ORPP&E Webinar

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Session: R&D Committee Workshop Series: Convened Committee Review vs. Designated Review

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Soundia Duche: All right, well welcome everybody to our second workshop in the R&D Committee workshop series. My name is Soundia Duche and I lead ORPP&E’s education and training efforts. And I’m going to be moderating today’s session. I’m pleased to be joined by Ms. Laurie Grevious, who is with the Rocky Mountain VA, and Dr. Paska Permana who is with the Phoenix VA Health Care Center. We’re going to be focusing today on R&D Committee convened board review vs. designated review. So really now we’re getting into the operationalization of the review process. Last week we spent a lot of time talking about the review criteria, the things the R&D Committee needs to review and determine when they’re approving VA research. We talked about how to document that. We provided you all with some sample tools to enable you to do that. Now we’re going to be talking about, really, how the R&D Committee works, how the designated review process works. Paska and Laurie are going to be sharing with you all, similar to last week, about the strategies and techniques they use at their facilities. And then also, as before, we’ll be providing you all with some tools. Now, those tools can be found in the handouts section. I also sent out a number of the tools, or all of the tools in an email earlier this morning. All right? So with that, let’s get started. I’m going to ask our panelists, we’ll start with you Laurie, if you can introduce yourself and maybe tell everyone a little bit about your facility and your research program.

Laurie Grevious: Sure, thanks Soundia. We have a large research program here at the Rocky Mountain Regional VAMC. We have around 440 protocols, and that consists of human, bench, animal, not human, and exempt research. And we also have three very large groups within our program. We have the COIN, that’s through Denver, Seattle, that’s funded by HSR&D, we have a GRECC that serves for the geriatrics research, we have a MIRECC that oversees the mental health population. And that’s about it.

Soundia Duche: Okay, awesome. And Paska, if you could introduce yourself.

Dr. Paska Permana: Yes, hi everybody. Yeah, I am the human research protection program officer at Phoenix VA, and I’m also an investigator. My admin tasks include updating the research program SOP and forms, educating the research community on current regulations and processes. I also work together with committee, research committee coordinators and research leadership in streamlining processes and recurring reports to RO for human subject studies. In Phoenix VA, in addition to the research and development committee, we have an internal IRB and SRS. We also use an affiliate IACUC and IBC. We also use the VA Central IRB and the NIH All of Us IRB. Currently we have 117 active studies, consisting mostly of human subjects research. Specifically there are 31 human data only studies, 28 human subject studies involving [unintelligible 03:17] with subjects, 44 human subject studies involving lab also, and 19 lab only studies.

Soundia Duche: Awesome, thank you Paska. Excellent. Glad to have both of you. Thank you. So these are the objectives, which I’ve already discussed. So, let’s move on and start with the R&D Committee membership requirements.

Now, VA policy specifies very clearly in Directive 1200.01 the minimum requirements for the R&D committee. Which you can see those requirements on the slide, so I’m not going to spend time reading over them. I want to hear from our panelists. We want to get a sense of how your R&D Committee is composed. Let’s start with you, Paska. If you can share with us a little bit about how large your committee is. What types of departments are represented. Whether you use alternates. Give us a little flavor on how you all have composed your committee.

Dr. Paska Permana: Sure. We have nine voting members for our R&D Committee, consisting of four in medicine, two in mental health, one surgery, one radiology, and one pharmacy. We also have five alternate members, so the quorum is five for our meetings. And just a comment that we actually have our IRB chair and SRS chair also as members of the R&D Committee.

Soundia Duche: Are they voting members, Paska?

Dr. Paska Permana: They are actually voting members, yes.

Soundia Duche: Thank you. And now Laurie, what about you?

Laurie Grevious: Yes, at our site we have 11 voting members, and we have two alternates. Our voting members consist of, we have four or five clinicians, and we have our director of the COIN that serves as an alternate, and we have a PI from the COIN that serves as a voting member. We have the chief of medicine, we have the psych, MIRECC director, and we have the assistant director from our GRECC. Also we have our IACUC chair that serves as a voting member. And we have 16 ex officio members.

Soundia Duche: Sixteen, nice, good.

Laurie Grevious: Yes.

Soundia Duche: Quite a large committee. Now Paska, you mentioned you have five alternates, so I’m sure that you don’t really have a problem with quorum requirements. Laurie, have you guys ever had a problem?

Laurie Grevious: Yes, there was one time that it happened this year. Our chair and our vice chair were unable to attend, so we used a new temporary chair that’s under the new directive, and he was, we were able to use, one of our members was, he was a past R&DC chair, and he was happy to serve in that place. And at the meeting, everybody appointed him as the chair with no objections.

Soundia Duche: Wonderful. Nice to see how the alternates process is used effectively. So now, VHA Directive 1200.01, that was revised this year, opened up a new pathway, right? For the review and approval of research by the R&D Committee. Historically, we always had to convene meetings. We had to have all members, not all members present, but we had to convene a meeting where we had at least a quorum present in order for the R&D Committee to conduct and approve research. As of January, the designated review process allows the R&D Committee to review and approve research outside the committee. So outside of a convened committee meeting, let me specify, outside of a convened committee meeting, if the activity meets one of the six activities that are designated in 1200.01, paragraph 9e all right. If that is the case, then the review can be conducted either by the chair of the R&D committee, or a voting member designated by the chair.

