ORPP&E Webinar
Date: February 2, 2021
Session: New Year, New Platform - Help Make Sure it Works
Presenter: Soundia A. Duche, MA, MS

This is an unedited transcript of this session. As such, it may contain omissions or errors due to sound quality or misinterpretation. For clarification or verification of any points in the transcript, please refer to the audio version posted at
http://www.research.va.gov/programs/orppe/education/webinars/archives.cfm

Soundia Duche: Welcome everybody. I'm going to share my screen now. This is the- Let's see. Perfect. Hopefully, you guys can see. So this is a repeat of a presentation we did, I think it was January 14th, 13th or 14th. But essentially where we're testing our new platform that ORPP&E has been using for our national Webinars. And so we're gonna be using the CISCO WebEx Events platform. So it's a bit different than our GoToWebinar platform. Thanks to our last test, it was pretty successful, but there were a couple of additional things we wanted to work out. And then also we wanted to give an opportunity for those of you who couldn't make it, or who maybe didn't hear about it, to learn about the ORPP&E resources that are available to our researchers, and research administration, and people in compliance, and oversight of research. Which we're gonna be sharing with you today.

My name is, Soundia Duche. For those who don't know, I'm the director of education and training for ORPP&E. And one of the things I'll share with you, some of the things we do in education and training, and we're gonna be focusing like I mentioned on the different resources that are available. We want to talk a lot about the searchable FAQs which was something we released late Fall of last year. And we want to make sure you all know about it as well as know how to use it. And so the latter half of this training is kind of see, like a heavy emphasis on the searchable FAQ database. We want to share with you all how it was developed, give you some background. We're going to do some search methodologies with you all. So come prepared, you know, with some questions. As Kate mentioned we want to test out our ability to unmute people. Because going forward we want to really make use of that. You know, it's hard enough just talking where people can't interact. And we know you all would like to sometimes be able to clarify your questions. And so we hope going forward in our Webinars that you're going to see more interaction and hear from your other colleagues. I think I've covered most of that.

And just for anybody new to the VA, we want to welcome you. And just give you a bit of background on ORPP&E. So we're responsible for- Why is this blocking my sight? ORPP&E, we're responsible for all policy and development and guidance for human research protection in the VA. We're also responsible for national training and education in human research protection throughout the VA. And then we created, and we implement the VA Central IRB. I'm in charge of training and education and I work very closely with many of you all in the field who have your own training programs. We've been able to really benefit I think last year by working

collaboratively with people in the field to bring you on as presenters where you can share your best practices, collaborate with your other colleagues, help forge those relationships. And I hope we'll be continuing that this year.

And so as I mentioned, one of the things I wanted to do as part of this Webinar is really, make sure people know what resources are available to them. One thing we found from our last Webinar, we had maybe about 200 people there, is that certain things which we thought people would know, or things that we advertised and send out notices about, somehow that's being missed. And so we're going to be really reflecting quite intently this year on how do we improve our communications in the field? How do we better make sure that the resources that are available are—that you're aware of them essentially. So one of the things I want to mention is that last year, one of the things we did as part of this effort to make sure that the field has information, that you can easily access information, is where possible we tried to consolidate all the information. Be it our guidance documents, our Webinars, our tools. We tried to consolidate them in a central place. Or at least easy access. And so where was that? That was the ORD Human Research Policy and Guidance webpage.

Okay? Now I'm going to pull this up, hopefully many of you guys know this page, or have been on it. But if you haven't that's okay, that's the purpose of this Webinar. Bookmark this. Really, bookmark this page because if there is any webpage as far as ORPP&E and ORD, this is the page that you want. If you're doing research administration, if you're an investigator. This is the page to come to because it's really central. This page has all of our guidance documents. If you scroll down here you'll see all of our guidance documents. It also has links from this page to our FAQ database. You can see it here. It has links to the ORPP&E toolkit, which we're going to talk about. Sample templates. Back in 20, I think it was 2018, December 2018 when Molly first came, Dr. Klote. She released maybe about 60+ tools and we continue to upgrade, edit those tools and such. And you can find all of those here on this website. Our Webinars, we record all of our Webinars. And we post those recordings. Right? Yes, there's a separate webpage for that, but you can just come here. So what we did was rather than have our information in so many different places, those webpages still exist, but we tried our best where possible to consolidate them to one page so that you can easily find everything. And so this page is really central and really important for you to know about.

I think from here I will go on and just go straight to the toolkits because the next bullet in my slides talks about the toolkit. And what are toolkits? Last year we released three toolkits. And again, this is our effort to make sure that the research community has the information they need and can access it effectively and efficiently. And so what we did with our toolkits is, we took a topic. For example exempt research, going to pull it up here.

And we tried to consolidate all the information that we have created, that ORD's created about this topic. And so for example here you have a link to all the videos. All the flowcharts on exempt research. We have memorandums related to exempt research. So those templates, remember I told you those 60+ templates that Dr. Klote had released back in December 2018. The ones related to exempt research can be found here. And as they get updated, we make

sure we try to update this place. So Webinars, we've done a lot of Webinars related to exempt research. Again, they've been put here.

So what we did in our toolkits is we've taken individual topics and tried to consolidate the information so you can go to one place. Now late last year, we collaborated with the research support division to release a research information security and cybersecurity toolkit. This was our first collaborative effort and we really, really liked working with others. Because it gets to extend our reach, right? In terms of what the research community needs and helps us to help get them the information. And so we worked with the research support division. They had so much information, an abundance of information in so many different places. And so we worked with them to help consolidate that information.

