Financial Conflict of Interest

>> Diane Dean: Hi. I'm Diane Dean, and I'm the Director of the Division of Grants Compliance and Oversight in the Office of Policy for Extramural Research Administration, part of the Office of Extramural Research at NIH, and I'm here to talk to you today about Financial Conflict of Interest. Financial Conflict of Interest is a requirement that's been in place since actually 1995, but more recently in 2012, the regulations were revised, and the regulations apply to grants and cooperative agreements as well as contracts. The requirements are fairly identical. In the grants world, it talks about application, and in the contracts world, it talks about proposals, but other than that, the requirements are the same. However, since I am in the grants world, I'm going to be talking to you today. My references are all going to be to grants. This slide shows you the regulatory citations in case you would like to see those in the Code of Federal Regulations and read up on them. So what is the purpose of the regulation? The purpose of the regulation as this slide says is to promote objectivity and research, and that's what the actual purpose is, is to protect the scientific research by ensuring that no ... or giving at least a reasonable expectation, but we hope to ensure that no ... that all of our research would be free from bias by investigators' financial conflicts of interest. So who is covered by this regulation? Each institution that applies for or receives a grant or cooperative agreement from NIH. Any investigator that is named by the institution, and that's investigator as defined by the regulation, is covered by this requirement, and individuals that receive awards are also required as the recipient. SBIR and STTR grant applicants and awardees, you will note, are not covered, but Phase II SBIR/STTR applicants and awardees are. So a few reminders of things that are often overlooked or perhaps misinterpreted, and one is the requirement for disclosure of foreign financial interests. Because this one was a little ... causing a bit of confusion, NIH clarified this with a guide notice a while ago, and it clarifies that investigators have to report disclosure ... They have to disclose, I'm sorry, their financial interests from foreign institutions of higher education. Investigators, and this also includes for self-recipient investigators, have to redisclose those interests that are received from foreign institutions of higher education or the government of another country. As NIH is working through foreign-influence efforts, we are also reviewing our FCOI processes when addressing that area. Another policy clarification is disclosure of reimbursed or sponsored travel. We've clarified that the institution's FCOI policy, so there is the federal regulation, which we've talked about, and then each institution is required to implement the requirements of that federal regulation into their own policies, so institutional policies with respect to disclosure of reimbursed or sponsored travel can establish a threshold for investigator disclosure or to sponsor travel. It does not have to be $0 threshold there. And also, to clarify disclosure at the time of application, we clarify that, at the time of application, the institution has to have up-to-date disclosures on hand. That doesn't mean that, at each application, the institution has to go through a new disclosure requirement, so we are raising these issues up to help institutions in their implementation. Some important reminders about institutional policies, and we chose the ones in this slide based on different issues that have arisen and questions that we get, so with respect to applicability, as I stated before, the regulation applies to any individual defined as an investigator. Now when we think about investigators, we think of the PI, or the principal investigator, but in this case, the investigator is defined much more broadly by design, so you will see here that an investigator always means the project director or the principal investigator but also means any other person regardless of the title or position who is responsible for the design, conduct or reporting of research funding or proposed for such funding, and we've given examples, and that can include collaborators. It can include consultants and any other person that fits that role. So it's very broad, and we believe it's broad by design to cast a wide net to help safeguard, NIH-sponsored research, and so we encourage institutions to consider the role of a person rather than their title when thinking about who is an investigator and then subject to this regulation. Also, before I leave this slide, I want to take note that it's applicable to the institution, and one of the other institutional responsibilities in this whole project, in this whole area of financial conflict of interest is to make identified financial conflict of interest publicly available on a website and also to make their financial conflict of interest policy available on a website, so there's information in the regulation about those two requirements as well. We talked about disclosure of sponsored travel. It's in the initial disclosure is subject to what is given to the investigator within the preceding 12 months. This slide gives you more details on what must be disclosed and, again, the threshold that's established by the institution. With respect to reporting requirements, institutions are required to submit an annual report. They submit an initial report, an initial report to NIH when an FCOI is identified, but then annually thereafter they are required to submit at the same time as the annual progress report as it says in the slide, annual report to NIH to either update the information about the financial conflict of interest by saying it is no longer being held or by letting NIH know that it is still being held and managed by the institution. Record retention is also something that is often overlooked. This gives you the ins and outs of record retention that institutions must maintain the disclosures of financial interests, documentation of the institution's review and response to those disclosures and whether or not they resulted in a financial conflict of interest and all actions under the institution's policy, which would include management of the financial conflict of interest, the retrospective review if one is ever required and of course any outcome of a mitigation report. Another place where institutions sometimes have difficulties is not so much in establishing a management plan for the investigator with a financial conflict of interest but actually monitoring a management plan, so we encourage institutions that their policies address the institution's requirement to monitor and determine how that is going to look and how it's going to be done and recorded. And of course the FCOI reports that you send to NIH include a confirmation that the investigator has agreed to and has seen the management plan. A retrospective review, which I just referred to, is a process that the institution goes through when an FCOI is not identified or managed in a timely manner, which would include the failure of an investigator to disclose a significant financial interest or the failure of an institution to review it in a timely manner. If there's also a failure to comply with the management plan, the institution will have to do a retrospective review, but the retrospective review, you notify NIH promptly and submit only the mitigation report if the retrospective review determines bias. Otherwise, the retrospective review is maintained at the institution. These are the key elements of a retrospective review. They are available in the regulation. They're also available on the NIH website where we've posted a lot of information and FAQs