Megan: Next slide, please. Next slide. Thanks, Parker. Good afternoon, everyone. We’re going to start off with a few important updates. If you have not already checked your site’s IRB information sheet wizard completion rate, please do so, as there are currently more than twenty sites with the completion rate of 50% or less.

As a reminder, all human research projects must complete the IRB information sheet wizard and projects under the oversight of an affiliate or external IRB are also expected to complete this wizard. Please continue to work with your investigator community to ensure awareness of the IRB information sheet requirement, and we do thank you for your efforts so far.

Next, the VA Central IRB is currently updating all submission forms. The new submission forms will provide improved instructions, better usability, and have also eliminated redundant questions in order to provide a more efficient experience for the research team.

In addition, the VA CIRB is making minor changes to some of its processes, as well as the respective forms. The new VA CIRB submission forms and process changes will be released in two scheduled phases in June so, please do keep an eye out for future updates and webinars. The first webinar will be held on June 13th and you can sign up for that on the VAIRRS web page and that is included on the reference slide.

Finally, the VSAC recently met to review current personnel tracking processes. The VSAC determined personnel tracking should occur separately from the project coversheet tracking, and this will provide a more efficient means of updating study personnel and associated training requirements. The VAIRRS team is currently working on a draft personnel tracking form. Further updates will be provided as development progresses. If you have not already, please do subscribe to our VAIRRS newsletter so you can keep up with important announcements and program updates, and that link is included below.

And with that, I will turn this over to Angie to begin the presentation. Next slide, please?

Angela Foster: Thank you, Megan. Good afternoon, everyone. Thank you for joining us for our monthly webinar series. Today, we’ll be talking about data available. This is a part of our Data Integrity Series. This is a presentation that was given to the chairs at the national meeting, as well as the AOs at their national meeting. We thought it would be useful to present it to the great community so that we could all have the same information.

I will be starting off the presentation today and then, I’ll be turning it over to Alex Devine, who is on our Dashboard team. And Alex will be giving you a live walkthrough of the dashboard.

A special thank you to the Dashboard team, as well as our Comms team on putting together the presentation for today. Next slide, please.

A quick review of our objectives; we’ll talk about the various platforms where you can access your data, as well as how to access the dashboards. We’ll talk briefly about how the dashboards were developed and then, go into the live demonstration of the dashboards. Next slide, please.

Our data platforms; the use of IRBNet generates a very rich data set of your committee and project activity. However, as with any system, the output is only as good as the input. A large portion of the VAIRRS data set is dependent on your researchers, the administrators, as well as your members, completing their tasks in IRBNet.

ORD’s big push for the completion of the PCS and IRB information sheet is grounded in the need for an enterprise-level view of the research conducted across the country. Prior to the implementation of IRBNet, we did not have that visibility.

The VAIRRS team is called upon to answer questions related to ORD’s research activity and operational issues. We can receive very basic questions such as; where is AI research being conducted? Or we can get more complex questions like the average number of amendments that are reviewed by VA IRBs in a one-year period.

Our ability to respond to this information without burdening you with a day to call and providing accurate data is, again, dependent on that data being input into the system.

Once that data is input, the ways that you can access are from two mechanisms. One is the IRBNet Insight Reports and the second is through the VAIRRS Dashboards. Now, the IRBNet reports are provided directly from IRBNet and the dashboards are developed and maintained by our own VAIRRS Dashboard team. Next slide, please.

The IRBNet Insight Reports are canned reports that are sent by request via email. The reports are provided in .csv format, which has no formatting, and the .csv files are viewable in Microsoft Excel, or they can be imported into Microsoft Access, if you’re more familiar, or even to the server.

Prior to deploying the VAIRRS dashboards, we did create a few macros that you may find helpful with formatting the Insight Reports. As I said, once you receive it in their raw form, there is no formatting, but the macros that we published that are in VAIRRS University would help you format those to make them easier to digest.

If you would like to receive an IRBNet Insight Report, your local IRBNet point of contact or your power user can request import directly from IRBNet. All they need to do is send an email over to the IRBNet support email account requesting a specific report. Next slide, please.

