Diane Dean: So thank you for joining today's presentation on Financial Conflict of Interest. My name is Diane Dean and I work in the Office of Policy for Extramural Research and I'm going to be your moderator for the next 45 minutes. I am pleased to present Kathy Hancock, who is our presenter on Financial Conflict of Interest. The format today will be a short prerecorded presentation followed by a live Q and A with our presenter. While the presentation is playing, you can send us your questions and we'll be able to answer them as we go.

Kathy Hancock: Hello. My name is Kathy Hancock, and I'm representing the Division of Grants Compliance and Oversight in the Office of Policy for Extramural Research Administration at NIH. I'm here to talk to you today about Financial Conflict of Interest. Financial Conflict of Interest regulations are not new. The Department of Health and Human Services published regulations governing Investigator Financial Conflict of Interest in 1995, and in 2011, they revised the regulations. The regulatory citations and provided here on the slide. The first one is applicable to grants and cooperative agreements, and the second one is applicable to research contracts. We're going to focus our attention today on the grants and cooperative agreement regulation. The two regulations are very similar, but there are some differences. The grant regulation will refer to applications, while the contract regulation will indicate proposal. And then, there's some other differences in the definition section of the contract regs. I also wanted to point out to you that the Financial Conflict of Interest requirements are included in the NIH Grants Policy Statement. So, the section that I've indicated here, 4.1.10, is where you're going to find information about FCOI requirements. Another section within the Grants Policy Statement is section 15.2.1, Consortium Agreements and Written Agreement. And within that section, you'll find information when you have a subcontract on a grant and what the requirements are related to Financial Conflict of Interest. Okay. So, what's the purpose of the FCOI regulation? This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH or Public Health Service grants or cooperative agreements will be free from bias from .. . resulting from Investigator financial conflict of interest. So, this regulation is focused on, again, Investigator FCOIs and not Institutional FCOIs or conflict of commitment or standards of conduct. The objectivity of research is of paramount importance for obtaining and maintaining public trust of NIH-funded research. And again, this is related to biomedical and behavioral researchers that have financial interests outside the Institution in which they work, that may be constituted as a Financial Conflict of Interest. So, who's covered by the regulation? First, is each Institution that applies for or receives Public Health Service or NIH grants or cooperative agreements. So, this includes domestic, foreign, private, public, for-profit, not-for-profit institutions. It does not cover federal agencies. It also covers individuals who meet this definition of Investigator, and that is an individual who is planning to participate in the research or who was participating in the research that, again, meets this definition of Investigator. And then, when an individual, rather than an Institution, is applying for or receives Public Health Service or NIH research funding, it would apply to them. The regulation also applies to Phase II applicants and awardees. It does not apply to the Small Business Innovative Research or Small Business Innovative .. . or Small Business Technology Transfer Phase I applicants or awardees, but it does to the Phase IIs. So, once you submit a grant application to NIH, you .. . When you are subject to the reg, you are certifying your Institution's compliance that you have a policy in place that implements the regulation. So, what is a Financial Conflict of Interest? A Financial Conflict of Interest means a Significant Financial Interest that somebody has could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Significantly means that the financial interest would have a material effect on the research. So, again, I want to direct your attention to the regulation to look at the definition of a Significant Financial Interest because I have used that in this .. . on this slide. So, again, when I told you that when you submit a grant application to NIH, you are certifying to NIH that you have a policy in place, a written and enforced policy in place that implements the regulatory requirements. So, it's very important for you to understand the regulatory requirements. At a minimum, your policy must be applicable to Public Health Service, or in our case NIH, grants and cooperative agreements and to researchers that meet that definition of Investigator as in the regulation. The FCOI regulation is very prescriptive regarding the requirements that institutions must follow. You're going to see, when we're going to go through these requirements, that if you use all these .. . The regulation provides a framework for developing your policy and you're going to see that with all these requirements and everything that you need to have in order to meet those requirements, to incorporate into a policy. So, beginning in December, December 1, 2020, Institutions were required to submit a copy of their policy on FCOI in the Institution Profile Module of eRA Commons. And this was announced in an NIH Guide Notice last year on September 30th, 2020. NIH funded recipients must submit the policy in that IPF Module in order to get funded from NIH. So, it's very important that the policy is submitted at the time when NIH is talking to you about the funding of your application. So, if an application was submitted by your Institution and you know that the policy has not been submitted, NIH will not be able to issue the award without the submitted policy. So, noncompliance will cause either the NIH staff to delay the issuance of your award, or we may impose specific award conditions or take other enforcement actions to address compliance with the requirement. Again, like I told you, the regulation is very prescriptive in the requirements that Institutions must implement to comply with the regulation. One of the requirements is to train Investigators about the FCOI regulation and about the institution's FCOI policy. It's important that Investigators understand the Institution's