FCOI and Other Support: NIH and Grantees Working Together

Session Transcript: 2022-2023 NIH Grants Conference

Ben Weinstein: I'm pleased to introduce to you today our expert panel consisting of Mr. Romeo Tengey and Ms. Diane Dean. Thank you, everyone. We know you are anxious for the main presentation, so let's get started. Romeo and Diane?

Romeo Tengey: So my name is Romeo Tengey. I'm an Assistant Grants Compliance Officer at the NIH Office of Policy For Extramural Research Administration. And Diane will introduce herself.

Ben Weinstein: We seem to be having trouble with Diane's audio. Romeo, why don't you continue until we can get Diane's audio fixed?

Romeo Tengey: So today, we will cover some key topics regarding commitment transparency, financial conflicts of interest, Other Support, disclosure requirements for FCOI and Other Support. We will go over the who, what, why, when, and then we will also talk about some best practices. And I will turn over to Diane now.

Ben Weinstein: It looks like we're still having trouble with Diane's audio. Romeo, could you pick up this slide, please?

Romeo Tengey: Okay. So on this slide, we will talk about transparency and reporting of all research activities, domestic and foreign. Openness and transparency enables productivity, collaboration and helps ensure appropriate disclosure of potential conflicts of interest and commitment. The consequences of nondisclosure threatens the integrity of research, Federal interests and distorts NIH funding decisions. That is why transparency and reporting is really critical. Next slide, please. So the key concepts that we are talking about financial conflicts of interest. Now a financial interest or relationship which could directly and significantly affect the design, conduct or reporting of NIH-funded research, and then we also have Other Support/Conflicts of Commitment. That is conflicting obligations between and among multiple employers and entities. Next slide, please. So on this slide: The sources of the requirements that allow us to really stress these transparency commitments. As you can see, we have 45 CFR Part 50 Subpart F and then the NIH Grants Policy Statement Section 4.1.10. Next slide, please. So the purpose is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of NIH-funded research grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. Next slide, please. So who must disclose? Investigators. Investigator is defined by the regulation as the PD/PI or any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research that is proposed or funded by NIH. Other persons may include collaborators or consultants, for example. Now the next slide, please. Now, what must Investigators disclose? Investigators are supposed to disclose their significant financial interests and those of their spouse and dependent children to their institutions. Now, what is a significant financial interest? Remuneration, for example, salary and any payment of services, consultant fees, honoraria and paid authorship, greater than $5,000 a year; equity interest in a publicly traded entity, subject to a dollar threshold, and in all non-publicly traded entities; intellectual property rights and interests greater than 5,000 a year; and sponsored travel that is reimbursed over $5,000 a year. So when must Investigators disclose this information to their institutions? Now, at the time of application and then within 30 days of acquiring or discovering a new SFI, and then on an annual basis as prescribed by the institution.

Diane Dean: Hi, Romeo. Can you hear me?

Romeo Tengey: Ah, yes, I can hear you now, Diane.

Diane Dean: Okay. Sorry for all these technical difficulties.

Ben Weinstein: Not a problem, Diane. Do you want to take .. .

Diane Dean: Technology is great .. .

Ben Weinstein: .. . it from here?

Diane Dean: Yes, technology is great when it works. So thank you, Romeo, for giving introductions for financial conflicts of interest.

Romeo Tengey: You're welcome.

Diane Dean: So I'll pick up here about what NIH does with the information you submit to them [Indistinct] and principally this is done by the NIH Program Officials. They are the ones that have the scientific expertise and the knowledge of the funded programs to determine if the institutions' actions are sufficient to manage the reported financial conflict of interest, and they may determine, however, that more information is needed, that more clarification is needed or perhaps that the institutions just are not sufficient enough to manage the conflict. So the issue here is though, with financial conflict of interest, it's not to eliminate them because, as we talked earlier, the importance of transparency and clarity is .. . These are how we build on our relationships and our collaborations in science. The object of this is to identify the conflict and then manage it so that it doesn't present a bias to NIH-funded research. Next slide. So who is responsible then for ensuring that NIH gets the information that is needed, and it's both complete and accurate? The recipient institution has ultimate responsibility to NIH for ensuring that everything that's submitted to NIH, every report, every piece of information is complete and accurate, and that's goes for FCOI as well as Other Support. However, Investigators, in this particular case as defined by the regulation, have a very important role, and that is that they are responsible to the institution to make sure that the institution gets complete and accurate information because the institution is then going to report that information to NIH. So, yes, the recipient institution is ultimately responsible, but also, yes, the Investigator plays a pivotal role in making sure that the information is passed on to NIH in a correct way. Next slide, please. This is just a depiction of how the FCOI regulation works and how oversight works. So you'll see that the institution is in the middle of this depiction showing that it is responsible both to the Investigator for ensuring compliance and to NIH for providing information. The Investigator also, though, is responsible to the institution for disclosure and complying with institutional policies, and the institution is responsible for implementing the regulation and ensuring appropriate oversight. NIH, of course, also has a part in this by providing education and outreach and oversight of compliance by the institution. So with this, Romeo, I'm going to turn this back to you once again.

