Parker Cunneen: All right, good afternoon everybody, and welcome to today’s ORPP&E webinar. This is going to be our first CIRB Quarterly Webinar, so I’m excited to get that started. My name is Parker Cunneen, and I’m going to be your administrator today. I just want to go over a few housekeeping items before we start the webinar. This is a webinar style, so everyone’s going to be on mute except for the presenters. So, there’s going to be no audio on your end. This presentation is being recorded and can be found in the ORPP&E archives after the fact if you have any technical difficulties or you know someone who needs to view this presentation after the fact. Slides were emailed to everyone in advance of today but can be found in the link I just posted in the chat and/or in the Q and A.

If you’d like to address any questions to the presenters, please do so in the Q and A box. That can be found in the bottom right-hand of your screen. If you don’t see it already, click those three dots, and a Q and A box should be one of the options. Make sure you address your questions to all the panelists, and we will save some time at the end where questions will be addressed. At the end of the webinar, you’ll get a quick survey. We do appreciate if you’d take a couple minutes to fill that out, and we can improve our experiences going forward. With that, I’m going to pass it off to Angela Foster, who’s the program manager for the Enterprise Research Data Systems at ORPP&E.

Angela Foster: Thank you, Parker. Good afternoon, everyone. Thank you for joining us today to discuss the Central IRB Project Reconciliation Process. My name’s Angela Foster. I’m the VAIRRS program manager, and I would also like to introduce our other panelists, Dr. Don Workman, VA IRB Network Director, and Mr. Jeff Newcomb, VA NODES ADO at Omaha VAMC. Thanks to Dr. Workman and Mr. Newcomb for providing guidance today. We’re on our topics. Great. So, for today’s discussion, we will address the what and why of project reconciliation, how to determine when projects are eligible, how those projects are reconciled, and also, we’ll discuss the options for projects that are not eligible for reconciliation. Next slide, please.

What is project reconciliation? So, I’ll give some historical context that explains the need for this process. The first significant milestone occurred in February 2020, when VAIRRS started onboarding medical centers to IRBNet. Each research program was given the opportunity to upload their active projects. The active projects included those that were under the oversight of the VA Central IRB. When the site uploaded their active projects, it essentially created a local version of that Central IRB project. The second significant milestone occurred in March 2021, when the Central IRB onboarded to IRBNet. Like the VAMCs, the Central IRB also uploaded their active projects to the IRBNet. And in many cases, the Central IRB’s upload created a duplicate project referred to as the Central IRB project shell. Immediately after the CIRB’s onboarding to IRBNet, we started addressing the duplicate projects by reconciling the local version with the CIRB project shell. You can view the previously held webinars where we discussed reconciliation on the ORD webinar archive page that Parker referenced at the beginning of our discussion. To date, we’ve reconciled over 100 duplicate projects. Next slide, please.

So why are we reconciling? There are three primary reasons to reconcile projects. The first being duplicate projects can cause confusion. The study team may see both the local version and the central IRB project shell on their My Projects page. The research office may only have access to the local version of the project in this submission manager. And this is the case when the central IRB project shell has been transferred to the PI but the project has not been submitted through the local research office. And it's also worth noting that central IRB project shells are linked to the multisite study if applicable. The local version of the project is not linked to the multisite study. Lastly, the \_\_\_\_\_ [00:05:23].

Parker Cunneen: Angela, I think we lost your audio.

Angela Foster: ...allows the study team to archive the withdrawn project and only see the version of the project that will be used going forward.

Dr. Don Workman: Angie, Just to update you, we lost your audio after you said something like the last point.

Angela Foster: Oh, I’m sorry. So, duplicate projects. Did you hear that, when I started with the duplicate projects?

Dr. Don Workman: Yes.

Angela Foster: Okay, so for that to reduce the clutter that’s in your submission manager and your My Projects page, the reconciliation allows the study team to archive the withdrawn project and only see the version of the project that will be used going forward. And of course, the reconciliation process consolidates duplicate projects. You’ll see when we get to the process description that one version of the project is withdrawn. The version that remains should reference the withdrawn project to ensure the project history stays intact. Next slide please.

