Megan: Afternoon, everyone. Just a couple of important announcements before we get started.

If you haven’t recently checked your site’s Therapy Information Sheet Wizard complete rate, please do so. As of now, we have reached a 68% completion rate.

As a reminder, all Human Research projects must complete the I R B Information Sheet Wizard and projects under the oversite of an affiliate or external I R B are also expected to complete this wizard. Please continue to work with your investigator community to ensure awareness of the I R B Information Sheet requirement.

Next, during the May/June Change Control Board Meeting, the following seven forms were updated or added to the ORPP&E Standard Form Library on I R B Net and on SharePoint. We’ve included those below for reference.

Next, VAIRRS University has added a new spotlight feature to highlight the latest program updates. You’ll find the links to what’s new, as well as the latest VAIRRS webinar and newsletters all in one place. Of course, if you would like to learn more about VAIRRS University, the recording of the VAIRRS University Walkthrough Webinar is available on our website.

Last, if you would like to keep up with important announcements and program updates, we do ask that you subscribe to our VAIRRS monthly newsletter and we’ve provided that link for you below.

With that, I will hand it over to Angie to get into the webinar.

Angela Foster: Thanks, Megan. We can move forward to the next slide. I will be the primary presenter today. I’m Angela Foster, the Program Manager for VAIRRS.

Also joining me for our Q&A panel is Mr. Tony Laracuente, the Director of Field Operations, Christina Bennett from Cleveland, Jessica Kroll from the Central I R B and Jennifer Ordman from Hines. Christina, Jessica and Jennifer also represent the VAIRRS Change Control Board. Next slide please.

Good afternoon, again, everyone, and thank you for joining us today. What we’re going to talk about is our new and updated wizards. VAIRRS will publish three new wizards in the fall.

The Investigator Tracking Wizard will capture information previously submitted through ePROMISE. The Study Team Tracking Wizard will capture, of course, your study teams, and the COI reporting, and EHR access questions, as well as a delegation of duties question.

The Office of Research Reviews is planning to deploy an ERDSP wizard in the coming months. This ERDSP wizard will replace the current PDF version and there will be more information coming out from the Office of Research Reviews when that wizard is deployed. Next slide please.

As far as what has changed, the Project Cover Sheet has been revised to remove the personal tracking. We do have a number of changes to the I R B Information Sheet to improve logic flow and to clarify the language that’s presented to the end users. Next slide please.

Why are we publishing new wizards? Well, our goal is to improve efficiency for the users completing the wizard while also collecting the data needed for the committee to review the project and at the same time, provide ORD with the data needed to support enterprise level reporting.

Our goal, again, is to not increase burden, but to reduce burden and increase efficiency. Next slide please.

Let’s talk about the new wizards in more detail. The Investigator Tracking Wizard is for investigators only—as its named—and this includes principal investigators, co-PIs, co-investigators.

There are components in this wizard that must be updated annually. We expect to deploy the wizard in September 2023. Prior to deploying and throughout the fall, we will hold specific webinars for the wizard and we’ll hold office hours to address any questions that the users may have in completion of those wizards.

Again, we’ll hold these office hours and webinars throughout the fall, so that if your investigators need help they can come to us and not burden you with their questions. We are trying to minimize the burden to those local research office staff as much as possible by providing these additional resources.

The wizard itself is fairly short. There are a total of four logic-based questions. The wizard is not associated with a project, so we will have special instructions to create a new package or new project in I R B Net specifically for your annual updates.

We’re still working out the details. But like I said, we’ll have more information to come. In future webinars, we’ll walk you through. We’ll have a component accompanying handout that you can refer to, so that everyone will have the information that they need on-hand to go through and complete their wizards. Again, the Investigator Tracking Wizard is not associated with a specific project.

In the next slide, you’ll see there is an icon that you can double click. Next slide please.

That will open the Investigator Wizard Outline. What this is, it’s just a Word document to supplement the actual interface in the I R B Net platform.