Ben Weinstein: Romeo, you're on mute. Thank you.

Romeo Tengey: Sorry about that, thanks. So now we will discuss Other Support's disclosure requirements. The next slide, please. So on this slide we have the sources of disclosure requirements. The first on the list is the NIH Grants Policy Statement Section 2.5.1 regarding Just-In-Time procedures. NIH requests information on other active and pending support as part of Just-In-Time procedures. Next on the list is the NSPM-33. That is the National Security Presidential Memorandum-33. Now, NSPM-33 requires all Federal research funding agencies to strengthen and standardize disclosure requirements for institutions and researchers that are receive federally funded awards, and NIH policies align with the NSPM-33 disclosure requirements. And we also have the National Defense Authorization Act Section 233, which covers disclosure of funding sources in applications for Federal research and development awards. Next slide, please. Now, what is the purpose of disclosing Other Support? It is very important to disclose Other Support in order to identify and resolve overlap in applications before an award is made. Overlap can be scientific, budgetary or commitment overlap, and overlap of any kind is not permitted. Next slide, please. Now let's explain each type of overlap. Scientific overlap occurs when the same research is proposed in more than one application or is submitted to two or more funding sources for funding consideration. Budgetary overlap occurs when budgetary items such as equipment or salaries that have already been funded by another source are required in an application for duplicate funding. And commitment overlap occurs when an individual's time commitment exceeds 100 percent, or 12 person months, regardless of whether salary support is requested in the application. Next slide, please. So who must disclose Other Support? Other Support information is requested for all individuals designated by the recipient institution as senior/key personnel in an application. However, this excludes Program Directors, training faculty and individuals who are involved in the oversight of training grants. This also excludes individuals who are categorized as Other Significant Contributors. Other Support is also requested for all senior/key personnel in the progress reports when there has been a change in active other support, and here also it excludes Program Directors, training faculty and individuals involved in the oversight of training grants. Next slide, please. So when should Other Support be submitted? One, when requested by NIH as part of the Just-In-Time procedures; two, in progress reports when there has been a change in active other support for senior/key personnel; and three and very important, as soon as undisclosed Other Support information is discovered by the recipient institution, it should be reported immediately to NIH. Next slide, please. Now, what must be disclosed as Other Support? So Other Support includes all resources made available to a researcher in support of and/or related to all of the researcher's research endeavors, regardless of whether those resources have monetary value and regardless of whether they are based at the institution, the researcher identifies for the current grant. So as you can see on the slide, Other Support includes resources and/or financial support from all foreign and domestic entities that are available to the researcher. Other Support also includes consulting agreements when the PI or other key personnel will be conducting research as part of the consulting activities. And Other Support also includes in-kind contributions such as office or lab space, equipment, supplies or employees or students supported by an outside source. Now, if the time commitment or dollar value of an in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates. Next slide, please. Now, it is important to realize that Other Support does not include training awards, prizes or gifts. Other Support also does not include start-up support provided to a key personnel by the applicant organization, and not also .. . And not considered as Other Support are consultant activities where the PI or other senior/key personnel is not conducting research as part of the consulting activity. And institutionary resources such as co-facilities or shared equipment that are made broadly available should not be included in Other Support but rather listed under Facilities and Other Resources. Next slide, please. So how is Other Support information used by the NIH? Now, NIH staff review and assess Other Support information prior to award of the grants to ensure that sufficient levels of effort are committed to the project, there is no scientific overlap, there is no budgetary overlap, there is no commitment overlap and to ensure that only funds necessary for the approved project are included in the award. Next slide, please. So who is responsible for ensuring that complete and accurate Other Support information is reported to NIH? One, recipient institutions are responsible for reporting complete and accurate information to NIH; and two, senior/key personnel are responsible for disclosing complete and accurate information to their institutions. And now I will turn it back to my colleague, Diane. Over to you, Diane.