Now, as I said, the reports are canned. We do have a menu of which reports are available to you. You can find a copy of the menu or the IRBNet Insight Reporting Guide, which is the formal title, on the VAIRRS University.

A few of the available reports are the Review Process Report, a report of your reviewer activity, of course, all your active projects, and you can even get a report that details all of your packages that are pending review. Again, this is just a subset of the available reports. Once you review the guide – well, you can browse through the guide and see all of the canned reports that are available. I encourage you to go out to the VAIRRS University and view in the IRBNet Energizers folder the document title, IRBNet Insight Reporting. There, you will see a full listing, description, of all of the reports that are available. And these are the same reports that we use to develop the dashboards, to populate the dashboards so, you would essentially be getting the same data we see for your site. It would just be in raw format and not presented in the dashboard. Next slide, please.

Our second mechanism of viewing data is the VAIRRS Dashboards. The dashboards were developed to bridge the gap between the collection of the data and obtaining information from the data. And when we set out to build the dashboards, we put together focus groups of different roles; RCO role, administrators, AOs, ACOSs, to collect the requirements for the most useful metrics for that particular role. Again, the primary data source for the dashboards is the same IRBNet Insight Reports that would be delivered to you on your request.

We are constantly seeking feedback and ways to improve the dashboards. Recently, we added training records for all study personnel that are listed in the project coversheet. Again, that coversheet hasn’t been completed, we can’t provide that information to you. But we are over 80% completed for the project coversheet so, if that project has completed their coversheet, listed their study personnel, we’re able to present that data to you in the dashboard.

We’re also working on identifying your projects that are oversight of the Central IRB. I gave, again, this presentation at the IRB Chair Meeting, which prompted a discussion about committee performance and committee turnaround time. That discussion has now led to our Dashboard team and our stakeholder from the Tampa VA to work on a prototype of a committee turnaround time dashboard that would be incorporated in all of the field dashboard pages. That’s just an example of how we are incorporating feedback to improve the data and enhance the data that’s presented to you. Next slide, please.

So, the dashboards are the major mechanism used to provide the ORD research stakeholders with information about our research activity. Our consumers include, of course, ORD leadership, Secretary’s Office, Dr. Clancy, the office that governs the ERDSP reviews, the EHRM, ORO. Our newest stakeholder is Office of Nursing Services, which sought information on nurses conducting research.

So, you can see, just from the fourteen or so dashboards that are on this page, there’s so much interest in research activity. And the way that we can respond to that interest is, again, having a full accurate dataset in IRBNet that enables us to respond to these inquiries without burdening you with data calls. Next slide, please.

The dashboard pages and the metrics included in every facility’s dashboard include your active projects, your wizard completion rates, data on human and animal and safety projects. Again, your training records for study personnel listed in your wizards. And there are also pages in the dashboards for your closed and your expired projects.

The metrics that are on this slide, again, were collected from our focus groups. We tried to meet the need, as much as possible, with the data that we have. Again, we are always looking for ways to improve and refine. When we get to the end of the deck, you’ll see a link where you can go and provide feedback to us. If we can update the dashboards, improve the dashboards to better support your day-to-day activities, we are always anxious to do so. Next slide, please.

So, the next three or four slides are actually screenshots of the CRADO’s dashboard. And we chose to show you the CRADO’s dashboard so that you can see in the field what we see in ORD.

The second set of screenshots is the actual field dashboard, and that’s the dashboard that’s been designed for every site on IRBNet. You can request access to your site’s data. When we switch over in a few minutes, Alex is going to give you a live demonstration of these dashboards and he’s going to present to you the CRADO’s dashboard, as well as the national view of the field dashboard.

So, with that, I’ll turn it over to Alex. And Alex, if you can please provide the demonstration.

Alex Devine: Yes. Thank you very much, Angie. My name is Alex Devine and I am a member of a team of contractors at the Titan Alpha Group that helps \_\_\_\_\_ [00:14:06] with development and publishing various dashboards. Let me try to share my screen now. As Angie mentioned – I hope you can see my screen now. We figured that it’s better to arrange for a live walkthrough with these dashboards rather than showing the screenshots only. So, let me start with the CRADO dashboard, which was developed primarily for the use by the ORD leadership and \_\_\_\_\_ [00:14:37].