policy because your policy may be more restrictive than the regulation. So, again, the regulation states that individuals, that meet the definition of Investigator, must be trained on the regulation and the Institution's policy prior to engaging in PHS, or Public Health Service research, every 4 years and when certain circumstances apply, such as the policy is revised that would affect the Investigator's responsibilities, an Investigator is new to the Institution, or if an Investigator does not comply with the policy or the management plan. The NIH has posted a slide deck on its FCOI web page that provides an opportunity for you to train your Investigator's or your Institutional staff about the FCOI regulation. So, I encourage you to take that opportunity to have your staff get trained on the regulation by viewing that slide deck. So, who must be .. . Who must disclose Significant Financial Interests? The regulation states that individuals who meet the regulatory definition of Investigator, which is the PD/PI always, and then any other person, regardless of their title or position, who the Institution considers is responsible for the design, conduct, or reporting of the NI .. . of the research that's funded by the Public Health Service or NIH, or proposed for such funding, which may include, for example, collaborators or consultants. So, we tell you that in FAQs, that you should consider the role rather than the title of those individuals and the degree of independence in which that individual works. So, it is not a good idea to limit the applicability or the definition of Investigator to titles, such as PhDs, faculty, coinvestigators, because then you run the risk of noncompliance. And again, Institutions determine who meets the definition of Investigator. This isn't an NIH responsibility. So, not only all right Investigators at the prime Institution subject to the disclosure requirements, but if you subcontract any work to a third party, then the subrecipient is also subject to this regulation and therefore Subrecipient Investigators are also required to disclose their Significant Financial Interests for determination of a Financial Conflict of Interest. Depending upon whose policy applies to a Subrecipient Investigator, whether it's the subrecipient's policy or the prime's policy, then the Subrecipient Investigator would be disclosing their SFIs to whoever is .. . assumes that responsibility of reviewing a disclosure. And again, I've just provided the information here on the slide about the written consortium agreement and, again, the need to address FCOI requirements when you do establish a consortium agreement. So, now, what SFIs, Significant Financial Interests, must be disclosed? It would be the Investigator's Significant Financial Interests and those of the Investigator's spouse and dependent children that are related to the Investigator's institutional responsibilities. So, if I'm an Investigator on the grant and I work, let's say for a university, I would need to disclose my Significant Financial Interests that are related to my research responsibilities I do for the university and my teaching responsibilities that I do for the university, because those are the two responsibilities that I have. But I wanted to share with you some examples of what is a Significant Financial Interest. So, it'd be any remuneration, royalties, equity interest, reimbursed or sponsored travel that an individual, if I was that Investigator, that I may receive from an entity outside the organization in which I work. So, basically, what I want to emphasize also is that the Investigator is fully disclosing their Significant Financial Interests. I'm not making any determinations about whether or not something is an FCOI or not and whether or not then I need to disclose. I am fully disclosing Significant Financial Interests that I have or my spouse and dependent children have, that are then going to be reviewed by somebody at the Institution for making a determination of FCOI. I also wanted to point out some areas within the Significant Financial Interests disclosure requirements that NIH has provided some clarification on. One of them is foreign financial interests. The NIH had posted an NIH Guide Notice, NOT-OD-18-160, on March 30th of 2018, and we also published an FAQ to address this. And basically what we wanted to emphasize or clarify is that there's no exclusion of disclosure of financial interests from foreign institutions of higher education. So, if I work for a foreign university and I get additional resources or income from another foreign institution of higher education, I would be required to disclose that to my foreign university that I work for. NIH is looking at our FCOI processes as we are addressing foreign influence efforts. So, when must SFIs be disclosed? Again, the regulation is very prescriptive. Investigators must disclose their SFIs and those of their spouse and dependent children at the time of application, within 30 days of acquiring or discovering a new SFI, and on an annual basis, that is prescribed by the Institution. NIH also clarified in a frequently asked question at the time of application. And what we clarified is that every time an Investigator submits a grant application to NIH, they're not required to fill out a new financial disclosure, unless there are changes that need to be made from the disclosure that's already on file. So, if you have a process in place for an Investigator to review their disclosure on file and to certify that there's no changes, then you don't have to get a new disclosure each time somebody submits an application to NIH. So, how is an FCOI identified? The regulation states that Institutions need to assign a designated official or officials to review a financial disclosure. And so, the person who is assumes that responsibility, whether it's one person, two people, or a committee, the first thing that they will do when they review a financial disclosure is ask, "Is the SFI related to the NIH funded research?" And if the DO or DOs are not able to make that determination, they can ask the Investigator about the relatedness of the Significant Financial Interest to the NIH supported project or proposed project. Now, if the determination is "Yes, it is related," then the DOs will ask the next question. "Could the Significant Financial Interest be affected by the research or is the SFI in an entity whose financial interest could be affected by the research?" And if