Diane Dean: Thank you, Romeo. Thank you.

Romeo Tengey: Thank you.

Diane Dean: So you've heard us talking about the requirements for financial conflict of interest and Other Support. Who is responsible for reporting? What do they report? Let's tie this all together now and see what we're talking about, and that is what's at stake if these things are not reported to NIH and are not reported accurately, and this is something that affects all of us, not just recipient institutions but also NIH. So the first is the integrity of the science. We were trying to promote transparency and promote accountability and objectivity for research, and when this is not upheld, the public loses its trust in the integrity of research. We want to prevent overlap. We want to make sure that when NIH funds its science that its research dollars are being spent wisely and that we're not paying twice for the same research or for the same equipment or for effort, when research dollars are so scare that we want to make sure that they're appropriately used. We want to protect the institution's reputation. We don't want any dispersions on scientific integrity, and of course we want to promote compliance. We want to make sure that this information is submitted to NIH and submitted on time, so that NIH can appropriately use this information and prevent any negative outcomes. Next slide, please. So we decided to share with you a couple of case studies to show you .. . Illustrate what's at stake and to talk about transparency and the importance of transparency, two points that we have been stressing here, and also what happens when things go wrong. So let's look at this first case study, next slide. Thank you. So Person A, a professor at 123 Medical University .. . which happens to be a domestic entity .. . failed to disclose the following, the person: Their various foreign affiliations, their positions, their foreign funding, not only with grants but also contracts, their honors, their awards prior 8-year period, 2012 to 2020, no disclosure to the institution; nor did this person disclose their significant financial interests to the institution which included multimillion-dollar investment. Now, these are real case studies, so just so you know. Included multimillion-dollar investments in another company, and actually it was a company that the person had founded. They had more than a 57 percent equity ownership interest in the company, and the person was the founder, president and signing official of the company. And when the University asked for their annual significant financial interest to be disclosed, the individual said, "No, I don't have any significant financial interest to report." This is tantamount to a false statement. So based on the information that was provided by this individual to the University, the University had no reason to have any financial conflict of interest to report to NIH and did not report any financial conflicts of interest to NIH. The University only became aware of the situation when NIH inquired about the company that this person had and its role. Then the University became aware of the information. Next slide, please. Next .. . Thank you. So the University did an investigation, and they found that there indeed were SFIs, significant financial interests, that the person had not disclosed, and they reviewed those significant financial interests and found that in fact there were financial conflicts of interest that should have been reported to NIH. So they did a retrospective review which is something that's required by the regulation, that requires the institution to go back over the time, and in this case it was 8 years, to determine if those undisclosed interests had any kind of an effect on NIH-funded research that biased the outcome. That's a big undertaking. It's a big undertaking for a small amount of time for an institution, much less 8 years' worth of investigation by the institution. NIH then also worked with the institution to develop a corrective action plan to address those issues. What went wrong? What .. . Were there were internal controls that were strong enough that should have maybe not prevented this, if someone was trying to hide it, but certainly to detect at some point? Was that the issue? Was there training needs? So we worked with the institution to develop a corrective action plan to address those deficient areas at the institution, and here's what happened. The institution ended up refunding funds to NIH because of the FCOI issues and its policy, its policy and not adhering to its own policy and the effect that it had. The person was prohibited by the institution from participating in NIH-funded research activities for an entire fiscal year, and the person was replaced as PI and senior/key personnel on any of its .. . of this person's NIH-funded grants. They were asked to develop a robust plan for oversight of this person. So this person is on a corrective action plan. The institution is developing a plan for its oversight of the person as it's on the plan and to make sure that they provide FCOI trainings and disclosure .. . and how to .. . I'm sorry, to attend FCOI trainings and how to provide disclosures and when. We also asked the institution to assess their FCOI program, including the ability to identify and develop appropriate management plans. So all of this was necessary because information was not accurately and completely disclosed, so not only did it have an effect on the institution, a very costly effect, they had to refund money to NIH, but also they had to develop programs and institute oversight, and all of that costs money. But also it cost NIH money in the sense that the research that we had was in jeopardy. So next slide, please. And I'll turn this over to Romeo for the second case study.