When you look at your My Projects or your submission manager page, and you see multiple version of the same project, how do you know when those projects are eligible for reconciliation? The most important factor in determining eligibility is whether there are multiple study actions submitted using the Central IRB shell. For instance, the initial Central IRB project shell will have an IRBNet ID that ends with a dash one. And that’s the first image on the slide with the checkmark. If the study action has been submitted using the Central IRB project, the IRBNet ID of the latest package will end in a dash two or dash three or an even greater number, as pictured in the second picture on your slide with the X. When we evaluate whether the project can be reconciled, we’re looking to see first if there’s only package, that dash one package, or if there is an additional package, is that package an actual study action or is it just an administrative submission such as the project cover sheet. And we’ll go over in a later slide what happens when a project is not eligible for reconciliation. Next slide, please.

For the next three slides, we’ll go through each step of the reconciliation process. Once we go through each step, the following slide will illustrate the entire process in a workflow diagram. So, step 1, the initial step, is of course the identification of the duplicate project. The project can be identified by the study team, coordinator, or the research office. It’s critical that all parties communicate the desire to reconcile the project to ensure awareness across the board and to make sure that the correct project is used going forward. Step 2, once all the parties agree that the project should be reconciled, the research office will submit the request via email to the Central IRB. And that’s an important update. Previously, we had not implemented this step, but going forward, we will only accept requests for reconciliation from the research office. And that again, is to assure awareness of all parties. Upon request, Central IRB will review and verify that the project is eligible for reconciliation, and we will respond back to the research office with the next steps. Next slide, please.

Moving on to step 4, once the research office is notified that the project is eligible, the research office will create a new special events package within the local project and submit that new package to the Central IRB. The submission type of that package should be in other, and the package should also include a submission note so that once it’s received in our workspace, we know how to direct the package. Step 5, Central IRB then updates the package within the local project with the review details of the last Central IRB review and will also include a note in the discussion and remarks section referencing the reconciliation and the IRBNet ID of the project that will be used going forward. The local project is then linked to the multisite study and the Central IRB project is unlinked from the multisite study and is withdrawn. A project mail will be sent within IRBNet to all project contacts notifying them of the completed reconciliation. And if that sounds a bit confusing, it will be clarified when you see the workflow diagram. Next slide, please.

Once the research office is notified of the completed reconciliation, you have the option of updating the project title in IRBNet within the withdrawn Central IRB project shell. And the purpose of that is to prevent it from being used going forward. In order to change the title, you would simply create a new package, edit the project title, we suggest that you include archive at the very beginning and the date that the project was archived, and the package is submitted to your local workspace where you can record an administrative review type and acknowledge board action and a withdrawn project status. The study team can archive that withdrawn project so that it no longer appears in the My Projects page. To archive the project, you will click the yellow folder icon that has the down arrow, which appears next to the project title. For those projects that are archived, you can view them all by selecting the show archived projects link above the project title column. Now archiving is only available on the My Projects page. It’s not a feature that we have in submission manager. We suggest that you use tags or even a dummy agenda to help organize your submission manager. Next slide, please.

And this is the workflow diagram. It just reiterates the process that we went through. The diagram details the roles and responsibilities for each step. There is one correction that I’d like to point out. In step 3.0, which is here at the bottom, the blue diamond at the bottom. If the project is determined not eligible in this step, we will communicate back to the research office why the project is not eligible, and then the research office can forward that communication on to the study team. I realize it’s a bit small here on the screen, but hopefully you have the slide deck in front of you and can view each of these steps in the workflow. Next slide, please.

Let’s go over the options for projects that are not eligible for reconciliation. Option 1 is to continue using the local version for submissions to your local committees and the Central IRB project for submissions to the Central IRB. It’s perfectly okay to maintain both versions of the project. You can organize your workspace using tags, dummy agendas, which are available, the tags are available, in both My Projects and submission manager. Dummy agendas are available in the submission manager. The second option is for the research office to withdraw the local version of the project. If you choose to go this route, we strongly encourage you to follow to the steps we just discussed for updating the project title and including a description of the action referencing the Central IRB IRBNet ID in the discussions and remarks section. Next slide, please.