So you'll find their FAQ, you'll find their guidance documents, bulletins, templates are coming soon. Webinars, they've done a lot of Webinars. And then what's so fantastic because there's so much that goes into getting different approvals depending on what type of information security device you're using, what type of platform you're using. There's loads of information on here, on what the approval office is for different applications. Mobile devices. If you have to get an ATO there's information here. So again, what this toolkit did was consolidate that information as best as possible. Make it easier.

So now let me try, if I can get back to my slides, that'll be the million dollar question here. Not happening, getting back here. There we go, okay. So I talked about toolkits already. And then the last thing I'm going to talk about, so we'll spend more time later on, is the searchable FAQ. Okay? I'm not going to follow that link now because we're going to spend a lot of time on that in the latter half. But before we really get into the searchable FAQs, I wanted to make sure, we wanted to get a sense of, 1; are you aware of some of these resources? And if you are aware, how often do you use them? And so Erica is going to pull up a poll in a moment, and it's going to ask you about that ORD Human Research Policy and Guidance webpage. That one that I showed you at the beginning that has like links to everywhere. We want to get a sense from you about how often do you use it. And the options are going be seldomly, occasionally, frequently, or I never knew this existed, pretty much. And that's okay. Just be honest. I always tell people the difference between seldomly and occasionally is; seldomly is I know about it; I just don't really get to it. Occasionally should be no, I do know about and I do use it. You know? Maybe not as often as I should, but I do go there from time to time. And so Erica if we can go ahead and launch that, that would be awesome.

Erica: Okay, do you see it? It's launched.

Soundia Duche: Yep.

Erica: People are answering. And just remember to hit the submit button when you're done answering. And we have about 15 seconds left. Okay. Here come the poll results.

Soundia Duche: Thank you Erica.

Erica: Do you see them?

Soundia Duche: We do. It's hard for me to see the percentages. So if you can read those out, that would be great.

Erica: Oh. Let me.

Soundia Duche: Okay. I think it's just, it's there but I think. Well maybe. Oh I have to make it. I just have to move it. [unintelligible 0:10:38].

Erica: Okay, so we have here seldomly. I seldomly use the website, 21%, 23% occasionally, 5% frequently, 9% first time hearing about it. And 42% chose not to answer. Okay?

Soundia Duche: Thank you, Erica. So we're going to go to our next one. Don't know why people didn't answer. Is it- are you having a hard time finding the polls? If you can just let Kate know before we go onto the next one. Kate, what are people saying, anything?

Kate: We just didn't feel like answering. Nothing in the Q&A or chat yet about the polls. But I'll look for those.

Soundia Duche: Okay, thank you. If we need to give you more time, let us know before we launch this next one. So I'll talk it through and then I'll wait for Kate to let me know if we're a go on launching it. So remember I talked to you and I showed you the three toolkits that we have so far that we've published. And our hope is this year to publish two or three more. It takes a lot of effort to publish a toolkit, because 1; you really need to have a lot of information. And sometimes like for example in the case of the R&D Committee toolkits we have to develop that information first. We needed to develop a lot of sample tools on the R&D Committee. We needed to have the Webinars. So we did that last year. And that enabled us to be able to create that toolkit. As a plug for our toolkits we're always looking to collaborate with folks. So if anybody has an idea for a toolkit, maybe for you know people who are in the, doing clinical trials, maybe some of our specialists, that could be, you know might be an interesting topic. Like auditing. That might be an interesting topic. But so our next question is, have you used any of the toolkits? And options will be not yet, yes the exempt research toolkit, yes the R&D Committee toolkit, yes the research information security toolkit, or again, never heard about it. But you know, Sounds interesting. And for this one you can select multiple. Oh, Kate, did you hear anything before Erica launches it?

Kate: People just didn't want to answer.

Soundia Duche: Good, that's okay.

Erica: Okay, here it comes. Oh, my goodness. A lot more people are answering now.

Soundia Duche: Oh, they felt guilty. Ha, ha. It always works.

Erica: [laughs]

Soundia Duche: [laughs] And Erica, just watch the time, because I think you gave, you can adjust the time on this.

Erica: I see that. That's why I made a- Yeah. Okay. So we're going to close the poll in 3, 2, 1. Okay. And we are- Oh, so you can see the poll this time.

Soundia Duche: Hm?

Erica: Can you see it? Can you see the answers?

Soundia Duche: I can see it, not the results yet. No, because I don't think- It says the poll- To me it says it's ended, but you have to display results maybe.

Erica: Hm.

Soundia Duche: You know I think it's counting down. Remember how it gives that extra time? Because now we can see it. I think it gave some extra time because you ended it prematurely.

Erica: Okay. Well here we go. We have 37% that said they have not yet used the toolkit. Sixteen said exempt, 17% R&D, 7% information security, and 14% first time hearing about the toolkits.

Soundia Duche: Okay. Okay. Better.

Erica: All right?

Soundia Duche: Thank you for the increased participation, guys. And I will just say this, at the end for those who choose to complete the survey at the end of the Webinar, once you've exited, if there's ideas for toolkits that you would like to see, please put that in suggestions. Okay? All right? So our last poll is a two part poll. So please pay attention. You're going to have to scroll down before you hit submit. Because we want you to answer both questions. So first it's a multiple choice. How often do you use ORD searchable FAQs? You have the same options as you had before. Seldomly, occasionally, frequently, or never heard about them. And then the second part is we want to know, just you know a sentence, or I don't know a word or two, short phrase, what have you found most challenging about the searchable FAQ? Sometimes it's nothing's challenging. But it's going to help us as we really figure out how best to optimize it for you all. Okay? So Erica, if you can launch it. Remember guys, two parts. So scroll down, answer both before you hit submit.

