ORPP&E Webinar

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Session: R&D Committee Workshop Series: Review and Approval of Research

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Soundia Duche: Good afternoon everyone, my name is Soundia Duche, and I lead ORPP&E’s education and training. I am so thrilled to be able to present the first workshop in the R&D Committee Series. And we’re going to be focused on review and approval of research. And assisting me with this workshop is Ms. Christina Bennett, who is the R&D Committee coordinator at the VA Northeast Ohio Healthcare System. So welcome Christina. We also have in the room with me Dr. Karen Jeans, who is our director of regulatory affairs here in ORPP&E. We have Ms. Sarah Rule, who is our senior regulatory affairs manager, and on the phone we have Dr. Kristina Borror, who leads ORO’s policy and education department. So thank you all. Now I’m going to go ahead and show my screen, so we can get started. We have a lot of people on the call today. Or at least registered for the call. And so we’ll do our best. We have questions, as Carol said, we’ll have the Q&A session at the end, but really we’re only going to be taking questions on today’s topic. Okay? We designed the series so that we have time, adequate time to work through all of the issues related to R&D committee responsibilities, over the next eight sessions. Christina, if you could take a moment to introduce yourself, and tell people a little bit about what you do at the VA Northeast Ohio, how long you’ve been at the VA, to just give us a little flavor of what all you take, you handle.

Christina Bennett: Absolutely. So, hi, I’m Christina Bennett, like Soundia said. I’m the R&D Committee coordinator at the VA Northeast Ohio Healthcare System. Our main medical center is in Cleveland, Ohio, and just to give you a little background about our program, we have what I would call a medium sized research program, with about 250 active studies currently. The majority of our research involves human subjects. Right now we have about 175 non-exempt human subjects protocols, but we also conduct animal and laboratory research, and we have our own R&D committee and subcommittees to include our own IACUC, IRB, and SRS.

Soundia Duche: Excellent, thank you Christina. So what are we going to be talking about today? We’re really focusing on the R&D Committee’s review and approval of research. And helping in doing that, Christina is going to be sharing some of the practices that her local site uses to review and approve research. And then we’re going to be sharing some tools with you. These are not mandated tools, by any means, but it may assist you as you evaluate how best to implement the regulatory requirements for R&D review and approval of research. We’re also going to be talking a little bit about feasibility alignment assessment. This is something that Dr. Klote talked about in, back in November, when she did her webinar which launched this whole series on R&D Committee responsibilities and differentiating R&D Committee’s responsibilities from the institution’s responsibilities, as well as the IRB responsibilities. Okay? And so, you may have seen this slide from Dr. Klote’s presentation. I just want to really focus everybody again on what is the purpose of the VA R&D Committee? We all know that really it serves a unique function in the VA, many institutions don’t have an R&D Committee. But for us here in the VA, we’ve instituted the requirement for VA R&D Committee approval, because it serves a critical role as part of the institutional governance structure. Okay? But the R&D Committee really does a host of things. And all of its requirements and responsibilities are not included on this slide. But just a key, to hone in on a few key things, the R&D Committee really serves a critical role in deciding which studies should be conducted at a VA institution. And to ensure that the studies are conducted in a manner in which they comply with all applicable statutory and regulatory requirements, as well as are consistent with the VA mission. The R&D Committee, what we’re going to be talking specifically about today, we’re going to talk about the responsibilities in reviewing and approving research. The R&D Committee can require changes and modifications to the research, and of course they do have the prerogative to disapprove research. And then finally, on the slide again, the R&D Committee does much more. They’re also responsible for reviewing operations of all research related committees and subcommittees. And they do this according to their own SOPs on what they review and how they redo it, but that is one of their responsibilities.

What does R&D Committee review? They review specifically VA research. Okay? VA research. What is VA research? It’s research conducted by VA investigators, whether they’re compensated, whether on a WOC appointment, or an IPA appointment, but it’s research conducted by VA investigators while on VA time or on VA property. And that research includes many things. Animal research, human subjects research, both exempt and non-exempt research is approved by the R&D Committee, and then non-human subjects research as well, which would include basic laboratory studies, as well as studies on non-human subjects data, those types of things. So any research activity that involves our VA investigators working on their VA time or on our property would have to be approved by the R&D Committee, prior to being able to start.

How does the R&D Committee do that? what does that look like? What we’ve shown here is what we consider a typical review process. We recognize that a number of you may do different types of reviews, right? You may have, this represents the sequential flow of information into the research office, through the subcommittees, then on to the R&D Committee before going to the investigator. Some of you may do parallel reviews. This slide does not mandate an approach. But I dare say I think if we were to canvas you, maybe about 60 to 75% of you probably use this model. And so in thinking about this, if we were to take a human subjects protocol, it comes into the office. Maybe there’s some type of administrative review, then it goes to all the various subcommittees. If it’s non-exempt it would go to the IRB, if it’s exempt, it may go to the IRB for determination, but it could also go many other places. Right? Everybody may do things a bit differently, or some people may be in the process of changing that, and that’s okay. Then it would go for R&D Committee for review and approval, and that’s what we’re going to be focusing on today. And then, finally, it makes its way to investigator, whereby the investor gets the final approval notice from the ACOS of R&D alright. So this is typical. I know there’s a lot more going on at many of your institutions. And I’m going to ask Christina if she can share with us, does this look like what you all do?

Christina Bennett: Yeah, so I would say overall this is similar to, you know, how we do things at VA Northeast Ohio, but some of the important details of our process aren’t captured in this diagram.

Soundia Duche: Okay. So give us some examples.