Okay, so that was the brief review of the reconciliation process. If there are any questions in the Q and A, we can move forward and address those questions now, and I’ll ask Dr. Workman and Jeff to step in. And I’m not seeing where there are any questions in the Q and A box already. So, now is the time, if anything was not clear that was presented, please ask your questions now and we can discuss.

Okay, so Laurie asks can you explain what a dummy agenda is and how that works? A dummy agenda is essentially an agenda that gets created in the submission manager. You can assign a date that is not feasible. For instance, you can assign a date from January 1990, or something that won’t get mistaken for an actual agenda date. And all of the projects that are not being used can be assigned to that agenda so that when you open your submission manager, it’s not so cluttered.

Dr. Don Workman: Angie, if I could just add, on the Central IRB, we have agendas that are dated the last day of the year, so December 31, 2022, and there’s one for each of the managers so that if a project is assigned to them, the project could be moved into that agenda. They work on it until it’s ready to go to a live agenda, or if it’s an expedited review or exemption, they process it and it goes from that to a completed agenda. Over.

Angela Foster: Thank you, Don. Okay, if we need additional help, can we get one-on-one help? Yes. You can contact me on Teams or via email, and I’m happy to set up a time where we can share screens and discuss the process. I’ve met with quite a few individuals over the past year so that additional help is available should you need it. Okay, next question.

Parker Cunneen: Angela, I see they’re just coming in now so they may not be in the PowerPoint as they're coming in. Would you like us to just read some of the next ones?

Angela Foster: I’ll go down. I’ll scroll down to the next one, Parker. Thank you. Is it a problem if both the local project and Central IRB project have project cover sheets? Is that duplicate data in VAIRRS? So essentially, no, it's not duplicate data in VAIRRS because each of those project cover sheets are attached to a separate IRBNet ID. If you think about it in terms of a database, for instance, each would be its own row. Now, if you're thinking about it from the perspective of the study, then yes, the study would have two project cover sheets in the system. But hopefully, the study team has not gone through the process of submitting the cover sheet in both of those projects because that’s not necessary.

The next question is from Brittany, not a question, but I’m not even going to lie, I’m completely confused. And that’s quite all right, Brittany. I’m sure that if you’re confused, you’re not the only one. If you’d like me to go through those steps again, we have enough time to do that, or you can contact me on email and we can set up a time to discuss one-on-one.

Art is asking if the audio got cut out. My interface is fine. If you can’t hear me, then put something in the chat because that means we’re having--

Parker Cunneen: You’re fine now. Angie, it was just that brief time that I told you about that you were out for about 30 seconds.

Angela Foster: I see, I see. All right. Is it -- no, we’ve already gone through that. Okay, you may wish to clarify that archived projects that still have unread notifications, they will not disappear from My Projects until the notifications are read. Very good point, Kristen, and thank you for pointing that out.

Does the reconciliation only apply if a local site went live with IRBNet before Central IRB finished their upload? In other words, if our site migrated our studies after Central IRB did their migration, are there any projects that would be eligible for reconciliation? Central IRB, unless you are from one of four sites on the west coast, the Central IRB was the last site to onboard to IRBNet so it’s not likely that you have onboarded your projects after the Central IRB. If in fact you did onboard after the Central IRB, one of those four sites, it is possible that you have a duplicate project in your local version, in your local workspace.

Can you please explain what the limitations of going with options one and two versus what is outlined in the flowchart? Is it okay to use option one/two for all of our Central IRB projects? So it is okay if all of your projects have a duplicate Central IRB project shell, then yes. If you choose to go the route of option one and maintain both versions, that’s perfectly okay. If you choose to go the route of option two, which is withdrawing your local version and only using the Central IRB version, then that is also okay as long as you follow those steps that we’ve outlined, which are recording the reconciliation and the discussion and remarks, referencing the IRBNet ID of the project that will be used going forward, updating the project title to prevent it from being used again. The few steps that we’ve discussed already, if you will follow those steps, then you should not have an issue.