Erica: And don't forget to scroll down and answer the second question. And then don't forget to hit the submit button. Okay. We're almost out of time. There we go. And do you see the poll results, Soundia?

Soundia Duche: Yes, I do.

Erica: Okay. So we have 25% say they seldomly use the FAQs searchable database. Sixteen occasionally, 1% frequently. Whoever that person is you need to like make a medal or a badge or you know something really awesome. One of those candy bouquets or something.

Soundia Duche: We'll have you promote it.

Erica: [laughs]

Soundia Duche: Make you a spokesman for us. [laughs]

Erica: Yeah. Twenty percent, 27%, this is good that this is the first time hearing about the FAQs and hopefully they will give them a try. And I don't know if something wacko happened with question number 2, but nobody answered it. So maybe that was something on our end that-

Soundia Duche: Okay. Well, okay. Let us know in the chat box guys. If there was something if you submitted it before, you know realizing that there was a second part. So just shoot us a quick message in the chat box. Alrighty. Thank you, Erica.

Erica: Alrighty.

Soundia Duche: All right. So. I don't want to incriminate anybody. This is not the picture of anybody's actual office. Well maybe, but I won't name any names. [laughs] But you know one of the things we try to impress to you all is that, please don't send questions to individual ORPP&E staff. There may be times, obviously, where you have to. And obviously once you've started a conversation you continue it. But one, sending questions to just one person because you know this person and this person always gets back to you, it doesn't allow us to really benefit from knowing what types of questions the field is having. Because it's hard for us to track it. Two, it sometimes makes that person overwhelmed because they're getting so much incoming. From the field, from their normal office, from dealing with other departments in the agency. And it's just not helpful. The third thing is, honestly it's so easy. And you guys know this right? For emails to get buried. You know? It comes in on the Thursday, you think you're going to get back to it. Next thing you know, you're out Friday, you come back Monday, there's 10,000 other emails. You just lose track of it. Not to say, you can't lose track if you send it to a mailbox. But at least it's easier, or less likely to get buried. So we ask you guys, please, to the extent possible, don't send questions to individual ORPP&E staff members. So where do you send the questions, you ask.

Great, question. And I have to admit, I don't think we've done a very good job on kind of advertising the various mailboxes that exist. And so we're going to be working on that this first quarter. Figuring out how best to get that message out. Figuring out how best to incorporate the list of these mailboxes on that ORD Human Research Policy and Guidance webpage so you see it. But in our group, in ORPP&E we manage about 1, 2, 3, 4, 5 mailboxes. And they're mailboxes for different types of things. So if you're dealing with COVID-19 there's an expanded access coordinator mailbox to send your questions. ORD COVID-19 has a regulatory mailbox for COVID-19 related research questions. There's a mailbox for IRB reliance and single IRB exception requests. There's a mailbox for VAIRRS questions. And then lastly there's a regulatory mailbox. And the regulatory mailbox is the oldest of all of these. It dates back to probably 2013. I remember, because I was here when it was set up. But if you have a question that can neatly fall into one of these categories, please send it there. The VA Central IRB has their own mailbox. I probably should have put it here actually. But they have their own mailbox as well for VA Central IRB questions. And so anyways, when you have general questions try not to email the person who you've always sent it to because they always get back to you quickly. We have mailboxes. And the other thing is, when you send it to the mailbox, usually we try to get back to it fairly quickly. You'll get an automated message that says we'll get back to it within 3 to 7 business days. If you don't hear from us, send another response to the mailbox. Don't send another response to your buddy to say, hey I never heard. You know, let the timeframe elapse. If it's urgent send a response again. Highlight it with that, you know red flag thing, hey you know this is urgent. But we're really trying to better manage and be able to categorize what the issues are. And believe it or not we do. We do categorize them.

So here's an example for the ORD regulatory mailbox. Messages that go there, questions that go there, we track. And in 2019 we had about 242 questions that were sent and responded to in the regulatory mailbox. And oftentimes, those questions involve a lot of back and forth. You know. Sometimes they'll be determinations, sometimes someone will ask a question and we have to get more information. Send us the protocol, send us the document, send us the agreement. I manage, I'm responsible for the ORD regulatory mailbox, and I have not done the analysis for November and December. But through end of October, we responded to about 416 questions that were sent to the regulatory mailbox. I feel through the end of the year that probably took us up to about 600 questions through the year. Close to 600. But in that process then, we're able to see where are the top questions. And we do a lot of analysis. I cannot tell you on what questions we get that go into the mailbox. So for example, in 2019, some of the top topics were exempt research, R&D Committee, informed consent. In 2020, you know some of those were the same, but the order shifted. So informed consent was a huge topic. Probably because of remote consent. Right? We got tons of questions about remote consent. And recruitment, that was a big topic. R&D Committee stays on the top list. So it really gives us 1, do we have enough information, where do we meet out there for the field, do we need to generate more guidance, more FAQs? It also allows us to respond to your questions more quickly because we can go back and see, oh, we've gotten that question before, here's the answer we already provided. Boom, boom, boom, you get your response that same day or soon thereafter because we've already given that response. Now sometimes there's a delay just because I may be out of the office, or I might be swamped with other things. And so I don't get

to your question in the regulatory mailbox. That's why we say please allow us that 3 to 7 business days.