Christina Bennett: It’s like, for example, yeah, so for example, we perform sort of a detailed pre-review when the study is submitted to the research office. So, we have our own unique process. All new study submissions are sent as a complete package to me, before they go to any of the subcommittees. So they’re submitted to me as the R&D coordinator. And I complete an administrative review, which basically ensures making, making sure all required documents were submitted, and then reviewing in detail those documents which pertain to the R&D Committee. And I communicate with the PI about any missing documents, or necessary revisions, before the study moves forward in the process. But then, for human subjects research, the next step is to send the study to what we call our pre-review team, which includes the IRB office administrative staff, the privacy office, and the information systems security officer. And their goal is really to review the study more in depth, in the protocol, to make sure the study is in the best shape possible before it goes to the committees for formal review. So, that’s a big part of our review process, and where I think the most time and most work is spent, revising and clarifying the protocol. And then once that is complete, it’s forwarded to the applicable subcommittees for review and approval, and eventually to the R&D Committee. So, that specific process isn’t required by policy, but it’s the one that works the best for our institution.

Soundia Duche: Very interesting. And let me ask you, Christina, during that pre-review process, where you have the PO, ISSO, and the IRB office, do you have an IRB member?

Christina Bennett: No, the administrative staff. So the IRB administrator\_

Soundia Duche: Administrative.

Christina Bennett: \_and or the analyst.

Soundia Duche: Okay. Okay, now, during that process, if issues and deficiencies are identified, do you then communicate that to the investigator? And do they have an opportunity to modify things before it moves forward?

Christina Bennett: Yes, absolutely. So that’s generally the purpose. So we usually go through a few rounds of revisions, communicating and getting more additional information from the investigator and kind of making clarifications so that it’s ready to move forward.

Soundia Duche: That’s wonderful. And then one last question, because I love this idea. So, let me ask you though, your POs and ISSOs, would this constitute their initial review or their final review?

Christina Bennett: So, we tackle this as a two-part process, which again, is not required by policy. But we have the PO and ISSO review the study during that pre-review process, so that any major issues with privacy and data security are addressed before the study goes to the IRB and the other applicable committee. So, then after the study is, you know, reviewed and approved by the IRB, the PO and I still conduct a final review, just to confirm that no changes requested by the IRB would affect privacy and data security issues.

Soundia Duche: Excellent. Okay, that’s very helpful. Now let me ask you one last question. What we don’t see on this chart, before things get to the research office, when the protocol was submitted for pre-review, is there anything that happens that you all do at your facility? Any discussions that occur, or any evaluations or assessments that are done?

Christina Bennett: Yeah, so I think there’s a number of things that are kind of worked out before the protocol is actually submitted for review. One of those things is the budget, which is typically negotiated before the protocol is submitted. So, for VA funded studies, the budget is generally reviewed as part of the grant application, before the study is even funded. By our administrative office, our grants coordinator, the R&D Committee, and then eventually a budget is approved by the, whichever VA central funding office. [Loud bang] Sorry. For non-VA funded studies, those are typically administered through our NPC, and the budget is generally negotiated with a sponsor before the study is submitted. And then eventually becomes part of the [unintelligible 11:09].

Soundia Duche: Excellent.

Christina Bennett: And yeah, uh\_

Soundia Duche: Very helpful.

Christina Bennett: \_and that’s\_

Soundia Duche: Oh please, go on, there’s more?

Christina Bennett: Oh, yep, I was just going to say, and we also have a unique process for conducting scientific review that’s done before the\_

Soundia Duche: Oh yeah.

Christina Bennett: \_the study is submitted for review, so for studies that have been peer reviewed by a federal peer review committee, like policy states, our R&D Committee relies on the findings of the peer review committee, so those are just submitted along with the protocol. But for all other studies, we have developed our own process where we require the investigator to find two reviewers, we like one of them to be a VA investigator at our institution, and those reviewers conduct a scientific review of the protocol using a review form that we’ve developed. And the reviewer then assesses the scientific merit of the study, and makes a recommendation whether this study should be submitted for review to the institution. And so the R&D Committee then relies on those reviews and their determination of the scientific merit of the study, but\_

Soundia Duche: Oh.

Christina Bennett: \_the goal of doing this beforehand is to ensure that the study has scientific merit before resources are even expended on starting that review process.

Soundia Duche: Exactly. And that’s done before the protocol formally comes into the research office. These three things.

Christina Bennett: Yes.

Soundia Duche: Excellent. Nice. And that’s key, because this leads very nicely into our next discussion, and slide, where Dr. Klote brought this up in November, feasibility and alignment. This is a concept by which in order to make sure that the whole review process is efficient, how do we stop any bottlenecks from being identified way downstream? In terms of whether a research study should be done at an institution, is able to be done given the resources required, and given the population of patients that tend to visit the facility. What are some of the things we can do upstream so that if there’s an issue we can identify it earlier. If a study really isn’t, it’s not feasible to conduct it at the facility, for whatever reason, sometimes facilities say we are not going to do research on X, Y, or Z, that we tackle this up front to avoid exactly what you had mentioned, Christina, resources being expended downstream, and then people having to go back and try to amend the study, more resources being used to make something approvable. And so one of the responsibilities of the R&D Committee is to determine whether the facility should participate in the research study. The R&D Committee is also responsible for helping to advise the VA facility director in, and provide recommendations regarding personnel, space, and other resources that are needed for the research program. So when, Christina, when you mentioned this, these types of things, the scientific review, the budget discussion, these things that you do upstream, before things even get to the research office, I was quite happy to hear that. And I’m sure in actuality, you know, many other sites may be doing some parts of these critical assessments before something is even submitted to the research.

And so definitely conducting a feasibility and alignment assessment, it’s definitely possible, and it’s something that many of you all may be doing, but perhaps you’re not doing it to the full extent possible. Perhaps there’s things that you should consider adding to those assessments, things that can be worked out before the protocol is even, starts the review process, enters the queue for review, and starts going through the various subcommittees.