the answer to either one of those questions is a yes, then you have a Financial Conflict of Interest. It's not a bad thing. We want people to have ties with industry. That's how we get good discoveries. But what we want are Financial Conflicts of Interest to be identified, managed, and reported to NIH. So, what are the reporting requirements when you have an identified FCOI? Well, NIH has developed an eRA Commons FCOI Module, which is different than the Institution Profile Module for submitting policies. So, when you have an identified FCOI, the Institution FCOI signing official will submit a report through the eRA Commons FCOI Module. There are data fields within the FCOI Module that will drive the information that is required for submission. There are typically two types of reports that we receive from the Institution. The first is the original report. That's when you have your initial report submitted to report the identified FCOI. This is a very detailed report. It will give us the entity name in which the Investigator has an FCOI, the nature of the SFI, whether it's consulting fees, equity interest, et cetera, the value of the SFI, and then some other information. The original report is due prior to the expenditure of funds under a new award or if the FCOI is identified during the period of the award, then it's due within 60 days of identifying the conflict. Once you submit an original report, then an annual report will be required. The annual report is a much more abbreviated report. It tells NIH about the status of the FCOI, whether the FCOI is being managed or it no longer exists. And that report is due at the same time that your annual progress report is due. The system is also set up to send out a reminder notification when an annual report is due, and that report notification goes out 75 days prior to the next budget period start date. So, what is required when there is noncompliance with a regulation? The regulation states that whenever an FCOI is not identified or managed in a timely manner, including the failure of an Investigator to disclose their SFIs to the Institution, failure of the Institution to review or manage such an FCOI, or failure by the Investigator to comply with the management plan, then the Institution needs to conduct what's called a Retrospective Review. And the Institution has 120 days for determining non .. . 120 days from determining noncompliance to complete that Retrospective Review. So, again, we expect the policy to include the time frame, 120 days. And basically, what the Retrospective Review does is it requires you to review the activities conducted during the period of noncompliance to determine bias in the research. The regulation also indicates that there are documentation requirements when you have to conduct a Retrospective Review. So, again, we expect that your policy will include this information, so that you will ensure compliance with the regulation. Now, there's another action that's required and that is following the Retrospective Review if bias is found, then the Institution needs to take further action. They need to mitigate the effects of the bias and they need to promptly notify NIH by submitting what's called a Mitigation Report through the eRA Commons FCOI Module. The Mitigation Report must include certain information as is outlined on the slide. If bias is not found, then no further action is required. What are the Public Accessibility requirements? The regulation specifically says that Institutions have to post their policy on a public website, and this is provided in the NIH Grants Policy Statement in that section 4.1.10. The other requirement is to make certain FCOI information publicly accessible for FCOIs that are held by senior/key personnel. So, if you had three people working on the grant and two people are identified as senior/key personnel, and you had three FCOIs identified for each person, you would only need to provide the FCOI information for those people who are indicated in the grant application as senior/key personnel. And that information is made publicly accessible by either posting the information on a public website or making the information available upon request. I mentioned earlier about subrecipient requirements and like I indicated before, your consortium agreement will need to establish whose policy applies to the Subrecipient Investigator. If you're working with a Subrecipient that receives a lot of grant support, then most likely you'll let them comply with their Institution's policy. But if it's an Institution that doesn't get NIH support, it may be easier for you to just have the Subrecipient Investigators disclose their SFIs to you for a determination of FCOI, and then your Institution would develop the management plan, monitor Investigator compliance, and report the information to NIH. In all cases, though, even if the subrecipient Institution's policy applies, if they identify an FCOI, they need to report the FCOI to the prime Institution and the prime Institution reports to NIH. It's the Institution's responsibility to ensure that Subrecipient Investigators meet FCOI training requirements and also to provide oversight of FCOI requirements for its subs and consultants. And this basically is concluding my presentation. This is a slide that provides information and resources. One of the things that I have learned in reviewing the policies that have been submitted to NIH over this last year is that Institutions were unaware about the requirement to submit a policy. And that is because they had not subscribed to the NIH Guide for Grants and Contracts. So, I can't encourage you enough to take action today to subscribe to the NIH Guide. This is NIH's way to communicate with the extramural community and provide you with information about policy changes, clarifications of policies, and Funding Opportunity Announcements. If you have any questions regarding FCOI related matters, you can send an e-mail to the FCOI Compliance mailbox and I also wanted to refer you to the FCOI website, which has a lot of resources material including the FCOI training that I told you about, frequently asked questions, reporting information, and a Policy Development Checklist, and then the NIH Guide Notices, that actually have been published over the years, related to FCOI. And then, just some additional information and material that I don't plan to go through but, again, here's just information that you can refer to in the future. Thank you.