Late in Fall 2020, what we did is Erica, who was our polling coordinator, she was very instrumental in helping us revamp the regulatory mailbox. Now- Database. So back in 2019, early 2019, Erica created the database that allows us to track this information. Right? So when we get questions, every couple of months we go in and we scrub the question and put the responses in the database that Erica created. And that's what allows us to do the analysis. Well, Molly came to us and said, hey, I really feel we need to be able to get the information, that would be great information in these policies and guidance documents and FAQs, but it takes people a lot of time to go through them. And to even know which guidance document might have information, might have on the question. So what we did was, we made a big effort of, we revamped the database, Erica revamped the database for us to make it so that we could start including what we call published FAQs, published guidance documents. So if you think back, if you go back to that ORD Policy and Guidance webpage that I showed you. And you just scroll down, and you'll see all these wonderful guidance documents, and all these wonderful FAQs. So what we did was we went through those—and lots of times our guidance documents, the majority of it is question and answer. Right? So there'll be a question and a response, question and response. And so we took all of those questions, and all of those responses, and we put them in the revamped database. So that now you don't have to necessarily go through all of the guidance documents. But you can go through this searchable FAQ database that's however many—27% of you didn't know existed. [laughs] You can go through them and be able to search, right? For keywords to find the question. We've had two releases, so far, back on October 1st, when we first had our launch of the FAQ database, the searchable FAQs. We released about 200 FAQs. And then in December, mid-December we released an additional 150 FAQs. Now at any point in time we're able to retract FAQs. And in fact we're going to be doing that because of the recent technical amendments, we're going to have to go back and retract some of those FAQs and update them. But so we're constantly able to retract and add. And because of the analysis from the regulatory mailbox, and seeing where the questions are, we're able to say, okay. What's not in the database that we need to focus on generating more guidance, and more FAQs?

So here, just to show you guys, here's a picture of the great database that Erica created for us. And we're able to now input both questions that we get from the regulatory mailbox, as well as questions from the published FAQs and published guides. If it's something that came into the regulatory mailbox we'll enter number 2, the date it came in, the question, the response that you see there. If it's something that comes from a published guidance document or if we just need to create an FAQ, we'll enter that information into number 3. Number 2 stays blank. That section. Section number 3 gets answered, then 5 and 6, the question response are exactly the same. What this means is we're able now, we have a 1,000, I think it's a 1,044 records in here. Right? So while we only have approximately 350 published FAQs. Now the next effort, you can imagine right? Those who have already gone there ahead, you know where I'm going. So the next effort is, now we can say, what are the questions that we've gotten, right? A lot of questions about in the regulatory mailbox. And do this analysis of what's not published already

that we haven't featured in the searchable FAQs, and now we can prioritize what guidance we need to put out. And that is exactly the effort that we're about to undergo in our office.

I've said all of these things. This is where you can find the searchable FAQs. And we're going to actually go through them. So I'm not going to go through this link right now. But you can go too. It has it's own webpage. So if you want. If you're in the business of you know, keeping track of multiple links, add this. Or better yet, just save the human policies, ORD Human Policy and Guidance webpage link. So you can always access the FAQs from there. Right up at the top. You'll be able to access it. As I mentioned we have about 350, a little shy of that, 342 FAQs in the database as of December 31st of last year. In the December launch that we did, those additional FAQs we also changed the methodology whereby we added the Boolean operator 'and' again this helps you refine your analysis. So that you don't have to scroll through, you know, I don't know 15, 20 outputs because you're trying to find something on R&D Committee and continuing review and so you just put R&D Committee and everything under the sun related to R&D can be found. Now you can put R&D Committee and continuing reviews, and get that shorter list of maybe 10 records, right? And so that was something we wanted to do at the very beginning, but we needed some additional time. And so that's now an option.

So let's talk, we're going to be going through the database. But I want to talk about how you get a hit, or multiple hits from your search. How you get a lot of successful searches. Because I know it's frustrating when you go in, right, and you test, you try, and nothing pops up. And you get frustrated and then you never come back, right? The way the database is set up is each entry, every question and answer, every FAQ, is tagged with multiple keywords and phrases. Okay? And so a hit occurs when what you put in the search box matches all of or any part of the keyword. So for example, if in the search box you put continuing review, any record that we have tagged continuing review, continuing review documents, continuing review process, anything that has that continuing review in there will come up. We're not Google. It's what I told the last group when we did this, right? It's literally looking, match by, word for word, character by character to get a match. There's no intelligent operation going on here. Maybe you know, in the future we'll get some contractors in and some computer programmers, and they'll be able to make it very fancy. That would be awesome. Right? Maybe that will happen next year. Maybe that will happen in 2 years. But right now, it's just me. [laughs] Sitting late at night, after the kids go to sleep. Literally entering anything I can think you might associate with the particular question. And I'm typing in all variations of that word. So for R&D Committee, a keyword would be R&D, literally R and D. There will be R and D Committee. There'll be R and D C. There'll be Research and Development Committee. Because people will, people think differently and people use different terminology for the same concept, right, the same topics. So you won't get a hit, right, if the word you entered does not match any of the words in, that were used to tag that FAQ. If you misspell your search term you're not going to get a hit. So you know you spell research, you're looking for Research and Development Committee and you invert the E and A in research, the word is spelled wrong. There's no intelligent you know analysis going on or processes. It's not going to equate REA or RAE with research, right? So you're not going to get a hit. So if you misspell words you don't get a hit. What this means is, when you don't get a hit, try one more time. Just to make sure you didn't do something wrong.

