Common Compliance Pitfalls & Strategies for Success

Laura Gray: Okay. Good afternoon. I'm Laura Gray, and I'm joined by my colleague Philip Smith, and we're the Division of Grants Compliance and Oversight within the Office of Policy for Extramural Research Administration at NIH, and today, we'll be talking about common compliance pitfalls and strategies for success. Today our session is live, and so all the attendants are muted during our presentation, so if you have any questions while we're presenting, please feel free to type them in the Q and A part of your webinar, and we'll get to them at the end of the presentation as much as possible, and if we don't get to them, we'll reply to you via e-mail from the compliance inbox which we'll share at the end of the presentation. So with that said, let's talk about some common compliance pitfalls. So first off, what is compliance? Well, you can come up with many definitions for compliance, and here are some to consider that we've listed on the slide, but basically what compliance is, is doing the right thing, and what can recipients do to ensure compliance? Well, recipients must ensure the safeguarding of all the assets that the federal government provides through grant funds, and in order to do that, they have to ensure that funds are being expended in accordance with the authorized purpose for which they were given, and they can do that by managing the required financial management systems and organizational monitoring systems to ensure adherence to terms and conditions of award, and here is listed a few of those systems that recipient organizations should have. On this next slide here, you'll see to fulfill compliance requirements, federal award recipients must have institutional policies in place to ensure proper stewardship of funds and monitoring programs. For example, institutions must have written policies and procedures for financial management requirements and systems. These policies and procedures should be well-communicated throughout your organization as well as understood and easily findable so that you can access and reference them throughout the project. And all the things that I've been mentioning or highlighting are detailed thoroughly in the federal regulation in 45 CFR Part 75, the administrative requirements, cost principles and audit requirements for HHS awards. The required monitoring systems that I mentioned are outlined in the regulation, and I'm going to step through a few of those that we want to highlight. So in particular I wanted to bring your attention to subparts C and D of this regulation, so part C, it covers preaward requirements for a federal award, and subpart D covers postaward requirements for a federal award, and you'll see under the post we have a few examples of those requirements which you're probably familiar with such as closeout. These are the commonly referred to requirements in postaward, and you can find out all the details when you look in the federal regulation. And now I'm going to hand it over to my colleague, Philip Smith, to talk about cost principles.