Jeff Newcomb: Angie, this is Jeff Newcomb here. I just wanted to chime in on that one, as well, just with personal experience. So, what I’ve seen from quite a few sites is if the coordinators are understanding the difference between their local study versus the clinical Central IRB study, there’s two different numbers, if they’re maintaining that information well and understand it, it might be your best option to stick with that number one, so to speak, kind of leave it as is. Now, if there’s confusion, that’s when you, in my opinion, start to look at that number two to see if you can reconcile. But if things are moving along smoothly, everybody understands the process, you may just want to leave it as is. That’s just my two cents there.

Angela Foster: Thanks, Jeff.

Dr. Don Workman: Jeff, if I could just have a caveat, one of the issues is auditing. And if you’re keeping two systems, you should have it very clearly documented somewhere which is the source document so if FDA comes to audit, you know exactly which project you want to pull up because if you have two that include the same information or very similar information, one of them needs to be the one that’s the official record. That’s all. Excuse me. Over.

Angela Foster: Thanks, Don. Okay. Independent of Central IRB, we locally have the problem of study teams creating duplicate protocols in IRBNet. Can we fix those without IRBNet support? If so, can a live demonstration of how to do that be accomplished on this call? There’s really not much to demonstrate. I will just elaborate a little bit on that. If the study team has created a protocol and it’s duplicate, if that protocol has not been submitted to your research office or research administration workspace, it can be deleted. If it’s a work in progress or a draft package, it can be deleted by whomever created the package. Now, if the study team has created a duplicate project and submitted that project to your local research administration, it cannot be deleted. The best way to move forward is for the research office to withdraw that submission and the study team to archive that duplicate package so that it won’t be used again going forward.

We’re planning on closing out our study in the next month. I assume it isn’t worth the time and effort to reconcile the projects in IRBNet. In my opinion, no. It’s not worth the time and effort. If you’re closing within the next month, then you wouldn’t really have any need for reconciliation at this point.

How have other sites managed Central IRB projects that require two packages for the same submission, one local and one CIRB? So, I can’t speak to the local experience of this, Art, but I can say if you’re using the Central IRB project for submissions locally as well as submissions to the CIRB, then it would be creating multiple packages within that same project. The Central IRB has expressed that they only want documents related to their review so that really dictates that you would have to do a separate package for those submissions.

Dr. Don Workman: Hey, Angie. This is Don again. If I could just add, a number of sites do it this way so packet one goes for local research office review and includes maybe safety committee forms or other forms that might be needed for R&D committee, but then package two is either submitted by the research office, or more often by the study team, once package one has been accepted by the research office. And it’s package two that comes to the Central IRB. Over.

Angela Foster: All right. Thanks, Don. Okay, Susan asks from the IRBNet reports perspective, if you reconcile the duplicate numbers, which active study report will these studies show up on, the IRB or &D? How does this impact the study data on the dashboards that are in test mode? Great questions, Susan. If you reconcile a project, you are essentially withdrawing one version and moving forward with the other. So the version that’s withdrawn will have a project status of withdrawn, and the version that’s going to be used going forward will have a project status of active. The active projects report pulls every active project at every board for your site. So, if the local version is going to be used going forward, that will appear on your active projects report. If the Central IRB’s project is going to be used going forward, it should only appear on the Central IRB’s active project report.

Now, this is going to get a little tricky because you can have a project that’s reviewed. Let’s just say we’re using the local version. We’ve reconciled the project. We’re using the local version of the project. That local version has gone through one or more reviews locally, and it’s gone through one or more reviews at the Central IRB. In that case, it will appear on both the local site’s active projects report and the Central IRB active projects report. Now when we get to the dashboards, so the way that the dashboards are set up right now, we are not reflecting Central IRB’s projects on the local dashboards, and that is because of this duplicate project issue. We are, within the VAIRRS program, working to identify all of the duplicate projects in the system. It will take us some time. There’s roughly 1300 some odd projects that are duplicated. And it’s not an easy process. It’s almost manual by eye going through the entire list and matching it up with an active project at the local level.

Okay, so that is the last question I’m seeing, from Susan. If there’s any other questions, please enter them in the Q and A box. And again, if you have a question that you’re not comfortable putting in Q and A or you just want to have a one-on-one to discuss the process, please reach out via email, and I’ll be happy to set up a time where we can discuss further.

