Angela Foster: Thank you Parker. Alright. Good afternoon everyone. Thank you for joining the VAIIRS monthly webinar for October. The topic for this month’s webinar is the Research Financial Conflict of Interest Module for Investigators and Committee Members. Our panelists today are Dr. Jeans from Regulatory Affairs. Mr. Christopher Britt from OTCs Ethics Specialty Team. And Tony Laracuente, Director of Field Operations for ORD. Thank you Karen, Christopher, and Tony for joining. So before we jump into the content of today’s webinar, we want to make sure that we clear up any misconceptions regarding the COI module.

First use of the module is optional. There is no mandate that requires use of the IRBNet COI module. Nor is there any mandate to change your existing COI submission and review processes. For investigators on the call, you will continue to follow the guidance provided by your local research office and COI administrator. The IRBNet COI module is not associated with any directive or mandate. The proposed Research Financial Conflict of Interest Directive is still in the review process. And at the present time, we do not have an expected date of when the directive will be published.

The module is offered as a convenience and your site may determine whether or not you choose to use the module. Dr. Jeans, Mr. Britt, and Mr. Laracuente are on the call to answer any questions that you may have related to the COI policy or processes. The purpose of today’s webinar is to provide an overview of the module from the investigator and committee perspective. If after viewing the functionality, your site would like to use the module, you may contact IRBNet support or you can contact VAIRRS at the vairrs@va.gov to request that your COI administrator be given more in-depth training on the module. Next slide please.

So we’ll review the three-step process to create and submit a COI disclosure and how to view the status of COI review. The process is a very straightforward and I expect we’ll have plenty of time at the and to answer any questions. You will see the optional use statement throughout the presentation. This is to reiterate the optional use of the module for anyone that may join the webinar after our announcement. Next slide please. One of the primary benefits of the module is the conversion of the paper OGE 450 VA to an electronic smart form.

The smart form mimics the original form and also allows for electronic signatures. The roles that interact with the module are the investigator, COI administrator, oversight committees, and the ethics specialty team. Today’s session will focus on the investigator and committee perspectives. Again, the COI training session on the use of the module is much more detailed and available to any site that chooses to use the module. The COI training is hosted by IRBNet and specifically focuses on the use of the module. Any policy or process related questions can be addressed at the end of the presentation. Next slide please.

There are three steps to create and submit a COI disclosure in the IRBNet COI module. Those three steps are creating the disclosure, linking the disclosure to a project, and submitting the disclosure to the COI admin for review. And we’ll cover each of the steps in the following slides. If an end-user is affiliated with a site that has chosen to use the module, you will see the MY COI button in your left menu. If you are affiliated with more than one institution and one of those institutions has chosen to use the module, you will see the My COI option available to you. Selecting the My COI button will open your COI page. At the top of the page, you’ll see the create an initial interim or annual disclosure link. Next slide please.

The next section includes a search function that allows you to perform a string search of the project field, which also includes the IRBNet ID of the project associated with the disclosure. You can also search the Doc ID, which is the identifier for each disclosure. You can also set your filter buttons to search for disclosures that have been shared with you or disclosures that have an action pending that you must complete to move forward in the review process. Next slide please. The final section on this page is your disclosure queue. This section resembles the project queue on the My Projects page. The Doc ID is the first column. That is the unique identifier for each disclosure. The project field is that IRBNet ID and project title for the project associated with the disclosure. The disclosure type is represented in the purpose field.

Date of the disclosure was last modified. The review status. A next due date which would be assigned by your COI administrator. And there’s also a series of icons. The single page icon allows you to view a PDF version of your completed smart form. The series of paper icon opens the document history of the form. The pencil icon allows you to edit your smart form. The lock symbol represents whether the disclosure is locked or unlocked. Similar to a project, the disclosure is automatically locked upon submission to your COI admin. The admin has the capability to unlock the disclosure submission in the event that edits are needed or if more information is required. The final piece in that little section is the view summary link and that will open the disclosure summary page. Next slide please.