Philip Smith: Thanks, Laura. So now let's take a moment to talk about cost principles, so what are cost principles? Cost principles, in general cost principles establish principles for determining cost allocability for grants, contracts and other agreements. Cost principles define direct costs and indirect costs or otherwise known as F and A. On this slide are references to the cost principles applicable to the different types of institutions. As you can see, for-profit institutions are subject to the cost principles located in the federal acquisition regulation, and state and local governments, Indian tribes, nonprofit organizations, hospitals and institutions of higher education such as the University of Maryland can be found in 45 CFR 75. The cost principles apply to all NIH awards including modular awards and awards under SNAP with one exception, that exception being individual NIH fellowship awards. The allowable use of funds for those awards can be found in NIH Grants Policy Statement Section 11. When thinking about cost principles, you'll want to keep in mind the four tests of allowability. Those tests are: one being reasonableness meaning, is the cost of the good and service being considered and the associated dollar amount of that good or service reflect the action that a prudent person would take under the same circumstances when the decision to incur that cost are made? Also you want to ensure that the cost is necessary to complete the work of the grant. Next, you have allocability. For allocability, you'll want to ensure that the cost was either incurred in whole or in part to advance the work of the grant. If so, then the charge is allocable in whole or in part. Next, you have consistency. This requirement requires that all costs must be treated consistently for all work of an organization under similar circumstances regardless, of the source of funding. And then lastly we have conformance which requires that a charge is allowable under the terms and conditions and laws that regulate that specific award. Now we'll move on into audit requirements. Listed here we have the different regulations where the audit requirements for the different institutions are housed. Please note that foreign organizations will follow the same audit requirements as for-profit organizations. Next slide. When thinking about audit requirements for NIH awards, one key point that you'll want to keep in mind is that NIH grant recipients that expend $750,000 or more within a year of federal awards are subject to audit requirements. We also have listed on the slide the due dates for audit reports. We won't go too deep into that, but please keep in mind that delinquent audit submissions can result in the imposition of sanctions and/or possible loss of federal funds. Here we have a summary of our audit requirements. This summary is organized by the recipient type. The summary also provides information on where to submit audit reports. And next we have a summary of the federal requirements of which we just covered. This table is also organized by recipient type and nicely summarizes the location of the appropriate administrative requirements, cost principles and audit requirements. And lastly we have a slide here that references documents that can be of great use to you when managing NIH awards. First, we have the NIH Grants Policy Statement or NIH GPS. This document serves as the standard terms and conditions for all NIH grant awards. Next, you have the Notice of Award or NoA. This document includes the general and specific conditions applicable to NIH awards that recipients must comply with. This document is your bread and butter, and you'll want to refer to this throughout the life cycle of your grant award. And then lastly we have the NIH Guide to Grants and Contracts. The NIH publishes new policy requirements in this guide, and typically on an annual basis around this time of the year, NIH will revise the NIH GPS to incorporate these policy changes that were published in this guide. If you have not done so already, I do recommend subscribing to this publication as it will be the best source to keep you up-to-date on all NIH policy changes. So now we'll take a moment to dive into some common compliance pitfalls. First we'll cover excessive cost transfers. Next will be allowable costs, then administrative and clerical costs and finally debarment. So compliance pitfalls, jump right in. Cost transfers, with cost transfers, recipients must maintain documentation of cost transfers and must make them available upon audit or other review. Cost transfers should be documented with adequate justification, explanation and be certified by a responsible official within your organization. As with any other charge, you'll want to ensure that the transfer meets the test of allowability with the charge being reasonable, allocable, consistently applied and conformance. Now I'll turn it over to Laura to discuss supplies and entertainment.

Laura Gray: Thanks, Philip. So, yes, we're talking about common compliance pitfalls and common questions that we get regarding compliance, and so we wanted to highlight a few of those related to allowability. So for instance, the allowability of office supplies is covered in appendix three of 45 CFR Part 75, and it details that office supplies must normally be treated as F and A costs or indirect costs because they have a common joint purpose amongst various projects, and so in general, they must be treated as indirect costs. However, there are circumstances in which office supplies could be treated as direct costs, and that would be if there was a specific research purpose or unlike circumstances which it would be reflected in your approved budget for the project and allowable based on your terms and conditions of award as well as your institutional policy. And I wanted to mention institutional policy because while your institutional policy must comply with your terms and conditions of your NIH award, it can be more strict. So it can say that office supplies can never be direct costs, and as long as it's compliant with the terms and conditions of award for NIH, it can do that. It can't be less strict, but it can be more strict, so you want to be familiar with your institutional policy as well as your Notice of Award. And then another example that is commonly discussed are entertainment costs. So entertainment costs such as food are unallowable, and in general that's true. Entertainment costs are unallowable, but like everything, there could be exceptions. Entertainment costs can be allowable if there's a programmatic purpose that's authorized in the budget or in writing in a prior approval from NIH for that particular award as well as being allowable based on your institutional policy, and you can reference some of this information in our NIH GPS in section 7.9.1. I also wanted to go in a little bit more detail about food in the next slide, particularly meals because that's an entertainment cost that we get questions about quite a bit. And so this slide reflects that meals are allowable on a research grant when these three different instances occur, and that's when they could be provided to subjects or patients on a particular award if they don't duplicate costs. For example, if that study is providing patients with per diems, they couldn't be ... per diems that would cover their meals, they can't be given meals as well because that would be double-dipping. The meals could be allowable if they're integral and necessary part to a meeting that's disseminating technical information about that particular award, and if they're consistent with the terms and conditions of award, noted in particular terms and conditions of your NIH award. But even if one of these circumstances did occur, you also have to ensure the four tests of allowability like Philip discussed. It has to be a reasonable cost, so you wouldn't expect that a meal on a award would be a five-course meal. That's not a reasonable cost on a grant award. That's not necessarily something that you would pull out your checkbook and pay for, for a technical meeting, and so you have to think about what a prudent person would do. Is that an allowable cost based on the reasonableness test? You also have to consider what your institutional policy says, and many institutions just across the board say meals are not allowable on grant awards to be safe, and so if that is the case and you have a more stringent policy at your institution, that needs to be followed. And now I'm going to hand it back over to Philip to talk about bit about administrative costs. Philip?

