question. Parker, are there any more questions?

Parker Cunneen: It looks like there are a few. And I think, Kristina here is just sorting through them, and we'll have them up in a moment.

Jessica Kroll: Okay, great, thank you. While those questions are being sorted out, I'll just make an announcement now, too, that at the Central IRB, we're happy to share any, and all of our internal workflows that we've developed along with our QA tool. So please feel free to reach out to Lindsey or myself following this, and we'll be happy to share those resources with you.

Parker Cunneen: And Jessica, it, it looks like there's no more questions on this particular topic. So so that may be the end of the, the ones for this webinar.

Jessica Kroll: Okay. Great. As I had mentioned, Lindsey and my contact information is on the last slide of this deck. So please feel free to reach out to us if you have any specific questions, or would like for a slip like for us to share our materials with you, we would be happy to do so. So thank you.

Parker Cunneen: Fantastic. Well, thank you for the presentation. And thank you for the audience for tuning in. There you can see the information for our IRB administrators. So if there were probably any questions that were unanswered, they're likely the folks to reach out to, if it was an off topic question.

But, but we thank everyone for being here, and for our audience, please do take a moment to fill out that post-webinar survey. We, we do look at it every time and we just share it with our panelist to improve these webinars. So that'll pop up on your screen. And thank you for taking the time. And everyone, please have a great afternoon.

[END OF TAPE]