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>> The broadcast is now starting. All attendees  
are in listen only mode.

>> Welcome to the NIH webinar on financial conflict  
of interest reporting requirements. And a  
demonstration of the eRA Commons FCOI module. My  
name is Cynthia Dwyer. I am a communications  
specialist in the NIH Office of Extramural Research.

We are very happy to be hosting this event today and look forward to spending the next hour and a half with you. There will be a recording available approximately three to five business days after this event. You'll be able to find it on the nice FCOI website at that time. Kathy Hancock is one of today's presenters and she'll be discussing the Q and A procedures for today's webinar momentarily. However, if you have any technical difficulties, please use the chat box located in the webinar toolbox and send an email to our organizer.

This webinar today is presented live, but without a camera. Therefore, to help give you a better idea of who you are going to be listening to over the next hour, I want to show you a couple still photos of Kathy Hancock, who is our customer relationship manager. I'm sorry -- of Kathy Hancock, who is our NIH assistant grants compliance officer and Scarlett Gibb, who is our NIH customer relationship manager for the eRA Commons.

And now, what you've been waiting for, on with the show, here's Kathy Hancock.

>> Thank you, Cynthia. Well, welcome, everyone. The purpose of the webinar is to review the reporting requirements applicable to the 2011 Revised Financial Conflict of Interest regulation that affects NIH grants and cooperative agreements.

The webinar will also include a live demonstration -- as Cynthia mentioned, to show how to submit FCOI reports and other related reports in the updated eRA Commons FCOI Module.

We also will review the different types of reports that are now required and other actions that can be taken within the Module that are related to FCOI.

After my presentation, Scarlett will provide the demonstration using some test data to explain the enhanced features within the module.

And lastly, we will provide an opportunity to address your questions related to FCOI reporting requirements. We are close to 1,000 log-ins for this webinar; therefore, we encourage you to limit your questions to FCOI reporting requirements, only, and ask that you send any other FCOI-related questions or any questions we are not able to address during the

webinar to the FCOI compliance in-box.

The email address for the FCOI Compliance mailbox is provided at the end of the slide set on Slide 46.

We can't begin without providing the regulatory citation numbers and the web links for the regulations governing investigator financial conflict of interest. This information is here on the slide for your reference and information.

As you know, these regulations were published last year on August 25th, 2011.

If you're not familiar with the revised regulation, we encourage you to review the resources we have made available on the NIH FCOI website, including a webinar, web-based tutorial and PowerPoint presentations with case studies.

The web address to access this information is also provided at the end of the presentation under information and resources, Slide 39.

Although we have included the regulation citation number for contracts, this presentation will focus on FCOI reporting requirements applicable to NIH funded grants and cooperative agreements.

So the implementation date of the -- of the regulation is fast approaching as many of you all know.

In fact, it's only 10 days away or on August 24th.

So this means that all NIH applicants and/or funded institutions must be in compliance with the 2011 revised regulations by this August 24th.

We know that you all have been working hard to implement all of the new requirements, including revising your existing policies consistent with the revised regulation. Please be aware that institutions should have their FC0I policies posted on their available public websites and have their FC0I investigator training programs in place by August 24th.

It's important to note that the regulation is not retroactive. So this means that it applies to each Notice of Award that is issued on or after August 24th. This is important in considering compliance with an implementation of the regulation.

So just as an example if your institution has a grant that's ongoing, for example, it was issued

before August 24th, the project is subject to the 1995 regulation until the next Notice of Award is issued on or after August 24th, 2012.

Therefore, depending upon when the NoA is issued, regardless of the budget period start date, the award may not be subject to the 2011 revised regulation until the next fiscal year award.

So what do institutions report to NIH?

Institutions are required to report any identified financial conflict of interest for its investigators and any subrecipient investigators, which includes collaborators and consultants. Therefore, when applicable, if a subrecipient institution is relying on its own FCOI policy, the subrecipient institution is responsible for identifying, managing, and reporting identified FCOIs to the prime awardee institution. The awardee institution has the responsibility for reporting identified FCOIs to the NIH.

Therefore, when the -- when an institution submits an FCOI report, the system has been set up to prompt the institution to address whether the FCOI report is

applicable to a subrecipient institution.

And this is nothing new.

If the institution chooses yes to the subrecipient question, the institution will be required to enter the name of the subrecipient investigator, the institution name, including all of the other data elements that are required for the submission of an FCOI report by the regulation.

So what is an FCOI or a financial conflict of interest?

As I said, institutions are required to report identified FCOIs for investigators to the NIH. An FCOI is a significant financial interest that an investigator or subrecipient investigator has, including their spouse and dependent children, that could directly and significantly affect the design, conduct or reporting of NIH-funded research.

We ask that you refer to the definition section of the regulation in 50.603 for a definition of SFI and for more information.

How are FCOI reports submitted to NIH?

FCOI reports are always submitted to the NIH for

grants and cooperative agreements through the eRA Commons FCOI module. FCOI module is the reporting tool and it can be accessed via the eRA Commons website. In order to get -- before we go ahead, in order to get a better idea of your audience, could you let us know -- if you are responsible for submitting NIH -- for submitting FCOI reports to NIH?

We'll let you know later the results of our poll.

Okay. So what are the features of the FCOI module?

The features of the newly enhanced module allow the institutions to electronically submit FCOI reports and supporting documentation. This obviously isn't anything new. But the enhanced module will now allow the institution to submit a new FCOI report, under initiate 2011 FCOI report tab, an annual FCOI report, revised FCOI reports and a mitigation report, which are all new with the implementation of the 2011 regulation. The system also continues to allow the institution to submit additional information when it's requested by NIH staff.

Other features of the module allow the institution to search and view FCOI reports and associated data

that was previously submitted through the Commons.