You can see all of the questions, all of the response options, as well as the logic that’s laid out for you. I’ll briefly walk through the outline and I just ask that when you’re in, you open it up, so you can view it on your computer.

Page One is completed by all investigators. It’s collecting demographic information, as well as details about the VA appointment.

Page Two is just one question and it asks about their university appointment. The reason it’s just that one question on this page is to direct the logic for the subsequent pages.

If they use a response, but they do have a university appointment, on Page Three, they’ll be presented with more questions about that appointment.

The last page—which is Page Four—is taken directly from the Investigator Profile in ePROMISE. On that page, they respond to questions about their research interest and specialty.

At the end of Page Four, the wizard is completed and the investigator can submit it to your admin workspace for acknowledgement. Next slide please.

The Study Team Tracking Wizard—now this is for the study teams as it’s named. It’s for investigators and Study Team members. It’s all investigators that are required to submit for the financial conflict interest or report for outside compensation and Study Team members for which training which needs to be tracked should all be included in the Study Team tracking wizard.

Unlike the Investigator Tracking Wizard, the Study Team Tracking Wizard is associated with a project. Mr. Laracuente is on the panel today to address any questions related to the new yearly Outside Compensation Reporting requirement.

Outside of this webinar, you can expect that there will be more information coming from Mr. Laracuente’s office when that requirement is implemented. We expect to deploy this wizard in September 2023, the same time that the Investigator Wizard goes live.

Again, we’ll hold additional webinars throughout the fall to assist study teams with completing the wizard. We’ll also hold office hours, so users can drop in and have their questions answered.

Now this wizard has six logic-based questions. In the next slide, we’ll walk through that outline quickly as we did for the Investigators Wizard. Next slide please.

Again, if you could double-click the icon to open up the outline on your end and you can view as I go through and describe each of the pages. Page One of the wizard collects basic information for the Principle Investigator, as well as the COI and outside compensation questions.

Page Two is just one question and this is for the EHR access. Based on the user’s response to this question, they will be presented with other pages to collect more information.

If they respond no that this study does not require access to the EHR, then the EHR specific pages will be skipped and the user will not be presented with those questions.

That goes along with Page Three. If they respond yes, they’ll see Page Three. If they respond no to the EHR access, they will not see Page Three.

Starting on Page Four, those of you that are familiar with the PCS—the Project Cover Sheet—the Additional Personnel section? That’s what you will see on Page Four of the Study Team Tracking Wizard.

In addition to the questions that we already asked, we’ve added a question to collect their delegation of duties. That’s something new you’ll see in this release of the wizard.

Going on to Page Five, again, if the user responded earlier that they have or require EHR access, they will see Page Five for the additional personnel that they have entered. If they responded no, then they will not see this page.

Moving forward to Page Six, now this page collects the COI and Outside Compensation for CO-PIs or other investigators on the study. Again, if they responded to their role. When they respond to their role, if they selected that they are an investigator, they’ll see Page Six. If they selected they are another role on the Study Team—not an investigator, but another role—then they will not be presented with Page Six.

As you can see, it’s fairly simple. Six pages—two of which the users will not see based on their response to Page Two. Next slide please.

Again, the ERDSP Wizard will be published by the Office of Research Reviews. They will have more information in the coming months related to that wizard. We’ll also work with them to make sure VAIRRS University is updated with resources. If we can work together to present on any webinar, we will do that to make sure we reach a large audience. But you can expect more information to come in the coming months. Next slide please.

Let’s talk about the changes to the PCS and I R B Information Sheet. Next slide please.

For the Project Cover Sheet, the changes are fairly minimal. The primary changes are the removal of the Personal Tracking sections and the COI Disclosure Questions. Again, those have been moved into the other new wizards. There’s no need to collect that information in the Project Cover Sheet wizard.

Now the Project Cover Sheet wizard will be only collecting information on the project itself and not the personnel on the Study Team. Next slide please.