This is something funky, but if in your search you use a plural form of the search, of the word, and we haven't tagged it with the plural form, you won't get a hit. To avoid that, I've tried my very best to always tag things in a plural form. So continuing review, would be continuing reviews. That would be the plural form in the key, it would be tagged with that. Because what happens is, if you put in continuing reviews, with an S, and I have not tagged that with the plural form, continuing reviews, as far as the system is concerned, the word does not match. It can be a shorter- You could put in part of the phrase, and it searches and says, oh I see that part of the word, and that's fine. But if you go over, which happens a lot with plurals, it's a problem. We've tried our best to avoid that by anticipating where you might do that and putting that in the key tags. And then lastly, you won't get a hit if we don't have the topic in there. You just won't. And we only have 350 topics in there. So I understand. I know the next questions are how are we supposed to know what's in there? And we're going to talk about that right now. And we gave you guys a handout that shows you what's in and what's not in the database.

And I'm going to try to figure out how best to include some of that information on the webpage. So that people have a sense of what's in there to reduce frustration. Here's an example of a search on R&D Committee, whether the R&D Committee is required to approve lifecycle actions of studies that are under its oversight. So what that means is, does R&D Committees have to do continuing reviews and amendments on studies that are under, if the sole oversight is the R&D Committee. For this FAQ, here are all the keywords associated for this. Research and Development Committee approval, because some people might think Research and Development Committee approval. R&D C, RDC, R&D Committee, continuing reviews—here's our plural form. Annual reviews—here's our plural form. Amendment. Reportable event. So anything that we think you might associate when you're trying to find out this information we've tagged it. And it's in your, you know, slides as an example. I'm not going to go into this one, but again, here you see all the different keywords that we've associated with this particular FAQ. And we've put this because I think it's important for people to understand how the search is being done. And we're going to be trying again to revamp the website so that you can either have some examples of what keywords to use, or what keywords are associated with the topic to make it easier for you.

So what's in the database, and what's not in there? What's in the searchable FAQs. When we did our analysis of the topics that are covered in the searchable FAQs with more, greater, or equal to 10 entries. Here's a list of what's in there. So if you're looking for stuff on COVID-19 we probably have you covered. Right? If you're looking for stuff on email or text messaging, whether it can be used in research, there's a lot of records on that. What this does by doing this analysis, it tells us where we need to focus our efforts. So right now, when we're generating new FAQs, we're not going to be focusing on email and text message. Does that mean we covered everything about emails and text messages? No. But it means that in terms of prioritizing it, that's not our priority right now. All right?

The things we do need to prioritize are those that don't have many entries, or none at all. So interestingly enough, when you look in the FAQ database, we only have 4 records, right now, on amendments. Right? That might be IRB amendments, that might be R&D Committee

amendments. I don't even know. But there's only 4 of them. In terms of certificates of confidentiality we only have 2 records that talk about certificates of confidentiality, but that's really the focus of that FAQ. So these are some of the ones that we need to focus on. And we will be focusing on them. Right? So here's a list of things that you're not really going to find in there. And when I say you're not going to find them, not that there won't be a reference in an FAQ to the word data, but what I mean is that, that's not the core topic of the FAQ. Okay? So expedited review, surprisingly, we don't have any information in the FAQ database on that. So you're going to go there, you're going to try to find something about expedited reviews. You're not going to find anything, you're going to get frustrated, you're never going to go back. That's not our goal. And so somehow our plan is to make it clear to people what's in there, and what's not. And address the issues as quickly as possible. Okay? You have this information in the handouts that we gave you.

I want to make sure I leave at least 15 minutes for searches. So here for example are some examples of searches. And I'm just going to go through one set, maybe two so that I can get to answering your questions. Let's go over the first one. So, let's say I have question, so you have a question about, hey, is there anything on obtaining informed consent remotely. Because that's the biggest hot topic, right? We gotta go all now remote, our subjects, our prospective subjects are remote. How do we do it? So one way you could do it, okay, let me just look. Informed consent. And normally you want to start as broadly as possible. So if you were to type in, in your search box, informed consent, you would get about 32 records. Okay? And that would be all FAQs that are tagged with informed consent. That could be informed consent forms, informed consent documents, documentation of informed consent, right? Anything. It could be if you were looking for the key information. Right? If there was an FAQ about key information that FAQ would be tagged with the words informed consent. So 32 hits. Now 32 is not a huge number. Okay? It's not like 90. So you could go through those 32. You could also type in remote informed consent in the search box and you would get about 16. Right? Now what's interesting is, remote informed consent, because a lot of times people say when they think about remote informed consent they also mean electronic consent. They kind of go back and forth and use the words interchangeably. For remote informed consent you'll get 16 hits. And those hits will be about things like DocuSign, My HealtheVet, Azure RMS. They'll be how do you obtain informed consent remotely, right? So you're not you know going to be getting that signature face to face. You don't have face to face contact. If you typed in electronic consent, that 16 number drops to 5. Right? And what's interesting is, it's a different subset. You still get your DocuSigns. So you'll get that, well because DocuSign can be used remotely. It's also truly an electronic means of getting informed consent, it's electronic consent, digital consent. You'll also get iMedConsent. Right now in VA, iMedConsent is electronic consent, but it's not remote consent. Because for iMed, my understanding at least is you have to be face to face. It's something that deploys in the hospitals. Right? And so just to give you a sense of how you kind of go through down the layers. I'm not going to go over these other examples, except to point out that for the second box, what guidance is available on using combined ICF and HIPAA, you see this last one here, HIPAA and informed consent. Where that capital AND is, that's the Boolean operator. So remember I mentioned that was something new that we rolled out mid-December. So what that means is if you typed in HIPAA in the first search box, and informed