The contents of the disclosure summary page include a summary of the disclosure submission along with messages sent or received in the COI module. The submission history for the disclosure and assigned due date for the next COI submission. And you can also see a list of all interest that were included in the disclosure submission. From this section, you can select the interest type, which is in blue, which signifies it’s a link. Or you can select the details link to view the disclosure detail page. Next slide please. The disclosure detail page provides details for each interest that was disclosed when you completed your smart form. From this page, you can access any documents that were attached, the review status, published board documents, and the management plan details if one exists. Note that the published board documents and management plan details are completed post review. So you would not see anything in those sections prior to the review of your COI submission. Next slide please.

So to begin a new disclosure, you will select the link at the top of your My COI page, create an initial interim or annual disclosure. Next slide. From here, we will start to build your disclosure submission. the first thing that you will do is select the project drop-down, and from here, you will select the project that is associated with your disclosure. If you have not already created the project, you can select the blue link that says create the project. And from there, you can create the project. All projects step that appear on your My Projects page will also appear in this drop-down, even projects that are a work in progress will appear here for you to select. The next field is select a COI form. And this is where you will select the OGE 450 Alt VA smart form. Finally, you will select the disclosure purpose annual initial interim and then you will select continue to be taken to the smart form. Next slide please.

We won’t walk through the smart form; however, we would have a PDF output of what that smart form looks like. And Kat if you can open that PDF now. And just give us a minute to switch over. And while we’re waiting, the smart form if there are no disclosures, the smart form takes…or no interest to disclose, a form takes less than a few minutes to complete. It’s logic-based like all of the smart forms in IRBNet, so depending on a response, you may be prompted for more questions. The form allows you to sign electronically. If you could scroll down Kat to the very end so we can see the signature section. There we go. There we go. So at the end…scroll back up just a little bit please. Yes. At the end of the form in the acknowledgments section, you are provided the capability to record your initials and signature in the smart form and they will be printed here on the PDF output. So there’s no need to download the form, sign it externally, and upload it back into the system. All of that can be done within the actual smart form. Alright, I if we can go back to the slides now. Wonderful. Thank you. And onto the next slide please.

So once you’ve completed your smart form, the next step is to link your COI submission to an actual package in IRBNet. Next slide please. You will move from the CO module to your My Projects page. From there, you will select the project and in most cases, this will be the first package if you’re submitting for an initial disclosure. However, if the project is already established, let’s say for instance you’re submitting an annual disclosure, you will create a new package within that existing project. You’ll want to make sure that all study team members have been provided access to the project in IRBNet, otherwise, you won’t be able to link their COI submission to this project. To link the disclosures for you and your team, you will select the link/unlink COI disclosures located at the bottom of the designer page. Next slide please.

Again, in order to add disclosures for your study team members, those users must be shared on the project, and they will need to complete their COI disclosure in their account. From this page, all users shared on the project with the COI disclosure will appear in this list and you can select the appropriate disclosures to link to the package. Next please. So active you’ve linked the…or selected the appropriate disclosures and selected save, the next step is going to be to submit your package to the COI administrator. Next slide please. You will select the submit this package button strike if you were submitting a study action or any other action for your project. Make sure you select the correct workspace for the submission. Your local COI workspace will appear as a default board. If the investigator is affiliated with multiple sites, the COI board for the institution identified on the project will appear in this default list Next slide please.

While submitting the disclosure, you can select the submission type as disclosure and add any relevant comments. The next step will be to select the submit button. Once submitted, the disclosure is immediately sent to the COI administrators workspace and the COI administrator receives a notification to alert them of the submission. So once the COI submission has been forwarded on to the COI admin, the investigator and committee can view the status of that review. Next slide please. So for the investigator, the status is available on your My COI page or by opening the project itself and going to the project overview page. The project overview page will provide review level information for the COI submission package and the COI status for each study team member. Now you cannot see the details of another user’s COI submission, only the status of the review. You can also view the review status and details of your COI submission on the My COI page. Next slide please.

Now for committees, the COI status is also available on the project overview or the submission detail page under the project team tracking. Now there are three different icons that you will see in this COI column next to the username. They are three different colors of triangles. So there’s a yellow, a green, and a gray. The gray signifies that there has been no COI submission in IRBNet. The yellow signifies that there has been a submission and it is pending review. And green indicates that review is completed. Next slide please. So that again, was a very straightforward process. It was all of the steps that are needed to create a COI submission, link that submission to a project, submit it to your COI administrator and how the investigator or committee can view the status of the COI review. Again, I just to reiterate that use of the module is optional. If the module’s functionality supports your existing process, you are more than welcome to use the module. However, there is no mandate that requires use of the IRBNet COI module. Next slide please.