As you see there, what looks like a webpage, a directive webpage – for the purpose of this presentation, let me enlarge my screen and go to the presentation mode. Here, this is the first page of this product and you can use this menu at the bottom to go to the page that you are particularly interested in. This first page provides general information what this deck, what it’s about, what information it contains, and how it can be used.

Just a word of caution. I’ll be seeing this CRADO dashboard and the next dashboard I’ll be showing to you in the admin mode. So, your screens may look a bit different when you get access to these dashboards.

As I mentioned, there are a number of navigation tools in this product and if we go to the next page here, you will see the VISN summary page. You see that it contains very general – so, this confirmation here at the top of the screen. It has a number of active projects and active packages at ORD-level sponsors, institute locations. This table here in the middle of the screen it contains \_\_\_\_\_ [00:16:00] for particular locations. Most importantly here, this table at the bottom contains the list of the projects, research projects, information of which you may receive from VAIRRS.

As for the navigation, we’ve got this search tool here. If you have some particular project within cancer or angiogenesis, you can put this word in here, click Search, and the dashboard will filter only those projects for you. If you have – for instance, these blue boxes here, we call them “filters.” If you’re interested only in the projects in particular VISNs – let’s say VISN 6 or VISN 5 or both of them – you will see that there’s information there about changes once you filter the dashboard using this filter tool. A word of wisdom; please, when you leave this page, don’t forget to click the Clear All Filters button to make sure that other pages that you’ll visit are not affected by your choice of filters here.

So, if you go into the next page, it has information about the project coversheets that we received from you. Similarly, the next page has information about the IRB Info Sheets that we received from all those sites. Let me just reiterate that our dashboards are as good as the information that we got from you, the information that we got through IRB Info Sheets and Project Completion sheets.

When you go to the Active Projects Map, it contains information about the research projects but it’s structured geographically. If you want to see the picture in the particular location, you can move the cursor to the particular location and you will see the data that pertains to this location currently.

Going to the next page, ORD projects here; this page contains, in addition to the various data, it contains some financial data from RAFT. Here, the projects are sorted by the funding source and IRB risk level. Again, this page is primarily designed for the ORD management.

All Projects page, it just contains the full list of active projects that are included in this database without the extra tools. So, if you want to work with this table only with the complete information with this table, it’s on the last page.

So, let me move onto the Field Staff Reporting Dashboard. This is what was developed to show the most granular level of information related to such projects. Though it has some general information that was designed for the CRADO report, you will see that this dashboard is actually a more detailed one.

We’ve got a standardized form and design for all the dashboards that we developed. You can see that on the crawlers, the boxes, they are all standard. We have got a couple of pages from CRADO dashboard included into this field dashboard report like PCS calculations, IRB Info Sheet Completion. So, when you get access to this dashboard, you will have information that is related to your location only. I see that as a \_\_\_\_\_ [00:19:48] for all the locations at the VA that may increase [inaudible] \_\_\_\_\_ [00:19:54] time.

So, next page will show some general statistics about the funding and risk levels of the ORD research projects.

And then, we go to the next page, which is called Active Project Detail Page. You will see the most comprehensive table of the research projects here. You will see that they’ve got about 20,000 projects. We’ve got, again, filters and a search box here to facilitate your search of the projects here again. Just one additional tool we shall call “drill-through function.” If you are interested in a particular project in here and you don’t want to scroll down the page and you want to see all the information about the projects on one page – about a particular project in one page – you can use the right click to go to this menu. It can just drill through, see project detail here, and it’ll see the detail, the full page that covers this project completely.

In this dashboard, you will see that they’ve got, also, particular bridges related – that covers human subject research, animal – animal research, safety research, review process, plus project detail, training.

And finally, the final page – we’ll call it “Dictionary” – if you’re not sure what information is really provided on this dashboard, you can go to the last page, which contains a detailed description of what information is included in the dashboard.

Let me just say a few final words, like final comments. So, let me stop sharing my screen, as well. So, if you’ve got any feedback on functionality or design of the dashboard; so, if you feel that a new dashboard should be developed, please get in touch with Angela Foster. We’ve got standardized request forms and we’ve got standardized processes for design and development and \_\_\_\_\_ [00:22:20] of the dashboards will be happy to be of help. \_\_\_\_\_ [00:22:23] will be provided.