So in thinking through, what are some of those things you might want to consider? We look at certain questions to ask, right? At your institution, can we even do this study? Is it aligned, is it relevant to the VHA mission? Can our resources support that study? That would be something. Getting assessments from the different departments, if they’re key departments that maybe need to be involved, to determine do they have the bandwidth to support this research, given current clinical requirements. Also, do you have the patients? Right? Do we have the patients to be able to enroll and meet our enrollment targets? So that later on we’re not getting amendments, the research office isn’t getting amendments justifying the enrollment of non-Veterans, mainly because you cannot reach your enrollment targets based on the number of Veterans with the condition being studied. If those types of things can be at least assessed upstream, maybe then one can make some changes and create a protocol that’s more approvable, or maybe decide this is not the direction we should be going. Things like that. So again, Christina mentioned some things that they do, and I’m sure there are many of these things many of you all do, but now you are being more focused and deliberate about it. Non-Veterans, right? If a study involves non-Veterans, should that be done? This is something that might, you might want to evaluate more upstream before you get down the road and find out that, no, you know, we don’t have the budget to handle research related injuries, given the nature of this study. So just some things to think about.

But let’s now go into, really, what comes into the research office. And what we have here is a list of items that come in, this is not an all-inclusive list, by any stretch of the imagination, okay? I know so much comes into the research office. But what this list does, what we did was we picked out two things that really are key things that will eventually flow to the R&D Committee, because they are critical to the various assessments that the R&D Committee is required to make. And so we’re not going to tackle all of them, probably going to tackle a good many of them on this slide though. Because I want to hear from you, Christina, I want to hear from you on, for example, one of the things the R&D Committee is required to do is assess the availability of qualified research team members. That’s one of the things that our policy requires. So how do you do that? what does that look like at your facility?

Christina Bennett: At the Cleveland VA this is really our research office task. In order to assess the training and qualifications of study personnel, our institution requires that all investigators and study personnel have on file, with the research office, a number of documents to include a CV or resume, any updated training certificates, like for example, for human subject protection education, and a research scope of practice. Which is not required by policy, that’s just how we choose to document training and qualification. So then when I conduct my administrative review, when I first receive a new study, I check our database to verify that each study team member has the appropriate documents on file, and that they reflect the work proposed in the potential study. And then the study won’t reach the R&D Committee or any of the subcommittees if the requirements have not been met.

Soundia Duche: Okay. And then how do you communicate that to the R&D Committee that they have all those requirements? You just write a statement, or is there a checkbox somewhere?

Christina Bennett: So it’s really part of my initial checklist, and it’s not explicitly stated, but our SOPs have that as more of a research office task, and the committee understands they won’t get a protocol unless those requirements have been met.

Soundia Duche: Excellent. All right. Let’s move on to conflict of interest statements for investigators. And let me just, not a caveat, we all know, for those who don’t know, there is a moratorium on implementation of the requirements in 1200.01, in the directive 1200.01 on the conflict of interest committee. Okay? There’s a moratorium on that. You will be getting more information in the new year, in terms of, you know, what’s required, or not. What we’ve asked you all to do is continue business as usual. So however you were evaluating conflict of interest, continue. So with that said, Christina, how have you guys been evaluating your conflict of interest? And how does that information flow to the R&D Committee?

Christina Bennett: So we really have been using the form as our policy, and that’s, you know, duplicated in our local SOPs. But the R&D Committee members do not see the conflict of interest forms. Those\_

Soundia Duche: Okay.

Christina Bennett: \_are submitted to me, as part of the initial study package. I review those to make sure they’ve been submitted for all of the investigators, and if there’s no conflicts reported, the form is just stamped, dated, and initialed to indicate the document was reviewed, no conflicts were reported. But if a potential conflict is reported, that is if they answer yes to any of the questions, the conflict of interest form is forwarded to our ACOS of R&D, who is our signing official, and then the process moves forward from there.

Soundia Duche: Okay. And the process would be involving, okay, it moves on. So, now, let’s, we already talked about resources and budget, you specified for you all that’s something that you do before the study even comes in. But one of the requirements of the R&D Committee is to be able to assess the availability of required resources right? I think the policy says investigator time, appropriate location where the research will be conducted, and required resources. Can the study, again, be conducted here? And so, I know many of you all in the field, some may use departmental letters of support. Some may use impact statements. We actually have Dr. Paska Permana on the line, who is the human research protection program officer at the Phoenix VA, and their site uses impact statements. So Paska, while I pull this up, we’re not going to be delving into the particulars of the form, unless you would like to, but what I want to hear from you is how do you all use this? And how is this information conveyed to the R&D Committee?

Dr. Paska Permana: Good afternoon everybody. So, in Phoenix the service impact and pharmacy impact documents are necessary for the R&D Committee to assess the feasibility of the study, in terms of support from the impacted services. So entering adequate support early on should minimize or prevent delays or obstacles during the conduct of this study. The forms are typically completed by the study teams, before submitting the study package for committee review. The forms are filled out by the PI or study team, in consultation with the relevant services or departments. And or with the research pharmacists, in the pharmacy department here. The research office, or the research foundation administering the funds will consider the cost stated in this document, when negotiating the budget for the study.

Soundia Duche: Okay.

Dr. Paska Permana: And so the study package, including this impact document, is something to produce to the research office. The admin staff will conduct a pre-review, to check for signatures from the service chiefs. Indicating that they have agreed on the services to be given for the study.

Soundia Duche: Okay.

Dr. Paska Permana: Now, if the R&D Committee reviewer has questions on the budget for these services, they can always get input from the research office, or research foundation managing the funds, at any time or during the R&D Committee meeting.

Soundia Duche: Okay,

Dr. Paska Permana: Per lo\_, per local policy, locals of Phoenix, this document will need to be signed by the service chiefs before the study receives final approval by the R&D Committee.