And we do have a few frequently asked questions that we’ve received for the sites that had early access to the module. One is, what if the project isn’t listed? And again, in this case, you can either exit out of the module and go to your My Projects page to create a project. Or you can use that convenient little link that was right there that allows you to jump over to your My Projects and create the new project. If a study team member is not listed when you are building your disclosure or your package, either they have not been shared on the project or they’ve not completed their disclosure form. So you’ll want to verify that that user is shared and if they are shared, then you will want to follow up with them to make sure they complete their disclosure. Where can you get help with questions about a disclosure or how to submit a disclosure? For sites that choose to use the COI module, your COI administrator will be provided extensive training and will be able to help you navigate. They can also reach out to the vaiirs@va.gov email address and we will also provide assistance. Or if necessary, forward you over to IRBNet support. Next slide please.

Well, that concludes the presentation. We can now go over to our Q&A and get your questions answered. And just give us a minute as we bring your questions up. Alright, our first question. Why would a site not want to use this new module? What is the downside of using it versus the paper forms currently being used? So I’ll take the first stab of that and Karen, if I misspeak, please jump in. So the module has a defined process. Not all sites use that process. So whilst our hope is that sites will find it useful based on your local procedures, if your process doesn’t fit with the module, then it’s up to you to make that decision of whether or not you’ll want to use the module.

Karen Jeans: So this is Karen. And Andy is right. Indeed it’s right. When the bank takes advantage of the COI module it’s at the smart form. But indeed, it does have a defined process. This process cannot be modified. So if that process is alignment with your VA facilities process, then it would be up to your facility to determine whether or not it wishes to use \_\_\_\_\_ [00:25:35] module or not. So that’s why it is optional at this time. Thank you.

Angela Foster: Alright. If a PI is on many projects, can you search for a project when you create a new COI disclosure, or do you always have to scroll through the drop-down menu? So you do need to scroll through the menu. There is no search capability within that drop-down field. How do we eSign the smart form? I think I missed that. No you didn’t miss it. We did not go through in demo the actual smart form itself. But if you use the module and you’re completing the smart form, at the end of the smart form, the user must enter their initials and that information is then populated into the PDF output along with their account credentials that are used to sign the form. To sign the COI smart form, is that done with IRBNet credentials or some other means? That is done with your IRBNet credentials.

We were initially told that financial COI forms should not be a part of IRBNet. But now it seems like it is. Has something changed? If we are using paper forms, can they now be uploaded into IRBNet? What changed is the COI module. Prior to the deployment of the module, we only had committee workspaces for the RNDC and subcommittees. So with the deployment of the module, we now have a secure partition section where the OGE 450 can be completed. You can upload if you would like only in the COI module, not in the standard committee workspaces. But that’s a great question. Thank you for bringing that up. When would someone share a COI with you as a researcher? Well, I’ll turn that to you Karen. I believe that gets into more of the requirement of the COI of who completes the COI.

Karen Jeans: I mean, when would someone share a COI with you as a researcher? I mean with you…or I mean, if we’re talking about the financial disclosure, I’m actually not sure what we’re asking here. That’s my problem when I’m trying to interpreted it. The researcher is going to complete the form, the form is going to be sent to the SCOI administrator depending upon whether or not…what is the review it’s going to be sent. Yes or no to OGC ethics. OGC ethics is going to evaluate whether or not there is an actual COI. And then the committees are never…and please, something that’s very important to emphasize, the committees are never going to get the actual nature of the disclosure in terms of, for example, let’s say Karen Jeans has stock in Glaxo. That’s never going to be disclosed to the committee. It’s whether or not that if one existed that it was resolved or not. So that’s another important issue.

Angela Foster: Thanks Karen.

Karen Jeans: For that question, please follow up with us. Thank you.