So now what we’re going to do, we’re going to spend time talking about both pathways, but let’s go ahead and start with designated review. That’s new. That’s the more exciting one, something I think a lot of people were very happy to see in the revision of the directive. And some of you may not have implemented it quite yet, or maybe struggling with how to implement it.

So, we’re going to engage our two panelists here, and ask them questions, and help illuminate how they have implemented designated review. And they’re going to share towards the end of this section any successes and challenges that they may still be having in implementing the designated review process. All right? So as I mentioned, remember it can be done outside of the committee. I think I’ve already talked about who can do it. One thing to note, final approval must be reported to the R&D Committee at the next meeting of the convened R&D Committee, and be included in the minutes. All right? So let me ask you, Laurie, have you all instituted the designated review process? And if so, who performs your designated review?

Laurie Grevious: Yes, earlier this year it was discussed at our RDC meeting that we, they decided that everybody should serve as a designated reviewer. All of the voting members due to the varied areas of expertise and areas researched. So, we’ve had much success using that. It’s far more efficient than going with the convened meeting. We had this noted in our\_

Soundia Duche: And then, so how do you go\_

Laurie Grevious: \_oh, I’m\_

Soundia Duche: Yes.

Laurie Grevious: Yes, we have this all documented\_

Soundia Duche: Sorry, go ahead.

Laurie Grevious: \_in our SOPs, that includes all voting members, including our alternates.

Soundia Duche: Okay, excellent. Including your alternates, very nice. Paska, what about you all?

Dr. Paska Permana: In Phoenix the R&D coordinator emails the R&D committee chair, who will then assign the designated reviewer for a particular study that is eligible for that pathway. And that is also documented in our SOP that, you know, the members of the R&D Committee can be designated reviewers.

Soundia Duche: Okay, all members, Paska, all voting members?

Dr. Paska Permana: Yes.

Soundia Duche: And your alternates as well?

Dr. Paska Permana: Yes.

Soundia Duche: Now, one of the things to note, that designated review can be used to approve research. The designated reviewer can require modifications. They can go back and forth with the study team, to make modifications. The designated reviewer cannot disapprove research though. Okay? They do not have the ability to disapprove research; they can refer a study back to the convened board for a convened board review. Now, curious, have you all had a situation where the designated reviewer has referred a protocol back to the convened board? And if so, if you recall why they did that, that might be helpful.

Dr. Paska Permana: In Phoenix, one time we actually had that happen, in which a designated reviewer basically asked a question on the review that, you know, the person had conducted, at the convened R&D meeting. And it generated a big discussion, and it actually resulted in the R&D Committee making a decision as a whole convened meeting committee.

Soundia Duche: And I have a question, did the, when the designated reviewer brought that issue up on the reviewer form, did they bring it to the research administrative staff who then took it to the chair of the R&D Committee? I’m just curious to know how that got back to, and resulted in the convened board, or did he say, I have this issue, I want it to be reviewed by the convened board?

Dr. Paska Permana: So in that particular case, yeah, that particular case, actually, it wasn’t necessarily going through the R&D Committee coordinator, per se. The designated reviewer just kind of brought it up in the meeting. As a, just a question that, you know, the person thought would be very easily addressed. But as\_

Soundia Duche: [Unintelligible 11:46]

Dr. Paska Permana: \_I said, it turned out to be a big discussion. And then that’s when the\_

Soundia Duche: Oh, that’s fun.

Dr. Paska Permana: \_the R&D Committee decided to make a decision as a convened meeting.

Soundia Duche: Yeah, no, very interesting, we like to hear that. What about you all, Laurie?

Laurie Grevious: Nope, we have not had that, had this at our facility, yet.

Soundia Duche: As I mentioned, you know, final approvals by the designated reviewer do need to be reported back to the convened committee, and included in the minutes. And later on, when we get to the convened board section, we’ll actually show you some examples of how that’s done.

So now if you recall, I mentioned, I directed everyone to 1200.01, paragraph 9e, where it has six specific activities that can be reviewed by designated review. So what we’re going to do here, what I did was I kind of broke it up into two categories of three activities each, right? The first kind of represent instances where the protocol has gone to the convened R&D Committee, the convened board typically has reviewed it, and I say typically because that last one could be, could fall into the other bucket as well. But, let’s just assume that the R&D Committee has reviewed that by convened board, and then they require some additional changes that they say can go through the designated review process, because it meets one of these three. It could be it has minor changes to a protocol, just minor changes that the R&D Committee stipulates they can be reviewed outside of the convened board by designated reviewer. It could be contingent on a subcommittee’s approval. So let’s just say the subcommittee has reviewed a study, they have issued their approval, but it’s contingent on X, some type of modification. Minor mods usually. And then the convened board has reviewed that protocol, but the subcommittee has not issued its final approval. The convened board can say, we will approve this study contingent on the subcommittee issuing its final approval. Okay? The third option is if the committee has reviewed the study and we’re still waiting for ISSO or PO review. And so that can be reviewed by the designated reviewer to confirm that the ISSO and PO have conducted their final review. Now, Paska, let me ask you, for these three, have you all used the designated review process at your facility for any of these three activities? And if so, any issues or special instances that come to mind when using this process?