Philip Smith: Thanks, Laura. So administrative and clerical costs, so we're going to talk about direct charging of these costs. Typically when these costs are charged to your grant, they should be charged as indirect costs. However, if there is a need to direct charge, you'll want to make sure that you're meeting the conditions set forth in NIH Grants Policy Statement Section 8.1. There's four conditions stated in this section that need to be met in order to direct charge these costs, the first condition being administrative or clerical services are integral to the project or activity, the second being individuals involved can be specifically identified with that project or activity. Third, such costs are explicitly included in the budget. And lastly, the costs are also recovered or not recovered, also recovered, not recovered as indirect costs, excuse me, sorry. So this last condition is referring to what Laura mentioned earlier in that double-dipping. We want to ensure that we're not taking the same charge and paying for it as a direct cost and an indirect cost in that we don't want to be paying for it twice. Next slide. Now we'll dive into salary and administrative clerical costs a little further as far as in the context of direct charging. For these costs, NIH prior approval is not required as long as those conditions which I just previously discussed are met. However, prior approval would be required if additional funds for those costs were being sought, or the incurrence of the cost constituted a change in scope. More than likely, you wouldn't see these costs constituting a change in scope as administrative and clerical staff normally do not have an impact on the aims of the project. For modular awards, you'll want to make sure that these costs are detailed in the personal justification. You'll want to make sure that the person's name, percent of effort and role are provided in that justification, and the justification documents how the four conditions or requirements would be met. Now I'll turn it back over to Laura to talk about debarment.

Laura Gray: Thanks, Philip, and I understand our slides are having difficulty advancing. We understand that's an issue, and we'll get to that shortly, so thank you for letting us know about that, and while we're doing that, I'll go into debarment. So here is what you need to know about debarment. Debarment is any organization or individual that has been debarred from eligibility of NIH grants cannot be paid with NIH funds, and that could be if the individual is in a primary recipient institution or in a sub-recipient institution. So that's the main takeaway from debarment is if someone is debarred and on the project, they can't receive NIH grant funds, so any charges that are made to NIH grants to such individuals are unallowable and must be returned to NIH. So let's say for example that while you regularly check that all of the individuals involved in grant awards are, I understand you do, are not debarred, let's say that one slips through, and one was on an application. That application was awarded. The grant is in process, and then based on your routine checks for debarment, you found that there was an individual on a National Cancer Institute grant, and that individual is debarred. So if that happens, you have to immediately report that situation to your office of sponsored projects and to each of the funding institution centers at NIH that that individual is on an award which was funded by that institute. So those are some of your key takeaway points from debarment, and we're going to go. I see that we're on case study one, but I think we're still on debarment, so I'm going to just give you a little bit more information on debarment and one slide back. And so these are the regulations for debarment and suspension, and they're implemented as a term and condition of all HHS awards, and these regulations highlight in detail that suspension and debarment are exclusion actions taken to ensure the federal government is only doing business with entities that are presently responsible to handle federal funds. And some of these regulations deal with both suspension and debarment, so let me talk to you about what the difference is. Debarment is a final exclusion decision for a specified period of time and is generally the result of conviction or finding of fact. And suspension is a temporary action that's immediately effective to protect the public interest. So if you don't remember anything else about debarment, hopefully you remember this last slide, and you'll ensure that prior to drawdown of funds of each grant award, recipients must report to NIH funding IC if recipient or any of its principals have been debarred or excluded and disqualified from receiving federal funds. And when you hear principals, you might think principal investigators, and that's true. It includes principal investigators, but it also includes a much broader definition that's included in the regulation for you to reference, and so principals in this definition are just really referencing any individual that's in a position on this award that has influence over the development or outcome of an action on the award, and so that's very broad. So that includes principal investigators, but it can also include staff scientists. It can include consultants. It includes the authorized organizational representative. Any individual that has a position that can influence the development or outcome of an action on an award is defined as a principal for debarment and should be checked prior to being put on an application, should be checked prior to drawdown of funds for particular grant awards and on a regular basis within your institutional policy. So with that, we're going to test a bit of your knowledge, and we're going to go to case study number one, and I'll turn it back over to Philip to do that.