Angela Foster: Alright, next question. Must COIs be manually linked or will they automatically show up in project team tracking similar to trainings? If your study team member is shared on the project, then they will appear in project team tracking just as they do today with the training information. The only difference is that there is a new column for the status of the COI review. But the user must be shared on the project. Can a COI disclosure be linked to multiple projects or does a new one need to be filled out each time for each project? No. The COI disclosure cannot be linked to multiple projects. Each COI disclosure is distinct to an individual project.

Does each investigator have to create a new package or is it one package for all investigators for a given submission? So for creating the COI disclosure, each investigator would need to do that in their own account. However, when you are submitting the package for review, then all of those COI disclosures are linked to one package. If a PI submits a disclosure and our local COI admin wants to submit it to OGE for a review, can that be done through IRBNet? Yes. There is a workspace for the OGE specialty review team and the COI administrator will know how to submit it to that team once they’ve gone through their training. Where does the COIs go who reviews them? So the COI submission is going to your COI administrator at your site or whatever site is assigned to review your…conduct your COI review. And the COI administrator is the individual who actually performs that review.

How is the investigator’s signature recorded on the smart form? I believe OGC found objection if an investigator provided an electronic signature that did not include their VA email. Or VA digital signature making the form completion problematic if the investigator was wanting to complete a COI from a non-VA computer. The smart form prompts the user to enter their information, their initials for the initial section, as well as their name, email, and other credentials in that second section of the acknowledgment area. And that is what gets populated onto the PDF form. Will there be an option to receive a COI determination letter that can be used for IRB submissions. The committee can access or see the status of the COI review and the project team tracking. We do not have any letter templates right now in the workspace. If that’s something that your site needs, then please reach out to us and we can start that discussion on how to upload a determination letter template.

Karen Jeans: Yeah, this is Karen. I’m sure that the individual…very glad someone asked this, for many of our affiliate, many of VAs do not use external VA’s IRBs, so excellent. Thank you for asking that question.

Angela Foster: The COI module is used for VA CIRB and local IRP. That’s a question. So it’s up to your facility to decide whether you want to use the COI module. The second part of this question is, does the COI module replace uploading COI’s for initial VA Central IRB studies? Dr. Workman our IRB network administrator could not join us today however, to speak for the central IRB’s processes. However, they do have access to the module, and they will be communicating about their requirements on whether or not they want to continue their current processes or just use the module to confirm COI review.

Karen Jeans: And this is Karen again. I want to reinforce that again; research financial conflict of interest disclosures are required by VA investigators of any VA research not just human subjects. So I want to make sure that that is emphasized as part of this webinar. Thank you.

Angela Foster: Can you remind us how sites request to get the module if we decide to use it? So you have two options. The first option is contacting IRBNet support directly and your local IRBNet administrator will know how to do that. Your second option is contacting us at vaiirs@va.gov and we can facilitate that communication with IRBNet support. When the COI directive is published, will the use of the module within VAIIRS be mandated? Karen if you could take that question.

Karen Jeans: I would be more than happy to take that. So as many of you are aware, VA has not had a research conflict of interest policy in decades. In fact, to my knowledge ever. And so indeed this year the research financial conflict of interest directive was placed into pre-concurrence. Part of that pre-concurrence was indeed use of a model, an electronic model to ensure consistency. And so, yes, there will be…the plan is again, this is graphed. We’re not at final stage yet, but it is anticipated that we will indeed…ORD will mandate the use of this module as part of the ORD policy directives for research financial conflict of interest reporting. Thank you.

Angela Foster: Does IRBNet track when a financial conflict of interest is required who was an investigator? No. IRBNet does not distinguish between an investigator and a non-investigator as a study team member. That is up to the individual study teams to track that information. Does this remove the necessity for a concurrence form? And I’m not familiar with the concurrence form. Karen, are you familiar with that?

Karen Jeans: This is Karen. This sounds like a local requirement for some. This is not again derived from a policy requirement nor am I familiar what the concurrence form is for. So this may be part of your local VA facility’s processes. So the answer is, we don’t know because there is no concurrence form that is required as part of this. This would go back your local policies. Your local requirements. Your local SOPs. Thank you.