Dr. Paska Permana: Yeah. Yeah, we actually have used designated reviewer for the second and third bullet points. And we have not had any issues.

Soundia Duche: Okay. Laurie?

Dr. Paska Permana: There’s no instance for the first one yet, so.

Soundia Duche: Nothing for the first one, no minor changes yet, okay.

Dr. Paska Permana: Correct.

Soundia Duche: Laurie, what about at the Rocky Mountain VA?

Laurie Grevious: Yes, also here the second and third bullet. For the second bullet there was, it was contingent on SRS, which they usually meet after R&DC, so it was very convenient to have this designated review option. The study did not have to wait for another full month, due to the new reviewer process. And also, we’ve also had to use the pending, or contingent upon the PO and ISSO.

Soundia Duche: Okay. Excellent. Great. So now this next slide represents the other three activities. And these tend to be more protocol specific. Okay? So, 1200.01 paragraph 9e also allows you to use the designated review process when you’re reviewing activities that fall into one of these three buckets. First one being if it’s an exempt human subjects research study or it’s a protocol that was approved by expedited review by the IRB. Second one is for single patient expanded access protocols that were approved by the IRB chair or another appropriate IRB voting member. And then the third one is a little bit of a catch all for all protocols that do not involve human subjects, BSL level three or higher containment, and some other things. Very minimal risk type studies. If they’re using animals, I think there’s a specification here, USDA regulated animal species or any animal research involving no more than momentary pain or distress to animals. Okay? Now, we’ll start with Laurie here. Have you all used the designated review process for any of these three activities?

Laurie Grevious: Yes, for the first bullet. We’ve used it for exempt human research and expedited. Especially under the new common rule, there’s been quite a few more exempt research that comes through every month. I’m getting more and more with all the expanded new categories. And also, we’ve used the single patient expanded access protocol. We had one, a drug that was approved by the IRB chair, and I was able to move forward with the designated review process, and then get the, get it out to the PI before, without using the convened meeting. Also, for the third bullet, definitely for not human subjects, we have a lot of those at our site too. And bench, we use a designated review monthly.

Soundia Duche: Okay. And then one point to note that you see on the slide, if a protocol is eligible for the designated review process, just want to note that any subsequent actions that require R&D Committee review, right? So for example, an amendment or continuing review. This would most likely be the case when a study is under the sole oversight of the R&D Committee. Doesn’t always have to be the case, but most likely. Those actions can also be reviewed by designated review. But just something to keep that in mind. Have you all used that designated review process for any subsequent actions?

Laurie Grevious: This is Laurie, yes.

Soundia Duche: Oh. Go ahead.

Laurie Grevious: This is Laurie, yes, we did. We had an exempt study that used the, that had an additional survey, and also we’ve used it for personnel changes.

Soundia Duche: Excellent. All right, so documenting designated review. Now we talked a little bit about this last week, where we went through an initial reviewer template, in detail, and we showed you how that can be used for documenting the review by either the convened committee or the designated reviewer. So I don’t want to go into that. I do want to mention, I’m not going to open it here, but there is also a checklist that we gave you in the tools that can be used for that first group of activities that can be reviewed by designated review, which are things to confirm, you know, the conditions, right? ISSO, PO reviews have now been received for any minor modifications. So you have that tool in your handout that we sent. Once the designated reviewer has done their review, has confirmed everything, now we get to the whole approval thing. Right? The designated reviewer has signed off saying is good. I’m going to give you guys a little twist, and we’ll start with maybe you, Laurie.

Laurie Grevious: [Unintelligible 19:28]

Soundia Duche: What is the final R&D committee approval date for studies that underwent review by designated review, I’m going to say in its entirety. So that second group of projects where the study came in, the designated reviewer was assigned to the study, they reviewed the study from beginning to the end, it did not go to the convened board. What would you consider\_

Laurie Grevious: Yes.

Soundia Duche: \_the approval date?

Laurie Duche: Yes, once they sign off on that review they also date it, and that date is the approval date.

Soundia Duche: Okay. Good. And now, Paska, I’m going to pass this one to you. What about the case, the other example, whereby the study goes to the convened committee first, it meets one of the three criteria or activities where it can go to designated review following convened committee review, what is the approval date in that case?

Dr. Paska Permana: It would be the date of the designated review final approval.

Soundia Duche: Nice. Good. And really, I just wanted to say to illustrate and remind people that designated review is approval by the R&D committee. The designated reviewer is acting on behalf of the R&D Committee. They’re not doing it in a convened committee study, but it’s still a member of the R&D committee, a voting member that’s doing the designated review. So the date that they sign off that everything’s final, that is the final approval date for the study. Okay?

We’re going to, I was going to ask about this now, but because we had some technical issues at the beginning we can hold your comments for the end, Paska and Laurie. In our summary about kind of, you know, anything you guys have experienced and want to share about implementing designated review.