consent in the second search box, you're going to get 2 hits. And that will include an FAQ on scanning ICF and HIPAA, because it talks about HIPAA and informed consent. And that will also include, I believe the FAQ, there's only one out there in our database, about actually when can a combined, an ICF and HIPAA authorization form be used. That was a question that's being asked. Right? When I can use combined ICF and HIPAA when the study involves banking. If you type in HIPAA and informed consent, it's looking for all the records that have anything to do with HIPAA, and anything to do with informed consent, that are tagged with both. So its looking for ones that have been tagged with both HIPAA and informed consent. And that scanning comes up because in that FAQ the way it discusses, it must talk about scanning both ICF and HIPAA. So again, this is more for your reference.

But now I think we have about 15 minutes left, and this is where we're really hoping, we want to test out the unmute. And so if you have a search, you can type it in the Q&A, or you can just tell us I have a search, and Kate's gonna try to find you and unmute you, and let's do it together. Let me hear from you, how you would do it, and let's see if we get a hit and then we'll try something else. Let's see if this opens. So Kate, do we have any volunteers?

Kate: We don't have any volunteers yet. But I'd like to thank everyone for sending their questions for us at the end. There are some great questions everyone submitted already.

Soundia Duche: Okay. We don't have volunteers. Oh. I think we have a volunteer. Can you see her?

Kate: All right. I do. Holly, [phonetic 0:41:27] I'm going to unmute.

Holly: Hello.

Soundia Duche: Hi, Holly.

Kate: Hi.

Holly: First I just want to say, this is a terrific presentation.

Soundia Duche: Thank you.

Holly: And I have been in RCO, I think, it feels like for a hundred years, but probably more like 4.

Soundia Duche: [laughs]

Holly: And I'm just really learning a lot from this.

Soundia Duche: Good, I'm glad.

Holly: Like I- Yeah thank you. So in terms of like a question that I had recently was, it was about informed consent on exempt studies. And because like we had some studies that were exempted that had informed consent documents. And I got like conflicting answers from people. So I would have loved to have been able to go here.

Soundia Duche: Absolutely.

Holly: And now I will. But I'm not sure exactly how- what- so I'd love to learn from you.

Soundia Duche: Absolutely.

Holly: Thank you.

Soundia Duche: And one thing I will say, Holly contact me offline if you want to talk about it. I'm not going to spend time answering people's questions about that, not that you asked that one.

Holly: Oh, okay.

Soundia Duche: Happy to talk to you about the search. No but we're gonna do exactly that. We're going to see, is the information in here? Okay?

Holly: Yeah.

Soundia Duche: Good. Your question is perfect. And I'll be honest. Look, I won't say anything. Last time I spent all this time saying, oh, I don't think that topic's in there, and then I did a search and it was.

Holly: Oh.

Soundia Duche: So this topic, we could do two ways. Okay? We could type in informed consent. Right? Think big. I'm not going to do that because I already told you guys. There are about 30+ you know records in there. So we'd have to scroll down and see is there anything. I can type in exempt. The issue is, I don't think we have all that much about exempt in there. So I could just say exempt. I could say exempt research. If I've done my job right, either of them should kick up anything that's been tagged.

Holly: Okay.

Soundia Duche: I don't know how much we have. Oh, there we go. See. I always do this to myself. I'm like I don't think we have anything. So we have 8 and we do. We do. So you could scroll through here and see is there something that meets, right? Or let's take ourselves back out. Let's make it easier for ourselves. Because what if we had 80 records about exempt research. So let's do exempt research, and then I would do informed consent. Right?

Holly: Okay.

Soundia Duche: And what we should get is something that says, you know exempt research is not subject to the common rule, and therefore doesn't require informed consent. Right? You don't get that because we don't have that particular FAQ in here. So at this point, we send the message to the regulatory mailbox. And we address it.

Holly: Okay.

Soundia Duche: What's interesting though is, I would go through if I were you the exempt questions, because a requirement, right, in a 1200.05 is that you have to get the subject's permission, or you have to for certain types of research, right, you have to inform them that it's research and there are certain things. That's not called informed consent. So might there be a question about that in this database? And there might be. But it wouldn't popup with informed consent, but it should have. Right? And so I would scroll through that list it gave for exempt research and see if there's anything that touches on that.

Holly: Okay.

Soundia Duche: I could try right now to come up with some possible keywords, but I don't want to spend more time, you know dillydallying about that. And if you don't see anything, contact us and we'll be happy to answer that question. And again, hopefully in the next few months you'll start seeing more, and possibly even that question addressed in a published FAQ.

Holly: Well now that I've attended this and seen all this, I'm just gonna start trying this as much as I can.

Soundia Duche: Yay.

Holly: Using it as often as I can.

Soundia Duche: Wonderful.

Holly: And I'll probably find a bunch of stuff in here.

Soundia Duche: Sure thing. I mean there's 350 records of something. [laughs]

Holly: Yeah.

Soundia Duche: You know? That's a good starting point right?

Holly: Right.

