Katrina: Announcements before we get into the presentation, the first one being that the VAIRRS Strategic Plan and a couple of new web pages have been published on the VAIRRS website. I highly encourage everyone to go and visit and definitely look at the VAIRRS Strategic Plan which spans all of the goals and objectives from FY22 to 24. Another update is for our field staff dashboard. A new page has been added that reflects the study team training data. For all those that have access to the field STAP dashboard, please review that new page, and if you have any feedback, feel free to submit it to our dashboarding team at vaiirs@dashboards@va.gov. Last but not least, VAIRRS is revising the VAIRRS mentor program, and in the upcoming future, we’ll be offering paid opportunities for subject matter experts to serve as VAIRRS mentors and we will have more information coming to the field once that program gets up and running. As always, please subscribe to the VAIRRS newsletter, and program update to keep up with important announcements and program updates. That is it. With all that being said, Kat, if you can go to the next slide and I will hand it over to Jessica to start her presentation. Thank you, everyone.

Jessica: Thank you, Katrina, and thank you, everyone, for joining the webinar today. Next slide. The objective of the webinar today is for the Central IRB to outline a new submission process for when a Principal Investigator/Study Chair new project has multiple Co-PIs located at different VA facilities. If all Co-PIs are located at the same VA facility, the submission process outlined in this webinar should not be followed. Next slide.

Before we begin, I would like to review some important Central IRB definitions that are applicable to this submission process. First, Principal Investigator/Study Chair, also known as PI/SC. That is the investigator with responsibility over the entire project. The PI/SC oversees scientific, technical and day-to-day management of the research conducted across engaged and non-engaged local sites. PI/SC also commonly refers to the application process for getting Central IRB approval. Local site investigator, or LSI, is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research conducted at the local site. LSI also refers to the application process for getting Central IRB approval for the investigator in the site where the study will be conducted, which is linked to the PI/SC application, but distinct from it. Co-Principal Investigator, or Co-PI is an individual who shares equal oversight and responsibility with the other Co-PIs for the conduct of a research project, all of which is detailed in the above PI/SC definition.

Lastly, lead Co-Principal Investigator is being defined specifically for this Central IRB submission process, and for purposes of IRBNet for one of the co-PIs must assume the lead Co-PI role. The lead Co-PI will be responsible for creating the project in IRBNet, sharing it with the non-lead Co-PIs, and make all required submissions to the Central IRB. The lead Co-PI will be the named recipient for all Central IRB notifications and communications for the project. Next slide.

Here, a workflow diagram has been developed to outline the submission process that we will be reviewing today. This workflow, along with detailed instructions, will be made available on our Central IRB website, and in our IRB Mac Forms and Templates Library following this webinar. Next two slides.

I would like to call out some important notes for everyone to keep in mind as we go through the steps of this new submission process. When Co-PI’s are located at different VA facilities, one of the Co-PIs will need to assume a lead role. IRBNet only allows for one lead Co-PI in the system regardless if there are multiple Co-PIs. The lead Co-PI will take responsibility for submitting the PI/SC new project application to the Central IRB. All Co-PIs, both lead and non-lead, must submit the PI/SC project to each of their local Research Administrations prior to submitting to the Central IRB. This process will ensure local oversight of each investigator’s involvement on the project. It’s important to note that the Central IRB cannot describe the review process that occurs at the local Research Administration, as each site’s process varies. Please contact your local Research Administration or local site liaison for specific instructions. Next slide.

To best describe this new process, we will be going through, step-by-step, of an example scenario of a PI/SC new project application that has three Co-PIs all located at different VA facilities. One is located at Atlanta, one at Boston, and one at Cincinnati. All three Co-PIs have equal responsibility in oversight of the project, and in this example, all three Co-PIs will follow these instructions when creating and submitting the project in IRBNet. Next slide.

Step One, one of the three Co-PIs will need to assume the lead role for this project. The lead Co-PI will create the PI/SC new project in IRBNet, and compile all applicable submission forms according to our standard process outlined in the Central IRB guidance document titled Instructions PI and LSI New Project Submission.