Philip Smith: Thanks, Laura. So for our first case study, we have a situation where a university employee transfers expenses from one account to another and annotates the cost transfer stating to correct an accounting error. The university's internal audit group takes exception. Why? So we'll move onto the polling for this question. You have four possible answers. We'll give you about 30 seconds to input your answer, and then we'll discuss it. Okay, I think we've given sufficient time, so great. We have the results here, so it looks like a slim majority of you answered all of the above which is wonderful. That's the answer we were looking for in that all three of the conditions above are a reason why your internal auditor may take exception to the documentation of the cost transfer, the first one being that it took too long to correct the error. Once the error is identified, you typically should correct the error within 90 days of the identification of the error, the second one being that there was no justification. As we talked about earlier in our presentation, you would definitely want to have a justification with your cost transfer, and third, the transfer, there was no certification from a responsible organization official for the transfer, and with that, you would definitely want to make sure that your responsible organizational official has certified and signed off on the cost transfer. So again, thank you for your responses, and now we'll move on into our second case study. Laura will be covering this one.

Laura Gray: Thanks, Philip. So let's say you're driving to the office, and your principal investigator gives you a ring and says, "On your way to the office, can you please pick up some office supplies, and how about you pick up some donuts for the lab meeting this morning as well?" And so you do, and when you get to the office, the PI says that you should charge those costs to the award, to the grant award. But then your department administrator takes you aside and says, "No, you should charge those to departmental funds." Our question is, why? Why did the department administrator take exception and tell you to charge it to departmental funds? We're going to go to the poll and let you test your knowledge. Okay. That's excellent. It's like you guys have been doing this for a while, so it seems like the clear best answer is the one that you picked, and that's number one. The best answer is because these costs do not apply directly to the grant, and you're correct. Like we discussed earlier, office supplies must be treated as indirect costs or F and A costs because they have a common purpose amongst various projects and so are not a direct cost to an award generally. And donuts, to our knowledge based on this case study, are not a specific unlike circumstance that is outlined and approved in your budget or prior approval for that award, and so they aren't direct charges for that award, so thank you for your answers with that. I'm going to move on and let Philip do the next case study, case study three.

Philip Smith: Yep. All right. Thank you, Laura. We're on the right slide, looks like. Great, wonderful. So in this case study, we have, "Dr. Admins from the University of Education submits a research grant application that seeks salaries of administrative and clerical staff as direct costs. Are these costs appropriate?" So let's move to the poll and see what everyone thinks. Again, we'll have four different possible answers. Please take your time and read them thoroughly and provide us with a response. Great. It seems like we've given enough time. Let's see what our results are. Well, it looks like we have a large majority answering for number four which is exactly what we would like to see. As we discussed earlier, generally these costs should be treated as indirect costs, and there are instances in which you could possibly charge these costs as direct costs, and those four conditions that we discussed earlier must be met, and again, you can find those conditions in section 8.1 of the NIH Grants Policy Statement. So now I'll turn it over to Laura to cover our fourth and final case study.