Soundia Duche: Okay. And who\_

Dr. Paska Permana: But it\_

Soundia Duche: \_determines which services need to sign off, or which services are impacted? Is there a hierarchy? Or how do you determine that, you know, there’s three services versus five services that need to sign off on a particular study?

Dr. Paska Permana: Yeah. Sure. Well obviously the PI of the study will have to know which services will be impacted. But we, here in Phoenix we also have what we call study navigators, consisting of various admin staff that can actually shepherd the PI and study team to identify the services and the service chiefs, or perhaps POCs within the services that will do the assays. You know? That will be needed\_

Soundia Duche: [Unintelligible 22:58]

Dr. Paska Permana: \_for the study. And in Phoenix the typical impacted services are clinical pathology, for example, to assay blood samples. Radiology, for example, for MRI, surgery to collect tissue specimens, et cetera.

Soundia Duche: Excellent. Excellent. Thank you.

Dr. Paska Permana: Yeah, and I just want to point out something on the pharmacy impact form. We actually have\_

Soundia Duche: Sure. Let me bring that up.

Dr. Paska Permana: Yeah, we have a specific document for pharmacy impact, because a lot of, especially studies using drugs, will request support from the pharmacy. And so the pharmacist support can actually be standardized as listed in the item on the form. As items on the form. Now, also the benefit for using this, actually, for example, this item can itemize the labor cost for the pharmacy, there’s a pharmacist to close the study, right? Now, this information can actually be used by the service chief of pharmacy for labor mapping. So it also benefits these services that are impacted. For their labor mapping.

Soundia Duche: Nice. Very helpful. Now Christina, do you all use something similar at your facility?

Christina Bennett: We do. We have a very similar form and process to the service impact statement, and we just call it a letter of support. Our process is\_

Soundia Duche: Okay.

Christina Bennett: \_a little bit different for pharmacy. So we don’t have a pharmacy impact statement, but instead investigators are instructed to submit their protocols to the research pharmacist for review when their protocol involves drugs. And then our, if applicable, our pharmacy and therapeutic committee will actually assess the feasibility, logistic, cost, of the proposed research and eventually issue a letter of approval. Which the PI then submits to me as part of their study package.

Soundia Duche: Nice. Very helpful. The last item on this slide we’ve already covered, in terms of documentation of scientific review. You all have a very nice and thorough process. As you mentioned though, you know, what the policy requires is that there be a process. And so if the study is peer reviewed, it is acceptable to just accept documentation of peer reviewe as your, as evidence of your scientific review, or you can have your R&D Committee also perform the scientific review during their review. You can map it up however you want. I really like the way you all did it, however it’s very labor intensive. Do you ever have problems actually with your investigator being able to identify people to perform that review, Christina? The way you all do it.

Christina Bennett: We occasionally do, especially for new investigators, and we usually try to guide them to someone, for example, in their service, that might have the expertise to review the protocol, and occasionally our ACOS will fill in conducting one of the two reviews. But generally, it’s not too much of an issue. We’ve tried to develop a little bit better network for the teams.

Soundia Duche: Okay. Very nice. Alright, the next slide we’re not going to go over that much, because we’ve covered a number of these things. You already spoke to us about the PO and ISSO review, how you all do it. Let me just ask you, for your description of research activities, you, that’s the whole protocol, you get that in, does that go to the R&D Committee then? Along with all the accompanying documents from the subcommittees?

Christina Bennett: So for studies under the sole oversight of the R&D Committee, I put together a packet of study materials for review, that includes the full protocol and a number of other study documents. For studies under the oversight of a subcommittee, we used to provide an abstract in lieu of the full protocol, but recently we’ve been moving toward just making the full protocol available. In instances where R&D Committee members have questions it’s nice to just have the full protocol there for review.

Soundia Duche: Agreed. That makes a lot of sense. Alright, so now everything’s come in, you guys have done your pre-reviews, your administrative reviews. Your PO, ISSO have done theirs, it’s gone through the subcommittees, now it’s time for R&D Committee. Or for those maybe who do R&D Committee in a different way, it’s time for R&D Committee review. And our policy allows for two approaches. Okay? The traditional approach is convened board review. Whereby the committee convenes, you meet quorum, and all actions are done, including the review and approval of research, which is our focus today. Okay? You can use the primary reviewer system or not, we’re going to be talking about, you know, the whole process of convened board review next week. Now, in the newly revised 1200.01, released early this year, included in the options was designated review, which allows for review outside the committee, okay, by either the chair of the R&D Committee or a voting member designated by the chair for activities that fall into one of six specific categories or instances. Okay? We’re not going to go into that today, because again, next week we’re going to be talking in detail about the mechanics of convened board review and designated reviews. So if you plan to ask any questions about that, please hold that for next week. Because we have a wonderful team who’s going to be talking all about that next week.

But now, regardless of which route you take, right? Whether it’s convened board or designated review, the R&D Committee is required to make certain determinations. We’ve talked about a number of them already. And in terms of how the R&D Committee does that, be it the designated reviewer, or primary reviewer, prior to going to the convened board, the way you do that is up to your site. One approach is to use a reviewer form. And a reviewer form is nice because it kind of allows you very nicely to document what’s been decided. It also can serve as a reminder, right, if you’re going to use this to help assist with the convened board’s meeting, of all of the requirements that the R&D Committee is required to do. And so we’ve included here another tool, not required to be used, it’s just a sample, but we’re going to walk through the tool, not in depth, I’m going to give an overview of the tool, and we’re going to focus on how the key sections of the tool correlate with the requirements and the determinations that the R&D Committee is required to use.