 When compiling this submission of Form 108A, which is the Co-PI/SC New Project Application Supplement, it must be completed for each of the non-lead Co-PIs and be included in the new project package. Additionally, the project cover sheet Wizard must list each Co-PI, and their primary VA location, as requested in the form.

Step Two, the lead Co-PI will share this project as illustrated below, with each non-lead Co-PI, and assign each of them full access to the project. Full access will ensure that each of the non-lead Co-PIs will receive all email notifications and communications from IRBNet for the project. Next.

The lead and non-lead Co-PIs will simultaneously submit the project, for example, Package One, to each of their local Research Administrations. Please note, a single package can be submitted to more than one board. In this instance, all Co-PIs can submit the same package to each of their local Research Administrations for review, as you can see illustrated in the image to the right.

When the lead and non-lead Co-PIs submit the package to their local Research Administration, they will need to include in the comments section that this is a project with Co-PIs located at different facilities, with the lead Co-PI being listed as the Principal Investigator in IRBNet, and on the submission forms. This is important for non-lead Co-PIs as that information will not be listed as Principal Investigator when they submit to their local Research Administration. Non-lead Co-PIs can direct their local Research Administrations to review the Form 108A and project cover sheet where they are listed as Co-PIs.

Step Four, each local Research Administration will complete their local review. This could include conflict of interest determination, obtaining an ACOS sign-off on Form 102, et cetera. It is important that a Form 102 with ACOS sign-off for each Co-PI lead and non-lead must be uploaded into the package of the project that is submitted to the Central IRB. Please note that this step allows the local Research Administrations to have awareness and oversight of the Co-PI’s role in the project.

Step Five, after all local Research Administration reviews are complete, the lead Co-PI will submit the project to the Central IRB. The package that is submitted to the Central IRB should only include documents that are required by the Central IRB. Please do not include local forms.

The Central IRB will review the new project during the administrative review process. Revisions, clarification or other requests may be made prior to the submission receiving Central IRB review. This process will occur utilizing IRBNet’s unlock and lock function so that you can add, remove, or revise documents all within the same package.

Step Seven, after final Central IRB approval is received, each Co-PI will follow their local R&D Committee policies to obtain final approvals at their local Research Administration. This is the final step in the Central IRB submission process for the PI/SC New Project Application with multiple Co-PIs.

Now that we have reviewed the submission process, I would like to address some additional considerations that come up following Central IRB and local R&D approvals for the PI/SC New Project. The first question, will the Co-PIs have to submit an LSI application after final R&D Committee approval of the new project? Following local R&D Committee approval, each Co-PI may be required to submit an LSI application to the Central IRB. This is the same as with any PI/SC project, and will be based on the Co-PI’s engagement and local research activities. Our standard process outlined in the Central IRB guidance document, titled Instructions PI and LSI New Project Submission, should be followed if an LSI application needs to be submitted. If there is uncertainty on whether an LSI application needs to be submitted for a Co-PI, then please consult with the Central IRB manager overseeing the project.

Will all Co-PIs be named as Principal Investigators in IRBNet and in Central IRB determination letters for the project? IRBNet only allows for a single Principal Investigator to be listed on a project, and in order to support this process, the investigator to be named will be the lead Co-PI. Currently, there is no capability to name Co-PIs within the IRBNet system. As a result, the lead Co-PI will be the named recipient, and all Central IRB determination letters and other official communication for the project. However, when necessary, the Central IRB will document the name of each non-lead Co-PI, and the name of their VA facility within the body of those letters or communications.

Who will be responsible for making future submissions to the Central IRB? While all Co-PIs share equal oversight and responsibility, the lead Co-PI will submit all future submissions to the Central IRB for this PI/SC project given the parameters within IRBNet.

Who will receive project notifications, for example, project expiration notices? All Co-PIs will receive IRBNet notifications for the project because each event will have been granted full access to the project.

And that is the end of the submission process, and we can open it up to questions.

The first question is, do you consider Co-PIs and Co-Is to be the same? For purposes of this workflow, I would say no. Co-PIs are Co-Principal Investigators who are sharing the same oversight responsibility for the project overall, where a Co-Investigator would be someone who would be underneath the Co-PI. Yes, so those two would be different.