Here, let me stop and ask back onto you, Angela.

Angela Foster: Thank you so much, Alex. We will move into the Q&A portion of the webinar now. And if we need to go back to the live demo, we can do so. But otherwise, I’ll just reference really quick; the last slide in the deck for today’s webinar has a full list of references, links that are available. There’s a link to go and request access to your dashboard. Of course, there’s links to all of the VAIRRS resources. But I just wanted to make note of that slide in case you wanted – if you did not have access already, you wanted to go out and request your access, you would do so by clicking on the Dashboard Request when you get to the first link on that slide.

With that, we can move into our Q&A.

Parker Cunneen: Angela, I apologize. I am having a technical difficulty here pulling it up on the screen so, I'm just going to real that aloud for you if that’s alright with your team.

Angela Foster: Okay.

Parker Cunneen: So, the first question is; I currently get the following alert when I access the dashboard; the shared report view isn’t available. We couldn’t load the sender’s customized view of the report because it expired. You’re viewing the reports into default view. When I click okay, I can see the report with the current data. Am I seeing a current dashboard or do I need to do something to see a customized view?

Angela Foster: It sounds like you’re viewing the current dashboard but I'm a little concerned about the error message that you’re getting. So, I’ll ask if Alex or Nana could reach out. Who is the submitter of that question?

Parker Cunneen: Suzanne Hough.

Angela Foster: Okay, great. Thank you, Suzanne. We’ll reach out to you directly to figure out what’s going on.

Parker Cunneen: And that’s our only question for the moment but I’ll remind everyone that the Q&A box should be in the bottom right-hand corner. If you have any questions, just address them to all panelists.

Angela Foster: And we have this time slot until 3:00 so, we have plenty of time to take more questions. And again, the IRBNet Insight Reports are available. Just talk to your local point of contact who can submit that request. The reports can be sent to you at any interval that you choose.

If you are seeking access to the dashboards, then, you would click the link that’s in the slide deck and you can enter that – enter your request directly to the Dashboard team. And any user can request access to the dashboards at your site. You don’t have to go through your IRBNet point of contact for that.

Parker Cunneen: And we have another question here. How do we know if our site submitted the IRB Info Sheet?

Angela Foster: You would be able to go to your dashboard to the IRB Information Sheet page on the dashboard and on that page, you can see every project that we are tracking that should have an IRB Information Sheet and whether or not that Information Sheet has been completed.

Parker Cunneen: Can you show how to use the macros you talked about for the Insight Reports?

Angela Foster: I can’t show it live. I don’t have anything queued up right now to actually go through the process. But on the University, the webinar where we presented the macros is stored. So, you can review that webinar. We went through the process. We did a live demonstration of how to install the macros locally so, all of that information is out there on the VAIRRS University site.

Parker Cunneen: I like the search option in the site dashboard. However, we can have an issue of key terms not being entered in the IIS as it is not a mandatory field. So, it makes the search less robust. Can the key terms field become mandatory?

Angela Foster: That’s a great suggestion. Whomever submitted that comment, I would ask if you could also email us at VAIRRS@VA.gov. But yes, that is something that we could work on. We can present that to the CCB for their review.

Parker Cunneen: And our next one is; how do you find your local IRBNet point of contact?

Angela Foster: It should be an administrator in the Research Office. If you don’t know who that person is, you can email us at VAIRRS@VA and we’ll do some digging and find out who your local point of contact is.

Parker Cunneen: That’s what we have so far. Give folks a couple seconds, a couple minutes, to see if they want to ask any more questions.

Here’s another one. It’s unrelated to this webinar but; this morning, a study coordinator told me that the Advarra IRB has instructed them to review their ICFs to be on a VA ICF template. Is that accurate?

Angela Foster: I apologize; I have no insight into that and I can’t answer that question. You can reach out to the ORD Regulatory bots if you need information on the Advarra IRB. But we don’t have any insight into that.

We will continue to – I’ll wait to see if there are any more questions. It looks like folks are dropping off, Parker, but I’ll continue to wait to see if anything else comes through.