For the I R B Information Sheet, we do have a number of changes that we’v3e communicated over the summer. The changes to the I R B Information Sheet are available in the Sandbox environment.

If you are located in a Research office, you still have your Sandbox environment from our training days. You can go into the Sandbox using the Investigative role, and create an I R B Information Sheet, and see the difference between the prior version.

The most notable change is the Updated Logic Flow for local site investigators that are submitting to the Central I R B. For our next step, we will actually walk through the wizard in the Sandbox and I will act in the role of a local site investigator for an improved, multi-site study that is submitting to the central I R B. Next slide please.

While we switch over to our Sandbox, I am going to share my screen. If I can just get a thumbs up or a confirmation that you can see the screen?

Participant: Yep, we can see it.

Angela Foster: Great. I am going to login as an investigator. Sorry about that.

(Long pause)

I am logged in as an Investigator/Data Researcher. I am in the Sandbox environment. This is not a production environment. The VA Medical Center Institution for this particular environment is called “Local Bill VA Medical Center”.

I am an LSI on an approved study. Here, I’ll go to the Project Overview page. You can see here. Here’s the lead site. It’s approved already at the Sunnydale VA.

Here’s my LSI application here at the local bill VA Medical Center. Already started building my package as you can see. What I’m going to do now is go to the Designer page and here is the Information Sheet wizard that I’ve already started completing.

I’m going to open that up. Go back to the very beginning and here’s our Introduction page. Now as I stated earlier, I am walking through this as though I am a local site investigator submitting my initial application for review to the central I R B.

Our next question is, “Am I submitting to a non-VA I R B?” Response is “No”. “Is this a multi-site project?” “Yes”. “Are you at LSI submitting to the central I R B?” “Yes.”

What this does is invokes the LSI logic for the I R B Information Sheet. Now as an LSI, there are some questions that the PI answers that I don’t answer. I am not presented with those questions as I walk through the wizard.

The LSI specific questions I will see. I am just responding to these questions just to show you the different response options. But it’s again, you can see all of these options in the outline that’s referenced in the last slide of your slide deck.

Again, I’m just responding to the questions. Some are required, some are not. Those that are required, I’m entering in test information and scrolling through this page.

You’ll see that some of these questions are new. Here, again, we’re asked about our risk benefit, again, putting in some test information for the required questions. If anything does not apply, you can answer “N/A”.

We go to our International Research questions. Our Recruitment Strategy and I’ve just selected CPRS. Usual care, I’m going to respond no. Certificate of Confidentiality, again I responded no. That takes us to the end of the wizard and I’ll preview what we’ve just completed.

You should be able to see it. Let’s see. I may need to change my sharing settings. Just give me one minute.

(Long pause)

Here is the printout of the I R B Information Sheet that we just completed. Because this is an LSI submission, you see this checked here for “LSI Submission”. There is an N/A on the Risk Level Assessment by the PA because this is, of course, not the PIs wizard. This is the LSIs wizard. If you need to see what the PI submitted, you can—as an LSI—go to that PIs package and open a copy of their completed wizard.

But again, all of the information that I’ve entered is available. There is guidance text in the italics. It’s for the reviewer, to help them navigate through the wizard.

All of my response options are visible and all of the sections that were not presented to me were checked with this N/A box. That’s to show that they have not been presented to me as an LSI. That information was completed by the PI.

I’m just scrolling through quickly. There’s quite a few sections that we were not presented with either because we’re an LSI or because of how we responded to the logic-based questions.

Again, the LSI does have access to the PIs package. Just pull their completed wizard. We’ve reached the end of the Information Sheet. Based on our responses, there was no additional required documentation and that concludes the LSIs completion of their wizard.

I’ll stop sharing now. Megan, if you can pick back up?

(Long pause)

Now we’ve reached, I believe, the final slide in the deck. Here, you can link to all of the outlines that we’ve discussed. The links will take you to their SharePoint where we’re storing these wizard outlines. If you want to refer to them, I encourage you to do so.