Diane Dean: So, hi. This is Diane. We've gotten a lot of good questions, Kathy, and I thought maybe we could start looking through and answering some of those. Are you ready?

Kathy Hancock: Yup.

Diane Dean: Okay.

Kathy Hancock: I am.

Diane Dean: Lots of good ones.

Kathy Hancock: Yeah.

Diane Dean: The first one. "Should Institutions submit their FCOI policies at the time of NIH grant application submission?"

Kathy Hancock: Good question. The requirement is not that you don't have to submit at the time of grant application. The NIH will not be able to issue the pending application until the policy is submitted. So, what I had indicated is at the time that NIH is talking to you about funding your application, if you know that the policy has not been submitted, then it would be a good time to submit it so that it doesn't delay the issuance of the award.

Diane Dean: So, they could actually submit it any time as long as .. .

Kathy Hancock: Any time.

Diane Dean: .. . it's prior to award.

Kathy Hancock: Right.

Diane Dean: Very good. Okay. This one is about Significant Financial Interests. So, "Significant Financial Interests as defined by the regulation include IP rights of interest upon receipt of income."

Kathy Hancock: Uh-huh.

Diane Dean: "Does the $5,000 threshold apply here or does .. .

Kathy Hancock: Yes.

Diane Dean: .. . or does any income from IP constitute an SFI?"

Kathy Hancock: Yeah. Actually NIH posted an FAQ on this. It's E20. And we found in the preamble to the final rule that there is a $5,000 threshold for IP rights and interest. So, Institutions could include a $5,000 threshold even though the SFI definition doesn't include the threshold in that definition section.

Diane Dean: Okay. Thank you. "If a person is considered a key personnel under FCOI, does that mean they need to be listed in key personnel section of the grant application SF424 or can they be listed in other personnel? I'm thinking of a research associated and postdoc types of positions."

Kathy Hancock: Okay. First of all, let's focus on the definition of Investigator and not on senior/key personnel, because it really .. . They're two different things. The regulation is applicable to individuals who meet the definition of Investigator. And so, those individuals need to disclose their Significant Financial Interests for determination of FCOI. The regulation does define senior/key personnel, but it's not the same definition that is in the NIH Grants Policy Statement. And the reason why the regulation defines senior/key personnel is because there's another requirement in the reg that talks about public accessibility of identified FCOIs. So, the public accessibility of FCOIs applies to those individuals who have been indicated as .. . or have been identified in a grant application, progress report, or any other report that's submitted to NIH as senior/key personnel. So, there .. . This terminology senior/key personnel in the regulation is only applicable to public accessibility, not having anything to do with disclosure or identification of FCOI for individuals.