So let’s just move onto the Convened R&D Committee review. And really here, this is something most of you guys are familiar with, you’ve been doing this for years, you’re pros at it, we get it. So what we wanted to do, this is probably more for the people who are new, newer, and maybe in the process of revising or optimizing their polices and procedures, we wanted to just share some examples, okay? So, I’m going to, this is the pre-meeting checklist, that is used at the Rocky Mountain VA, so I’m going to pull it up, Laurie, and ask you if you can share a little bit about how you all prepare for your convened meetings.

Laurie Grevious: Yes. Mainly once we get quorum it’s ready to go and get ready for the next, our upcoming meeting. Get your VANTS line scheduled and get those minutes out to the R&DC for their final review and comments. And then the focus becomes our protocol actions. All of the reviews that have happened since the previous meeting, and until the upcoming meeting, I keep those in a folder, and get them PDF’d, and combine them for the meeting, and include them in the agenda. And they’re also included as an attachment within our, my final minutes. Also, I’m collecting from our, I work very closely with our IACUC or SRS and the IRB to collect all of our protocol actions, everything from initial reviews and amendments and closures, and also in our agenda we note any expirations. And I’m also checking if they’re, if they’ve been approved to continue, if they remain lapsed, or if they’ve been closed by the IRB. And if so, I need to check with our SRS, make sure it’s closed with them also. And then this table that you see, this is one of the tools that I use as my studies come in from the IRB. I’m always checking and making sure what is, what’s remaining, what’s not completed, and what is completed with each study, as far as, we call them the O’s, the ISO and the PO. Has it met scientific merit, relevance to the VA, SRS, and also more so after R&DC is making sure that if it’s [unintelligible 23:37] involved I have to move on with that. And if it’s also sent to an R&DC reviewer, this is also noted, and then we use an Access database to collect our, all of our, mainly all of our approval dates, and then as everybody knows, to ePROMISE. Also, we also have, we have an R&DC shared drive, where we put all of our, most of our meeting minutes, and any supporting documentation for the upcoming meeting. Also, collecting minutes from our subcommittees and committees. And also another option within the directive is if you're not using the final minutes, you can also use a findings and recommendations from your subcommittees. Which we also use that at our site. And then, and if you have any other items that are kind of like miscellaneous, I always work real closely with our RCO, if there’s anything that needs to be addressed, and inform the R&DC and our HRP coordinator, she’s always overseeing if there’s any non-Vets, international research, or any specialized populations. And also our tissue banking goes through our R&DC for final approval. And also as a reviewer of the program they should be reviewing any of your MOUs, FWAs, or if you’re finalizing your SOP for your R&DC, as we have been this year. And it will be in the months to come. Keeping them abreast of all changes coming up.

Soundia Duche: Thank you, Laurie. Okay, and I’m, I will just let people know, know we’re at the time, but because of the technical issues we will go longer, and we will allot at least 15 minutes for questions.

Laurie Grevious: Okay.

Soundia Duche: All right, so now, we prepare for our meeting, Laurie, we’ve used your checklist, we have everything in, now we’re conducting the meeting. Paska, you’ve provided this wonderful agenda template, and we’re going to use this, we’re not going to go through all the items of this template, but we’re going to use this, Paska’s going to highlight, kind of walk us through a typical meeting by highlighting a few of the key items in the agenda.

Dr. Paska Permana: Sure.

Soundia Duche: I’ve got it up for you, Paska.

Dr. Paska Permana: Okay, thank you. So, when the meeting starts the R&D coordinator will take attendance and note if there are enough, that there’s enough quorum, sorry. And then the first call to order was done, it is usually done by the R&D Committee chair. Then the committee will go through the R&D minutes, to approve the minutes from the previous meeting. And then the committee will also review subcommittee minutes from IRB, SRS, or other committees as applicable, including the CIRB. And the committee will also look for items pertaining to the Phoenix facility. If there are any. And then, the next section is actually updates on, from the subcommittees in terms of highlighting items during the subcommittee meetings or discussions that may not necessarily be pertinent or not highlighted in the minutes, per se, but topics that may generate more discussions in the R&D meeting. The next section will consist of RCO audits, things that the R&D Committee will need to know. And then the R&D Committee will begin reviewing new protocols, as well as then noting protocols that have gone through designated review approvals. Both for initial review as well as for continuing review. And the committee will also review protocols that are ongoing, continuing reviews, as well as protocols that are being closed. Then the committee will address old or unfinished business, and then also discuss new items, if there are any. And then one of the last things that the committee will do is also get updates from research leadership in terms of any programmatic topics. Just to make sure that, you know, the R&D Committee is informed. And that includes updates on financial status, both for general status as well as for individual studies that are potentially at risk. And if there’s an educational item that will also be presented at the meeting, and then that is the whole meeting pretty much.

Soundia Duche: Thank you, Paska. And we have this tool if you have any questions about any of these tools, you can direct them to Paska or Laurie. Okay? All right, so we’ve done our meetings. The R&D committee has done their various approval of items. Now there’s a lot probably that has to happen after the meetings. And so, Laurie, you have this post-meeting checklist here, that you’ve provided. And so if you can just kind of walk us through, not the details, because everyone has the tool, but some of the things, maybe highlight or just how this could be used to help your facility and other facilities.

