ORPP&E Webinar

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Session: Updates to the VA Central Institutional Review Board (CIRB) Memorandum of Understanding (MOU)

Presenter: Annette Anderson, MA

**Soundia Duche:** Good afternoon everybody. My name is Soundia Duche and I lead the training efforts here in ORPP&E. I have the pleasure this afternoon to welcome Ms. Annette Anderson, the VA Central IRB Administrator. Annette’s going to be giving a presentation updating everyone on the VA CIRB Memorandum of Understanding. Now this is a repeat of last week’s presentation that Annette did on October 3rd but all are welcome. So Annette, I’m going to show your screen so that you can get started. Carol I’m not seeing the show your screen for Annette, yet. Oh she’s already showing her screen. Wonderful. All right, Annette.

**Annette Anderson:** Okay. Good afternoon everyone. I’m Annette Anderson. I’m the VA Central IRB Administrator and I have been the Central IRB Administrator since the very start of the VA Central IRB so I’ve been here a while. I want to reiterate to everyone on the call that this presentation is specifically geared towards local site research personnel such as our Local Site Liaisons, RCOs, AOs, ACOSs. It is not really meant for study team members. We will not be going over policies and procedures for submitting and reviewing studies. We are planning another webinar in a couple of months to do that but this webinar has specifically been developed to focus on the relationship that the VA Central IRB has with all of our supported sites through which we are listed as an IRB of record. And even more specifically about the changes we have recently made to the Memorandum of Understanding.

So I will go ahead and get started here. And for an overview I would like to just give you a very short, short overview of where we are now at the Central IRB. I’m assuming a lot of knowledge on your part about the Central IRB already so I won’t be spending a lot of time on that. Then we’re going to go over the changes that we’ve recently made to the MOU. We will go over the coordination and approval process for the MOU and the process for updating the FWA. We are adding a second panel of the Central IRB so in order to do so, we will have to have you update your FWA to add that second panel. Then we’ll briefly go over facility liaison responsibilities and then I would also like to touch on the way we communicate with the local sites, particularly through the use of our VA Central IRB SharePoint site in which we are going to have some changes in the next week or two and also some availability of some site-specific reports that we have that I’m not sure everybody is aware of.

So for those of you who have been here as long as I have, you’ll know that the VA Central IRB started and was instituted in 2008. So it’s been a little over, or almost exactly 11 years now since we actually reviewed and approved our first study. You can see from the slide that we reviewed our first study in August of 2008 and we approved it that October. And as of 30 September of this year, the VA Central IRB is overseeing or in the process of reviewing 248 studies involving a little over, or almost, 1,700 sites. Our Institutional Official is the Under Secretary of Health for Discovery, Education, and Affiliate Network, that is Dr. Caroline Clancy. And the Human Protections Administrator for the VHA Central Office Human Research Protection Program is my direct boss, the Director of ORPP&E, Dr. Molly Klote. We review funded multi-site studies for all VA facilities that list the VA Central IRB as an IRB of record. And I still get lots of questions about do we review studies funded by other sponsors besides VA? And the simple answer to that is yes we do. We review studies funded by other government agencies such as DoD, DOE, and we also review studies funded by non-profits, consortiums, and even industry sponsored studies, so yes. We didn’t use to but that changed about two or three years ago.

Now the requirements to use, I’m just going to briefly go over this because most facilities have already completed this step. But the requirements to use the Central IRB is that you must amend your Federalwide Assurance to list the VA Central IRB as an IRB of record and then affiliated NPCs must amend their FWAs as well. That’s because since we now do review studies that are funded by other than VA, the NPCs need to also add us as an IRB of record. Then you have to also enter into the Memorandum of Understanding, which is the focus of our presentation today. And then you need to develop Standard Operating Procedures for using the VA Central IRB. So that’s very quickly what the parameters are for using the Central IRB.

Now I cannot emphasize enough that the Memorandum of Understanding is our foundational document. This is one of the first documents that we drafted when we first started the Central IRB. It is the foundation on which everything else flows in regards to the relationship that we have with the local sites. So our goal with this Memorandum of Understanding and what we hope we have done with all of our various iterations of it, and I think this is our fourth revision, is to spell out the respective authorities, roles, and responsibilities of the VHA Central IRB Office HRPP, the VA Central IRB, the local VA facilities, and the affiliated NPC if applicable to your facility. Facilities that do not use the VA Central IRB will not be able to participate in studies reviewed by the Central IRB. So that means if we’re reviewing a multi-site study that there’s five VA’s participating in and you’re a sixth VA that wants to participate in this, if you don’t have an MOU with us and you don’t list the VA Central IRB as an IRB of record, then you will not be able to participate in that study. Okay we ask, as part of our MOU, that the local facility Medical Center Director appoint a local site representative that will serve as our points of contact for the study. And the main point of contact is the liaison. And then we also ask that a designee be appointed to review initial studies that are approved and to provide local site comments. I would say about 30%, 40% of the liaisons are also the designee. So you know we say there’s two functions. You can appoint one person to do both or you can have a person do each one. That’s totally up to the Medical Center Director. And as one of your handouts, I did include the template that you use to have your Medical Center Director sign and send to us that designates who these individuals are. So whenever there’s a change in one of them, you just need to have that signed and sent to us.