Review the outlines—especially the new ones—to get familiar with them. If you have any questions or suggestions, we welcome those in our VAIRRS@VA.gov inbox.

We can also at this time, move to our Q&A to answer any questions. Thank you so much.

Participant: Don’t worry. We’re going to bring that up in just one second.

Angela Foster Thank you.

Participant: I just want to remind folks. I see there’s one question in the chat. Just remind folks to please put those in the Q&A box if they can.

Angela Foster: Our first question, “Will Investigator Tracking Wizard be tracked via the Trainings portal or will it be more similar to the COI module? How will oversite committees be able to verify annual update of the sheet if that is a requirement?”

What is required is the outside compensation question and we’re still working through the details about how that will be verified. But it will not be in a mechanism similar to the COI module. That’s a whole separate module in I R B Net that required a lot of work from the vendor as well as some contract modifications.

We’re not planning anything of that nature. It will more than likely be just an acknowledgement in your Admin workspace.

How we track that? We are still working through those details. Tony, if you’re on, did you have anything to add in response to that for outside compensation?

Tony Laracuente: No, not at this point. We’re still working through the issues and trying to figure out what’s the best approach. But we’ll definitely nail that down in the next month or so.

Angela Foster: Thank you. The idea is to get this information out in front of everyone as soon as possible--hence the webinar today—so that we can get all of your questions and feedback prior to our actual deployment. Next question?

“Suggestion—can you make some wizard questions as requiring an answer? For example, in the current wizard, people do not always fill-in primary staff location. This is useful to know to ask questions if they are at an unexpected location.”

That’s a great suggestion and we will certainly take that under advisement as we go through our last round of editing. Thank you.

“Will Study Team tracking delegation of duties negate the need for separate scope of practice form?”

This would be up to your local SOPs. If any of our CCB members have anything to add in relation to this question, please do so. But it would only negate the need if that is an acquirement in your SOPs.

I was, oh. I’m sorry.

Christina Bennett: As far as I’m aware, ORD doesn’t have a scope of practice requirement. That’s—like you said—a local policy issue. It would be up to your site to decide if the Delegation of Duty section of the study Staff Tracking Wizard would meet the same goal and provide the same information as your current scope of practice form.

Personally—at Cleveland VA—that information wouldn’t overlap with our Scope of Practice forms. We’ll continue to use the scope. But you can always reassess once you start using the wizard and see if there’s still value in collecting the scope.

Angela Foster: Thank you, Christina. “I was unable to follow along with the wizard handouts and I’m wondering if the Study Team Tracking COI section negates the My COI tool. We’ve established the new COI process at our facility and do not want to cause confusion.”

That’s a great comment/question and I encourage all of our sites to use the new COI module. But there are some sites that have elected not to use that module. We can’t remove the question until we get everyone on board using that module.

Tony Laracuente: Angie, can I add that just as a head’s up going forward when Director Tool .13 comes out you will be required to use the module. You might want to start planning on moving into that module sooner than later.

Angela Foster: Thank you, Tony.

(Long pause)

This is related to the I R B Information Sheet. “Since the risk level and review type have been eliminated for LSIs and they cannot indicate it’s seeking an exempt category, how would LSIs of studies seeking exemption from Central I R B complete the form.

Jessica, did you want to add to this question a response?

Jessica Kroll: Thanks, Angie. Yes, I can provide a response. The risk level and seeking of an exemption category or an expedited category, all of that is determined at the PI level and will be documented in the PI Information Sheet, discrimination letter, etc.

All of that information will be on file within I R B Net. When you submit the LSI application, we’ll already have that information that this is an exempt project and can process accordingly.

But I would like to note that when we are making an exempt determination or an expedited review, those are being done at the PI level. We’re not doing those determinations for each LSI project that is submitted. Thank you.

Angela Foster: Thanks, Jessica. Next question please.

(Long pause)

“Will we be able to clone the old version of the Project Information Sheet to the new version, so we don’t have to reenter everything?”