Laura Gray: Thanks, Philip. So case study four, let's say that you recently learned that a post-doc working on an NIH award for your institution had not disclosed she was debarred from defaulting on her student loans, and so unfortunately, you determined the situation had gone unreported for a period of 3 years, and during that time, her salary had been paid with NIH grant funds, so now what do you do? Well, let's go to the poll and find out what you guys think we should do next after you find out. Okay. Excellent, it's like you guys have been listening to this presentation. Thank you. The majority of you, almost all of you responded with the response C or three, and that is the best answer because it's when you find out that someone is debarred and has gone unreported and has been on a grant. You must immediately report that situation to your office of sponsored projects and to the funding institutes and centers at NIH for which that individual is listed on the grant awards, so thank you very much for that. I wanted to also mention that you might be familiar with SAM, and that's a mechanism that's used to communicate individuals that are debarred or excluded from funding at federal agencies, and checking SAM is not a requirement, although it does fulfill all requirements. But regardless of the system that you do use, recipient organizations must have a system in place to determine whether the principals, all of those people involved in the award, if they're excluded or disqualified from receiving federal funds. And that must be done prior to application, prior to drawdown of funds and on a regular basis that your institutional policy should outline. So with that, we thank you so much for listening to this presentation. We've seen that you have voiced questions in the questions and answers during the talk, and now we're going to have a few minutes. We're going to go to our moderator and have her give us some of your questions that you've been waiting to be answered.

Diane Dean: Okay, we do have quite a few questions that have come in. The first one is, "I understand that cost transfers need to be documented. Can you provide a template for this documentation that is acceptable to NIH?" Philip, you want to try to answer that one?

Philip Smith: Sure, sure, great question. Unfortunately, there's no specific template that we have that we could provide that you could use to document cost transfers. However, in the Grants Policy Statement as we've previously discussed, cost transfer, the requirements for cost transfers can be found there, and it does detail what's needed to document the cost transfer. The transfer must be supported by documentation that fully explains the transfer, provides justification or fully explains the transfer and the error, provides justification for the cost, and then also you'll need to have that responsible organization official sign off on that cost transfer. So, yeah, so basically sorry we can't provide you with a template that you could use to document cost transfers, but we do provide a framework in which you could use to address the requirements.

Diane Dean: Okay, thanks, Philip. Laura, let me find one here for you. Here is one. "I have a question about effort requirements for key personnel. The Grants Policy Statement says that a reduction of effort by 25 percent or more applies to key personnel. If someone is listed as key personnel on the application, but the Notice of Award does not name them specifically, are they still subject to the 25 percent rule?"

Laura Gray: That's an excellent question because we get that quite a bit, and it can be confusing because institutions can designate additional staff as key in your application, and that's fine. But individuals not named on your Notice of Award from NIH are not considered key to NIH, and so only individuals that are reported on your Notice of Award is key or pertain to that 25 percent rule. So the ones that are noted as key on your Notice of Award are always your principal investigator and then those senior and key personnel that NIH has named on your Notice of Award, and that prior approval request can be found in 8.1.2.6 Changes in Status. And thank you very much for that question.

Diane Dean: Okay. Let's see. Laura, I have another one for you. "I spoke with my program official about the allowability of meals on my research grant, and she said that they are never allowable. What should I do about that?"