Soundia Duche: And I promise to really get more in there. And useful stuff.

Holly: And at first, when I first started this, you first started talking, I kept sending this question about, there's so much information on this ORD homepage, what do you think we should bookmark as our CO's. But then I started looking at it a little, as I was listening, and I'm just going to bookmark the home ORD, and I see how now to get to all of your toolkits. And so yeah. Thank you.

Soundia Duche: And that wasn't always the case. I'll be honest. It wasn't always the case. You know we had things in 10,000 places. So we didn't, you know?

Holly: Right, right.

Soundia Duche: We're giving you guys whiplash. So we apologize for that.

Holly: That's okay.

Soundia Duche: We're trying to get better. We're trying.

Holly: That's okay. I'm just so glad. I think, oh gosh, I wish everyone would attend this.

Soundia Duche: Yay, well good. Well thank you Holly, thank you. Any other volunteers, Kate?

Kate: All right. Our next volunteer is going to be Ellen Martin [phonetic 0:46:42]. I see that you've already resolved your search, but we're just going to use your example anyways. Ellen, you are unmuted.

Ellen Martin: Oh, hi. Can you hear me?

Kate: Yes.

Soundia Duche: Yes, Ellen, hi.

Ellen Martin: So I was trying to look for a designated review procedure for R&D. So I wanted to make sure I could send my reviewer somewhere easily. And I found it by using shorter terms that you guys gave me that I learned today. So thank you.

Soundia Duche: Oh, you're welcome, you're welcome. And what I want to do, because I didn't do a good job with this with Holly. So let's just do it quickly. R&D C—hopefully, this works, you never know—designated review. And you know you could just put designated review and let that be your only search term. And you should get, you know, a designated review for the most part is only associated with R&D Committee. But I know that animals use designated member reviews. And we would tag them similarly because people would always use those words interchangeably so. If we wanted R&D C and designated review, typing in both I got 4 hits. Right? What I want to show you guys here is, we don't see this in your case. We don't see the

keywords. What I'm doing is I'm operating on our test development website, because I wanted to be able to highlight to you how the keywords are used. So for this question about, can an R&D Committee chair or a designated member review, what, approved research or designated review. The key terms were R&D Committee, as well as designated review. And that's pretty self-explanatory, gee, Soundia. Ha, here's a better one. Okay. This question is asking about designated review process and single patient expanded access, right? Can the R&D Committee use designated review for the approval of expanded access. And so now, the keywords have followed the R&D Committee. All the various ways you could say R&D Committee. It has the various ways of where you think you would say designated review. DR. I probably should have put designated member review, because if there's someone in the animal community you might switch gears and you might call this designated member review too. I'll be honest. I was calling it that for awhile as well. And then expanded access protocol. So just to give you guys a sense of, you know, this next question is about non-Veteran designated review and the R&D Committee. Now you start having all kinds of other things. I don't know why this says test, test. All kinds of other keywords. So thank you.

Ellen Martin: Thank you.

Soundia Duche: Mm-hmm. Another question. And we can go to questions too if we don't have any searches.

Kate: I think we just have one left from Amy Burns [phonetic 0:49:29].

Soundia Duche: Okay.

Kate: Amy, we're about to unmute you.

Amy Burns: Okay. So I just had a quick question about something that I was searching for last week about medical records, when they needed to be created or updated for mostly non-Veterans or employees. So I was just thinking of keywords to search for that.

Soundia Duche: Exactly, right. So CPRS would be one. I don't recall ever tagging something with that. But again you never know. That's for non-Veterans. So I always think, let's start bigger, right? So I would say, let's just start with non-Veterans and I will tell you, I do a hyphen, because I think that's how it's done. Who knows? But we recognize, you know, you might mistakenly not put a hyphen. So hopefully non-Veterans will come up whether you put the hyphen in or not. If we do that, there are 4 records on non-Veterans. So that's not a lot, so we can kinda scroll through quickly. But I'm going to, you know we can scroll through and see if there anything about medical records. I want to go back though. Since there are only 4 records, I don't want to put non-Veterans and medical records. I just want to put medical records. Or medical record. Let's see if anything pops up. So there's one record about medical record. And this is about for employees participating in COVID-19 research studies, are there additional requirements for the research study team if a potential subject does not have a VHA medical record? So what's interesting is, VA employees a lot of times might be non-Veterans. And so I

probably should have tagged this one with non-Veterans as well. In which case, had you typed in non-Veterans and medical records this would have come up. But because I didn't tag it with non-Veterans had you put that in, it wouldn't have come up. Right? So I'm not perfect. I apologize. But again, I think this illustrates trying to go bigger if possible. Right? Try to get less granular. So before we start going and using the and, let's see how many records are we even dealing with. Right? So non-Veterans pulled up, we only had 4. So we just scrolled down. But then I could, let's step back and let's see if medical records pop up anything. And sure enough it does. And if you read through this, this might give you some information that's helpful to your question. I don't know. But just to give you a sense of kind of how to think strategically when you're doing the searches, given the limitations of our methodology. We haven't gotten Google onboard yet.

Amy Burns: Great. Thank you.

Soundia Duche: Mm-hmm.

Kate: All right, thank you. And yeah, I think we can switch over to the Q&A section.

Soundia Duche: Perfect. I'll let you take that over, Kate. Do I need to stop sharing—oh perfect.

Kate: All right. And can everyone see my screen?

Soundia Duche: Yep.

Kate: And this is the first question we have.