This process—oh God, I’ll read the question. Where is the LSI in all of this? This process was specific to the PI/SC workflow. Following this presentation, we are going to be developing some additional guidance around multiple Co-PIs. That will include adding a Co-Principal Investigator after the project has been approved, and also additional guidance for when there are Co-LSIs. But the one thing I do want to note for LSIs is that it’s local site so, typically, the local site Investigator would be responsible for the work in their geographic locations. If there is an LSI in Atlanta, typically, if there was another Co-LSI, that wouldn’t be the case if it was at a different facility, let’s say, in Boston. Typically, if there’s Co-LSI’s, they’re within the same facility, and this process wouldn’t be applicable to that.

Are you saying that once the PI/SC application is approved, that each Co-I site has to send that PI/SC application to their own Research Admin R&D for review? Or is it just the Co-I submission that goes to the local Research Admin R&D? I would like to be clear that we are specifically speaking to Co-Principal Investigators. If it is a Co-Principal Investigator that is named on the project, then they will submit the application to their local Research Admin and R&D for review.

What is the difference between the Co-PI submission and an LSI submission? The best way to explain this is the Co-PI submission is along the same lines as what we call our PI/SC submission. At the Central IRB, our PI/SC submission is typically the Principal Investigator or Study Chair that has the main project. In this instance, there can be multiple PI/SCs, and they can be located at different VA facilities. The Co-PI submission is really just a way to process the PI/SC application through the Central IRB.

The PI/SC, the VA PCS, Project Cover Sheet, should list the Co-PIs at other sites. Should it also list the other Co-Is at other sites and/or other study personnel at other sites? That is a good question. I think I will make note of this and provide some additional guidance following the webinar, just so that we can have clear information on when other personnel should be listed on the Co-PI application versus whether they should be listed when it’s time to submit an LSI application. I think it will be based on their involvement in the PI/SC project versus their involvement at the LSI project.

Can you confirm, clarify whether Co-PI and/or LSI VA Project Cover Sheets should only list local site personnel? I cannot speak to the local requirements, but maybe, Angie, do you have any information on the Project Cover Sheet personnel section?

Angie: Sure, Jessica, thank you. The Project Cover Sheet should contain the list of personnel at that site unless—there’s a caveat here regarding the EHR access. If EHR access isn’t involved here, then we’ll need to make sure the appropriate individuals are represented on the project cover sheet, but if there’s no EHR access at your site, then the Project Cover Sheet should only include the personnel that are from that particular site.

Jessica: Thanks, Angie. Can administrative staff working with Co-PIs also receive notifications? Yes. Any personnel that are working on a project and are given access to the project within IRBNet, have multiple different options for receiving notifications. That will be delegated by the Principal Investigator, but you could have full access which is the access that provides those email notifications. You can have Bright Access or you can Read. But you can speak to the Principal Investigator and delegating that access to you within the system. Will IRBNet, in the future, build the capability to add Co-PIs and Co-Is? Angie?

Angie: We can’t mandate that that be added, but we are providing this feedback to IRBNet so that, in the future when they make system updates, that those options can be added. But due to the nature of our contract, we cannot make that request now, but we are providing them this feedback.

Jessica: This is more of a statement. This is confusing a bit. Locally Co-I and Co-PI are used interchangeably to refer to any additional investigator listed. They are not co-leads with the PI. Yes, I can understand that. That’s one of the reasons we wanted to develop specific definitions for this process as it relates to the Central IRB.

Are Multi-PIs the same as Co-PIs? Again, giving in to this definition, I know there are a lot of different definitions out there, so we will be working off of the definitions that we have written up at Central IRB.

Are there any specific considerations or guidance that would differ for exempt projects with multiple Co-PIs? I don’t think there would be any differences, but I will make note of this for the additional FAQ and guidance that we’re going to put out for this topic.

A study with Co-PIs was recently reviewed by the Central IRB and received approval with conditions. It was only reviewed by the lead Co-PI Research Admin and forwarded to the Central IRB. Is it okay to have the non-lead Co-PI Research Admin RDC review the project after Central IRB full approval? The 102 for the non-lead Co-PI was submitted with the initial package. I would recommend sending an email to the manager responsible for this project and copying myself on that, and we can come up with a solution. It’s hard to say in terms of grandfathering, and what to do with some of these projects that we have processed, but it can be worked out offline.