Okay as far as oversight goes, this has just been a recent change with the new handbook or, sorry about that, new Directive 1200.01, that the VA Central IRB is now an external committee to the local site but it’s still an internal VA IRB. So that’s a change because we used to be a subcommittee of the R&D. And that’s an important change because if we’re no longer a subcommittee, you no longer have to review our minutes, or either really our annual report. However, because we have developed such a good operating relationship with our sites we have decided, here at the Central IRB, to continue to make these reports available to you and to continue to make the minutes available to you. So there will be no change in that from our side. We will continue to post the minutes on our SharePoint site under the liaison folder and we will continue to provide you copies of the annual report. So how you utilize those, you know, in your evaluations that you have to do for external IRBs per 1200.01 is going to be up to your local site, but we are going to continue to provide those to you. Okay like I said, we still have the local site comment period for your designees to comment. We still use local site liaisons. We still interface with the local research compliance officers and, of course, we still fall within, as everyone does, under the VA Office of Research Oversight. I should mention at this time, and I think we forgot to in the beginning, is that Kristina Borror and Priscilla Craig from ORO are also with us on this call today and they will be available at the end of this presentation to help answer questions.

Okay so currently the VA Central IRB is composed of 14 members from across the country comprised of, we have two co-chairs, we have 10 scientists, and we have one affiliated non-, two affiliated, no, we have one non-affiliated non-scientist, and one affiliated non-scientist. So we have two non-scientists, one’s affiliated and one isn’t. Sorry about that. I’m tripping over my tongue there. Okay. We have four non-voting members. We have an individual who is from the VHA National Center for Ethics in Health Care. We have an individual from the Office of General Counsel. And we have two privacy officers assigned to us from VHA Central Office, Stephania Griffin and Kim Murphy. They’re both very active with us. And we have two information Systems Security Officers assigned to us. Those are both from the National Information Systems Security Office. Currently they’re Terry Peters and Terry Taylor but Terry Taylor is moving on to another position within that same group and someone else is being assigned to us. So that will be happening in the next two or three weeks.

So we’re having an upcoming structural change that I want to briefly touch on, well not briefly but it’s part of the reason we’re changing the MOU is that we’re adding a second panel as part of the VA Central IRB. And we were hoping to have the first meeting of this panel scheduled for early November. It’s going to be composed of some members of the current panel plus a mix of new members and it will have two new co-chairs. It will follow the same meeting schedule as our current panel does and it will use the same policies and procedures. So we’re hoping that this is going to be fairly transparent to both local sites and study teams. So when I say Central IRB from henceforth, I’m actually meaning both panels. Because both panels are going to be under the umbrella of the VA Central IRB. And there will be a panel one and a panel two. It’s going to be supported by the same administrative staff we currently have. We are looking at getting additional support in the very, very near future. And we’ve set up the structure such that it should be fairly easy to add more panels in the future or terminate a panel. It’s just depending on workload and we will look at that very closely. Our goal is to make each panel leaner in that we want each panel to have between 10 to 12 voting members instead of currently we have 14 to 16 voting members. But when we have two panels, we’ll actually have more reviewers. So hopefully we’ll be able to handle an increased volume if that happens.

Okay. So now I want to go into the actual changes that were made to the MOU in this revision. You should have received, as part of the handouts that Soundia sent you, two revised MOU templates. The first one includes the NPC as signatory authority on the MOU. And on that particular one, I sent these out also early last week I believe. Please disregard the template I sent out for this because I forgot to include the NPC signature line on there. I thank you because several of you emailed me and pointed that out to me. So the handout that you have, the template that you have, for that particular template that was sent out by Soundia this morning does have the signature line on it. So please use that one, the one with the signature line was also uploaded to our public website so you can also get it from there. And then the other template is for those facilities who don’t use or have an affiliated NPC. So you got the two templates. You only need to use one, depending on whether you have an NPC or whether you don’t have an NPC. Okay. So I’ll mentioned at this point that ORO has reviewed this updated version of the MOU and their comments have been incorporated into it.