Institutions will continue to receive email notifications to confirm NIH's receipt of the FCOI reports and other related reports. And submit additional information after an FCOI report has been submitted as requested by NIH staff.

And lastly, a new feature has been added that will provide institutions with email reminders, when an -- when an annual FCOI report is due.

So how to get access to the FCOI module? To gain access to the FCOI module institutional Signing Officials must assign FCOI roles to users in the eRA Commons. There are three different types of FCOI roles. One is called an FCOI role and this person manages the FCOI reporting process for the institution. So the person or persons would be able to initiate, edit, submit, revise, view and delete records or documents.

Only the institutional Signing Official can assign the FCOI role. The second role is an FCOI assistant role. The person or persons serving in this capacity can assist with data entry and completion of FCOI

reports.

And third role is the FCOI view only role. The person or persons with the FCOI role can delegate the view only role to a person or persons within the institution. And this role allows individuals to view information that has been submitted by the institution in the FCOI module.

So what additional information is required in a 2011 FCOI report?

Well, as I mentioned, the new features were added to the FCOI module this past June to collect the additional information that's now required by the 2011 regulation. So in addition to the information that was provided under the 1995 FCOI report, the new information to be provided includes the name of the entity, with which the investigator has a financial conflict of interest; the nature of the significant financial interest, the value of the significant financial interest within the prescribed dollar ranges that are included in the regulation; a description of how the financial interrelates to the NIH-funded research and why the institution

determined that the financial interest conflicts with such research; and, lastly, a description of the key elements of the institution's management plan.

The enhanced module has been designed to capture this additional information when the institution chooses the tab initiate 2011 FCOI report.

The system prompts the user to insert the name of the entity as it appears on its public website. The user is also instructed to select from a drop-down menu the nature of the significant financial interest, with choices such as equity interest, non-publicly traded entity, intellectual property rights, payment for services, other, et cetera.

Note that when you choose other, the institution is prompted to provide an explanation that describes the significant financial interest in a text field.

Continuing on the user is also prompted to select the value of the significant financial interest from a drop-down menu.

The module also prompts the user to include a description, as I said before, of how the financial interest relates to the NIH-funded research and why

the institution determined that the financial interest conflicts with such research.

This information is submitted via a text box or in an uploaded PDF file. So please be sure that the information submitted is complete and it includes the data elements required by the regulation.

The FCOI module displays a listing of this required information on the screen to remind institutions about the specific reporting requirements.

The institution is also prompted to submit a description of the key elements of the institution's management plan, which is also displayed on the screen for your information and assistance.

And again this information is also submitted via a text box or an uploaded PDF file.

We discourage institutions from submitting a copy of the management plan itself, since any information that's submitted to NIH is subject to the Freedom of Information Act and is foible. In addition, although it's not required, it would be helpful if the institution submitted this information in the format that's provided in the regulation and as shown in the

following slide. Although it's not a requirement.

We again remind you to be sure that the FCOI report is complete and contains the required information before it is submitted to NIH. Because any incomplete FCOI reports will be rescinded by NIH staff, requiring the institution to resubmit a new report.

And as previously mentioned, this slide just provides the key elements of the management plan that are -- that are to be included in the FCOI report.

So what additional information is required as part of the FCOI module? The institution is also required to address a question to verify whether or not the FCOI report is submitted in compliance with the regulation. So the module includes a compliance question, which reads as follows: Does this FCOI report include a failure with the FCOI regulation?

So you may ask how is non-compliance with the regulation defined? Well, the institution should choose yes to the compliance question if an FCOI is not identified or managed in a timely manner for any of the following reasons: One, the investigator

failed to disclose a significant financial interest; two, the institution did not review or manage a financial conflict of interest; or, three, the investigator failed to comply with the management plan.

This information will be provided in a help screen and will also be added in the FCOI user Guide to assist the institution in addressing the question.

Now, if the institution chooses yes, the institution will be required to address other questions related to the completion of a retrospective review and the need to submit a mitigation report, if bias is found, upon completion of the retrospective review. As many of you all know, these new requirements are consistent with the 2011 revised regulation.

So what happens when the institution submits an FCOI report that includes non-compliance? In situations of non-compliance, the institution will choose yes to the compliance question. When yes is selected, an additional screen appears to allow the institution to address whether the retrospective

review has been completed. It's important to note that the retrospective review may still be ongoing when the FCOI report is submitted, since the institution has 120 days from determining non-compliance to complete the retrospective review. If this is the case, the FCOI report should be submitted, even though the institution will indicate no to the question addressing completion of the retrospective review. The system also allows the system to submit a mitigation report when bias is found following the completion of the retrospective review and it allows the system to submit a revised report if needed. Revised reports may be required when submitting a mitigation report following completion of the retrospective review or to update the previously submitted FCOI information or specify the actions that will be taken to manage the FCOI going forward, again, following the retrospective review.

More information about these reports will be provided later in the presentation.

Before we go further, let's get some information from you.

Have you gone into the newly enhanced FCOI module and clicked initiate 2011 FCOI report?

Provided here is a quick summary of the FCOI reports, the contents of each report and when they are required.

These reports are all provided to the NIH through the eRA Commons FCOI module. And we hope that this will be a helpful resource for you at your leisure to look at.

Now, we will begin to review each type of report.

How to get started, initiate 2011 FCOI report.

As we mentioned before, institutions may submit 1995 reports since the regulation is not retroactive. Therefore when the FCOI module is opened, you will see two tabs on the screen. One is labeled initiate 1995 FCOI report and the other is labeled initiate 2011 FCOI report.

The eRA Commons will retain the ability to submit a 1995 report for an undetermined period of time to accommodate the reporting of identified FCOIs during the period of awards that are subject to the 1995 regulation.