Diane Dean: So, it's any individual that the Institution, the entity would determine as senior/key personnel as they report to NIH versus what .. .

Kathy Hancock: Right.

Diane Dean: .. . Who is named in the notice of award. That's a great .. .

Kathy Hancock: Right.

Diane Dean: .. . question. Thank you. Gosh, there's coming in. This is wonderful. Oh, this is a good one. "Are there any particular types of SFIs, that if related to research, always constitute an FCOI?"

Kathy Hancock: No. This is .. . Again, the designated official has the responsibility to review Significant Financial Interests and then one, determine whether or not it's related to the research, and then, if it constitutes an FCOI, if it could have a direct or significant effect on the design, conduct, and reporting of the research. So, it depends on the determination.

Diane Dean: So, for example, two Investigators could have the same Significant Financial Interest and it might be an FCOI for one and not for the other based on their research portfolios, for example. Is that right?

Kathy Hancock: Is that a question?

Diane Dean: No. No, that's my .. .

Kathy Hancock: Yeah.

Diane Dean: That's my statement. Yeah. So, it's .. . As Kathy said, it's not the SFI itself, but it's how it relates to the research that the Investigator is working on that makes it a conflict.

Kathy Hancock: Right.

Diane Dean: Okay. "Does the SO submit the report or does the FCOI officer role in eRA Commons do that?"

Kathy Hancock: Okay. Good question. The SO submits the policy to NIH in the Institution Profile Module, but the FCOI SO submits the FCOI report in the FCOI Module. So, there are two different roles. The FCOI SO submits FCOI reports to NIH.

Diane Dean: Okay. Thanks. "When in the process do you first start looking at whether you have an FCOI or an SFI?"

Kathy Hancock: Okay. The regulation requires that Institutions report identified FCOIs prior to the expenditure of funds. So, at the time of application, the Institution is required to collect disclosures or ensure that you have the disclosure on hand for people who meet the definition of Investigator. So, prior to .. . Again, at time when you know that NIH is going to be funding your grant application, that would be a good time to ensure that all your FCOIs have been identified or that the disclosures have been reviewed, so that you can report those FCOIs upon the issuance of the award to NIH prior to the expenditure of funds. The FCOI reports are not submitted until after award, so no award no conflict. But once NIH awards the grant, then you can submit the FCOI report in the module.

Diane Dean: Okay. Here's our next one. "If the disclosure .. . If in the disclosure form the Investigator states that he or she has no SFIs, should this form be posted in the eRA Commons Module, excuse me, or only forms that show the existence of SFI be posted there?"

Kathy Hancock: Okay. The disclosure forms are internal, so NIH does not get copies of disclosure forms. What NIH does receive is notification of a identified FCOIs. So, if there are no identified FCOIs, there is no reporting requirement. The module is not set up for negative reporting. It's only set up to receive identified FCOI information.

Diane Dean: Very good. Thank you, Kathy. "Does the requirement to submit FCOI policies in the eRA Commons apply to Institutions that only are grant recipients?"

Kathy Hancock: Well, not yet .. . not really because if you're an applicant, and then you can submit a grant .. . a policy to NIH through the IPF Module. So, you don't have to be a recipient. You can be an applicant.

Diane Dean: And you can be .. . How about grant subrecipients?

Kathy Hancock: Oh. NIH is not .. . If you know that you're going to be a prime, but NIH is not collecting policies for subrecipient Institutions. It's only for prime Institutions.

Diane Dean: Right. So, if a subrecipient is also a prime .. .

Kathy Hancock: Then we would have a policy, but if they're not a prime then we do not request the submission of a policy if you're only a sub.

Diane Dean: How about if you have an NIH research contract?

Kathy Hancock: No, this is only for grants and cooperative agreements.

Diane Dean: Okay. Thank you. "Are pending patent applications included in IP for the purposes of the $5,000 threshold?"

Kathy Hancock: Hmm. I don't think unless there is a value. We have an FAQ, I believe, on that, but from what I remember it's only if it has a value .. .

Diane Dean: Yeah.

Kathy Hancock: .. . over 5,000.

Diane Dean: Right. So, is Institutions may, if that's disclosed, want to make sure they track that in future Investigator disclosures, but we would not .. . The regulation would not kick in until there is some actual value there unless .. .