Laurie Grevious: Yes.

Soundia Duche: And first let’s give a shoutout to the [unintelligible 29:15].

Laurie Grevious: First of all, I w\_

Soundia Duche: Where did we get the tool from, Laurie?

Laurie Grevious: Yeah, thank you Little Rock. We thought this was a great checklist. It really encompasses everything that gets done after the meeting. Getting your letters to the ACOS, and then out to the PIs, and if there are contingencies, getting them, getting those out to those people that need to get those corrected. Also, if there’s any approval, if the minutes were approved, or if there is any corrections, take action on that. If your SOPs were already updated and approved, it’s always good to note that. Reportable determinations, we usually follow up with our RCO on those. And meeting minutes for the next step, , getting ready for the next meeting; get those out to the R&DC. And following up on any outstanding actions that need to be taken care of. This is a great checklist; we really appreciate this.

Soundia Duche: Thank you Laurie, and thank you Little Rock.

Laurie Grevious: Yes.

Soundia Duche: All right, I’ve\_

Laurie Grevious: Thanks.

Soundia Duche: \_I’ve included here the sample, a sample combined R&D Committee approval letter, we talked a little bit about this in last week’s training, I’m not going to highlight it, it’s in your handout. If it’s not in the handout tab here, it was sent out amongst the items that were sent this morning. We have a limit in terms of the number of handouts we can upload to the system.

But, all right, so I just want to talk very briefly about meeting minutes. Because there is a requirement that the meeting minutes for the R&D committee be documented. And include certain key things. And you have the list here of the minimum items that it has to include. And then I’m just going to ask Paska now, because what’s so wonderful about that agenda tool that Paska shared is that she uses that same tool for her meeting minutes. So Paska, just briefly if you can share with us a little bit about, you know, who does your meeting minutes, and how they use that tool; if there’s anything unique you want to point out. Do you record your meetings? Anything about how you now bring it all together and document it in the minutes, for meeting minutes, to meet those requirement in 1200.01.

Dr. Paska Permana: Sure. The person that actually generates the meeting agenda is the R&D coordinator. In Phoenix it’s Garrett Hatcher [phonetic 31:47]. And he also uses a recorder, like a real audio recorder during the meeting, as well as writing notes on the agenda. So just so that everybody understands, we display the agenda onto the screen during the meeting so people can, you know, have that in front of them. So, during the meeting, he will actually fill out information on the agenda with his notes. With information from the meeting noting the forum, who is recused, absent, and so on, so forth. Noting the votes, and then once the meeting is over, he can just finalize, you know, the notes on the agenda, basically that is now meeting minutes. And that is how the agenda becomes the minutes. That’s using the same template.

Soundia Duche: Excellent. Thank you, Paska. And so then you sign your meeting minutes, Paska?

Dr. Paska Permana: Actually, no. So if the R&D committee looks at finalized minutes from, let’s say the previous meeting, the R&D then votes to approve those final minutes, and that approval is documented in the minutes of that meeting.

Soundia Duche: Okay.

Dr. Paska Permana: And that way the minutes doesn’t have to be signed. And the\_

Soundia Duche: Okay.

Dr. Paska Permana: \_the R&D coordinator will then email the finalized minutes to our facility leadership. That includes the\_

Soundia Duche: Great.

Dr. Paska Permana: \_sorry, the director and, you know, other leadership.

Soundia Duche: Excellent. And that’s great, I’m glad you touched on that you email it to them. However you all do it, there is a requirement that the meeting minutes are distributed to the facilities’ leadership council. So if you know it works well for you, that’s great. If you all, you know, print it, and courier it, or walk it over, whatever your local processes, you know, is fine as long as they get the minutes. And just want to mention that typically that leadership council is composed of the medical center director, the associate medical center director, the chief of staff, and the nurse executive. That doesn’t mean that there might not be others that you’ve included in your SOPs that need to get the minutes as well.

And so now, I just want to kind of close out here by asking our panelists, what are your thoughts on the whole process? Designated review is new, I think pretty exciting, but just, you know, we’re undergoing a lot of change in the VA in terms of how we review and approve research, trying to optimize things. And so anything you want to share with the group in terms of how the convened meeting and the designated review process has helped shape things at your institution.

Laurie Grevious: Yeah, this is Laurie. I would say it’s shaped us. I like the efficiency of it. Having more control, not having to wait for a, to do a teleconference, having everybody wait for everybody to call in. Sometimes having, waiting for everybody to call in took longer than the meeting. So, having this, I was so excited to use this designated review, and it’s worked very well at our site.

Soundia Duche: Excellent. Paska?

Dr. Paska Permana: This is Paska, I would agree, yeah, I would agree definitely with Laurie that, you know, this designated reviewer method minimizes the time for studies to get a final approval from the R&D Committee. So, that’s really wonderful.

Soundia Duche: Thank you. And Laurie and Paska can be reached at their respective emails, that are found here. And thank you, both of you, for participating in this. We’re sharing your tools and sharing your knowledge and processes with the VA field. That’s one of the strengths we hope of this whole workshop series, that we’re bringing you your colleagues, and you’re hearing from them on how they do things, and hopefully you can learn from them, and they might help you make your projects [unintelligible 35:56]. And so with that, let’s get to questions.