The Project Cover Sheet is not. Well, the new version of the Project Cover Sheet has sections removed. You will not be able to take data from the Project Cover Sheet to create your Investigator Tracking Wizard or your Study Team tracking wizard. Those will have to be created at the initial submission. The entire wizard will have to be completed.

Now going forward—once you do your initial wizard—you can clone for your annual updates. You don’t have to redo it every year. Next question please.

(Long pause)

“Does each PI and LSI on the study have to fill out an individual information sheet?” Yes. Each PI and LSI would need to complete an I R B Information sheet if that’s what you’re referencing with individual info sheet.

The investigators—the PI, the LSI—would also need to do an Investigator Tracking Wizard because they are investigators. Next slide please.

“How will local site committees get information needed by the local facility such as pregnant participants, more than minimal risk, etc. if those are defaulted to NA for LSIs?”

Jessica, did you want to give a response to this one?

Jessica Kroll: Sure, Angie, and in the same way, all of that information is being documented at the PI level. Thinking about LSI applications that come into the Central I R B is providing that site specific information. But that project level information is being documented as part of that PI application.

With the PI application, there’s many in the protocol. They’re completing the Information Sheet documenting risk level and all of the other project level information.

The LSIs have access to all of those documents and to everything that was approved in the PI project. That’s where they can reference and access that information.

I just would like to note too that some of these changes that we did make with the LSI Information Sheet was to reduce redundancy and to reduce duplication of information that was having to be copied from the PI Information Sheet and placed into the LSI Information Sheet which often resulted in inconsistencies of information./

Christina, did you want to add anything?

Christina Bennett: Yes, Jessica. Thanks so much. I just wanted to add my perspective as an R&D Committee Coordinator about how local site committees can access that information.

As Jessica mentioned, the changes to the I R B Information Sheet mirror the structure of the existing PI application Form 108 the Central I R B had been using previously and the LSI104 where the 108 PI application contains the majority of the information and the LSI application talks about anything that’s going to be different from the main site.

Even predating I R B Net, we’ve always had to refer to the PI materials to get the full picture of the project. The I R B Information Sheet’s just mirroring that. A lot of those details in the I R B Info Sheet before these changes were still only contained in the MDPI version of the I R B Info Sheet.

What my site does is we access the project—that’s the PISC project—through I R B Net. Essential I R B has this wonderful feature where all of the LSIs are linked to the PI site using the multi-site share function in I R B Net. This makes it very easy for LSIs to get access to those main site materials as researchers and put together applications. But it also makes it very easy for reviewers, board members and local committee administrators to access the information from the main site and the other side.

You can actually go in through I R B Net looking at your LSI project, going to the project overview, and then access the materials that have been published for the PISC project. If it’s easier for your reviewers and for you as a research office to not have to go through those steps to look directly at the PISC project, you can just require your researchers. Include a copy of the PISC project cover sheet in their local submission materials for the R&D review.

That would not go to the Central I R B as they don’t need to review that in their package, but whatever package your local research office is asking for. We usually ask for a copy of the protocol, the PISC approval letter are some things that are in I R B Net but may not be submitted as part of the Central I R B material. I hope that’s helpful.

Angela Foster: Thank you, Jessica and Christina. Next question please.

“Since the PI wizard is not study specific, how will the Admin Team access that wizard? Through the PI profile?”

The plan at this point is that the PI would create a new project, attach the wizard to that project and it would live as an administrative project in I R B Net. They could use that same project every year, create a new package, clone the previously completed wizard, update anything that needs to be updated and submit.

That is our plan at this point. If anything changes, of course, that will be communicated when we get closer to deployment. Next question please.

(Long pause)

“Have wizards become shareable?” The PI and LSIs on a multi-site can access each other’s completed wizards. That is the extent of the wizards being shareable, but they can do that now. That’s not a new feature. Next question please.

“Can the LSI clone a wizard from either the study chair site or another LSI to then modify any site-specific answers?”