Okay. Now why did we need to do a revision at this time? First off we needed to put in there, of course, that we are going to include an additional panel. So that was one of the major reasons. Also we wanted to incorporate the 2018 Common Rule requirement. And at the same time, as many of you are aware, at the same time the Common Rule came out we had changes to 1200.05 and 1200.01 so we wanted to incorporate those changes as well. Also the renewal cycle for the current MOU, which currently the cycle was three years from the time it was initially signed, is coming up for many of the sites at the end of this year and early next year. So it was due for review anyway and so this is the perfect time to do that as we’re instituting a new panel and we have to incorporate all of the changes that went into effect earlier this year.

Okay. So I’m going to briefly talk about some over-arching general changes. Our goal was to streamline it as much as possible while still including enough specificity so there was no confusion about what the responsibilities of each signatory is. So we did streamline the MOU and we reduced it by about two pages and when I say that, I mean two pages from the original MOU that we had in the very beginning. So we have reduced it over the years so it is down by about two pages. That’s even adding the NPC in there and some of the changes that we needed to add now for the changes in the requirements. So I’m happy about that. Hopefully that makes it easier to read. Another reason we wanted to streamline it was we decided to take out things that are better addressed in SOPs that weren’t really necessary for an MOU. We updated wording and references to reflect current terminology such as the use of ISSO instead of ISO and changing Handbooks to Directives, etc. Some of the very routine things that needed to be done. As I mentioned, we clarified provisions that sites have previously indicated to us were confusing. So we added more specificity to those particular aspects of the MOU. And then we eliminated as much duplication as possible. We actually started using a few more abbreviations. And sometimes we repeated things in two sections and it only needed to be in one section so we did some elimination like that.

Now for the specific changes in the MOU. The agreement period is now five years instead of three. And I also should mention I have Lindsey Martin here with me, most of you who have dealt with MOUs and the changes in the MOUs and the changes in signatory officials are very familiar with her. She’s our MOU guru here in our ORPP&E. So she’s here and she will be available to answer questions after the webinar as well. We also added the references to the multiple panels of the Central IRB as I mentioned before. And then we also included that all of the panels must be added to the facility and NPCs FWA. Now I’ve added paragraph numbers on the MOUs for the rest of these that I’m going to be talking about. These paragraph numbers pertain to the template that has the NPC. The paragraph numbers differ slightly from the one without NPC. So when we refer to the paragraph numbers, if you’re looking at the MOU, it’s the one with the template that has the NPC in it. We also clarified when the Central IRB would charge for reviews and when it would not. And we changed the frequency of meetings to twice a month with the flexibility to cancel meetings for specified reasons. Now our intention is for both panels to meet twice a month. We will see how that goes. But that’s why we put the flexibility to cancel meetings. It may not turn out that way so we’re going to be working through this process but tried to make the MOU as flexible as possible to account for however that turns out to be.

We also added a provision that the MOU does not guarantee that all studies from a site or study team that meet the criteria for review will actually be accepted for review. I have a lot of, I won’t say a lot, but there’s been a number of study teams that fill out all the forms and then call me and say, they’re ready to submit and we didn’t even know about them. And we have to know and clear a study to be submitted before it’s actually submitted. So we wanted to make that clear. We clarified reporting requirements of the site to ORO, OHRP, and the FDA. Whenever we have a reportable event that we actually do report out to the Medical Center Director, there’s confusion about who does what. I think we made that very clear in this MOU. We also added a portion about how the VA Central IRB will perform limited IRB review. So that’s a new provision in there. It kind of takes the place of the exemption paragraph and we made it pretty detailed so it would be clear about what the VA Central IRB will do in regards to studies that are exempt and that need to have a limited IRB review. And then we noticed that we had a little bit of a short falling there in how we communicate. It wasn’t exactly clear in the MOU so we added a paragraph about how the Central IRB will distribute correspondence such as through our SharePoint site, email, or through a designated electronic platform, whatever that may be and that may be changing shortly.

Another area that we added more specificity to was the reporting of routine RCO audits to the Central IRB as well as reporting of apparent serious noncompliance. So that has been an issue of confusion in the past so we have added more specificity to that. There is a requirement that’s in the new 1200.01 is that if a facility uses another facility’s R&D Committee, that facility must ensure the MOU with the overseeing R&D Committee references studies approved by the Central IRB as an IRB of record. That’s in the new 1200.01 but it shouldn’t be much of a problem because most sites that would serve as your reviewing R&D Committee already have the Central IRB as an IRB of record anyway. So they’re very familiar with us and would be very familiar with any VA Central IRB study and how to oversee them for your site as well. So that really shouldn’t be an issue. And then we also added clarification about when LSI applications should be submitted. The reason we did that is because we’ve had a number of cases where a PI application is approved and even though they needed to submit an LSI application for that site because they’re recruiting and consenting participants, they don’t. And they use the model documents instead of using the documents that are validated and stamped with the IRB approval date. They use the model document. So we wanted to add clarification to that as well.