And while we’re waiting, on the VAIRRS SharePoint site, there is a page dedicated to the dashboards. On that page, you will find that same link to request access. There’s also a link for you to provide feedback if you have any suggestions. Or if you run into an issue with your dashboard or the way your data is presented, please don’t hesitate to reach out to us. Again, that feedback is vital for the dashboards to be useful.

Parker Cunneen: And we have another question. How can we remove submissions that appear on our dashboard when the submission was intended to be a new package; i.e., CR, versus a new project? It pulls down our PCS completion rate.

Angela Foster: That’s a great comment or question. If you find that there’s a project showing on your dashboard that should not be there, the first thing that you should look at is the project status in IRBNet. For most of the pages on the dashboard, we are pulling projects that have an active project status at your RNDC or a subcommittee.

So, we find that sometimes projects are closed out at the RNDC but left active in the subcommittee’s workspace. And in those cases, there’s a conflict with the information that we’re providing.

I would first ask that you review the project status at each workspace that’s tracking that project to ensure the project is closed out thoroughly, and that should prevent a project from showing on your dashboard.

Parker Cunneen: The next question is; at the beginning of the webinar, a new study staff document was mentioned. When will this be available for use?

Angela Foster: We’re trying to have the new mechanism for tracking personnel available this summer and we’re really trying to get it out by the beginning of July. We do have to go through the development process; you know, document the questions, the logic behind the questions, and then, send it over to IRBNet to have it actually input into the system.

That will take us a few weeks. Again, my goal is to have it published by the beginning of July. You will receive emails, you’ll see updates in the newsletter, or a program update, and we will schedule webinars – at least two – to introduce the new tracking mechanism before it goes live.

Parker Cunneen: Who all can get access to all reports to access different studies other than your own site’s studies?

Angela Foster: Only those that are in Central Office. If you’re at a field site, you can only see the data for your site.

Parker Cunneen: Any update on when TMS training will be available to, link such as city is?

Angela Foster: Unfortunately, I don’t have an update right now. We are still working on the integration. It’s really unfortunate that it’s taken so long, and the holdup has been purely administrative; it’s nothing technical. But we are still working on that and I apologize. I can’t give you a hard date. But I’d rather not give an estimate that will just be another delay.

Parker Cunneen: Still having a problem with changing PIs when the main PI leaves the station. Is there a way to allow the committee coordinators to change the PI when they leave without notice?

Angela Foster: What happens when – I mean, if there’s no – someone has to be the lead for that project. If the old PI has left without notice and there’s a new individual that’s the lead for that project, you can work with IRBNet Support to have them transfer ownership of the project to the new individual in the absence of the old PI transferring the project from their account.

I mean, situations like this are very – we handle them on a case-by-case basis. So, I would say email IRBNet Support or you can email us at VAIRRS@VA.gov and we’ll work with you to have it resolved.

But it is, I understand, difficult when the original PI is no longer in the system or no longer active and it makes it very difficult. We will work with you to resolve that issue.

Parker Cunneen: That’s all I'm seeing for the moment.

Angela Foster: Okay. And again, we will remain for another few minutes to see if there are any last-minute questions.

Parker Cunneen: Here’s another one. How will a review committee know when a PI completes their conflict of interest within the new add-on?

Angela Foster: There is a project team tracking section in the Submission Manager. When you select that project team tracking option, it will show you – once your site has elected to use the COI module – it will show you whether or not the PI has submitted for COI and it’s pending review, whether it’s submitted and it’s completed review, or whether it’s – and there’s no COI or whether they have submitted in there is a COI. There’s a green indicator, yellow indicator, red indicator. But you won’t see that if your site has not elected to use the module.

Alright, and we’ll give it one more minute, see if anything else comes through.

Alright, Parker, I think we have all of our questions for today.

Parker Cunneen: Perfect. Well, I want to thank the presenters for this great demonstration and answering the questions, and thank our attendees for joining us. A quick reminder to fill out that post-webinar survey. If anything comes to mind, you can ask a question there or just give general feedback.

So, thank you, everybody, and have a great afternoon.

Angela Foster: Thank you.