So let me launch this form. We’ll just give that a second. And I will say, while this is loading, we provided this to you guys in Word so that you can tweak it, if you feel the need to. You might find that there’s some things in here that you hadn’t thought about before, and so you say, oh, this is useful, I might want to include that. Other things you may say, no, this doesn’t work for how we do things. That’s very small, is it not? Yeah, let’s not do that okay. All right, so the form. I see it’s, I don’t know how many pages, well, it’s divided into about five or six sections. The first section is really your administrative things. Things that probably your research office will complete. Information on the PI, the project, the type of review for the R&D Committee, is it going convened or designated review, what type of study it is. Here’s some information that might be useful, a chronological list of approval dates, maybe this is not chronological, I’m not sure, but a list of approval dates, or determination dates, if the protocol has gone through other subcommittees already for review. Section C, training and COIs. This might be done by your research office, you might make your reviewers do this, but this is for you to assess, you know, that all members have completed the required trainings, whether there are any conflict of interest, those types of things. So we’ve put those, those are in section one, more administrative things.

Then they go to the meat of the form, starting in section two. Now, what this form does is it breaks out into very different categories, based on again what I said, the key determinations that the R&D Committee is required to make. I am not going to be spending time going over the specific questions, you have the tool, it’s there for your use you know. But let’s go through each section. So section A has questions about merit and relevance. One of the key criteria which we’ve already talked about, the R&D Committee has to determine the relevance of the VA mission and the care of Veterans, and ensure that the protocol, the study is scientifically meritorious. And so I think there is a question here about if the study has been peer reviewed, have you, has documentation of the peer review been received? That’s an option, you know, if it’s not, hasn’t been peer reviewed and you’re conducting the scientific review, these are questions to help elicit that information. And, again, can help serve as documentation that the R&D Committee assessed that.

Section B, we talked about that, determining appropriate resources. Is the budget sufficient? Are our resources sufficient to perform the study? In a case like this, if you use Paska’s impact statement, you would receive the impact statement, the reviewer then, based on the information provided, would make their assessments reviewing it, and then indicate in the reviewer form, you know, whether the resources are sufficient or not. Okay?

Moving on to section, oh, can anyone, can everyone hear me please? Don’t know how we lost, we’ve gotten a thing that someone has lost audio, can’t hear me. Can people hear me? Carol, Christina? Yes, okay, perfect, thank you so much. All right. Section C, privacy and data security. This lends itself to the R&D Committee’s requirement to ensure that there’s adequate privacy and security of data. There’re some questions related to that. Particularly, has your ISSO done their review, has the PO? We recognize that the timing, right, of the ISSO PO review may be before or after the R&D Committee reviews it. Again, these are just questions to make sure that this information is captured. Okay? At the least, it will prompt you that that’s something you need to make sure you do. Oh, lordy. Sorry everybody, don’t know what just happened.

Okay. Section D, non-Veterans. One of the requirements of the R&D Committee, oh, man, so sorry, is the approval of non-Veterans. Okay? So there are a host of questions here about the approval of non-Veterans. Okay? We are not going to be talking about non-Veterans today, folks, we have a whole workshop that Karen’s going to be leading, we haven’t set the date yet for that, but it’ll be sometime probably in January, and it’s two sessions from now. So it’s, yeah, so hold your questions on non-Veterans for that. But again, a reviewer form that asks questions related to the justifications for non-Veterans. Have you considered reimbursement of research related injuries? Those types of things.

All right, next section on collaborative research. You guys know, paragraph 10 in 1200.01 is dedicated to collaborative research. And what things that a protocol has to have. Right? The VA R&D Committee must ensure it only approves VA activities in a collaborative study. There are a host of things related to collaborative research that we’ve outlined here. What the directive does not state is that all those things have to be, it’s the R&D Committee’s specific responsibility to assess that. That’s not what we’re saying. But, if the study is approved as VA research, it must have addressed all of these things. So your local processes may have the PO and ISSO doing certain components of it. You may have others doing other components. What we’ve included here is the requirement that for VA approved research these are the things that need to be included. And as the VA R&D committee is normally the final approving body, before the ACOS signs off, they would need to ensure that either these things have been done, or there’s a plan in place to do it. I say a plan in place because you may have agreements and such that are in the process of being worked out.

Section F. And I’m sorry, I’m going a little slow trying to not have that prompt keep coming up. Section F is on exempt research. Okay? Why is exempt research here? Remember, we talked about the fact that the VA R&D Committee approves both non-exempt and exempt research. And so, if exempt research will be approved it needs to meet certain requirements. Now, we understand that some of these things will be done by the IRB. Particularly if the exempt category requires limited IRB review. What this question is saying is if it does meet one of the categories, that requires limited IRB review, is there documentation that that has occurred? Okay? Similarly, in 1200.05 there are some requirements, newly added requirements for studies, exempt studies when the study involves the investigator interacting with the human subject. Certain things that have to be provided to the subject. Somebody needs to make sure that’s being done. And so if it’s the IRB doing it, because we are the ones who are doing the exempt determination, and you have them doing a little bit more, that’s fine, but come time to approve it, you have to make sure that that protocol, that that information has been accounted for. That somebody has accounted for the fact that there’s a requirement in paragraph 10C about the investigator making sure that the subject has received certain information.

Lastly, let’s see, section G, medical center director approval and certification. Now there are specific instances when medical center director approval, or CRADO waivers, or various certifications are needed. For example, if you’re conducing international research, you need approval from the medical center director. Okay? Some of you at your facilities, this may be something that you do outside of the committee. This is something that’s tracked outside. We’ve put this here again as a reminder, and then sort of prompt, that for VA approved research that these are the things that are required. So if your study is international research, medical center director approval is required. This may be something that you decide to leave in this form or take out, but it’s a nice prompt to remember that these are some of the things that still have to be assured of. Okay?