Let's proceed to provide instructions for submitting an FCOI report under the requirements of the 2011 revised regulation.

So how to submit an FCOI report for the first time.

To submit an FCOI report, under the 2011 revised regulation, you would choose initiate 2011 FCOI report. It's important to note that the institution must select this tab, the initiate 2011 FCOI report, when reporting identified FCOIs for the first time under any type of award. Whether it's a competing or non-competing. So the details of the identified FCOI can be provided to the NIH as required under the revised regulation.

Therefore, if an FCOI report had been submitted under the 1995 regulation, and the FCOI still exists, the institution will choose initiate 2011 FCOI report when reporting on the ongoing FCOI that is subject to the 2011 regulation. FCOI reports submitted thereafter are submitted as an annual FCOI report, for each future year, that is within the current competitive segment, unless the institution reports that the FCOI no longer exists.

So when to submit an FCOI report?

As was the case under the 1995 regulation, provide initial and ongoing FCOI reports to NIH prior to the expenditure of funds under an NIH-funded research project, and within 60 days of identifying a new financial conflict of interest during the period of an award.

And also annually as required by the 2011 regulation.

So when not to submit an FCOI report?

An FCOI report is not required if the conflicting interest is eliminated prior to the expenditure of NIH-awarded funds per the regulation. Now, we're going to go through the annual FCOI report.

The following information will address the submission of an annual FCOI report.

So when to submit the annual FCOI report?

As mentioned earlier, the 2011 revised regulation requires the submission of an annual FCOI report, so this is something that is new to the 2011 regulation. Clearly spelled out.

Annual reports are due at the same time as when the

institution is required to submit the annual progress report. And that also includes a multi-year progress report or at the time of the extension of a project. Therefore, if the annual progress report is due 45 days prior to the start date of the next year's award, then the annual FCOI report will be due at the same time. It's important to know that these reports do not need to be sent to NIH on the same day. But they should be submitted on or before their due date.

Also remember that annual FCOI reports are not submitted with the annual progress report because, again, all FCOI reports are submitted through the eRA Commons FCOI module.

NIH is developing some guidance now to address one-time submission of annual FCOI reports for FY '12 non-competing awards that will be issued on or after August 24th. So this information on this class of grants will be posted widely to the grantee community. So just stay tuned for that information.

When are annual reports submitted?

Annual reports are submitted following the submission of a fully detailed FCOI report, which

would be after the institution has submitted the report under the tab initiate 2011 FCOI report. Please note that if the FCOI report was previously submitted, under the 1995 regulation, and the FCOI no longer exists, no further action is required by the institution unless NIH staff requests information on the previously reported FCOI.

NIH's request for additional information will be submitted to the institution through the Commons as it does currently to allow the institution to provide an explanation regarding the status of the FCOI via a text box or a PDF upload.

So what information is required in an annual FCOI report?

After submitting the detailed FCOI report, the institution will be required to submit an annual FCOI report thereafter for each future year within the current competitive segment until the institution reports that the FCOI no longer exists.

The annual report addresses the status of the FCOI.

The FCOI module will prompt the institution to address some specific questions related to the

previously reported FCOI.

One question that will be asked is does the FCOI still exist?

If the FCOI does exist, the institution will need to provide -- does not exist, sorry, if the FCOI does not exist, the institution will need to provide an explanation in a textbooks or an upload or to upload a PDF file that provides the explanation. When the institution provides an indication that the FCOI no longer exists, the FCOI report is removed from further reporting requirements.

If the institution chooses yes to the question, indicating that the FCOI still exists, the institution will be prompted to address another question regarding the management of the FCOI. The system prompts the institution to address the question are there any changes to the management plan? If the institution chooses yes to the change in the management plan, the institution will be prompted to provide information in a text box or upload a PDF file to explain the changes.

Okay. So far we have discussed the requirements

for submitting a 2011 revised regulation FCOI report and an annual FCOI report that follows the detailed report. Now let's review the mitigation report. Since this is something new to the 2011 revised regulation.

So what is a mitigation report?

A mitigation report is only required when bias is found in the design, conduct or reporting of NIH-funded research following the completion of a retrospective review. This would be in situations of non-compliance with the regulation.

As you may recall, a retrospective review is required when there has been a situation of non-compliance to determine whether there was bias in the research.

When bias is found, the mitigation report describes the institution's plan of action or actions taken to eliminate or mitigate the effects of a bias.

So what to include in a mitigation report?

When required the mitigation report must include the key elements that are documented in the retrospective review, per the regulation; a

description of the impact of the bias on the research project; and the institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

So how to submit a mitigation report?

Mitigation reports, like all FCOI-related reports, are submitted through the eRA Commons FCOI module. The mitigation report can be submitted with the initial FCOI report if the retrospective review is complete by the time the FCOI report is submitted. Or if this is not the case and bias is found, following the retrospective review, the institution must submit the mitigation report by selecting the revised FCOI report feature. The mitigation report is provided via a text box or a PDF attachment that is uploaded within the system. Now let's discuss a revised FCOI report and when that may be required or used.

So when is a revised FCOI report required?

As we just discussed, revised FCOI reports are used to submit a mitigation report when bias is found following a retrospective review.

A revised report is also used when the institution

discovers new information following a retrospective review that changes a previously submitted FCOI report.

For example, if the institution discovers a different value of a previously reported SFI or if they need to report a change to the management of the FCOI from what was previously reported under the previously submitted FCOI report.

Note that a revised FCOI report is not used for correcting errors and reporting. So let's move on to see how an institution should handle this type of situation. But before we do that, I just wanted to show you a summary slide that we have presented here that includes the different types of reports related to non-compliance with the regulation. Again, we're providing this to you as a quick resource to help you understand the reporting requirements when there is an instance of non-compliance with the regulation, hopefully you'll find this helpful.