Carol: Okay. The first question is, do local SOPs need to be revised before the designated review can occur? Or is it a discussion of agreement, document it in the minutes, no?

Dr. Karen Jeans: Okay, so in terms of, I think the question is whether or not you have to have an SOP. And the answer is yes. If you’re using a designated review process, R&DC policy, this is Karen by the way. Hi everybody. And it looks like Laurie and Paska, awesome, y’all are wonderful. Okay, back to business, I remember I’m being taped. Okay, so yes, the R&DC policies, 1200.01, paragraph, I think it’s 6e, requires that the R&D Committee must have written processes for any recurring processes. So yeah, you have to have written procedures for that in order to use it. You just can’t make it up as you go along. And again, it’s a recurring process if you decide to use it. Thank you.

Carol: Next question is, can small facilities submit a waiver for the 5 R&DC membership?

Dr. Karen Jeans: No. this is Karen again. Here’s what’s interesting about policy. And we get, I would say on an average a month, at least 30 requests about asking can we waive some type of policy within some type of ORD directive or handbook. And what you have to remember is that our policies are signed off by the undersecretary. Right now it’s signed off by Dr. Clancy. That means this is it. And unless there is a waiver process that is specifically set in, that the CRADO can waive, like, and like in the Office of Research Oversight, you know, there’s a waiver process in place for, you know, when there’s a part-time RCO or full-time. So, unless we specifically say a waiver is allowed by policy, the only way that a waiver could ever take place is for the person who signed the policy to overturn it. Which means that it would have to be reviewed by ORD, ORO, OGC, and then in this case Dr. Clancy would have to make a determination. So the answer is, no, there’s really not a process to waive that requirement. However, we are looking at changing policy to be able to change that requirement, in terms of the number, in the next VHA directive 1200.01. Thank you.

Carol: Okay, the next question is, if a PI submits an amendment to an R&DC only study that has been fully approved, can that amendment be approved by designated review?

Soundia Duche: Well, a R&DC only study would be a study normally that’s not under the oversight of any other subcommittee. Based on our list, that would typically be an exempt study or a study that would fall, possibly a nonhuman subjects research, if the study falls in one of the categories on this list, then that should not be a problem.

Dr. Karen Jeans: Yeah, exactly. It goes back into the issue of when we’re talking about R&DC only, okay, so it’s either going to be eligible for a designed review initially, or it’s going to be not eligible and it’s going to require a convened R&D Committee review. Then, if it’s a minor change, then it goes by designated review, okay, it had to be reviewed by a convened R&D, otherwise it was initially approved by the designated review process. So, yes.

Soundia Duche: Now, let me switch back, Karen.

Dr. Karen Jeans: Yeah.

Soundia Duche: What if you have a study that is exempt, but the R&D Committee chose, it’s eligible from designated review at the beginning, R&DC chose to review it at the convened board. An amendment comes in, can the amendment be reviewed by designated review?

Dr. Karen Jeans: Yep, again goes back to recurring processes. Policies and procedures for how you’re conducting your designated review and when you allow it and don’t allow it. Excellent. That’s good. Yeah.

Carol: Okay. The next question is regarding personnel changes, is that an item that should be reviewed by the R&DC? I thought the new R&DC directives listed items not requiring R&DC to review, full or expedited?

Soundia Duche: We don’t specifically talk about personnel changes. Because if we’re talking about changes in study team members, it’s interesting, you know. The common rule, nor FDA, if it’s an FDA-regulated study don’t mention this, and this is a situation that we were just talking about recently with our other federal colleagues, you know. But when it comes to when, when you’re changing investigators does that have to be approved? The answer is, yes. And so, when it comes to these other individuals, if that’s what this question is asking, then no, specifically it would not require approval, because it would not represent a change in the protocol. Unless that individual is specifically named in the protocol. Then you have a different situation. Because you’re actually changing the protocol when you're changing the study personnel or individuals that are listed. Thank you.

Carol: The next question is regarding the logistics of protocols approved by designated review. It seems like both presenters set the date of final approval based on the date of final designated review. So how is annual checks kept track of? Anniversary dates will be occurring throughout a month.

Soundia Duche: Yeah, so and we were given a question, I think in our workshop, that in the future can policy be set to make the approval date mimic the IRB approval date for the R&D Committee approval date. Right now the R&D Committee’s final approval date is the final date everything was approved, and continue review must occur within 365 days of that date. So if the designated reviewer approves that study on X date, continue review has to occur by 365 days, you know\_

Dr. Karen Jeans: [Unintelligible 42:09]

Soundia Duche: \_after, right? Date. Exactly.

Dr. Karen Jeans: Of that date. Uh-huh, [unintelligible 42:12]

Soundia Duche: For the designated review, could they, could the review happen before? Yes.

Dr. Karen Jeans: Yes.

Soundia Duche: It could. And then that would be the new date.

Carol: Okay. The next question is, our facility requires table format to be used, and I realize the templates are voluntary use, but can we claim exemption from the facility format? The minutes would be considerably shorter in length.