Angela Foster: I created a package with the study components consent protocol forms, but then when I created a COI, that made a new package. Once I submit the COI package, how do I submit the actual study documents package? So this is a great question. Actually, the COI package would be a separate package than the actual study documents package. Now you may need to upload your protocol or other supporting documents within your COI package. However, when you go to submit your actual project to the research administration workspace, that will be a separate package. So just to restate that, your COI package for instance will be package one. That goes to your COI administrator. When you’re ready to submit the project for review, that would be package two and that would be submitted to your research administration workspace.

Can a site have more than one COI administrator? I believe that functionally there’s no reason why more than one administrator could access the COI module. But again, this goes back to your local procedures and processes and identifying who your COI administrator or administrators would be. I understand this may not be a question that can be answered, but will there eventually be a mandate to use this module or do you think it will stay optional? And I believe Karen has already answered that question.

Karen Jeans: Yes. And again, when a directive does come out, again, the modules processes will sync with the director’s policies. So that’s why they will correlate together. So that’s why it is optional at this time. Thank you.

Angela Foster: Do projects that are submitted requesting non-research determination also require financial conflict of interest form? Karen.

Karen Jeans: I’ll take that. Yes. If the project request a non-research determination, then if it’s not research, there’s no VA investigators. Only VA investigators are required to submit the FCOI form OGE 450 Alt that is linked to a specific research project. So the fact that you’re submitting a request for a determination does not trigger with the response…the requirement to fill out the OGE 450 Alt VA. Thank you.

Christopher Britt: This is Chris from OGC. This will complete that answer. This is a general matter. If you ever have an ethics question, if it’s not attached to a research project or a study where you’re an investigator and you think you might have a conflict, then that’s something instead of submitting the Alt 450, you would just send that directly to the ethics specialty team. So just come to us with those kinds of questions.

Angela Foster: Thank Karen. Thank you Chris. Next question. Can the local facility require the use of the module? Again, that is a local decision. If you decide to use the module, then you can communicate to your investigator community about the new procedure for submitting a COI disclosure. If a site decides to use the module, does everyone affiliated with the site automatically get access to the My COI tab? Yes, you do. Any user affiliated with that site would have access to that My COI button, and your COI administrator would have access to the review module.

I don’t think we have the COI module option at our IRBNet site. I don’t see that option. How do we enroll? The first thing that you would need to do is have your local administrator reach out to IRBNet support or you can contact us at the vaiirs@va.gov email and we can get you started on use of the module. Does IRBNet require all staff tied to the project to complete a disclosure? Who determines who is required to complete a disclosure? I just want to address this first part, and then I’ll ask Karen to help. But IRBNet is not a governing body. IRBNet is the vendor of a software product that we use to facilitate and support our processes at VA. As far as who determines who is required, Karen if you could help answer that portion of the question.

Karen Jeans: Absolutely. Again, the form, the OGE 450 Alt VA specifies very clearly that is the requirement of the VA investigators. Again, it’s federal employees. We are required to follow the federal ethics laws. And again, the whole development of the OGE 450 Alt VA came out as result of issues involving this agency’s requirements to comply with federal law. So again, the form makes it very clear. VA investigators…if you’re a VA investigator listed on that project, you are required to complete the OGE 450 Alt VA. And Chris I will defer to you if you have any other comments you’d like to add on this.

Christopher Britt: Sure. If the question is about people who are not investigators, non-investigator study staff who think they might have a conflict, again, just send that directly to the EST. I would prefer they not fill out the Alt 450. Just send us the question, put the facts in an email and we can help you determine if you have a conflict. But again, if you’re an investigator, you do you have to submitted the Alt 450.

Angela Foster: Thank you. Can we upload waivers if they exist and relate to a project? And I am not familiar with the waiver for COI. I’ll defer to Karen or Chris to respond.

Christopher Britt: So I assume this is referring to a 208 Waiver. A 208 is a primary conflict of interest statute and for some investigators or some employees they receive a waiver which is a memo that says, even though you have a conflict, you are permitted to work on this thing, this study or whatever it is despite the conflict. So yes, if you do have a waiver that you think applies to the study at issue, then that would definitely be good for us to know so that it would accompany the Alt 450. So Angie, I think they can. The technical question, they can upload supporting documents including the waivers, so yes, that would important for us to have. Of course, we have that in our records, but we deal with a lot of issues, so we don’t always know off the top of our heads if someone has a waiver, so it would be helpful for us to be reminded of that.