And then we did put in a provision, just so everyone knows up front, that we do not review emergency use or non-emergency compassionate use requests. And we changed the notification requirement for termination from 60 to 90 days. So that really is it in a nutshell. Those are, I don’t even want to call them major changes, because they’re not really major changes. They’re mainly administrative changes to meet regulatory requirements, Common Rule requirements, new Directive requirements, and to improve our communication between our two sites. The bones of the MOU agreement have really not changed since the very beginning. If you go back and look at our MOU from the very beginning, four revisions ago, you’re going to see very similar structure, very similar things in there. So it really hasn’t changed over all these years all that much.

Okay. So now I’m going to briefly, and I do mean briefly, touch on processing the MOU for signature and adding the VA Central IRB panel number two to the facility and NPC FWA. And as I said, if you have any questions on this, please send them in to Carol and we will have Priscilla and Kristina Borror available after I finish this presentation to help answer those questions.

So Priscilla has asked me to emphasize that this process for getting the signatures on the MOU has not changed. It is the very same as we have used for all of our past revisions. So you should be familiar with it if you were, assisted us with getting the other revisions signed. If not, I’m briefly going through it here. So the MOU requires the signature of the Medical Center Director and it does require the signature of the VISN Director. And if you have an affiliated NPC, which I’m sorry I did not put on this slide, but it also requires the signature of the NPC IO, whoever that may be. The signature can be electronic. Once both signatures are obtained, or once all three signatures are obtained if you have an NPC, then you email that to us at the Central IRB. You can either email it to our, if you don’t remember who Lindsey is, or who I am, you can use our general email address also and those individuals who look at that every day will know where to send that email. Once we receive it, we will obtain the signature of the VHA Central Office representative that has been designated by Dr. Clancy to sign the MOUs on her behalf and currently that, again, is my boss, Dr. Mary Klote. She’s the HPA for the VHA Central Office HRPP as I mentioned earlier. She will sign those and then they will be emailed to ORO and back to your facility. Okay so that’s the MOU. And you can start on that now with the templates that were with your handouts or the template that’s on our, the public website. Again, do not use the one I sent you.

So now I want to talk briefly about adding the Central IRB second panel as an IRB of record to your FWA. I have not registered this panel yet so this is something that you don’t have to do at this very minute, but we have been actively recruiting individuals for our second panel. We’ve actually already on paper split our board and I’m ready to register the second panel. I will probably register it early next week. My intention was to register it this week but other things have overcome that but I am definitely registering it early next week. And once I get the notification from OHRP that it has been registered, and I have the registration number, I will send that out to everyone. I will send it out to all the Local Site Liaisons. And then each facility will need to update their FWA by adding that second panel as an additional IRB of record and in order to do that, you follow the normal process that you would do for whenever you update your FWA anyway. And that process is described at ORO’s website which I list right there on the slide for you. It’s a rather detailed, long list but it’s a very detailed step-by-step so you shouldn’t have any problem going through it. I myself, you know, have to go through and update the VHA Central Office HRPP FWA occasionally and so I also follow that process and found it very easy to follow. Now some of you may ask why do we have to do this because OHRP does not require it. Well ORHP doesn’t require it, but VA still requires it. VA still requires all IRBs used by a VA facility to be designated on the FWA. So that’s why we have to do it.

Okay. Briefly talk about changes in signatory officials. So when either the Medical Center Director or the NPC IO changes, you need to update your FWAs, as you should already know, within 30 days and submit to us a VA Central IRB Form 143 which is called the Memorandum of Understanding. You submit it to Lindsey or you can submit to me or you can submit it to our general address again. And you’re also required to complete the VA Addendum to the FWA. So that Form 143 was also included in your handout. So you have an example of that. It’s a very simple form that just says that one of the signatory officials has changed and they have read the MOU and then they sign it. It’s a simple one-page form that needs to be submitted to us so that we know that and then we can update our database. Once we receive it we will also send a copy to ORO so that they’re aware of it as well. Also when you do update your FWA, we do get a notice from OHRP because we are listed as an IRB of record for panel one. So we will get it and then of course you’ll be adding panel two. So whenever you update your FWA we get a notice. So if we have not received an amendment for that particular change in signatory official it’ll probably be Lindsey that will be contacting you asking if you’re going to submit an amendment. If we get an update from OHRP that changes the HPA or changes the phone number or something like that, then no, you don’t have to submit the amendment. We only need the amendment for changes in the Medical Center Director and the NPC IO. If the VISN Director changes we do not need an amendment for that either, okay?