Okay. So you may recall the rescind feature within the FCOI module because again this is nothing new. This is the action to take when the institution

discovers that an FCOI report was submitted in error. Let's pause for a moment, though, to ask the folks another question.

Do you understand the difference between a revised and a rescinded FCOI report?

FCOI reports submitted in error should be rescinded and removed from submission. The ability to rescind a previously submitted FCOI report is not new. As I said. Institutions may request NIH to rescind an FCOI report when the institution discovers that an FCOI report was submitted in error. Some reasons to rescind an FCOI report may include submission of a duplicate FCOI report. Perhaps you inserted an incorrect name of the investigator with the identified financial conflict of interest or the name of the entity that you entered in the system was incorrect.

NIH will also use the rescind feature when an FCOI report was submitted but is determined by the NIH staff to be incomplete and needs correction. So what to do when the institution needs to rescind an FCOI report?

Institutions need to contact, in this situation need to contact the grants manager as identified on the latest Notice of Award.

The Institution is required to send in a request and provide an explanation why the report should be rescinded.

NIH staff will take the appropriate action to delete the record from the system.

Included on the slide is the NIH Office of Extramural Research financial conflict of interest website that includes many resources, including this and other -- which will include this and other webinar presentations.

Please look for some additional postings in the near future. We plan to post some information regarding FCOI reporting requirements and we also will be updating the frequently asked questions in the near future. So this concludes my part of the presentation. However, before we start with the live demonstration, we wanted to ask one more question.

Do you know -- let's see, tutorial posted on the FCOI web page -- sorry. This is the question: Do you know that there is a tutorial on the regulatory requirements that NIH has made available as a resource for training investigators about the revised regulation?

>> Thank you, Kathy, this is Scarlett Gibb and I have taken over the screen for a little bit. I'm going to now go into doing a live demo for you all.

One thing that we did want to do quickly was maybe give you some of the results on these surveys, I don't know about you all, am waiting with baited breath here for these results. As soon as we get those up, we'll be sharing the results with you. While we're doing that, I'm going to talk about the system that I will be using and it is the -- it's going to be the Commons demo site. We have put this site up for you all to be able to -- to play with and to use data and train. So if you need to get some information on the Commons demo site and train your own staff, please call the eRA help desk or email them and they will help you get yourself set up in the demo site.

Do we have the results, guys?

As soon as -- ah there they are. The results are up. Do you know that there's a tutorial. Well, quite a few of you seemed to know that there was a tutorial. 70%, that's awesome. Do you understand the difference between revised and rescinded reports. 45% understand, 45% partially understand. That's good, you guys are a fairly well-educated crowd out there. Have you gone into the newly enhanced FCOI module, the part that's close to me. Most of you have not. Well, that's great because in a minute I'm going to show you some of the stuff that's live here.

So do we have one more? Any more of that? One more response on the survey.

Are you responsible for submitting FCOI reports to NIH? Well, we have the right people on the call here, so that's great.

So let's go ahead and get into submitting, creating, initiating and then submitting a financial conflict of interest with the system. FCOI with the system. I am in the Commons demo site, and I am an FCOI user. You will see there's a tab here that says

FCOI. When you click on that, you will now see another set of tabs. These tabs are to search to initiate a 1995 FCOI report, and as Kathy discussed, this will not be going away, because these are still valid and needed for those that are not currently ready for the 2011. But we're not going to be demonstrating that today. Then we will be initiating a -- a 2011 FCOI report. So we're clicking on the FCOI report.

For 2011 to initiate it.

And this screen is -- is pretty familiar if you have done a 1995 report. If you haven't, this is the screen that you're going to see, this is how you start your report.

You are required to know the IC code, the serial number, the support year. And I have a sample one out there.

If you know the activity code of the grant, that's good, too. But it doesn't hurt. It helps the search but you don't need it.

You need to know the last name of the person that has the investigator with the conflict. Good old

Buggs Bunny is having conflicts today.

You do not need to put in the middle name. Remember this is not the PI's name necessarily. This is the investigator with the conflict. At this point you are asked whether you -- this is the subrecipient report or not. If it is, you will see this box will open up, you will need to identify the subrecipient institution's name. If it's not, it stays grayed and you cannot enter in there.

The primary institution is required to report for the subrecipient institution. Any time I get into a policy area, I'm going to let Kathy, I might be directing some stuff to Kathy.

So at this point you're going to validate this to make sure that the grant number is a valid grant number. We do not let you submit electronically until it has been funded. That doesn't mean that you are not going to be following your policy regulations, but electronically it has to be funded at this point. Now it opens up the bottom portion, which is the 2011 difference. At this point you will put in the entity. That -- that is the entity where your significant

financial interest is. And then you select the nature of the significant financial interest. You are not limited to just these selections. We do have an "Other" selection that allows you to type in a description and choose that as one of your selections, but I'm going to select payment for services.

Over here we have our dollar amounts. We go as low as zero to 5,000 because we know that some of you may be more stringent in your own policies and would like to report lower values. We're going to report down here. It has not been added at this point. The SFI has not been added. You need to click on the add new SFI button in order to make it add.

We do it this way because for this entity, this person may have more than one significant financial interest and it is allowable for you to report more than one significant financial interest on this one submission. I'm only going to report one at this time, however.

Then you need to move on to number 2, for each significant financial interest include a description of how the financial interests relates to the funded

research identified. We have very large descriptions on the screen for you to give you an idea of what you need to put in here. At this point you can type in this information. Or you can upload. I will upload the next report.

The next report is number 3 and this includes the key elements of the institution's management plan and it includes A through F here. So we do tell you on the screen what needs to be included in the management plan.