Kathy Hancock: Right.

Diane Dean: .. . the Institution, I guess, sees that differently, if they .. . They might consider that an FCOI.

Kathy Hancock: Yeah.

Diane Dean: Okay.

Kathy Hancock: And just so you know, the frequently asked questions are posted on the FCOI main web page of NIH's Office of Extramural Research web page. So, if you just type in NIH OER FAQ in a search, you should come up with the page.

Diane Dean: Okay. Here's another one. "How do I know who is the designated official at my Institution? I am with a foreign Institution."

Kathy Hancock: Oh. I would start, I guess, with your research and contracts office. What I have typically found is people who deal with FCOI may be in a compliance office, a conflicts of interest office, or the legal office, like a general counsels office. So, you would just have to work with your institutional officials to figure that out.

Diane Dean: Okay. One of the .. . Okay. Some of these are .. . Sorry, I'm trying to .. . Oh. Here's one. The question just says, "Is there an FCOI policy template?"

Kathy Hancock: No. What we do have is a Policy Development Checklist. We don't have a template, but what I encourage Institutions to do is to go out on the web and look at other Institutions' policies. Because what I have found is that the policies look very much the same. The only thing that I see different is the designated official or officials. So, if you have a large institution, like a university, I typically see a committee is assigned that will to review a financial disclosure. For a smaller institution, like a small business institution, you would only see .. . In a lot of cases, we only see one person that's assigned. The regulation doesn't dictate how many people have to be assigned that role and like I said before, the regulation is very prescriptive. So, it provides the framework for developing a policy, training. It talks about who has to be trained, when they have to be trained. Disclosure, who has to disclose, what they have to disclose. So, hopefully that will be helpful to you to get a look at the other policies.

Diane Dean: Okay. And I think this is going to be close to our last question here. "What is a common way that undisclosed SFIs are discovered?" And maybe I'll take a little stab at this, Kathy, and we can kind of collaborate on this one. I think we've learned over the years that there's a number of ways. When you're thinking about Financial Conflict of Interest, don't think of it as a silo. Don't think of it as a separate entity from, say for example, when you are working with an Investigator on their other support, for that to be reviewed, or you're working on bibliographies or things like that. Because information in all of those sources are related to one another. And we have learned, at NIH, that by looking at FCOI reports, we also can evaluate that too for other support. So, I would suggest checking other sources of those types of information that are included in a grant application and also in publications. Many times you may find a publication that's attributed to one of your faculty Investigators that has not been disclosed. Some Institutions have Investigators certify that they have made complete disclosures and have other ways of checking disclosures through Google tools and things like that, but there's quite a number of ways that something like that may come up. Kathy, did you have anything you wanted to add to that?

Kathy Hancock: Well, just for example, you could be talking to somebody and discover that they have equity interest in the company but then they fail to disclose that to the Institution. So, there's ways just .. . I think the question was how do you know that there's somebody who didn't disclose an SFI then does have, how are those discoveries made? And it's through news articles where somebody said, "Oh, somebody has an SFI and there wasn't an FCOI reported."

Diane Dean: Yes.

Kathy Hancock: Because they know about their history.

Diane Dean: Yes. And training is a good way too. The more that Investigators understand what their disclosure responsibilities are, especially when they're confused maybe between FCOI and some other kind of other support. The more they understand what they need to do to comply, the better the disclosure process will be. So, that's also a very good tool .. .

Kathy Hancock: Absolutely.

Diane Dean: .. . for this. So, I think we're running out of time. I just want to wrap up by thanking you very much for your participation and your great questions that you submitted. If you have any additional questions, like I said, you can visit the exhibit hall and look for some of our tables or you can also submit your information to the FCOI mailbox, which is listed in the resources section of Kathy's slides. Your feedback is very important to us, so please take a moment to let us know what you thought by clicking on the session feedback button located with the description and the presenters on the auditorium list of sessions. When you are completely done with this seminar, please also complete that overall summary form in the navigation bar at the top of the page. It's very helpful for us to plan ahead and think about our seminars. And thanks, again, for participating and have a great day today.

Kathy Hancock: Yeah. Thank you, everyone.

Diane Dean: Thank you.