I’m just going over a few important notes from the presentation. The first is communication for on the local level that’s between the study team and the research office ensuring that all parties are aware of the desire to reconcile. It’s also important to include the Central IRB manager in your communication to the Central IRB so that they are aware of the situation, and that the Central IRB manager’s knowledgeable that the project may be reconciled.

Okay, we have another question. To archive a project is that user specific or project specific? Would the PI and research coordinator both need to archive the study in My Projects? Great question, and the answer is yes. Archiving a project is user specific so that it only impacts your My Projects page. It does not impact other users on the study team that have access to the project.

My Central IRB liaison is leaving VA tomorrow. And I will take over the responsibility. Who do I need to contact to ensure I have access to Central IRB submissions and documents? That would be handled by IRBNet support. You would need site liaison access to Central IRB projects from your site. It’s just one email to govsupport@IRBnet.org and requesting site liaison-level access.

Okay, I’m sorry I was late. I am unable to access the slides from the email that was sent out earlier. Is there a way to download them from WebEx? The slides are available via link at the very top of the Q and A box. Parker put in a link that you can click on to get to the slides for today’s webinar. The slides and the audio will also be posted to the ORD webinar archive, but it will take a couple of days before it’s posted.

Okay, if you tag the project archived and mark global, does this show on the PI screen so they know not to use the project? No, Wendy. When you use the tag function, that only impacts the workspace that you’re working in at that time. It does not impact the other individuals that have access to the project unless they are also working in that same workspace. Okay, we will stay on in case there’s other questions.

Okay. Is there a way to get a report of Central IRB shells in VAIRRS by site? We are not sure which of our studies have duplicates, and the list would be helpful to compare. Kelly, that is what we are working on right now. We’re identifying all of the Central IRB projects, which site that Central IRB project’s being conducted, matching it to the active project at that local site, and then we will send spreadsheets to the administrators that we have on record that will allow you to see exactly what the IRBNet IDs are for the Central IRB projects and to ensure that you also have access to those projects.

For multisite studies where there is one IRBNet number for the lead site, PISC level submission and each LSI site has their own IRBNet ID. However, some of the LSI sites also have a local IRBNet ID. As the lead site, is there any reason that it will be easier to ask the local sites to reconcile, or have it just be a personal choice? The only reason are those three reasons we discussed earlier. If the duplicate projects are causing confusion among the study team and research office, if the study team or their research office is having an issue keeping their queues organized, and by queue I mean submission manager and My Projects, those would be the only reasons to go forward with reconciliation for those projects.

[No audible conversation from [00:37:10] to [00:38:20]]

Parker Cunneen: Angela, I’m seeing a new question here. Is there a way to be alerted through IRBNet when there is a CIRB action or board document published?

Angela Foster: You should be receiving those alerts. If you’re in the research office, no, you would need to make sure one, that you have access to your projects that are from your site, and you would be able to, on your own, go in and see when a board action has been recorded. But you would not receive notification from IRBNet when a board action has been recorded or a document published.

All right, while we continue to wait and see if there are any more questions to come in, Don or Jeff, if I’ve missed any important notes, if you could please raise those, or if you think of anything else that should be shared, please bring that up to the group. I know each of you have a different perspective, Don from the perspective of CIRB and Jeff from the local perspective.

Don Workman: \_\_\_\_\_ [00:40:24 - cross talk]. Go ahead.

Jeff Newcomb: Sorry, Dr. Workman, I was going to say there was another question in the Q and A.

Angela Foster: Oh, I see. Okay. Thanks, Jeff. If a research office administrator asks the PI to share the study with the administrator giving him or her full access, then the administrator can receive notification of Central IRB actions like board documents being published. That works well at our site. And that’s a great point Kristine, and that references the previous question about the research office being notified when the Central IRB publishes a document. But the caveat with that is that you will see every notification for that particular project. So you’ll get reminders, you’ll get notifications when an action has been recorded. If the project mail was sent to all contacts, you’ll get that. So, keep in mind, if you have your researcher share the project with you, that essentially gives you study team level access, and that also puts you on the list to get every notification and reminder for that project.