Can IRBNet please add role of LSI to their dropdown list instead of only a PI option?

Angie: And again, we’re taking this feedback to IRBNet.

Jessica: Does the LSI submit two packages in IRBNet? One to the local RDC with VA Central IRB LSI submission for RDC to forward to the VA Central IRB, and separate second package to the local R&D for the local R&D review with the R&D submission documents? Please clarify. I think we will provide clarification to this question following the webinar. Again, it’s difficult for us at the Central IRB to speak to the requirements of the local Research Administrations, because each local R&D and IRB office have different requirements, and we are just not familiar with each of their requirements. We can provide best practices, but they may have their own policies or process in place.

Will written instructions describing all of the processes for Co-PI study submissions to the Central IRB be made available to everyone? Yes. They’re going to be made available on our website, and they’re going to be in our forms and templates library.

I realize you have focused on the Co-PI steps. Does the PI/SC go in first, and then the LSI for Co-Is after? In other words, does PI/SC have to be approved by Central IRB, and locally for Co-PIs, and then LSI applications go in for Co-Is? Correct. We try to stage the process for approving the PI/SC application first, in the event that there are any revisions or changes to the documents throughout the review process, so that when it comes time to submit the LSI application, you are able to work with all of the PI/SC-approved documents. The LSI application should begin after the PI/SC has received final approval from the Central IRB and your local R&D.

In Step Five, it states once the local Research Administration review is complete, the lead Co-PI will submit the project to the Central IRB. How is the local Research Administration notifying the lead Co-PI by IRBNet message? Once the IRB approves PI/SC, then an LSI package follows that same process, then both packages would go to global R&D for final approval, and ACOS letter published. For the first question, how is the local Research Administration notifying the lead Co-PI by IRBNet message. That is difficult for us to answer given that all of the local Research Administrations have their own practices. I would reach out to your local office and ask, or also reach out to the local site liaison. For the next question, once the Central IRB approves the PI/SC, then the LSI package follows that same process, so that is correct. Once the Central IRB approves the PI/SC, and then the PIC has received their local R&D approval, then an LSI package can be submitted. Then both packages, essentially at different time points, will be going through the local R&D for approval, and for ACOS letter to be published.

Which institution is responsible for FCOI review of a Co-PI? The site of the lead PI/SC or each of the Co-PIs local institution? This will be the responsibility of each of the Co-PI’s local institution, so at that step where they all simultaneously submit to their local sites for review, it’s at that point that the local site will conduct their Conflict of Interest review.

Moderator: I think that’s our last question, Jessica. Do we want to give folks a couple of minutes if there’s any others?

Jessica: Sure. We can give another minute or two. How do the Co-I sites get a copy of the protocol for local reviews? That’s the one benefit of IRBNet, and the one step that I illustrated a screenshot where you can send one package to multiple different boards. After the package for the new project is compiled and all of the documents are in there, each Co-PI can submit that package to each of their local Research Administrations for review. Within that package will be the protocol that they will be able to access and see. Each local site will see the same thing for each of those packages submitted.

Does the local site always use their own local Privacy and Info Security Reviews? How do we know if a main site PO ISSO review should occur? At the Central IRB, we do Central PO and ISSO review. There’s no need for a local Privacy or Info Security to occur for any research that’s being reviewed by the Central IRB.

You were saying that PI/SC should have a separate local R&D approval before the LSI R&D approval. Correct. We do have some guidance that might be helpful in putting a visual aid to this process, because I know it’s pretty complicated. We do have it on our Forms and Templates Library, and on our website, but the workflow describes that the PI/SC review process will occur first, and then once that review is complete through the Central IRB and you’ve received the R&D approval, it is at that point then the LSI can begin the submission process in a very similar manner. It would come through as a Central IRB, and then followed by their R&D approval.

How does the local site obtain PO ISSO reviews? So centrally, the Privacy and Information Security Reviews are rolled up into our IRB reviews so we help facilitate that process. The ISSOs, they provide a document that they sign off on, but the Privacy Review right now is more internal checklists so we don’t release those checklists. I think there will be more guidance coming out on this topic in the near future.