Soundia Duche: That’s not within our ability to, we don’t have a, we don’t address that in policy, it’s not a policy issue from our perspective. And so if this, this is required by the facility, then we’re going to ask, you know, is there a process that you can speak to your facility about? But it’s not an ORD policy issue, I wish we had, we could give a better answer on that, but it’s not a policy issue for us. Thank you.

Carol: This person noticed that subcommittee minutes are only reviewed and not approved in the agenda template. Do they no longer need to be approved? Or were they never supposed to be approved by the R&DC?

Dr. Karen Jeans: But we did deliberately, this is Karen again, put in 1200.01, and actually we, it was part of a carry over from 1200.05 as well, but that the R&D committee, it has to review it. But we specifically chose not to use the word approve. Because what does that mean actually? That you reviewed it. Was there any actions that need to be taken? Yes or no? But yes, it is a review, there is no requirement in policy to approve the minutes, because from policy perspective what does it mean when the R&D Committee approves the subcommittee’s minutes? It has no meaning. Thank you.

Carol: The next person is requesting the ACOS approval letter. They are saying it’s not found in the handouts for today.

Soundia Duche: Yeah, so the ACOS approval letter is not in the handouts on the system. We’re limited to five handouts. The ACOS sample letter was sent out for anybody who was registered for the training. They got it by email this morning, but yes, it was part of the packet for last week’s webinar, so that information can be found by going to our website, where the recording of that webinar is found, and the tool is there. If for any reason that tool is in PDF, I have not checked, email me and I will send you those tools. Okay? And the website is the last page of our, our presentation has the website information, last page of the PowerPoint.

Carol: Okay. The next question is, there is an argument about our meeting minutes having to include everything. Our minutes are 40 to 50 pages long now, including references. Every document reviewed, et cetera. Is this necessary?

Dr. Karen Jeans: Okay, so I am going to ask my fellow panelist, as well as our colleagues who spoke today. Is it necessary, it sounds, in many ways it sounds like transcription is occurring.

Soundia Duche: Yes.

Dr. Karen Jeans: Minutes are not transcriptions. We are very clear in 1200.01 what is required to be in the minutes. Now a lot of times, and this is, no matter what kind of committee is happening, you’ll see different levels of variability regarding, you know, what is the level of detail. But when it’s 40 to 50 pages, I don’t know how many transactions are occurring, but we do not require, you know, I would ask to reassess what is required in our minutes, and paragraph 6d, look at that, you know, it’s a short list. Again, it doesn’t have to be a transcription, it does have to state what is in the policies. Anybody else wants to comment? I’m seeing a shaking of heads here. Laurie, Paska, do you want to make any comments?

Dr. Paska Permana: This is Paska\_

Laurie Grevious: Umm\_

Dr. Paska Permana: \_I would, oh\_

Laurie Grevious: Yeah, sorry, go ahead.

Dr. Karen Jeans: Okay, so let’s hear it.

Laurie Grevious: Go ahead Paska.

Dr. Paska Permana: Sorry. I would agree with Dr. Jeans on this. Minutes are not supposed to be just a transcription of whatever is going on in the meeting. Also, for us, we actually in the agenda would hyperlink information of each study to be reviewed, to what we call a study portal, that contains all documents of the study. Even documents that have been reviewed by a subcommittee, for example. So not that we have to put all the documents in the agenda or minutes of the R&D Committee meeting, but the hyperlink can actually lead to any document that may be discussed, if necessary. So it shouldn’t really take pages and pages of the minutes.

Dr. Karen Jeans: Nice way. Laurie?

Laurie Grevious: And here at Denver, I would say the body of the minutes is probably 10 to 12 pages, but I always include things as attachments, so I’m not like rewriting a bunch of stuff, and it cuts down on rewriting.

Dr. Karen Jeans: Okay. That’s, that’s helpful. Thank you.

Soundia Duche: Thanks guys.

Laurie Grevious: Yes.

Carol: Okay.

Dr. Karen Jeans: Okay.

Carol: The next question is, the person is questioning why the nurse executive’s signature is on the R&DC meeting minutes?

Dr. Karen Jeans: What? I didn’t hear that one.

Soundia Duche: The nurse executive’s signature goes on the R&DC meeting minutes template?

Dr. Karen Jeans: That’s just their preference.

Soundia Duche: That might be their preference, but they said nobody signed their minutes. Paska\_

Dr. Paska Permana: Yeah, nobody signs the minute. I think it was on slide 16? It is, the minutes are distributed to the facility leadership council, that includes the nurse exec, typically. But not that a nurse exec has to sign the minutes.

Soundia Duche: Thanks for that clarification.

Dr. Karen Jeans: Thank you.

Carol: The next question is\_

Soundia Duche: [Unintelligible 48:51]

Carol: I’m sorry?

Soundia Duche: Oh, go ahead.

Carol: The next question is clarification on, they’re asking if they need to have the medical center director or chief of staff sign R&D meeting minutes?

Soundia Duche: As I think Paska mentioned, they don’t have to have anyone sign their minutes, and there’s no requirement in 1200.01, anymore, for meeting minutes to be signed. So, that might be a local policy or practice that’s in your SOP. So, I would double check your local SOPs, and this might be a good time to revise them. If you find that it’s not really adding anything for them to sign the minutes.