And then lastly, on section H, the question about ethical concerns. Are there any ethical concerns that have not been sufficiently addressed? And this is important, because it is not to say that one is redoing what a subcommittee is doing. But, do not forget that the R&D Committees has, it’s their prerogative that if they feel that some, they have concerns related to the protection of human subjects, or the welfare of animals used in research, or so on, that they can kick the study back to the subcommittee to address the issue, or disapprove the study if they feel that for whatever reason they don’t feel the study as designed is ethically sound. So again, this is a reminder that this is an R&D Committee prerogative as the final reviewing body for the institution. Again, think protecting the institution. All right?

The next sections now are more your reviewer recommendations. If you’re using a convened board review process and you have a primary reviewer completing a form like this, they would recommend what their decision is, and then it would go to the convened board for discussion. Okay? And the whole form would be possibly discussed at the convened board. If you’re using a designated review route, this also would allow for the designated reviewer to approve the study. Or indicate to the research office that we need some modifications, and then, you know, communicate back and forth with the investigator. Okay? And then finally, there’s an approval period here, should the study be under the sole oversight of the R&D Committee, then continue review would have to be required, and therefore you would indicate, this allows the reviewer to indicate their recommendation. Or if it’s designated review, the time period for which the approval has been granted. All right?

And now we are almost wrapping up here. Okay. As we mentioned, particularly with the medical center director approvals, there may be, and there are, some additional institutional and ORD requirements, even beyond what the R&D Committee does. And so somebody would need to track these to make sure that they are done. And in fact, I’m going to ask Christina, how do you all, are there any things that you have found that even after the R&D Committee approval is done that you still are tracking and making sure of? Before either you release the letter, or maybe you released the letter and you’re still tracking things?

Christina Bennett: So, we rarely need to obtain approval or certification from the medical center director or the CRADO, because we don’t really see research at our institution with children, pregnant women, prisoners. But we do occasionally have international research, which requires approval from the medical center director. So, in that case, we would reach out to the director after R&D Committee approval, but before we release that ACOS study initiation notification. We don’t hold approval for other agreements that are in process, like a CRADA, that’s negotiated by our NPC. And we generally keep in contact with the NPC throughout the study review and approval process. We have very few other agreements, like DUAs, and in that case the privacy officer would identify when that’s necessary during their review, and that’s typically done before R&D Committee approval.

Soundia Duche: Okay. Excellent. Thank you. All right. So everything’s done. The R&D Committee has approved it. Any other tracking that you need to do, that’s based on your local policies you say have to be done before the ACOS letter is sent, that’s been done. Now it’s time to communicate to the ACOS that the study is ready to be approved, you can send the notification out. How do you do that, Christina, at your institution?

Christina Bennett: So, here we use a combined ACOS and R&D Committee notification, for the study initiation, and that has kind of a summary, for the PI and study team, of all the actions taken on their study during the review and approval process, like subcommittee reviews and PO ISSO review. So once all those approvals are met, I draft that letter and send it to the ACOS for signature. And he also attends R&D Committee meetings, and you know, gets the agenda and the minutes. So that’s another way he’s notified of new studies that have been, you know, ready for approval.

Soundia Duche: Excellent. And when you send that letter to him, do you send any accompanying information? Or really that letter is sufficient?

Christina Bennett: It’s really just a letter, because that has the summary of all of the actions that have been taken, and reviews that have been done on the study.

Soundia Duche: Okay. Excellent. And we have, actually, we have the letter that Christina’s facility uses, as an example. I’m not going to go into it because you have that, and we’re at the time that we want to be able to reserve at least 15 minutes for questions. And so while the questions are coming in, I’m going to ask Christina, you know, any closing thoughts on the R&D Committee review process, things that have worked, things that you guys are working on changing at your institution, given the new directive, and given just kind of the change in approach of how we’re trying to emphasize and differentiate R&D Committee responsibilities from IRB responsibilities from the institution’s responsibilities?

Christina Bennett: Yes, so I think we’ve been working continually since we got the new directive, to make sure that our new forms are really guiding us to follow the policy and making it as easy and straightforward as possible to do the right thing, and that expectations are clear for our investigators, for our R&D Committee members, and for the research office. So, I would just say, in closing, I’ve been providing examples today of one approach, which works best for my institution, and even then, we’re continually improving on our procedures. So, I think the important takeaway here is that, you know, each institution implements a process that’s clear and well documented, and works to help their institution meet policy requirements.

Soundia Duche: Excellent. Thank you so much Christina. Wonderful.

Christina Bennett: You’re Welcome.

Soundia Duche: All right, I think, Carol, whenever you’re ready, we’re ready for the questions. Oh, and here’s Christina’s\_

Carol: and the first\_

Soundia Duche: \_contact information for folks.

Carol: So the first question is, would it be possible for people to contact the Northeast Ohio? They would like to set up a process similar to submitting a protocol.

Soundia Duche: That’s for you Christina, I have your contact information here.

Christina Bennett: Absolutely. So, my email is there, please reach out to me, I’d be happy to share our materials with you.

Soundia Duche: Excellent.

Carol: Okay, the next question is, people are asking for the handouts to be sent out again.

Soundia Duche: I will send them out. I apologize, because at about 10:09 I sent them out. It was a huge list. I sent it to 500 people, and BCC’d them. And so I will resend them, because I’m wondering, it seems there may have been a glitch in the system. So I will resend them. My apologies.

Carol: Okay, the next question is, how much time does it take to complete the whole process, from the beginning to the end of final approval?

Soundia Duche: [Truck honking] We apologize. Christina, I think that question might be directed at you. Do you have that data? From the time something comes into the reviewer’s office and goes through the process to final approval give an average, or?

Christina Bennett: Yeah, so typically we say from when a protocol is submitted to me, as a complete package, to when they get the final notice of study initiation, from the ACOS, is three to four months at our institution.

Soundia Duche: Okay.

Christina Bennett: And that’s for human studies.

Soundia Duche: Excellent.