Ben Weinstein: Romeo, you're still muted. Thank you.

Romeo Tengey: Sorry about that. Thanks, Diane. So now let's discuss case study two. This case study was about a Principal Investigator who did not disclose the following to the institution: Foreign funding on multiple foreign grants and other foreign affiliation; this particular Investigator was listed as a PI on some of these foreign grants and devoted significant effort on some of these foreign grants. This Investigator was also PI or key personnel on several NIH-funded grants. However, the Investigator's institution was not aware of all of these foreign grants and affiliations and therefore could not report or submit accurate Other Support information as required to NIH. Next slide, please. So let's see what the outcome was for this egregious case of nondisclosure of Other Support information. As soon as NIH discovered these foreign contracts and affiliations, NIH contacted the Investigator's institution and asked if the institution was aware or knew about that. The institution, the recipient institution, then conducted its own investigation and reported the details back to NIH. NIH then reviewed and analyzed the details and concluded that there was significant commitment and budgetary overlap. However, there was no scientific overlap in this case. We've had other cases where there was also scientific overlap, but for this particular case, NIH concluded that there was significant commitment and budgetary overlap but no scientific overlap. But because there was commitment and budgetary overlap, NIH negotiated a corrective action plan with the recipient institution regarding this particular Investigator. Now let's look at what the corrective action plan included. The corrective action plan included prohibiting this Investigator from being listed as PI or senior/key personnel for a period of 1 year on NIH-funded grants, replacing the Investigator as PI or key personnel on several NIH-funded grants, requesting bilateral termination of an Investigator-initiated NIH-funded grant where this Investigator was listed as PI. NIH also requested refunding of the Investigator's salary, fringe and associated F&A costs for all fiscal years where commitment overlap was identified. NIH also developed a monitoring plan for oversight of this Investigator's research activities which included FCOI disclosure training. NIH asked the recipient institution to develop this monitoring plan. So as you can see, there can be very serious consequences for not disclosing Other Support information, monetary and other serious consequences. And now I will turn it back to Diane for some best practices and takeaways. Over to you, Diane.

Diane Dean: Thank you, Romeo. So now what? Where do we go from here? I think what we've established is that there are requirements that must be met. They must be met by complete and accurate disclosure and reporting. So how do we, as partners, NIH and recipient institutions together, work to ensure that this happens? Because there's too much at stake for us not to address this, and we thought that it is a best practice that institutions, recipient institutions, review or .. . information before it's disclosed to NI .. . I'm sorry, review Investigator disclosure information to verify its accuracy. Now, there's .. . This is not a requirement of the regulation, but it is a best practice that we would like to discuss here with you today, and we've come up with several possible approaches with this, and there's several ways that we hope that you can use this information. One is to give you some ideas about things that may work at your institution, and you could use those things that seem to fit best into the climate and the policies at your institution. You could also use this as a risk-based approach. So for example, for new Investigators who may not be familiar with disclosure requirements, or for Investigators who have complex disclosures to make, or for Investigators that are forgetful sometimes about having interests and other associations that need to be disclosed, you may want to use combinations of these things. So it's very much being provided to you as a resource and endorsed at NIH as a best practice. And if you would, in the chat box, if you're doing anything at your institution already to work on verifying this information with the Investigator before you report it to NIH, we'd love to hear from you and hear what your ideas are and what your institution is thinking about. So let me quick go over this list that we have developed so .. . And again, remember that some of these are things that you might use for higher-risk situation versus just normal checking. So searching Internet sites to determine if there is public information available about possible other interests or affiliations with another entity and the individual that's disclosing. Cross-reference FCOI and Other Support disclosures, and by this we mean if the individual is issuing Other Support, check their FCOI disclosures to see if there's anything there that you might be missing and vice versa. It's a good body of information to have to check. Compare information from previous disclosures. Did something drop off? Why did it drop off? Review outside activity and consulting arrangements that are vetted through the institution. I don't know. You may have access to those approved. You may also have access for those that are disapproved which should also be a source of information for you. Review support included in publication citations that have been provided by the Investigator in grant applications. Talk to the Investigator about disclosed financial interests and Other Support to verify information with the Investigator or to gain further understanding. Review pertinent data and institutional files. Review travel information. Why .. . What was the purpose of the travel? Was it to travel to another state in the United States to do work at another institution? Well, what's the nature of that work? Is there anything there that needs to be disclosed that we need to know about? And perhaps instituting a requirement that Investigators certify that they are fully and completely disclosed or may face institutional disciplinary action. Again, please let us know in the chat your thoughts and some of the activities that you may already be engaged in. Next slide, please. So a few important takeaways, FCOI focuses on Investigator financial interests, whereas Other Support focuses on the resources available to the Investigator in support of their research endeavors, two different endpoints but all important information. For both, NIH funding may be affected by the outcome of both of these disclosures. They both pertain to both domestic and foreign entities and interests, and in both cases accurate reporting to NIH hinges on the Investigator disclosing completely and accurately to the institution. Next slide, please. Important reminders, if I haven't said it enough already, recipients are required to submit complete and accurate information. That is a very important message we have here. Institutions must ensure that Investigators understand their disclosure requirements. Policies at institutions must be current and must align with Federal requirements. They can be more restrictive and require more information, but they have .. . They cannot be any less requirements than the Federal requirements are. Institutions are expected to have systems, policies, internal controls in place by which they manage FCOI and Other Support, also must comply with Federal reporting requirements. Always notify NIH immediately if there are changes, and when in doubt, ask us early and ask us often. We're here to answer your questions and help ensure that you understand the requirement. Next slide, please. If you have any questions, you can reach us here at these mailboxes. There are several additional slides, as reference slides that follow this slide that we have provided, giving you some informational links and a summary table and some other good resources for you. I don't know. We probably have just a few moments for any questions. I'll ask for the moderators to let me know how that's going. If we don't get to your questions, certainly we will try to respond to them after the presentation. Thank you.