I'm going to show you what we do in the Commons to import files. They must always be PDF files. All of our Commons files that are imported and attached are going to be PDF files. That means that you need to convert what you are using to a PDF file it has to be under six megabyte. That does not mean you can change the little doc to PDF, that's not going to work and throw you an error, make sure that you have converted to PDF, once you have done that, you will see that here. At this point does this FC0I include a failure to comply with the regulation. You can choose yes or no. If you choose yes, you get more questions.

Because this is when you need to start actually answering did you complete a retrospective review or not? If you have not completed it -- of course as you heard Kathy say earlier, you have 120 days to do this, so your retrospective review completed or not, if not, that's all you have to do down at this point. If you say yes, you get another one. My mitigation report required. If bias was found, so if you say no here, you are done, if you say yes, we get more. If bias was found, this is when you will actually provide a mitigation report. I'm going to say no here. On this one report. We're going to save that and show you a mitigation report when we go do the revised FCOI.

At this point, there is also another upload. This is very optional. Lots of times this is used if it is sent back to you by the PHS voiding component and they would like extra, more information. And they're going to put it back into your box, you will get an email. At that point you could upload here. This is something that is definitely a very optional category. You may save it. And then it can be actually viewed by people or edited again. In your

institution you have not submitted it to us yet. But once you have saved and submitted it, it is -- it has come to NIH. And an email will go out.

Comments here will be in the email that will come into the IC that you are submitting it to.

And it tells you that the FCOI notification was successfully submitted to the agency and is now in submitted state. So that is the completion of a brand new initiated one.

Now, if you want to go back and revise one, let's say that you had one that did have a retrospective review needed to be held and it hasn't been held yet. And that sometimes happens when you have demo sites. Sometimes you get an error. So let me see if I can get back to where I need to be.

And this is the dangers of doing a live demo. There we go, I'm back begin, yay!

So this is what it's going to look like. And in production I guarantee you, you are not going to get that error. I can't guarantee anything, but we're hoping that you will never get that error. And you will search. Now you can search on the FCOI number,

you can search on the grant number, you can search on the investigator's last name or first name.

I'm going to search on Bunny. And you will see Buggs has quite a few or Buggs Bunny, Buggy Bunny. They all have some.

I have one in a work in progress, I have one submitted and one down here submitted for Buggs Bunny. So -- Kathy thinks that's funny. So when we revise, you are just going to click on this revision button. Let me go back and show you that again. You might have missed that revision button and I have this really, really cool tool here that allows me to highlight it and it's not working for me, hold on, come, there we go highlighter. Right here, that's where your revisions are. If you need to edit one, there. But any time that you need to revise, you will come into your search and you will revise and now I want to get back to -- ah. Revise.

So that's what happens when I play with tools.

So if you edit here, it will take you back into the report. Now, you'll notice the first thing that you'll see is that you are going to want a summary of

the revisions that are previously submitted to the report below. So you are going to enter your summary in here. I'm going to not fill that in so when I hit submit that you are going to see the little error that you get and then I'll fill it in. Right now we're going to go and do what Kathy mentioned earlier. You had a retrospective review needed but you hadn't completed it yet. So now you've completed it and a mitigation report is going to be required.

And we're going to import that mitigation report.

Now, you'll see here, this is where you now see that you have uploaded your mitigation report.

And when I go to save and submit, I got that error. I wanted to show you. See, if you are missing something, if we're missing anything that's required, you are going to get an error. In this case it says, you must enter the revision summary text when submitting a revision. And it's also asking me about permanent, deleting, [indiscernible] cancel, because I don't want to do that. Now, I need to put in a summary saying added mitigation report after retrospective review.

You guys might be a little more detailed than me, I'm being quick, but that's what I put in there.

Again, comments will go to the agency that you are submitting to in the email.

And voila, it's been sent and submitted. So now we've initiated a new and we've done a revision. The only last thing that I really need to show you is an annual report. Unfortunately, we don't have one of those in our demo site, so I'm going to go to our test site for that. Again, no -- all of this is test data, none of it is real, just wanted to let you know that. And we are going to search for an annual report that's due. And I'm going to search on a specific grant that I know we have in test that needs an annual report as a test.

And it didn't come up, so hang on a second, let me make sure that I got that in right because I probably typed it wrong. I did. So easy to do.

There ya go. And in this case, you will see annual report link here. That is what will let you know that an annual report is due.

So this is -- this is an annual report on an FCOI

that has an entity with three different significant financial interests there. The salary basically salary not from the award institution is the nature of the FCOI reported and it gives you the value. Now, you can at this point because we have all three of these, we have to report on each one. We can say it was managed, at which point it's going to ask you, it's going to give you this error message. This is something that I want to warn you all about. It's doesn't know whether I'm new or old or just did this now, so the error message is really not deleting the explanation for the FCOI altogether. It's just saying there's a possibility they are going to delete an explanation on this particular annual report that just came up. Since you are managing it, you are not really -- you don't well have one out there yet, so it's okay.

And then are there any changes to the management plan? If there are, at that point you need to say what the changes are. And we also again give you the upload option, which is kind of cool. Everywhere you are, we have uploads or you either type it out or if

it's a lot, you can put it in an upload.

Like I said, for all three of these that you have, all three of these SFIs have to be addressed in the annual report.

So this one no longer exists. Now, it's telling me that it's going to enter -- delete the data entered for the management plan. There was no data for the management plan in this at this time so it's okay.

You are going to have to explain why it no longer exists. Somehow it disappeared.

And again same thing here. And there was no change in the management plan here.

So now we have created the -- the annual report. We can save it. And we may submit it.

And as with everything, you have your comments.

Okay. So I have pretty much successfully created a new initiated a new one. I have revised one and I have done an annual report. So we're going to go to the emails that I wanted to show you the emails that you will receive when these are created. And we're going back to Kathy's presentation at this point because that's where we have put them.