Carol: Okay. The next question is, all our minutes and agendas are posted in SharePoint for anyone’s review, would that be sufficient in lieu of emailing to the ELT?

Soundia Duche: Would that meet the requirements if they distributed it? If they give the Executive leadership team access to the SharePoint Karen?

Dr. Karen Jeans: It’s about distribution. We don’t specify how, but you do have to be able to, again it’s, the test I always have for people is, you know, if someone comes behind you and says, okay, how are they distributed? And then if someone is, if you’re, if the individual or interview you’re going, okay, how do you use the minutes? And saying, we don’t know. You know, again, it’s making sure they know that when they’re there they’re supposed to be reviewed. They need to be looking at them.

Carol: Okay. The next question is, when does this go into effect?

Soundia Duche: Yeah, I’m not quite sure what\_

Dr. Karen Jeans: What go into effect?

Soundia Duche: \_what [unintelligible 50:34] effect, so whoever posed the question, maybe you can send a follow-on.

Dr. Karen Jeans: But 1200.01’s directives are in effect.

Soundia Duche: Yeah.

Dr. Karen Jeans: By, now, if we’re talking about, you know, there’s three sections of 1200.01 that are on discretionary enforcement, that’s not the purpose of this discussion today. We’re talking about convened review, designated review, this is all in effect. As of now. Thank you.

Carol: The next person is asking for examples of an R&D noncompliance checklist.

Soundia Duche: So, great time to advertise our future workshop series. Everything did have to be pushed back. If you all recall our first workshop was originally slated for some time in November, and we had to push it back, so all subsequent workshop dates have been pushed back. But we will have a workshop on noncompliance review and reports, so stay tuned.

Carol: The next question is clarifying if Paska said R&D minutes do not have to get a signature approval?

Soundia Duche: There’s no, yeah, there’s no signature.

Dr. Karen Jeans: No. no, and there’s no signature requirement in the policy, so again, in ORD policy. Now, what your local policies and procedures may state may be different.

Carol: The next question is, when can we anticipate guidance regarding continuing review of exempt studies?

Dr. Karen Jeans: Oh, by the R&D Committee continuing review of it. I don’t have a date. This is Karen, I wish I could put a date on it. We’ve got a lot of different documents, but I know that it’s not the answer you want to hear, but we’re working on it, I just don’t have a date.

Carol: Okay. And it looks like the last question. It says, the R&D Committee minutes need to go to the executive leadership. Can you tell me who is included in the executive leadership? Since the MCD and [unintelligible 52:34] sit on our R&D, can they just receive those minutes then?

Dr. Karen Jeans: And you’ve got that on one of your slides.

Soundia Duche: I did. [Unintelligible 52:42]

Dr. Karen Jeans: Yeah.

Soundia Duche: I said it was typically composed of the MCD, the Medical Center Director, the Associate Medical Center Director, the Chief of Staff, and the Nurse Executive.

Dr. Karen Jeans: It’s your quadrad.

Soundia Duche: So in terms of can they just, can those individuals just receive the minutes as part of the R&D Committee and satisfy the requirement that they received the minutes.

Dr. Karen Jeans: We require a distribution. That’s it. That contributes as a distribution of the minutes to them.

Soundia Duche: Yeah.

Dr. Karen Jeans: That’s why it’s\_

Soundia Duche: They’ve got it that way, then\_

Dr. Karen Jeans: Yeah.

Soundia Duche: You just want to make sure anybody else though, that’s not in your R&D Committee that requires those minutes as part of this requirement gets the minutes.

Dr. Karen Jeans: Right.

Soundia Duche: And so maybe I would suggest to cover yourself include it in your SOPs.

Dr. Karen Jeans: Yeah, how you distribute them.

Soundia Duche: Yes.

Carol: I’m sorry, there’s one more\_

Soundia Duche: Is that it?

Carol: \_question.

Soundia Duche: Okay.

Carol: There’s one more that just came in. Is it allowed that RCO audits be reviewed by DMR? 1200.01 states protocol.

Soundia Duche: So, that question I actually sent an email to ORO policy and education about that. Specifically when an audit does not have an incident of serious or noncompliance, can it be reviewed outside of a convened committee meeting? And this pertains to protocols that are not under the oversight of another subcommittee. We’re waiting on feedback from ORO, and then Karen will take that into consideration, and see if that conflicts with our policy for designated review. When it’s those subsequent actions.

Dr. Karen Jeans: Yeah, because ORO has the policies to review RCO audits. So, we will yield to them.

Soundia Duche: All right, so thank you. Well thank you everybody, we apologize for the technical glitch when we first started, but we hope you found this useful. Our next workshop is, right now we’re, we have one scheduled for late January, and that will be on the review and approval of non-Veterans. So stay tuned for more information on that. But this wraps up ORPP&E’s education and training for 2019. We wish you all a very Merry Christmas, Happy Hanukkah, Happy Holidays. Thanks for being with us throughout the year, and we look forward to, now we have a number of webinars already scheduled for January, so we will be talking to you then. Take care everyone. Bye-bye.

[ END OF AUDIO ]