and processes about retrospective review. You can find those there as well. And then as I said, if the mitigation report ... If the retrospective review determines that bias has been determined, then a mitigation report is required, which includes all of those elements of the retrospective review, but in addition, it asks that you describe the impact of the bias on the research project and describes the plan of action to eliminate or mitigate the effect of that bias on the research. Some other important reminders, and that is it is an institutional responsibility and also a subrecipient responsibility to inform each investigator, and that's the investigator that's defined under the regulation of the FCOI regulation, meaning the federal requirements of the institution's policy or implementation of the federal requirements and the investigator's responsibilities regarding disclosure of their significant financial interests. Institution must require training, and each investigator must complete that training at least prior to engaging any NIH research, at least every 4 years thereafter and immediately when any of these following circumstances apply: that the policy is revised so that maybe some of the requirements change when there's a new investigator to the institution or when an institution finds the investigator is not in compliance with the policy requirements. One of the institutional responsibilities with respect to financial conflict of interest is also the requirement that any subrecipients apply with the requirements of the financial conflict of interest policy and regulations, so we ask that that determination be incorporated as part their written agreement, that is, whether the subrecipient is going to use the prime recipient's financial conflict of interest policy and procedures or if the subrecipient is going to rely on their own financial conflict of interest policy and procedures, the difference being if the subrecipient relies on their own financial conflict of interest implementation and policy, they will go through the process and submit any reports to the prime recipient, reports of identified financial conflict of interest, to the prime recipient, who then submits those to NIH on behalf of the subrecipient. If however the institution decides that the subrecipient should follow the prime recipient's financial conflict of interest regulation and financial of interest policy, the subrecipient will then be required to submit all of institutional ... all of the investigator's disclosures to the prime recipient, who will then subject those disclosures to their own policy, that is, reviewing disclosures, determining financial conflict of interest exists, developing a management plan and then reporting those to NIH. So that's the distinction, but in any event, that should be incorporated as part of a written agreement so that there's an understanding of what institution is responsible for what with respect to financial conflict of interest. Again, another requirement for subrecipients is to ensure that their investigators also meet the FCOI training requirements, and also they must also provide oversight for the financial conflict of interest management plans and other requirements. Investigators are to disclose their financial interests that are related to their institutional responsibilities, and institutions then of course are responsible for reviewing those significant financial interests and how that relates to an NIH-funded research project and then determining if it represents a financial conflict of interest. There are several times during the period of a year, a 12-month period, where investigators must disclose their SFI, significant financial interests, to their institution. That is, as I spoke about a bit earlier, is at the time of application, so either at the time of application or perhaps on an annual basis as required by the institution, however that looks at the institution, the investigator is required to disclose his or her significant financial conflicts of interest to the institution or to the designated official, however that is implemented. And then annually thereafter, the investigator submits an update or however the institution decides to update that information annually, and then also within 30 days of acquiring a new significant financial interest, it must be disclosed, so those are the three reporting disclosure requirements for investigators. So I've already highlighted a little bit of the financial conflict of interest regulation, but I did want to go over some of the lessons learned now that we've been living with this for quite some time and about reporting. So when an institution submits an FCOI report, it helps to consider the following. Does the FCOI report clearly describe how the financial interest relates to the NIH-funded research? That is an element of the information that is provided to NIH, and it's very helpful if that is not just a template of information that is provided but truly does describe the relationship between the interest and the NIH-funded research, and then another element there is why the institution determined that there is a financial conflict of interest. In other words, which element, which part of that interest rubs up against the NIH-supported research that does rise to the level of a financial conflict of interest? Then does the financial conflict of interest clearly address all of the key elements of the management plan? Now we ask that you don't send us the actual management plan, but you are required to send us these key elements that I've listed here on this slide. Then, if a retrospective review is required, and as we talked about earlier, that's only required in those certain circumstances, and if one is required, it's not required that you submit one to NIH although NIH may ask you in certain circumstances to do so, but under normal circumstances, that is not required to be submitted to NIH, but if it does change a previous report that you've submitted or if it does create the need to submit an additional report, you do that as a result of a retrospective review, and also as I said before, if bias is identified, you must do a mitigation report. That is something that is submitted to NIH. Some additional lessons learned about FCOI reporting: Do ensure that investigators under the disclosure requirements. That's key in compliance with this FCOI regulation, and make sure that the disclosures are complete and accurate. Don't submit any private or sensitive information to us such as a business plan or, as I mentioned before, the entire management plan, and in the event that there's other information in that, please don't submit that to us because, once it's submitted to NIH, it's official record and could be subject to disclosure, so it's better if you don't submit them to us at all although we would try to protect it. And don't report any non-NIH-related FCOIs to NIH. Remember this is only applies to NIH-funded research. And this last slide provides some information and resources for you. We have a mailbox for inquiries about requirements. Anything about the financial conflict of interest regulation that we can help you with is here, and also the FCOI website, which is on our Office of Extramural web page, is listed here, and that site has a lot of resources on it for you. It has a lot of FAQs to talk about different elements of the requirements. It has information on developing your policy to assist you to make sure that you have everything in there that needs to be in there and that it complies with the regulation and other types of information and templates that should be helpful to you, so please visit the website or feel free to send us an e-mail with an inquiry about the financial conflict of interest regulation. And thank you very much.