Before I leave and hand over the presentation and we get to the Q and A's, I just wanted to let you know that all of these screen shots are also found in the -- in the -- in the FCOI user Guide, which you can find on the eRA.nih.gov page. Now we're moving over to Kathy's page. You can see that this will be the email that you see when a new one has been submitted to NIH.

And this is a copy of it and this is what the person who submitted it will get.

This one is a revised. So it's changed a little bit, there's some stuff, some wording has changed in it, but it's pretty much the same thing. The next one is the annual. This one is when an annual report has been received successfully.

This is when we have refused the mitigation report because this is important for us to know. So once you have submitted a mitigation report, we will send you an email on this one, also.

So ... now we are getting ready to go into our Q and A section. Assisting us with our questions and answers, we have Diane Dean, the director of the NIH

division of grants compliance. She has been going through your questions and is going to help us moderate the question and answer section.

>> Thank you, Scarlett. We've been receiving a lot of good questions and I've been able to address some of them as we go, especially those that aren't particularly related to reporting.

I would encourage anyone that has questions that either we couldn't get to today or that I wasn't able to completely address in this setting, to please submit them to the FCOI compliance mailbox and the address is at the end of the screen shots that you will see.

So I think that I will pose these questions to Kathy and Scarlett and you can let me know if one of you or the other would prefer to answer, for those that I'm not exactly sure where to go.

So the first one is a clarification on the pull-down menu for the nature of the identified financial conflict of interest. And the question is: Can you select more than one nature? Kathy?

Or Scarlett? Either one.

>> Okay. Yes. The system what you enter in one entity name and then report on each SFI separately. So you will -- you will then identify the nature of one significant financial interest and provide the dollar value of that SFI and then all of the other elements and then add a new SFI if there is more than one SFI for the same entity.

So then again you would identify that new SFI and the value of that other SFI. And you can continue to do that. Multiple times.

>> Okay. Thank you, Kathy.

And -- Scarlett, this may be for you. How many characters are you allowed for the description?

>> Sure. You are allowed 2,000 characters for the descriptions.

>> Great, thank you.

Kathy, is there guidance available for foreign institutions that also conduct NIH-funded research? And the second part of the question is: Are they also -- are they also to use eRA Commons for all reporting requirements?

>> *Hancock*: Okay. We have a lot of resources that are

available. First of all, the regulation is applicable to foreign institutions that receive NIH funding for grants and cooperative agreements. And the resources and the guidance that we have available are posted on the FCOI website.

The foreign institutions are also required to use the eRA Commons for reporting identified FCOIs to NIH just like any other institution.

>> Thank you. The next question is: If an FCOI report was already reported to NIH under the 1995 regulation, and the FCOI still exists and the award is still active, when will the next report need to be issued to NIH?

>> *Hancock*: I can address this, this is Kathy. The -- the annual financial conflict of interest report would be due at the same time that the annual progress report is due for the next year of support. So if the annual progress report is due 45 days prior to the start date, then the annual FCOI report for that year would be due on the same day and it is again submitted through the eRA Commons website -- FCOI module.

>> Okay. Thank you. Can you go over again, Kathy, the difference between a revised report and a mitigation report? Especially if you could make it clear, are they both submitted after a retrospective review?

>> *Hancock*: Okay. When there's a situation of non-compliance, the institution needs to conduct a retrospective review, which is a review of the activities that were conducted under the research project to determine whether or not there was bias as a result of the non-compliance with the regulation. If the institution determines that -- if they discover new information than what had previously been submitted to NIH under the original FCOI report, they would submit a revised report to update any information. For example, let's say originally when they submitted the FCOI report they investigated that the investigator received consulting payments at \$10,000. After they conducted the retrospective review, they discovered that instead of the investigator receiving 10,000, they received 50,000. So the institution would revise the FCOI report to

update the information that was previously submitted.

Now, in cases of when they conduct the retrospective review and they determine that there was bias in the design, conduct or reporting of the NIH-funded research, then the institution needs to submit a mitigation plan, which tells us what actions is the institution going to take or has taken to mitigate the effects of the bias. So they would submit a mitigation report to NIH to communicate that information to us through a revised FCOI report.

And as I mentioned before, you may be able to send all that information with the original submission if the retrospective review was completed and a determination was made that there was bias by the time you submitted the initial report. But it may not be the case. So that's why we added the feature to allow the institution to revise the originally submitted report so that they could then update the information previously submitted or, if necessary, to submit the mitigation report.

>> Okay. Thank you. I know that's a lot of information to absorb and we hope that you can refer

to the slides from today and the other resources on our website for this question and of course if you need further information, you can always write to us at the FCOI mailbox.

Thank you.

So here's a good one. So -- for Kathy. Is a rescind report the same as a do-over?

>> *Hancock*: Well, it may be. As I was explaining, the situation for rescind can be done either at the institution level or the NIH level. So let's take the case of the institution level.

The institution may -- as we said, you know, submits reports to NIH. But they may have submitted a report in error. Some of our repeated, you know, situations we have seen is the institution discovers that they had submitted a report and then they maybe a week later submitted the same exact report so they submitted a duplicated report and they want to rescind or remove the second report.

So they contact NIH to rescind or delete the second report that was submitted in error.

The other way that we can use the rescind feature

is if the institution submits an FCOI report to NIH that is determined to be incomplete. So NIH will take the action to rescind the report and require the institution to resubmit with the required information.

>> Here's another question. Kathy, I think this is for you. If an institution has no FCOIs, is there a requirement to submit an FCOI report and also is there a requirement to submit an annual report?

>> *Hancock*: No. There is no requirement to submit any negative FCOI reports.

>> Okay. The next question is regarding the significant financial interest pull-down menu. Can you pick more than one?

>> I will take that, actually if we can go to my screen I can actually show them this.