Doesn’t the local PO need to review a 10250 and VA Central IRB doesn’t do a 10250? Please clarify. I can’t speak to that process. I can only speak to the Central IRB process. I’m not familiar with the 10250 so I don’t know if, Dan, you want to add any context to this. Please feel free to jump in. Or we can provide additional clarification following. We can provide some additional clarification following this.

PO reviews are required for regulatory audits, and if these are internal to the VA Central IRB, how are these audits supposed to occur? I think we’re jumping off track of the Multiple Co-PI submission process, so you can submit these questions and we can answer these following the webinar.

If local Research Administration only receives a lead Co-PI, PI/SC submission after VA Central IRB approval, how then should local feasibility assessment be done? What if that VA Central IRB-approved study is not feasible at one of the non-lead Co-PI facilities? In that instance, I would assume that facility would not provide a signed 102 which is the document that requires the ACOS sign-off. If we were not able to receive that document, that would be a halt in our review, and that can be evaluated at that time.

For my Co-PI submission, I had to have the local ERDSP form for the Central IRB submission reviewed and signed by the local ISSO. Is this standard? I can’t speak fully to the ISSO process, centrally, and their form, but we can provide a response to this question following the webinar.

Is the R&D Committee required by policy to review and provide an ACOS RDC approval letter for PI/SC applications, or is it just recommended best practice? I cannot quote the VA directives at this time, but we can provide an answer to this question following the webinar.

Local regulatory audits and Central IRB would be a great future topic. Who can have access et cetera, et cetera. I agree. We will definitely make note of that.

For special subject copulations, example, enrolment of non-veterans, which R&D should approve enrolment of these populations? Main site, or each local R&D for their own local sites? That is a great question, and I think I will have to get back to you following this unless, Don, you have any expertise in this area that you would like to jump in? I think Don might be having technical issues today so I won’t keep calling on you to answer questions. We will get back to you following this.

Who does the Central IRB consider responsible for reporting UPIRTSOs or potential not-compliance for a PI/SC protocol? The lead PI/SC or any of the Co-PIs? And this is a great question. We’re going to be putting out some guidance on this, specifically, if it needs to get escalated up outside of the Medical Center Director, and up to ORO, or to OHRP, so please stay tuned for some guidance that will be coming.

If the PI provides us with the 102, and the top filled out, and then we should get an ACOS sign-off, we can only upload to board documents. Should the PI then download and upload to the package to send to Central IRB for review? I think this might be a technical IRBNet question. There shouldn’t be any barriers to uploading a signed 102 into the documents, but you can always feel free to reach to us at the Central IRB or to the manager responsible for the project, and we can assist you with getting those documents uploaded into the package.

Is it correct to say that PI/SC submission process occurs first by the lead Co-PI, and then essentially gets repeated by the same individual wearing the LSI hat afterwards? Thank you—one more time here. Is it correct to say that the PI/SC submission process occurs first by the lead Co-PI, and then essentially gets repeated by the same individual wearing the LSI hat afterwards? Correct, yes.

When did this process go into effect? We had a recent multi-PI but only reviewed the LSI application. The PI/SC approval letter was included but didn’t review the PI/SC package. How do we correct this? This is brand new and it’s going into effect as of today, so anything that had occurred prior to this, I would suggest contacting the responsible manager for the project, and we can work out any issues that there may be.

Moderator: All right. I think that is finally the last one.

Jessica: Okay, great.

Interviewer: Awesome work. Thank you, Jessica. That was a ton of questions and we really appreciate you tackling all those for our audience here, and any of those follow-ups, we will save a record of the questions and we can get those out to the audience, as needed. Folks out there, for the attendees, we just want to thank you all for joining us and thank you for your great questions. The recording, I saw a couple of people ask about the recording. It will be available 48-72 hours after this live event, and it will be found on the ORPP&E webinar archive page which I posted in the chat, and in the questions, but with a simple Google search, ORPP&E webinar archive, you’ll be able to find it as well. And finally, if you do take the time when you’re signing off to fill out that survey, we would really appreciate it, so thank you all very much.