Now to briefly touch on Local Site Liaison responsibilities. I can’t emphasize enough that communication is key. I think what has allowed us to be successful is the great communication that we have been able to establish with our liaison. And I value each and every one of you. I enjoy meeting you at meetings and I always am very appreciative when you point out issues to us that we need to fix. You are the main source of pointing out to me problems in our minutes which we do amendments to. Most of our amendments that we do are because they’re pointed out by you as you go through and review our minutes. You let us know when we send it out, because we copy liaisons on all of our IRB letters, our determination letters, you let us know when somebody’s not there. They’ve left and not even told us. So we think it’s a really important function and, again, I can’t thank you enough, and also the RCOs. I want to add the RCOs in that. Some of the RCOs are also our liaisons so they serve double duty. We really rely on the local RCOs and the liaison as our eyes and ears regarding what’s going on at the facility when you’re talking about a single IRB, a multi-site IRB like the VA Central IRB. So I just want to take this opportunity to emphasize that. I can’t thank you enough. Not only from a Central IRB administrator standpoint but also from a Veterans standpoint. Because I recognize your dedication to your job. And as a Veteran, I also appreciate it from that standpoint so thank you. So as I mentioned, we copy the liaisons on all of our determination letters in which your site is listed as a participating site. So you’ll get copied on PI amendments because it affects your site. You’ll be copied on, of course, anything affecting your Local Site Investigator application. So we really try to keep the liaisons in the loop on that and that’s why it’s so important that we know when that has changed. We have updated our liaison handout. That is also part of the handouts that you were given and that contains specific responsibilities for the liaison. And we also added a section this time for Site Designees. Site Designees really only have one or two responsibilities so we decided to add that to the liaison handout, in particular because the liaison probably assists the designee most of the time in doing that and also because the liaison is, I would say, like I said, 30%, 40% is probably also the designee. So we have updated that and provided that to you.

Okay. Again I am stressing the importance here because effective communication is a two-way street. I’m kind of emphasizing this. We try to communicate with you but we can only do it if we have the right individuals listed in our database to communicate with. You can imagine with 108 sites, we can’t always remember who we’re supposed to, you know, send something to for what study so we rely on our database to do that for us. So whenever there’s a change in Local Site Liaisons, really, really please, I cannot emphasize it enough, let us know. Get that letter done that I had included the template in the handouts for you. We closely track your IOs, NPC IOs, the liaisons, the R&D Committee Coordinators, the Site Designees, and the RCOs. That’s really critical for us to know who those individuals are and to keep track of it. We also, as part of our database, also track the ACOS of R&D, the AO, and your local IRB administrators because occasionally we need to know who they are too and to send information out to them. So in order to do this, every spring, we will send out an annual call to update all points of contact at the site. And we do that by sending out a list of who we have on file and then we ask you to update that. And Lindsey gets a ton of changes every year at that time and she’s just overwhelmed with them. And that tells me that we have to do better in trying to keep up with all the changes that are taking place. So we’ve decided that we’re going to start instituting quarterly reminders. You know, we haven’t decided how we’re going to do that yet, but we plan to do that very soon and it’s most likely that we’ll be sending out something that says please update, you know please look over who you’ve got assigned to all these positions and let us know if there’s a change. Because Lindsey takes days and days to update everything and to validate everything and then she has to determine if there’s been IO changes that we weren’t informed about. She has to go through and have you start the amendment process. So you know, we really would appreciate you updating us as much as you can. If an IO changes, you know, two times in 90 days that’s fine, let us know.