Carol: Okay, the next question is, based on the purpose of the R&D Committee, it seems like a better workflow is to have investigators submit their research proposal to the R&D Committee, let the committee decide if this research should be carried out at the facility. Then it should go to the subcommittee. No need for R&D Committee to then approve the subcommittee approved project.

Dr. Karen Jeans: This is Karen. So, you know, this is a big debate. You’re going to have people on both sides of this. That some say that, you know, it gets back into the feasibility and alignment, and whether or not do we even want to look at it. And we being the R&D Committee hat. Or whether or not, hey, let’s let the subcommittees, if it’s human subjects, if it’s IACUC, let them look at it first and see whether or not it’s approvable or not. I mean it really does depend upon what the model is that your institution chooses to use. When we had the IRB and R&D training workshop, it was split down the middle. And so you’ll find some that do it concurrently, some where it is, where the IRB does it for human subjects or IACUC looks at it first, and others where they want a pre-review by the R&D Committee itself, or a designated reviewer if it’s eligible. For some there is actually a process where there is truly a, as part of feasibility, a group meets to say whether or not we even want it to come through. You know, we have concerns. And that gets back into what Soundia referenced on that reviewer checklist. That’s asked up front. So there’s lots of different models.

Carol: Okay, next question is, [clears throat] sorry [unintelligible 47:30] throat. How are the cost charges for the services determined?

Soundia Duche: Think that’s for you, Paska, your impact statement.

Dr. Paska Permana: Yes. The costs are determined by the PI and study team negotiating and consulting with each service that will be impacted. So it’s definitely a collaborative discussion. Before the proposal is even submitted.

Soundia Duche: Excellent.

Carol: Okay, the next question is, when the R&D Committee reviews a study with an attached budget, what happens if the funds included in the approved budget are not received as the PI stated? How do you follow up on the situation since the R&D Committee only provides initial review?

Dr. Karen Jeans: I am no help. [Unintelligible 48:20] \_

Soundia Duche: Yeah.

Dr. Karen Jeans: \_to hear how though, you know, sometimes this\_

Soundia Duche: [Unintelligible 48:21]

Dr. Karen Jeans: \_happens.

Soundia Duche: Yeah.

Dr. Karen Jeans: And this is Karen again, going about where we approved it based upon feasibility of having these resources, and then those resources don’t materialize. And so I would like to ask Christina and Paska how have they dealt with that, because that does happen.

Christina Bennett: So, I think that’s a question that my AO might be better able to answer. He deals with\_

Dr. Karen Jeans: Ah, okay, we’ll\_

Christina Bennett: \_budgets a little more than I do, so I’m not privy to that when that happens after R&D Committee approval.

Dr. Karen Jeans: Okay. And that’s, again, a great, I think that’s one of the, you mentioned that, again, about differentiation of roles.

Dr. Paska Permana: So I think for Phoenix I can just say that that’s the reason why we try to have all the negotiations on the budget, and CRADA be done preferably before the proposal package is submitted. But if there’s some things that will come up later, we try to resolve that actually before the R&D Committee even gives the final approval. If possible.

Christina Bennett: Very interesting question.

Carol: Yep. The next question is, is there any requirement for R&D only studies to have both the scientific reviewed R&D Committee member review, or can they both be done by one of the R&D Committee members?

Soundia Duche: Can you read that again? Carol?

Carol: Is, is there any requirement for R&D only studies to have both a scientific review and R&D Committee member review, or can these both be done by one of the R&D Committee members?

Soundia Duche: Okay.

Dr. Karen Jeans: If we’re talking about R&D only, alright, are we talking about studies with only R&D Committee oversight.

Soundia Duche: I think it would be the only oversight in there. Okay.

Dr. Karen Jeans: But, again, it gets back to, is this, like for example, is this an ORD funded study? Let’s say it’s an exempt study. You know, under the new rule. It’s going to have a scientific review. If it’s a study, I’m thinking of just pulling one out of the air right now, let’s say one that I know won’t have one, and that’s student research. Student research rarely has a true peer review. And let’s say it falls into one of the categories. And so, and it’s because it’s not a, uh\_

Soundia Duche: [Unintelligible 50:51] designated review [unintelligible 50:52]

Dr. Karen Jeans: \_no present designated review can be expedited. Which means that the other is oversight of an IRB. But let’s say that it’s one that’s under sole oversight because it’s exempt. Alright, so and there are other requirements, under paragraph 12, you know, we state that if it doesn’t have a peer review coming with it, that it can be done by someone else, that’s what Christina talked about, that then the reviewers that can do, are the reviewer itself. And so the designated reviewer for that exempt study, that student research project I just talked about, could do the scientific review right there. If that is what the question is meaning. If not, please follow up with me. But that’s what I’m hearing is the question.

Carol: Okay. For VA CSP studies, for which the CIRB is the primary IRB of record, when are local IRB Reviews required?

Soundia Duche: When are they required? Timing? Or are you saying are there some\_

Carol: Yes.

Soundia Duche: \_categories of CSP studies where they are not required? And maybe you can clarify that, because I know there are issues where we’ve gotten questions, if it’s just a coordinating center is an R&D Committee review required, verse if it’s a local site investigator or participating site. I’m wondering if that’s what the question is about.

Dr. Karen Jeans: But the bottom line is, is when a, and I think we do need some follow up on what this means, because they’re, the IRB, the central IRB of course is the IRB of record for, you know, these studies. For most of these CSP studies. But the activities of whoever is at these different VA facilities has to be covered under an approved R&D Committee protocol. And so that’s the answer. And so\_

Soundia Duche: They will always [unintelligible 52:20]

Dr. Karen Jeans: \_it always has to be covered. So, I think we’re losing an, I don’t think we quite understand the question here. But at the end of the day is that there’s always going to be a requirement for R&D Committee review, and approval of whatever is approved by the central IRB. Whether it be a CSP study or not. If we’re talking about the coordinating centers, sometimes on some of the sites they have umbrella protocols. And those cover a variety of different activities of the coordinating center. And those are, again, R&D Committee approvals, that they cover a number of different IRB studies. But I, not quite sure, so follow up with us if that’s now what you’re asking. And we’d be more than happy to answer it.