So when you go to pick the significant financial interest, you can only pick one at a time. However, for each entity, you can add more than one to the drop-down, to the area down here. So we have one here, we can pick a different one. With a different dollar range. I believe Kathy explained this one a

little bit earlier and it allows you to add another one to the group. So you can have intellectual property rights and then investment vehicles. They each have to have their own value added, so you would not total up the values at one entity. But you can add as many significant financial interests as you need.

>> Then just to note, too, that the second area for each SFI includes a description --

>> Hold on a second we lost my screen, Kathy.

Okay. My screen is back again. So -- so --

>> Okay, so then you can have multiple SFIs for the same entity and then you would address number two and number three you know would include all of the different SFIs in one. So it's not like you have to -- to do separate descriptions it can all be included in -- in one document to describe how all of those different SFIs relate to the research, et cetera.

>> Okay, thank you both.

Does the person with an SFI have to -- in order to report, I think what this is saying, let me start this

again. Does the person with an SFI have to have a Commons ID. Let's break that down, we know that the SFIs have to be disclosed by the investigator to the institution. So perhaps what this question is getting at is -- is does the institution have to have a Commons ID or the investigator have to have a Commons ID in order to submit a report?

>> Okay. Let's break it -- I will answer it broken down. The institution does need to be registered in the eRA Commons but the institution had to be registered in the eRA Commons to submit the application to begin with, so we are going to assume they are. Someone at the institution has to be assigned an account with an FCOI role, so this can be completed by someone at your institution. So some Signing Official at your institution will have to assign the financial conflict of interest role to an account and they can create a brand new account and assign it to someone or they can assign it to an existing account that exists out there and it can be added to any administrative role, such as a Signing Official, an administrative official, business

official, all of the administrative roles. That answers who can submit it and whether they need an account.

Now, does the person with the -- with the -- with the financial conflict of interest need to have a Commons account? No. That person that's a free form entry and so -- so the PI, of course, the primary Principal Investigator or anybody identified as the Principal Investigator would have a Commons account when they came in on the application, but -- but other people can be identified as -- as financial conflict of interest holders and we are not looking for a Commons account for those people.

>> Thank you, Scarlett. The next question has to do with the first screen when you indicate whether the report is from a subrecipient or from the institution. And the question is do you select subrecipient if the institution is the subrecipient or if the institution has a subrecipient?

>> The -- I can address this. The -- the institution that is submitting the report addresses whether or not they are submitting a report for a

subrecipient institution. So the question says subrecipient -- subrecipient report, yes or no. And the prime institution makes the selection of whether or not, again, you know, depending upon if this is an FCOI report for a subrecipient investigator, then they would say yes. And if they say yes, then the grayed text box becomes white, which then requires the institution to enter in the subrecipient institution name.

So in all cases it's the prime awardee institution that reports for any subs.

>> Thank you for clarifying that, Kathy.

Scarlett, can you submit two PDFs if they are larger than six MBs? Megabytes? Millibytes?

>> MBs, megabytes. Okay. So the answer to that is yes. You can. You can't submit it in that section. We only allow one upload per section. So if you -- if you want to switch, I'll try to get -- edit another one of these so that I can show you.

So you can see that when you've uploaded one and imported something, it's going to give you that

opportunity for that six megabyte and six megabytes is a lot of data, people. That's a lot. But if you do go over six megabytes, we do have this upload other documents, so there is another six megabytes here that can -- you can reference to one of these sections up here. So Question No. 2 or No. 3 can be supplemented with extra documentation here in the uploading of this document here.

And I can highlight it so people can see. This uploaded PDF section at the bottom is like an extra section for you.

Back to you, Diane.

>> Okay, thank you. Kathy, how do you report an FCOI for a grant that has not yet been funded?

>> *Hancock*: Okay. The FCOI report would not be submitted until the NIH awards the grant. And as was communicated before, an FCOI report for a newly awarded grant would be required to be submitted if an FCOI exists prior to the expenditure of funds under the notice of awards.

>> Thank you, Kathy. Scarlett, the FCOI view only and assistant roles do not appear to be listed in the

eRA Commons roles that can be assigned. Will these be added?

>> Well, they should be there so we will take a look at that and make sure that they're out there as soon as possible. To my knowledge, they should be out there for a Signing Official to assign to someone, so we'll make sure we get a look at that as soon as possible for you.

>> Thank you. We're trying to fit as many of your questions in as we possibly can. The next question, will we receive notification that annual reports are due?

>> Yes.

>> Thank you. Hold on.

Is -- the question is can you revise through eRA Commons but not rescind?

>> Yes, that is true, you can revise through eRA Commons, but rescinding has to be done on the agency end.

>> Great, thank you.

I'm sorry, excuse me. When reporting on a subawardee collaborator, does the prime awardee have

to upload the management plans created by the subawardee institution? Maybe we can clarify this just once more.

[i ndi scerni bl e]

>> Thank you.

Our Notice of Award was issued on June 1st, 2012. Do I have to comply with a 2011 revised guidelines? Regulations? Until the next grand award?

>> *Hancock*: Okay. I'm sorry.

>> Let me give that to you again.

Our Notice of Award was issued on June 1st, 2012. Do I not -- do I have to comply with the 2011 revised regulation until our next grant award?

>> *Hancock*: Okay. If your Notice of Award was issued on June 1st, then you would be subject to the 1995 regulation until your next Notice of Award is issued on or after August 24th. So it wouldn't be subject to the revised regulation until next fiscal year.

>> Thank you.

How do you enter reports for multiple investigators on the same grant?

>> *Hancock*: These would be treated at separate FC0I

reports. So each investigator, FCOI, is reported separately.

>> Is travel required to be reported if the institution determines that travel is a financial conflict of interest?