Yes, the LSI can clone the PIs wizard and then update for the site-specific answers. Next question please.

“When you say, ‘The Investigator Tracking Wizard is not associated with a particular project’, does that mean it cannot be added to a submission package for a particular project like the Project Cover Sheet, I R B Information Sheet can be?”

This is a great question. The idea is that the Investigator Tracking Wizard will live in that administrative project that I just talked about. If there’s a need that the wizard itself can be downloaded and attached to anything, it will be downloaded as a PDF and can be attached to any other project in I R B Net if that’s what your local procedures require.

However, the tracking wizard itself will live in its own project and be submitted to your local research administration that way. Next question.

“Will there be VAIRRS reports to download cumulative information such as information about all investigators?”

We are planning to leverage the dashboards to convey the information that’s provided in these new wizards. Just like now where we pull information from the PCS or the I R B Information Sheet and then report it on the local field dashboards. We will continue to do that with these new wizards.

If you have suggestions about how you would like that data presented, please submit those suggestions to VAIRRS@VA.gov. Next question please.

“What is the expectation for completing the updated wizards?” That expectation has not been set yet. We do know at this point that for the Investigator Wizard, all investigators will need to complete that wizard.

We have not set a deadline yet or had any expectations to communicate at this point. That information will be conveyed when we have our wizard-specific webinars.

For the Study Team Tracking Wizard, again, you won’t be able to pull information from that was previously submitted with the PCS to complete the Study Team Tracking Wizard. We’re thinking very carefully about how we deploy and what the requirement will be.

We don’t—again—want to introduce additional burden. We’re trying to think of the path of least resistance and what will be easiest for the investigators and study teams. Next question please.

“How is this going to work if the ERDSP is a wizard? Specifically, will people only be able to do it on VAIRRS or will they still have access to the PDF?”

That will have to come from the Office of Research Reviews and what their requirement will be for investigators completing the ERDSP as well as ISSOs reviewing the ERDSP. I don’t know what they will expect yet. There may be a requirement for everyone to use the wizard. It’s certainly my hope that all of the sites will use the new wizard that’s deployed.

But as far as requirements, that’s going to come from the Office of Research Reviews. Next question please.

“Will ISSOs receive instructions from OINT for how to transition to the ERDSP review in I R B Net?”

Yes. We are working with the Office of Research Reviews. Again, we’ll have webinars specifically for ERDSP and I am confident that the Office of Research Reviews will have resources also to assist in the completion and review of the ERDSP. Next question please.

“What is the difference between the COI module questions and the COI questions in the Study Team Tracking Wizard? Are they duplicative?”

No. The COI questions in the wizard are simply asking whether or not the COI submission has been completed. The COI module itself allows you to complete the Alt450 wizard, submit that wizard directly to your COI administrator and if the COI administrator has a need, they can submit it to OTC for review.

That’s the difference. The wizard itself only asks whether or not COI has been completed while the module allows you to actually submit for COI disclosures and to review those COI disclosures. Next question please.

“For the Staff Wizard, where does the Cooperative Studies Program fall and what are the expectations for what is reportable to the CI R B?”

Jessica, I’ll ask if you could respond to this or if you need more information, we can certainly ask this individual to put more information in the Q&A box.

Jessica Kroll: Thanks, Angie. There’s still some things to think through and to develop on how the Central I R B is going to utilize these new staff wizards.

Once we get to the point of those future webinars, we’ll be able to provide more guidance and instruction.

Angela Foster: Thank you, Jessica. Again, like I said, we’re trying to get this information out to you guys as early as possible. That has resulted we don’t have answers to all of the questions, but we will take these questions under advisement when we’re producing our final resources to assist with completing the new wizards. Next question please.

“Who are all these wizards for? They don’t appear to be useful for local staff. Are they intended for ORD to pull data centrally?”

They are first intended to supplement the review of the project. Secondly, they are intended for enterprise level reporting within ORD. Next question please.