Carol: Okay. So there’s a couple people asking where they can find the recorded webinar and the handouts after the lecture?

Soundia Duche: Sure. So, about a week after all of our webinars we, unless there’s a problem with the recording, it will be posted on our education and training webpage. If you received an email from me, one of my many emails advertising, in my signature line should be the link either directly to the education and training webpage, or it’ll be a link to the ORPP&E website. From there you will be able to find education and training. You want to bookmark that page, because we will always have all of our recordings dating back to 2018, even some from late 2017 are on that website. So about a week later. And normally, if you registered through the GoToWebinar system, you will get an email alerting you that the recording has been posted. And the handouts are posted there as well. But I will resend the handouts. because I think something funky may have happened when I tried to send them earlier this morning to folks who registered.

Carol: Okay. The next question I think is directed at Christina. Do you use an electronic submission platform?

Christina Bennett: Currently we do not. We have a number of PDF fillable forms and Word documents, but we are working toward an electronic system.

Carol: Okay. The next question is, should we adopt these forms and best practice examples?

Soundia Duche: So again, what we did with these tools is we wanted to give you guys examples of how to use it. Some of these tools are adopted from other sites and so on and so forth. So these are not in any way being mandated, they’re not even being sent out as best practices, because that would require a little bit more vetting than what we had time for. But we wanted to be able to give you, based on what the policy requires, some examples of things. So my best suggestion for you all is use it to the extent that it benefits you. Tweak it to the extent that it benefits you. If it’s not helpful, that’s okay. Keep doing what you’ve been doing. But as part of this series, one of the key things with the workshop is implementation focused. And so we’ve asked sites to send us information on the forms they use, and then we like to present the things that might be helpful for others. And share that. It’s resource sharing, that’s also one of the goals of the workshop.

Carol: Okay. The next question is pretty similar, but it’s why doesn’t ORD provide the field with a checklist of what needs to be done and relevant forms?

Dr. Karen Jeans: We’re actually doing that, been working on that. because it’s not as simple as it appears. Form development is very complex. Because we have different types of situations. Including R&Ds that serve multiple facilities, those that serve only themselves. R&D Committees that only do X activities. Some don’t have animal programs, so we don’t have a formalized checklist, that’s why we have the policies. However, some of those sections, as Soundia talked about, are under discretionary enforcement right now. And so, yes, once we finally get whatever we’re going to have, completed through the discretionary enforcement period, and figure out what we’re going to do with, particularly the COI committee, which is, again, problematic, then yes, part of ORDs, ORPP&E’s, you know, role is to develop tools and checklists. We would love to be able to publish as much as we can. And that’s what we try to do.

Soundia Duche: And I, and let me add to what Karen said. Back in December of 2018, we published a number of sample tools which can be found on our website. And so, again, most of those were geared towards more for the IRB, because this was, you know, in preparation for the common rule, revised common rule implementation. I think through this series you will find that you’ll get a number of tools, and to the extent we get to use them more, you might find eventually that some of them do make their way onto our repository of sample tools that are on our webpage. So do look there, you know, for examples of tools. There are at least 50-plus, but again, not so much geared towards the R&D Committee, that’s what this series will do, give us some tools to share. What’s your time?

Dr. Karen Jeans: One more question.

Soundia Duche: One more question, okay.

Dr. Karen Jeans: Let’s have one\_

Soundia Duche: Yeah, one more question, thanks Carol.

Carol: How involved are your PO and ISSO in the pre-review? Since there are some current reviews how do you coordinate that?

Christina Bennett: So I think this question is for me. They’re involved. So we call our process a peer review team, and we actually have meetings every week, Thursday afternoons. And we send out an informal VA email agenda, and that’s how we track all of the study approvals, and where things are. You know, like I said, we have a number of rounds of revisions, and so the PO and ISSO are a part of that, an integral part of that process. And there are a lot of issues where there’s overlap between, you know, data security and privacy and issues that the IRB needs to clarify. And that’s why we’ve sort of established this team to work together instead of having the investigator get these standalone feedbacks that might even conflict, we work together and discuss the studies, you know, as a group.

Soundia Duche: Since we are at time, we will now be concluding the webinar. I did want to point out that for those who are looking for the handouts immediately, we, yes, we did include them in, there’s a handout section of this web portal. Carol, can you just remind people where they can find that? because they might be able to download them before we close out.

Carol: Sure, it’s in the handouts portion, on the GoToWebinar panel. It’s closer to the bottom of it.

Soundia Duche: Okay. So, and Carol, if you can, we’re going to close on out, but if you can maybe give people another two or three minutes who might want to download that, before you end the webinar, that would be helpful. Maybe two minutes. But again, I will try to resend that email. We want to thank everybody for participating. Thank you so much, Christina, and thank you Paska, we really appreciate it, and we hope that sites, you know, appreciate hearing from you and sharing your processes. You have her contact information, she said you can contact her. So, again, use that resources. We hope throughout the series, you’re going to be hearing from your fellow VA colleagues in next week’s webinar, which we’ll be advertising soon, as well as all subsequent webinars. And so this is a great opportunity to help forge connections, and help people share practices, best practices. And, or just practices that they do. Right? Not everything has to be a best practice to be helpful. So again, thank you so much everybody, we look forward to you joining us. Our next workshop in this series is going to be focused on the convened meeting versus designated review. I should be sending out that notice tomorrow or Friday, latest, and that will be scheduled for December 19th, which is next Thursday. Same time, I think we’re starting at 2 PM. But look out for that notice. Thank you everybody, have a wonderful evening.

[ END OF AUDIO ]