>> *Hancock:* Yes. Travel is included, reimbursed or sponsored travel is included in the definition of significant financial interest. So if the institution determines that that significant financial interest constitutes a financial conflict of interest, then the institution is required to report that FCOI to NIH.

>> Is there an NIH training module available?

>> *Hancock:* Yes. On the NIH FCOI website, we have a web-based tutorial. We also conducted a webinar in November and we also have posted PowerPoint presentations with case studies that we presented at the NIH regional seminars this past year.

>> Thank you. Who do the confirmation emails go, to the FCOI role or the SO or both?

>> They go -- I know they go to the FCOI role. The person who submitted it. And I do not believe they

go to the signing official, no they do not. They go to the FCOI role.

>> Okay. So the confirmations go to the FCOI role.

Is this demo available for -- for -- I'm sorry. Is the demo available to users for training purposes?

>> Yes, it is. It is out there and it is available for people to use for training purposes. We will have instructions on how to create an FCOI user in it in the next two weeks. Right now, it's very easy to create Signing Officials and business officials and PIs. And there's a little trick to doing the FCOI user, so we will be putting the instructions out in the next two weeks.

>> I don't see the FCOI tab on eRA Commons. Is it just the Signing Official who can see that tab and not the PI?

>> Only the person with the FCOI role can see that tab. So even the Signing Official, if they do not have the FCOI tab, cannot -- cannot see that tab. If they do not have the FCOI role, I'm sorry.

So the Signing Official at the institution, any one of the Signing Official, can assign the FCOI role to

an account, at which point the FCOI tab will show up.

>> If the institution enters the name of the entity incorrectly, do you revise or do you rescind?

>> The -- the institution should request that the FCOI report be rescinded because the revised feature is only used following a retrospective review. We're not using that feature to make edits to reports. Unless it's following a retrospective review.

>> Okay. If there are multiple relationships with the same entity, each under \$5,000, but totaling \$15,000 in aggregate, do the relationships need to be reported?

How about if I take one?

If an investigator has multiple relationships with the same entity and in the aggregate they do -- they total \$15,000, you will see in the definition of significant financial interest that we are defining that in the aggregate. So if the relationship totals \$15,000 that would be above the reporting -- the disclosure threshold, excuse me, of \$5,000, they would need to be disclosed to the institution. The institution would review those, determine which of

them are -- which of them, if any, are financial conflict of interest and those that are financial conflict of interest would be reported to the NIH.

If someone leaves the institution that had the FCOI assistant role and the institution removes that person, does that change anything in the database on the FCOI reporting?

>> No, it would not. We have auditing based on roles but that person would not be -- it would only be linked to ones that they had viewed and they are not allowed to submit to the NIH, so it would not change anything at all.

>> Thank you. And Scarlett, could you -- another question here is could you explain more about the FCOI assistant role and what actions that role can do?

>> Sure. So as we have found with almost all of our functionalities and roles, the person that is responsible is very busy and active person in the organization and they could use a little help with the actual data entry. So we created a roll called the FCOI assistant that would allow the FCOI person to delegate to the assistant and let the assistant

create, they may initiate, they may enter data, upload some of the documents and just do the basic any types of entry in administrative work that needs to be done. How far, they cannot submit it to the -- to the agency in this case NIH.

So it would not allow them to submit.

>> Thank you, Scarlett. And I think we have time for one last question. Regarding the initial FCOI report, please confirm that it must be submitted after the award has been granted, but before the expenditure of funds. And the second question is who receives the emails?

>> *Hancock*: Okay. As with the 1995 regulation, it's the same with the 2011 regulation. So the FCOI report, the initial report, if an FCOI is identified, is submitted prior to the expenditure of funds. So once the award is made, then the institution is required to report the identified FCOI prior to the expenditure of the awarded funds.

And the email notification is sent to the FCOI Signing Official.

>> Thank you.

>> The email is sent to the FCOI Signing Official. There is an internal system and just to let you know that an email will also be sent to the grants management staff to let them know that one has been received by NIH, so that they can then start the review process.

>> And I think we can ask one more here. Are consultants who participate in an NIH-funded grant required to report a financial conflict of interest? I will take this one.

If the consultant meets the definition of an investigator, which is defined as the PIPD and any other person responsible for the design, conduct or reporting of NIH-funded research and the grant is related to their institutional responsibilities as a consultant, then the consultant would have to disclose, make a disclosure to the institution. So, yes, if a consultant -- meets the definition of investigator, then the consultant will be required to disclose significant financial interest.

I think that's all of the questions we have time for today.

>> Thank you, Diane, Kathy and Scarlett. This is Cynthia who kicked off this show for you. We also thank all of you for taking time out of your busy schedules. Before you rush to click off that signoff button and get back to all of the emails that came in while we were -- while we were presenting this information, we do have a couple of more final pieces that we want to share with you. One and we've been getting a lot of questions about this, it's regarding the PowerPoint presentation and when it's going to be available, so while you were listening intently, we now have those slides available on the FCOI web page under the resources section and in the FCOI training section. So the URL is available on the grants.NIH.gov website, as well as noted in the NIH Guide notice that many of you used to find information about this webinar. Also in the presentation, it's on Slide 39.

As we mentioned before, the recording will be available in about three to five days. So watch for that if you are interested in sharing it with others from your institution. As we work to provide the

latest information in a timely manner and in a variety of formats, we would really like you to do the exit poll, but we also encourage you to provide suggestions regarding the format and content of this webinar. Feel free to send us your suggestions to the [FCOIcompliance@mail.nih.gov](mailto:FCOIcompliance@mail.nih.gov) inbox. I will say that again because I might have been talking fast, [FCOIcompliance@mail.nih.gov](mailto:FCOIcompliance@mail.nih.gov). We hope you have a great day and that concludes our show.