Angela Foster: Thank you. Does the system require every one of the users shared on the project to complete the COI forms? so again, the system does not place requirements to do anything. The system only supports what your local procedures require. So the users that are shared on the project will appear in project team tracking. The icons will show gray if that user has not submitted a COI disclosure. But as far as the requirement, that is left up to you all to state in your procedures. This is a smart form. How will the information that is being collected be used? The information that’s being collected in the smart form will be used by your COI administrator to perform their review. There’s no other use case for that data that’s collected in the smart form. That information is protected. We are not getting any reports or aggregate data or anything of that nature related to the COI module. I know that we have a lot of our data presented on the VAIIRS dashboards, this is not intended to be used for any other purpose other than COI review. Besides the PIs, is there anyone else on a study who would need to complete a COI? And I defer to Karen and Chris for this question.

Karen Jeans: So Chris, I’m going to give you an example of one where I did for the audience here of one I gave…that I did defer myself. The keyword is, need versus require. So again, the VA form OGE 450 Alt is required be completed by VA investigators. But I had a study where the study coordinator had a relationship in terms of the…a financial relationship with the company that was conducting the study and she indeed did presentations on their behalf. Now again, she’s not a VA investigator. But that was one where indeed, I referred that to the OGE ethics specialty teams for their advice and evaluation of whether or not this individual had a financial conflict of interest that needed to be managed. And that’s one example where I had one that again, didn’t fit under VA investigator. And then I’m going to defer to Chris for his additional comments on this as well.

Christopher Britt: Well, this question asked PI. So let’s be clear, it’s not just PIs. It’s all investigators.

Karen Jeans: Again, \_\_\_\_\_ [00:49:49] also be clear for a completed COI, in terms of the OGE 450 Alt VA, any VA investigator has to complete it. So that’s just not the PI, that means the CO, a sub. But that is required for the OGE 450 Alt. But again, the example I just gave is where one with a study coordinator who had a financial conflict of interest with the company that she herself was doing the study with. And so that’s where I referred that to OGC ethics and they determined…she did not fill out financial conflict of interest form, but OGC ethics was involved with the consultation involving that individual. And that’s just one example that I have regarding that.

Christopher Britt: Right. So that just reiterates what we discussed earlier which is that anyone can have a conflict. Investigators have to submit the form and for someone research staff who’s not investigator who thinks they have a conflict, just contact the EST and we’ll work you through that.

Angela Foster: Will there be a list of those VA sites that have chosen to use the COI module? This would be a helpful resource for the multisite projects. So the PISC, CSPCCs, can know how the COIs will be routed and processed. So this is a great question. It’s not something that we’d considered publishing a list of sites that use the module. But I will definitely take this back and discuss it with Dr. Jeans and Mr. Britt and the central IRB, and we can determine whether or not a list should be published or not. Can we try this out in the training environment before making a decision? So yes. The COI module is available in the sandbox. There is a specific login to act in the role of the COI administrator. In order to obtain that login information, please have your local IRBNet administrator contact IRBNet support letting them know you’d like to try out the module in the sandbox and they can provide those credentials to you.

Is the smart form downloadable in case we are required to request an ethics review because of potential conflict? So if you need to send the COI to the ethics specialty team, that can be done directly in IRBNet, and your COI administrator will have the instructions to do so. But separate from that, the smart form PDF version is downloadable. Are study staff able to submit signed COIs on behalf of investigators with this new system? No. The only user who has access to the COI smart form is the individual user that owns the account. If a study team member shared on the project is not required to submit a COI form, will there be an indication that they are not required to submit one? I.e., how can the reviewer tell whether a particular study team member needs to submit a COI form? So I’ll give my perspective on this and then defer to Karen or Chris if they want to add anything. But the system itself does not distinguish between an investigator and a non-investigator. All individuals shared on the project will be included in the project team tracking section. And as far as the local procedures for identifying who is required to submit the form, I’ll defer that to Karen or Chris.