Soundia Duche: So are you going to do any training for the RCO's on VAIRRS? I envision that's coming. I do know we have some training, because I'm just working with Angela Foster who's the program manager. And scheduling training on VAIRRS specific to the VA Central IRB. Here's a plug, when you fill out your survey put in there that you'd like to see training for RCO's on VAIRRS. Please, put that in there. Because again, we look at the survey results and that helps inform how we develop things. And then I can take that back to Angela. I mean I can take this back, but I mean for this. But if it's the survey we all analyze our survey results after each Webinar. So she'll be able to see it. Okay. I find the main problem with using- Where did it go?

Kate: I'm sorry.

Soundia Duche: That's okay.

Kate: There you go.

Soundia Duche: I find the main problem with using the website is navigating and finding what one your looking for. If one goes to a landing page like dah, dah, dah, how do you get to the many pages that are being discussed? Okay. And that's where I'm saying that at least for our

resources that I talked to you about, the Policy and Guidance documents, the toolkits, the Webinar recordings, the searchable FAQs, go and bookmark the ORD Policy and Guidance webpage. It's in your slides. That will take you to the bulk of things that we at least produce. Right? You can go there, and you can get from there most of the information. You know if you're looking for information on merit reviews and all of that you're still going to probably have to go to the merit review page. There's also a page, one step up from the human Policy and Guidance webpage that has additional information. That probably will comprise the bulk of the other type of research related information you need. But start with bookmarking the Human Policy and Guidance webpage. And that can really help you. So you're not having to save- Because we have, each of these have individual pages. They all have individual pages. But this one, you just go to that one and you get the bulk of what you need. Where can you find the ORD mailboxes for topics? Based on Soundia's example would it be under HRPP? Or informed consent? Yeah. You know, it's not under any of them. And so that's when I really realized when I was creating this presentation, that I was like, I don't think we've really done a good job on advertising the mailboxes anywhere. Similarly the Listserv probably, all the Listserv's that are available. So it's not in the FAQ, it's not even on any websites. So that's something that we need to do. And that only really came to light, you know with this presentation when I did it January 14th. So we either have to put it on, if anything I'm gonna try to get it on that ORD Policy and Guidance webpage, if we can get it on there without further cluttering it. Because again, I'm trying to get everybody to go there for everything. Okay? So stay tuned.

Kate: I'm sorry.

Soundia Duche: But I can also add it as an FAQ. So that's an easy one to do? And where would be it? HRPP or informed consent? For the mailboxes, it would probably be under mailbox. I don't know. Communications. I'd have to think about that. If you have suggestions put it in the survey.

Kate: Okay.

Soundia Duche: If you're not sure of the location in the FAQ of your question. For example, if I was looking for the answer as to who needs to be informed of a serious adverse event would it be under adverse event, or reporting, or both? Good question. And we had this come up last time. It should be under any of those, right? So a lot of times, and there is one question in there. Because we pulled it up under the last training. Somebody asked something about adverse event and reporting for a committee or something. And there was an FAQ there. And that FAQ was tagged with, because the nature of the question, it was tagged with SAE, it was tagged with reportable event, it was tagged with UAP, it was tagged with all of these terms that were associated with reportable events, because the nature of the question touched on most of them. So but you can always start with just reportable event. You can start with SAE if you don't get anything. Try bigger, I always say. So maybe start with reportable event and then hone in from there. We could probably take one last question Kate, because we're already at 4. Okay. I occasionally use the searchable FAQ database. My biggest problem is not receiving search results. Could it be I'm not using the correct keywords? It could be. But honestly I think

it’s more that probably the information isn’t in there. I’ll be honest. What came to light from the last training is people said, what would be nice is having some type of dictionary of common keywords that are associated with topics. And so we’re going to figure out how best to do that. And place it on the page. Right? We don’t want you to have to go looking elsewhere. So it could be you’re not using the right keywords. But again, if you think bigger, right, you should be able to catch it. Once we include, and you look at the list of what’s not in the database, you’ll see unfortunately right now there’s a lot that’s not in there. And so that’s probably the problem. I know we didn’t get to all of the other questions, I don’t want to take us over. I am just curious, how many questions didn’t we get to, Kate?

Kate: There’s approximately 4 left.

Soundia Duche: Okay, perfect. So I will try to get through those questions and get back to people who had those questions. And I know that doesn’t benefit those who didn’t attend, right? So maybe what I’ll do is- I don't know. We’ll figure it out. We’ll figure it out.

Kate: [laughs]

Soundia Duche: [laughs] But anyway, I’ve got a lot of my plate from this. So I’ve learned so much from having this training in terms of what we need to do to do better. Help me, help me by completing the survey, letting me know where we can help you all more. What you want to hear this coming year, where you want us to focus our efforts, what’s challenging for you. So as we design our education and training curriculum, as we design what tools and things we need to focus on, we’re doing so with your needs in mind. Last year was COVID intensive. You know? And so some of our efforts on doing additional things got put on the backburner. But I think this year, we all kind of are more hopeful that you know, hopefully we’re more used to kind of managing under the current situation. But hopeful that you know the end is in sight in terms of our evolution of the situation that we’ll be able to get back to some of the basics that we weren't able to get to last year. And so with that, thank you all for participating. We hope you like the new platform. It’s different. We get that. But this is it. [laughs] All right? So this is what it’s going to be for us. Hopefully, you guys can all get on, because that was a big problem with GoToWebinar. All right, guys, thank you and have a great evening. Bye-bye.

[END OF AUDIO]