“When is myCOI going to be mandatory?” Tony? If you can give us any more information about when the directive is coming out?

Tony Laracuente: Yes, so thanks. Right now, we’re in a process of going through concurrent of the VHA directive 1200.13. Once that comes out, then there’ll be a period of implementation. We’re hoping that that directive will come out in the next six months or so. It just finished pre-concurrence and we’re responding to the questions as part of pre-concurrence. Thank you.

Angela Foster: (Long pause)

Thanks, Tony. Next question please?

“It’s not clear when these forms will need to be updated. Will there be an SOP ‘How-to’ for when certain forms need to be updated? For example, what wizard, sheets, etc. need to be updated for an amendment for LSI and/or PI amendments?”

To answer the question, yes. There will be an SOP. There will be a supplemental handout that the investigators and study teams can reference to. There will be webinars and office hours, so that we here in Central Office can answer any questions that the investigators’ study teams may have. Next question please.

“In the LSI application for expedited determination category, it’s not captured in the LSI determination level. This makes it difficult to communicate to the local facility R&DC. What category does Central I R B determine for the project? This is hard to track locally.”

This is not a question, more of a comment. But Jessica, if you have any response for this?

Jessica Kroll: Thanks, Angie. Yes, I feel it’s very similar to the response that Chris and I provided to an earlier question in that the benefit teased in I R B Net is that all of these determinations and the documentation is available through the PI project.

All the LSIs and the local facility have access to that documentation through the PI Project in I R B Net.

Angela Foster: Thank you. “It was told to me that no wizards are to be updated and submitted at the time of continuing review. Doing these annually at the time of continuing review would ensure they’re being reviewed and updated annually.”

Thank you. That’s more of a comment more than a question, but if any of our panelists want to respond?

We can move forward to the next question.

(Long pause)

“The plan is to have 163 new admin projects for our site—one for each unique PI. Will this data no longer be tracked and maintained in ePROMISE?”

That is correct. The data that’s collected in ePROMISE now would be collected in I R B Net going forward. You don’t have to go and do both submissions—one in I R B Net and one in ePROMISE. The investigator will only be submitting their investigator profile or Investigator Tracking Wizard in I R B Net. Next question please.

“Will the Investigator Tracking Wizard replace setting up Investigator profiles in ePROMISE or will research staff need to use this wizard to create new Investigator profiles?”

Tony, do you want to comment on ePROMISE?

Tony Laracuente: Sure. We still will need the Investigator profiles in ePROMISE and the reason for that is because it ties into RAD as well as sending money to new stations.

The wizard will be for the new profiles. Angie, did you say they’re going to be transferred over to ePROMISE? Is that correct?

Angela Foster: No, I did not.

Tony Laracuente: Sorry.

Angela Foster: I did not say that.

Tonay Laracuente: Sorry.

(Laughter)

(Crosstalk)

--there for a second. Sorry. Yes, we’ll still need the Investigator profiles in ePROMISE. What you’ll notice is we’re limiting the amount of data that’s going into ePROMISE.

Angela Foster: Next question please?

(Long pause)

“Clarification of an Investigator Tracking Wizard. What if an investigator has two very different projects with one set of personnel on one project and another set of personnel on another? Is everyone still listed on one Investigator Tracking Wizard?”

There’s an important distinction here. The Investigator Tracking Wizard is only for the investigator and it is not project-specific.

The Study Team Tracking Wizard is specific to the project. In this instance, the investigator would complete one Investigator Tracking Wizard and then they would complete a Study Team Tracking Wizard for each of the projects. Next question please.

“Can the investigators share their Investigator Wizard with their Coordinator Support Staff for annual updating?”

Just as you can share your project with individuals on the Study Team, you will have that same ability going forward even if it’s just an administrative project for your Investigator Wizard. You would be able to share that with another I R B Net user to assist with completing that wizard. Next question please.

“If we already have an approved ERDSP, will we need to complete the ERDSP wizard or will we be grandfathered in?”