Okay. So because communication is so important I did want to go over our SharePoint site a little bit because we’re always getting questions about where do I find things? So who do we give access to at the local site? Well on a routine basis when a study is identified, if a study comes in and it lists sites that are going to be potential participating sites on the application, the VA Central IRB and Manager will ask our SharePoint Manager, who also happens to be Lindsey, and also Erica Aulik from our office is also one of our SharePoint managers, to set up a folder. And then we automatically give access to the individuals listed on this slide; the Local Site Liaison. If you have a Primary and Secondary Liaison we allow for that but we only allow for two because our system only has two fields. So we can have a primary and a secondary but we can’t have a third and fourth one as we sometimes get asked for. We just really can’t manage that many people in our current database. So we really appreciate it if you’d limit it to the primary and secondary. We have a slot for an R&D Coordinator, RCOs. I think we have two, Lindsey, don’t we? We have two slots for RCOs, the Site Designee. And this pertains more to studies, but if there’s a coordinating center associated with the study, Coordinating Center Manager, we give them access as well. Then of course the study team. But I’m focusing on the sites. So you should get automatic access to that. You should see, when you sign-in to your SharePoint site, you should see that the study folder will pop up when you sign into SharePoint if you’re given automatic access to it. I need to mention also that, even though I said that liaisons are copied on all determination letters, we do also copy liaisons on acknowledgments. And what that means is when we get new studies in, you will be copied. This is something that the liaisons have asked me for in the past. We have implemented it, in fact, for several years now. So hopefully you find that an effective way of knowing when a new study has been submitted in case they haven’t informed your R&D Committee, or they haven’t informed your office that this study’s being submitted to the Central IRB. Of course we look for, we have the ACOS sign off on the application but sometimes the ACOS may sign it and not tell anybody. I mean I’ve gotten several cases of sites calling me in on a study that they said they never heard from the investigator at their site. So we have included the liaisons on those acknowledgment letters so you will know when a new study comes in.

Okay. This is what you will see. This next slide is what you will see when you sign on to our SharePoint site. Not very pretty but it is what it is. We’re not SharePoint experts here at the VA Central IRB. But if you see this screen and you wonder how do I see what I’m supposed to see, if you’re not familiar with SharePoint, you just go to the left and click on the first entry there under documents that says shared documents. You click on that and then another screen should come up.

This is my screen. This is what I see when I sign on. So it’s what you should see if you’ve been given access based on your site role. You should see the By Study Number folder and under that By Study Number folder, there’s a folder for each study that we’re currently overseeing or currently reviewing. And if you have access to it, that folder should show up on the subsequent screen after you click on Study Number. For liaisons, there’s a Site Liaison folder that you see. All liaisons have access to that folder as well. All of these other folders, you shouldn’t see. These are folders for the Central IRB or folders for the study teams.

Okay. Now here’s the Site Liaison folder and what this looks like. This is what the liaisons see. There’s a folder for Signed Expedited Listings and after each meeting, Lindsey has that listing signed by one of our co-chairs and she posts it here. And that was also at the request of the site because we are behind a little bit. We were catching up, but we’re behind a little bit in our minutes and our minutes don’t go out for at least a month after the meeting. So if you want to see what the IRB reviews under an expedited review, you see you’re pending a study there at your own site for your R&D Committee and you want to see the Signed Expedited Listing, it’s right there. That gets posted two or three days after the meeting whereas the minutes won’t get posted probably maybe until 60 days after the meeting. So that’s there for, at the request of the liaisons, we instituted that. We also have the Site Liaison and RCO information sheets posted. We have the minutes posted under the minutes folder and again we’re going to continue to do that. Even though that’s no longer required in 1200.01, we’re going to continue to do that. Currently the 2018, all the 2018 minutes have posted and the 2019 minutes have posted through August 9th I believe. Then the Central IRB roster is posted. Right now, of course, only one roster is posted for what we’re now calling panel one. I will post the panel two roster and appropriately label them panel one and panel two when that happens. So I will send out the email when we get the registration notice. And then I will post that panel two roster right here, to the central liaison site. Then there’s our table of reporting requirements in case anyone at your site has questions, you can always look at our table of reporting requirements. And then under the last folder, you have our annual report that we make available to all the sites and that’s for 2018. Only the 2018 report is available right now on the site.

Okay. Also I want to go over some things that we have available for the site out of our system. If you need these things, just let us know. We don’t routinely send these out to you. But we often get requests for them and so we have made some canned reports that we can just print out whenever somebody asks us for these reports and so I never really have gone out and said that these reports are available to you if you need them, we’ve just been generating them. But I did want everyone to know that if you need these reports, then all you have to do is ask for them. So we can give you a list of all the active studies, and these are active at your site by PI. We can give you a list of LSIs if you have an active LSI application at your site. We can give you a list of studies by funding sources, both PI and LSI. Or we can give you a list of SAEs and Protocol Deviations on a particular study by site. So if you need these, they’re available. You just have to ask us. Anybody on the Central IRB staff can go into our system and click on a menu item and print these out for you. And if you need other reports and occasionally you do need other specific reports, you need to just ask us and we can go to our programmers that manage this site for us and have them see if they can print those out for you. So we’re very open to doing this. We understand how difficult it can be sometimes to keep track of everything so we wanted to make sure that you knew these were available.