Ben Weinstein: Thank you, Diane, and thank you, Romeo, and thank you to everyone for joining us for this informative presentation today. We have just a few moments for questions which I'll pick from the questions-and-answers chat for our panel. The question with the most upvotes has been, "How long is an Other Support signature valid for? For example, if a signature is dated 6 months ago or even older but the Investigator has not had any changes, would we need to get it resigned by them after that long?" Romeo, would you like to take that?

Romeo Tengey: Yes. Well, if I understood the question correctly, the question is asking, "How long is the signature good for?" The most important thing to realize is that, well, Other Support is requested in the application as part of the Just-In-Time procedures. So if you are submitting an application, it doesn't matter how long signatures have been on there for. You have to submit Other Support. Where this might come in place is regarding the progress reports, right, and remember, Other Support is only requested in the progress report when there has been a change in active other support for the PI or senior/key personnel. So if there has been no change, if the Principal Investigator or senior/key personnel has not had a change in their active other support, then there's no need to report Other Support. However, if there has been a change since .. . Let's say when they submitted a written application and now they are in a progress report phase, if there's been any change in active other support for the PI or other senior/key personnel, then they have to submit Other Support so .. . And the Other Support has to have current signatures. So I don't know if that answers the question completely?

Ben Weinstein: I think we have time for one other question before we'll be required to end this. However, the question with the second most upvotes was, "Is it correct that for RRPRs .. . RPPRs, key personnel are the only individuals named on the NoA, or does it include anyone who was listed under key personnel in the proposal?"

Romeo Tengey: Okay, so very important distinction here. For purposes of Other Support, when we talk about key personnel, we are talking about those individuals that the recipient institution has designated as the key personnel. So we are not talking only about the people who are named as key personnel in the NIH Notice of Award. If your institution lists you or designates you as a key personnel, even if you are not listed as a key personnel in the NIH Notice of Award, you are considered key personnel for the purposes of Other Support, right? For the purposes of Other Support, we are stressing individuals designated by the recipient institutions. That is the key.

Ben Weinstein: Thank you, Romeo. I think that's it for our time.

Diane Dean: Can I just quickly take 10 seconds to also address the issue about, how long is a signature good for on Other Support? I think really the question is .. . The issue is to make sure that the information on Other Support is accurate. So if your institution has a policy that that's updated annually or semiannually, that would be the period of time that you would go with, but the real crux of the issue is to make sure that it's accurate.