I don’t want to speak for the Office of Research Reviews on this. But I don’t think that you would need to complete another ERDSP for an already approved project. I don’t think you will need to go back and retroactively do another ERDSP. It would only be for amendments or new projects going forward. Next question please.

“Are plans being made for a Privacy Wizard?” Great question! Yes, we are in the planning stages for a new Privacy Wizard. We are working with Privacy to get that outline built and then get the wizard built in I R B Net.

As we make progress with this, you can anticipate more information to be released in our newsletter and we will also have webinars to convey information about the Privacy Wizard. Next question please.

“With this new Investigator Wizard, won’t it list both active and inactive PI which will make it more of an overburdening on the office to ensure it’s updated every year?”

Again, the Investigator Wizard is not project-specific. It is not linked to an active project in I R B Net. It stands alone. The plan right now is it will stand alone as an administrative project. I’m not sure what this question is referencing when you say, “both active and inactive PI”.

Christina Bennett: Angie, right now in the ePROMISE system, investigators are listed as either active or inactive based on whether they currently have any active approved studies. This person might be wondering if we will be needing to provide annual updates, or everyone who has ever submitted an Investigator Wizard in perpetuity, or if there will be some distinction where Investigator Wizard does not need to be updated if that person does not have any active projects on file.

Angela Foster: Thank you, Christina. That is a great point and this is something that we need to consider when we are developing the SOP for the Investigator Wizard.

I don’t have an answer to this question just yet, but we will take this into consideration. Next question please.

“If someone answers ‘no’ to the COI question and then the COI module is subsequently completed, do you have them update the PCS?”

No. If your site is using the COI module—which as Tony stated, all sites will in the coming months—then you will be able to see whether or not that investigator has completed or submitted for COI and whether that review has been completed. Next question please.

“Will VAIRRS be auto-reminding researchers to complete these new wizards based on what date?”

The date, again, is something that we’ve not solidified yet. VAIRRS will do as much as we possibly can to remove or alleviate any burden locally on reminding investigators to get their wizards completed and for the annual updates.

What that process is I can’t say just yet. We’re still working through the details. But we are trying to assume as much responsibility as possible, so that you guys in the field don’t have to do or remind investigators to do their annual updates.

“Will RAD no longer be pulling data from ePROMISE? It seems like duplication would have to happen.”

RAD will continue to pull data as it does now. There may be some duplication. We are trying to alleviate wherever that potential exists at this point.

But as Tony stated, you will still need to create your Investigator profiles because that links to other systems. But the amount of data that you have to enter will be reduced in ePromise. Next question please.

“Would the Investigator Tracking Wizard and annual updates only be submitted to VACI R B, only to the local Research Office or to both? Who will be responsible for making sure these get done both initially and going forward?”

I go back to my previous response that the VAIRRS program staff will do as much as wee can to work with the investigators, communicate the expectation when the wizards will be completed, assist them with completing those wizards and the follow-up reminders for the annual updates. Next—

Parker: Angela? Angela, we have time for one more question.

Angela Foster: Oh my! Great, thank you. “For study specific wizards, they are submitted with a package for the specific project. How will the Investigator Wizard be submitted?”

Again, the idea at this point is that they would create an administrative project in I R B Net that will live on and they would be able to create a new package in that administrative project for the annual submission.

We are at time now. Thank you all for your questions. Whatever questions we could not get to we will respond and send out all of the Q&A along with the slides to everyone that’s on the call.

With that, Parker, I’ll turn it back over to you.

Parker: Yes, and I’ll remind folks I see there’s more questions. At the pace they’re coming in, I’m sure folks have more. I’m going to remind everyone that on the survey there is an opportunity to ask any unanswered questions and that will get to our panelists. Feel free to enter them there as well if you didn’t have a chance to get to your question or you’re just thinking of it now.

But thank you to everyone who attended and thank you to the panelists for presenting. Everyone please have a great afternoon.