Okay and then this is what, just an example of what one might look like. This particular one is just a blank report I had printed out on approved PI projects by site. So you could ask for a list of all studies at your site for which the investigator at your site is the PI, the main PI of all the multi-site study. And this is what you would get. You can see that you would get the IRB number, protocol title, the PI, the city and state which is your site, the date the project was approved, if it’s subject to continuing review, the expiration date, it’ll say whether it was transitioned, and the transition date if applicable. It also tells you what risk level, how it was reviewed, if it was reviewed expedited, the category, and whether it’s FDA regulated. So if you need that type of thing, it is available.

Okay. So we are going to be having, and I think I mentioned this at the very beginning of this presentation, we are going to be having some changes in the SharePoint system which is another reason I wanted to go over this with you. We have moved our SharePoint site to the cloud. That has already been done. That was done last week. We are now in a two-week user validation period that will end October 15th. So what this means is that the old site is still active. So nothing has changed at this minute for the users. You can still access the old site. You can still add things to it. Your study teams can still upload things to us at the old site but it will become a read-only site after user testing is completed. After we’ve gone through and said, yes, everything seems to be fine and that’s scheduled to be October 15th. After we do that then you will be redirected, if you try to go to the old site you will be redirected to the new site for a period of approximately 30 days. Now once we do clear it and say that we’re ready to use the new site and start loading everything to the new site instead of the old site then we will send out an email to everyone. We’re figuring out how we’re going to do this. We’re going to probably do it in groups. But we’ll be sending out an email to everyone giving you the new link. All the access permissions that you currently have should transfer. They seem to have transferred for us as we’re testing it. But we don’t know what’s going to happen once, you know, you can no longer access the old site. So all of them should transfer. You should only have to have a new link to get to this site. And then I will explain this all again when we send out the message. But I wanted to give everyone a heads up that this is coming.

Okay so there’s my contact information, Priscilla’s contact information from ORO, our general email address, our toll-free number, address, and our website. And our current two co-chairs are listed there. I haven’t added any new panel members yet.

And then this is the rest of our current staff, our IRB managers and our SharePoint, MOUs, and Reportable Event staff. You can see Lindsey’s right underneath the SharePoint and MOU heading.

So I believe that is all I have. So we can open it up to questions, Soundia if that’s the next thing you want to do.

**Soundia Duche:** Thank you, Annette. Carol, we’re ready for the questions.

**Carol:** Okay. The first question is, where are the approval documents for Protocol Deviations and SAE reports?

**Annette Anderson:** The approval letters? Yeah. We haven’t, we don’t load those. We send them but we don’t load them. So you should get them in the emails. There’s so many of them. We weren’t able to load them to our SharePoint site. We had all these restrictions on the amount of volume we could have on it so we don’t load those. The reports there so you can see that we have the report but the letters are not. But we send those with the email. So the liaisons should get those with the email. And of course, we can always provide them to you if you need a copy.

**Carol:** I don’t have any more questions.

**Annette Anderson:** That’s it? Wow.

**Soundia Duche:**  Give another minute in case any other questions come in. This went incredibly well with timing. Nope we’re not seeing anything here, so. Opps here’s.

**Carol:** Okay, well, oh okay.

**Soundia Duche:** How do we get the letters, the SAE and deviation letters?

**Carol:** That was what she just asked.

**Soundia Duche:** Probably sent a follow-up.

**Lindsey Martin:** So we, our CATs database generates the letters once all the information is inputted from the checklist the reviewer sends. It’s sent by email to the Local Site Investigator, any Local Site Study Coordinators that are listed in the database, the Coordinating Center Managers, and all the site liaisons. So if you need a copy, I would check with one of those before you email us asking for it. And then if you cannot find it from any of them, email myself, this is Lindsey Martin, and I can look and see if I can find a copy on our share drive or in the paper file.

**Soundia Duche:** Questions have come in.

**Carol:** Okay. Next question is what is the due date to file the revised MOU and FWA?

**Annette Anderson:** Okay. Good question. I didn’t mention that. We’re not giving a due date because I realize that everyone has, people are out. The VISN Director often can be difficult to get their signature and I haven’t registered for the FWA. I haven’t registered the additional panel yet. But all I would like to say on that is, please, as soon as possible and as soon as you get the message that the panel has been registered, please go ahead and get your FWAs updated as soon as possible. The second panel cannot start reviewing studies for your site until that has been accomplished. So no due date but we may establish one later on. But as of now, I didn’t feel comfortable putting one out because everything is not quite yet in place. But you can start sending those MOUs out for signature.