Karen Jeans: So again, it goes back to take us out of COI module itself. Again, it’s like even right now, how do you know whether or not you have something that needs to be sent to Chris for example? And again, it goes back to the training that all of us take regarding ethics training. And if there is something that we feel that needs to be reported, it needs to be reported. Now again, this is where the OGE 450 Alt VA came into play because we did have inconsistent reporting by VA investigators across the system and that’s how this is being standardized. But otherwise again, this is why this directive is coming out to discuss what do you do when you’re not a VA investigator. A reviewer can’t read minds. And so you when you have a list of names and they’re not a VA investigator, how do you know? You won’t know unless you have information that’s provided to you. And that’s again where we get into these scenarios where when someone finds out about it, that’s what it needs to be referred. And Chris if you have any other comments on this, I’ll welcome them.

Christopher Britt: No comments here.

Angela Foster: How do the COI administrators create determinations if there is a management plan that needs to be communicated to the investigator similar to committee determination letters? So the COI administrator has a separate toolset that we did not review today but would be reviewed in the COI admin training session. In that toolset, they can add discussion…sorry. They can add remarks to their review results, and they can also upload documents. So that would be functions that are reviewed at the COI administrator training session. On the financial conflict of interest form, it requires reviewing official signature. So how would we get that signed if the PI is the one submitting the form? Again, referring back to the toolset in the administrator’s module, they have the capability of signing for that review…in that reviewing official section. Not specifically related to the module, can Karen comment on what type of disclosures need to be bumped up to OIG for advice?

Karen Jeans: I think I’ve given some examples. That’s non-VA investigators. When it comes to the form itself, again, when there is a positive yes response on this, what we want is the SCOI administrators to look at that and see whether or not is it truly a…was the box marked correct or is it a false-negative. So it’s not the OIG either. It’s not the Office of the Inspector General. It’s OGC ethics. I think that’s just maybe a typo there. Because normally, the disclosures don’t go to the IG. They go to the different OGC ethics attorneys. So that’s the philosophy that we’ve been using and then some examples that we’ve given in this webinar today. Thank you.

Christopher Britt: And I’ll say, I’m working on some guidance that will be distributed to the FCOI administrators at some point regarding this issue of what to look for, how to review, what you can handle at your level, what to send to OGC. And we’re still working through that. But I think I’d echo what Karen said which is, really understand what the investigator is reporting. If it’s not clear what they think their conflict is, you should go back to them figure out what the actual facts are and if you think it’s a conflict, you can send it to us. But there will be information forthcoming regarding what you can handle at your level and what should be sent to OGC.

Angela Foster: Does this replace the VA Central IRB 115C supplement? No. Until the Central IRB issues instructions on the replacement of any form or a change to their procedures, everything continues as it has. The Central IRB again, Dr. Workman was not able to join us today. But they will be issuing instructions in the near term. But for now everything stays the same until you are instructed to do differently. Can a study coordinator place the FCOI for the PI? PI did the initial, study coordinator checks that nothing has changed, enters the form. So again, the only user with access to an individual’s COI smart form is the owner of the account. Even if a study coordinator is shared on the project, that study coordinator does not have access to the PI’s COI module. How does this process differ when the person completing the COI module for the project renewing their COI? So I believe this is asking about an annual submission or an interim submission. The process is not any different. That individual would go in, create their COI submission, create a new package in their project, link the COI submission to that project, and then submitted to the COI administrator.

Moderator: Angie, I think we can fit in one more.

Angela Foster: Okay. Does this connect with Central IRB to avoid filing both at the site and for Central IRB? So again, Central IRB was not able to join us today. However, until they issue any instructions that changes their existing process, everything stays the same for the Central IRB. And I believe that’s the last question that we have time for. If we did not get to your question, we will be sending out the Q&A in a written form so that we’ll have an opportunity to answer your question and get you a response.

Moderator: Fantastic. Well, thank you Angie as well to Karen and Chris. Thank you support staff as well in background for the panelists. And thank you audience for joining us today. As Angie said, we’ll be following up with that written Q&A. And as a reminder, if you all could take just a minute or two to fill out our post webinar survey, we would greatly appreciate it. Thank you all for coming and have a good afternoon.

Angela Foster: Thanks everyone. Bye-bye.