Are there different levels of access to Central IRB documents that can be set for the administrators? For example, the current liaison says she cannot see the Central IRB board documents, just the action itself. Other than having the protocol shared with the administrator, just wondering if there is a setting we can activate. So if the liaison has access to the project and can see, let me bring the question back up, and can see the action but can’t see the board documents -- if there’s a published board document, you should also have access to those board documents. I would suggest first that you email IRBNet support and ensure that you have the correct level of access. But they can certainly help with ensuring that you can see the published board documents. .But there’s nothing for you as an end user to activate, per se, to grant yourself access to that.

Okay, we’ll stay on for another few minutes to see if there are any last minute questions. Okay, we just got one in. Following up on Angie’s answer to Kristine about the liaison having full access which results in the liaison receiving lots of notifications, we have over 40 Central IRB studies so this isn’t feasible. What is plan B? Plan B is to ensure that the site liaison has the correct level of access so they can see the board action as well as the published board documents. If you cannot see the published board documents, then you need to email IRBNet support to ensure that the site liaison has the correct level of access.

Okay, we have one more question. Can liaisons see what documents are actually submitted in the package or just the approved board documents? So the site liaison should have access to the published board documents and the board document action.

All right. We know our liaison can see the documents, but do they have to keep looking to see when something has happened? That’s the challenge, being notified of the Central IRB actions like we were in the old SharePoint days. I understand that that is a challenge, not being prompted when an action has been taken on a package. Again, going back to the earlier suggestion about being added or granted study team level access, that would provide notification. But as having research office level access, you are not notified in that configuration. As far as I know, it is not available at IRBNet at this time.

Jeff Newcomb: Angie, this is Jeff. What I would recommend to those sites, the large research facilities, would be to make sure those steady coordinators or even the physicians, the local site investigators are under the understanding that whenever they have a project go through or the board gets back with them or Central IRB or whatever happens there with a project, that they notify that local liaison if that local liaison doesn’t have full access. I understand the comment of over 40 plus studies, that would be a ton of notifications. So, I get that, but what I would do is I would educate the coordinators or investigators to make sure that they’re notifying the liaison whenever something like that whenever something like that comes up. That’s, in my opinion, what the “plan B” would be there.

Angela Foster: Thank you, Jeff. Okay, next question. Does Central IRB lead sites have two Central IRB projects in IRBNet? And then if the local site created a shell, they would have three shells. How are these reconciled? Okay, so let me unpackage this question a little bit. Central IRB lead sets have two Central IRB projects in IRBNet. In some cases there is a Central IRB project shell for the lead site and then also a local version for the lead site. The next part of this question is then if the local site created a shell, they would have three shells. So, now we’re talking about two separate IRBNet projects, the lead site that could potentially have two projects, the local and Central IRB versions, and separately, a local sight who may have two projects, the local version and the Central IRB version. The reconciliation process is just as we went through. If the PI site has two projects, has a duplicate project, and that project is eligible for reconciliation, we would reconcile the PISC project. Separately, if a site has two projects in IRBNet, we would look to see if it’s eligible. If the project is eligible, then we would reconcile that local site, the duplicate versions for that local site. So, they aren’t intermingled. The PISC and the LSI’s packages are totally separate.

Okay, we’ve got one more question coming in. Does this reconciliation guidance apply to coordinating center projects that are separate from the PISC project? So the reconciliation process applies to any project in IRBNet where there is a local version of the project and a Central IRB project shell. Okay, we still have ten minutes -- if there are any last questions.

Okay, well, I again would like to thank you for attending today. I hope that this webinar helps to clarify the reconciliation process. And again, if you’re not clear or if you have additional questions, please reach out via email. We can certainly set up a time to have a one-on-one to clarify any confusion.

I would like to thank the Central IRB administrators and \_\_\_\_\_ [00:51:22 - cut out] for their support. Jeff Newcomb from Omaha, and Mr. James Blankenship from the Bay Pines VA, I would like to thank you as well for helping with refining the reconciliation process. Parker, it doesn’t look like we have any other questions coming in, so I think we can go ahead and conclude the webinar.

Parker Cunneen: Great. Well, thank you for presenting, Angela, and team. Thank you to the attendees for being here. As we said at the beginning, a survey should pop up when you guys sign off. Please take a minute to fill it out. We would appreciate your responses. Thanks.