**Carol:** Next question is, the RCOs cannot verify that the IRB record and the PI records are equivalent.

**Annette Anderson:** RCOs have access to our, the study folder. They’re routinely given access to that. So we put out there on there all of the approved documents for that study. The only things we don’t put out on there are CDs and COI forms. But other than that, all of the approved documents for any action that we take are put out on the SharePoint site. So RCOs should be able to go in and review them. And they routinely do because if they don’t have access, we get calls and we give them access and they go in and do it.

**Soundia Duche:** I think, Annette, she may be referring to the Reportable Events.

**Annette Anderson:** Oh for the Reportable Events? Yeah. If they need to see them they can go to the liaison. It should be in the study folder though and if they’re not in study folder, that might be a problem.

**Lindsey Martin:** In your regulatory binder.

**Annette Anderson:** Yeah. In the regulatory binder at the site. They should have them. If they don’t, let us know, I mean that’s an issue. Because we often say that they have to do something. So they should have them.

**Carol:** Okay. Next question is are there any guidelines on the SharePoint for submitting a new study to the CIRB or perhaps a good POC to help with the process for a first-time user?

**Annette Anderson:** Okay. For a first time user, they need to get in contact with me and I will run them through the process depending on the type of study. Because it can be different, way different, depending on what kind of study you have. So they should contact me. Now as far as submitting, after they talk to me and they’re ready to submit, there are instructions on our SharePoint site that will tell them how to do that, how to load it onto our SharePoint site. So they’re right there as they’re, in fact, Lindsey has come up with these instructions and they’re right there to use. There’s a PDF file I believe on the site, yes.

**Soundia Duche:** And that was Annette Anderson speaking when she said contact me.

**Annette Anderson:** Yes. Contact me Annette Anderson.

**Soundia Duche:** Annette.Anderson3?

**Annette Anderson:** Yes. Annette.Anderson3, you’ve got the contact information there. And yeah, I basically, I’m the main point of contact for all new studies because it can be very different depending on the type of study that they have or they may not even need to come to the Central IRB so, yeah. As I mentioned in the very beginning, they need to contact me before they start filling out all those forms.

**Carol:** I think the other one is, the next one is referring to the SAE reports again. The comment is we should be able to verify that the IRB record is the same as the PI file. We should not rely on the PI files for verifying SAE Protocol Deviation reports.

**Annette Anderson:** Okay. As again, you saw that we have reports that you can ask us for from Access that we can give you showing us that we’ve processed these reports. But our volume is such that to post all of these on SharePoint, and we’ve talked to ORO about this in the past, it’s just overwhelming for us and so we have not done that.

**Lindsey Martin:** The process for Reportable Events is once the report is sent to the IRB it’s logged into the database. And those folks, I had mentioned before, get an acknowledgment letter and then once it’s reviewed, the report is then posted back to SharePoint with the VA Central IRB number, whether it’s a Protocol Deviation or a SAE or a UAP. And then once the reviewer completes the checklist, then I send the determination letter to all of those folks. So the report is posted back to SharePoint for 30 to 60 days and then it’s deleted because we just don’t have the threshold on our SharePoint site to house all these documents for long periods of time.

**Annette Anderson:** And it was never meant to be an official record site. It was always meant to be a document distribution system. This issue will go away of course when we convert to the new enterprise-wide system. Most of you have heard that a contract was recently awarded to IRBNet and we will be using that. In case that’s a question. I think that was a question at the previous webinar. We will be using IRBNet. I don’t know where we’ll be in the tiered process to come on board for that. That hasn’t been determined yet but we will be using that. And again, if you have any issues, and RCOs are not hesitant to call me and we can provide any reports that you do need. One thing we try to do with these SAEs and protocol deviation reports is if we need something, we’ll say that and we will not close out the report. If we don’t need anything, we will say no further action. So if you’re auditing these things and you see the letter that says no further action, it means there’s nothing else after that. If we ask for something, then there may be another letter coming on down the line. But again, just call me, Lindsey, or the manager for that study which is on all the letters. We list who the manager is for that study. Just give them a call if you’re having difficulty with that.

**Carol:** No further questions.

**Soundia Duche:** All right. Thank you so much, Annette. This was wonderful. And thank you everybody for your participation. We will be posting the recording of this webinar probably by next week, Wednesday, if not before. So look out for that information. Next week, Tuesday, my apologies. With that, we want to thank everybody. Thank you, Dr. Kristina Borror. Thank you, Priscilla Craig, Lindsey Martin as well. And thank everyone for listening in. Please as Carol noted, complete the survey at the end so that we can get your very valued feedback, okay? Have a great evening. Bye-bye.