Laura Gray: Okay. Well, I understand you might be a principal investigator if you're speaking with your NIH program officer, and that's understandable. But it's important to remember that you should always direct your administrative and financial questions to your office of sponsored projects, who can respond on behalf of your institution and probably very well respond to your question about allowability because they're well-versed in it. But if your office of sponsored projects can't answer that question for you, or if you are within your office of sponsored projects and you have that question, then that authorized organizational representative in your office of sponsored projects, perhaps you, needs to contact NIH. But you need to contact the grants management specialist on that award, and it will be noted on your Notice of Award the name and contact information for that specific grants management specialist on each of your awards from NIH. And that person will be able to respond to your financial and administrative questions particularly based on allowability. It's important for you to understand that the program officer has a lot of expertise, but they're chiefly responsible for the scientific and technical aspects of the award. Thank you for that question.

Diane Dean: Thanks, Laura, for that answer.

Philip Smith: Great answer.

Diane Dean: And, Philip, here is one for you. "Is prior approval required for rebudgeting?" So this is evidently someone with a detailed budget. "For example, when reducing the amount of budgeting for salary and increasing the amount that's been budgeted for equipment, does that require prior approval?"

Philip Smith: Typically rebudgeting does not require prior approval, but there are instances in which you would want to pursue prior approval. And those instances would be when the rebudgeting results in what we call a change in scope which we briefly spoke about during our presentation, and the change of scope is basically the change in direction or aims of a grant project. And if your institution suspects that the rebudgeting would result in a change in scope, you definitely would want to consult with your grants management specialist to ensure that prior approval isn't required. And in this instance, I see that you're moving salary from salary to equipment, which that very well may constitute a change in scope depending on, if the equipment needed for that project, or would it be specifically used? Was it named in the budget prior to the rebudgeting? Things of that nature, and that's why we ... There are definitely a lot of variables that go into deciding if prior approval is actually needed, so we always recommend that you consult your grants management specialist, consult your office of sponsored research to make sure that there are no institutional policies that would govern your rebudgeting also and to get their consultation on the requirement for prior approval. And then another good place you'll want to definitely take a look at is your terms and conditions of award that are specific to that award which can be found in your Notice of Award in section four of that document, and there may be conditions there that don't allow for certain types of rebudgeting, does not allow for funds to be moved from a certain cost category to ... or out of it in general. So you'll definitely want to consult that document and then like I said, always reach out to your grants management specialist when in doubt.

Diane Dean: Thank you, Philip. Here is one on debarment. The question is, "How do we check for debarment? How do we check if an individual is debarred?" Would either one of you like to take that one?

Laura Gray: Sure, I'll take it, and please feel free to jump in. So like I mentioned, debarment is a requirement within the federal regulation on all HHS awards. Recipients prior to drawdown need to ensure that individuals aren't debarred or excluded from business with the federal government, and you can do that by using sam.gov. I'm not saying that you're required to use sam.gov, but sam.gov does happen to be the mechanism that regularly updates suspension and debarment exclusions for all federal agencies, and so it is one place that's easy to determine whether or not an individual on a grant award that has influence over that grant award is disqualified from receiving federal funds. But any system that you do use has to ensure that it checks regularly for debarred and suspended individuals.

Diane Dean: Thank you, and that sam.gov is a publicly accessible website, so people can check that free of charge.

Philip Smith: Right, and that's the Systems for Award Management is the acronym, yeah.

Diane Dean: Oh, very good, sam.gov. Okay, so I think that's it for our session today. We're wrapping this up, and we do have many questions that we unfortunately have not been able to get to, but we will try to be able to answer all of them. And if any of you have other questions after the session, you can send them to the grants compliance mailbox, and we'd be happy to answer them, so thank you very much.

Philip Smith: And I'd also like to point out that you can also join us on our Slack channel in our booth, yes.

Diane Dean: Oh, yes, thank you.

Laura Gray: And the grants compliance inbox e-mail is grantscompliance@nih.gov. I also want to point out that I see there's a lot of questions that we haven't been able to get to those, and we will get to those, but one of the questions was related to FCOI, and I just want to highlight the fact that Diane Dean did a great on-demand presentation that you can check out on the virtual seminar library to find out about FCOI regulations, so thank you very much.

Diane Dean: Thank you.