Philip Smith: Welcome and thank you for joining us today for today's presentation on compliance pitfalls. A few logistics before we get started. We encourage you to be engaged and ask questions, to ask a presenter a question, please open the Q and A icon at the bottom of your screen. You may want to open it as well just to see what other questions may have been answered. We will try to answer as many as possible either live or in a typed response but we may not be able to get to all of them. If you don't get your question answered, please stop by the exhibit hall and talk to our institute, center and program staff available during the seminar via chat or even 20 minute personal appointments. During this session, you are also welcome to use the chat feature also accessible from the bottom of your screen to share tips, experiences and information between participants. PowerPoints are currently available for most session in advance and a recording of the session will be posted within 48 hours. Both will be available in the same location where you logged into for this presentation. Now, I will like to introduce my colleague Alesia Brody, who will also be presenting with me today. The format for today's presentation includes a short prerecorded presentation followed by Q and A, so let's get started.

Philip Smith: Good afternoon everyone and welcome to common compliance pitfalls and strategies for success. We are excited to have everyone here with us, my name is Philip Smith and I am Assistant Grants Compliance Officer in the Office of Policy For Extramural Research Administration and NIH. I am joined today by my colleague Alesia Brody, who will start us off, next slide.

Alesia Brody: Thank, Philip. Hello, everyone, and welcome. So what exactly is compliance? You could come up with many definitions for compliance but basically it is doing the right thing. It is the effect management of public funds to maximize research outcomes. And the avoidance of fraud, institutional mismanagement and poor management of federal funds. What do recipients do to ensure compliance? Recipients have the responsibility to safeguard all assets, ensure that funds are spent in accordance with the authorized purpose and develop and implement systems to ensure proper stewardship of funds to ensure adherence to terms and conditions of each NoA. To fulfill compliance requirements of a federal award, recipients must have institutional policies in place that ensure proper stewardship of funds and monitoring of programs. For example, institutions must have written policies and procedures for financial management requirements and systems. These policies and procedures should be well communicated and understood by those that need to follow them and should be readily available and easily accessible. All of the things we have been talking about are found in 45 CFR Part 75, but now we are going to discuss the specific compliance requirements outlined in the regulation. Specifically, we wanted to bring your attention to Subpart C and D, pre and post award management, which outline the federal requirements. Some examples of post award requirements that you may have heard about are listed on this slide and includes standards for financial and program management, record retention and access, as well as closeout. Now, I'm going to turn it back over to Philip who will discuss the cost principles.

Philip Smith: Thank you, Alesia. Now let's take a moment to talk about cost principles. So what are cost principals? In general, cost principles establish principles for determining costs applicability for grants, contracts and other agreements. Cost principles define direct cost and indirect cost, otherwise known as F&A. On this slide are references to the cost principles applicable to the different types of institutions. As you can see, the for-profit institutions are subject to cost principles outlined in the Federal Acquisition Regulation and state, local governments, Indian tribes, nonprofit organizations, hospitals, and institutions of higher education such as the University of Maryland can be found in 45 CFR Part 75. The cost principles apply to all NIH awards including module awards and awards under SNAP, except of individual NIH fellowship awards. The allowable use of funds under those awards is included in the NIH grants policy statement under section 11. When thinking about costs in the context of the costs principles, it is important to always be mindful of the four tests of allowability. Those tests are reasonableness, meaning is the cost of the good or service being considered and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incure the cost was made? Also, is the cost necessary to complete the work of the grant? Next allocability, was the cost of the good or service 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 to the grant. Consistency, this requires that all costs must be treated consistently for all work of the organization under similar circumstances regardless of the sources of funding. And lastly, we have conformance which requires that a charge is allowable under the terms and conditions of the ... and laws that regulate that specific award. Next, we'll talk about audit requirements, listed here are the different regulations where audit requirements for the different institutions are housed. Please note that foreign organizations will follow the same audit requirements as for-profit organizations. When thinking about audit requirements for NIH awards, one key point to note is that all NIH grant recipients that expend $750,000 or more within a year in federal awards are subject to an audit requirement. Lastly, we've also included detail on the due date for audits. Please keep in mind delinquent audit submissions can result in the imposition of sanctions and / or potential loss of federal funds. Here for your reference, we have included a summary of audit requirements by recipient type, this summary also provides information on where to submit audit reports. And here, we've also included a summary of the federal requirements that we've just covered. This table is also organized by recipient type and nicely summarizes the location of the appropriate administrative requirement, cost principles, and audit requirements. Finally, here we have provided some references to documents that can be of great use when managing your NIH award. First, we have the NIH grants policy statement, which serves as a standard terms and conditions of all NIH awards. Next you have the notice of award or NoA, this document includes the general and specific terms and conditions applicable to the NIH award that the recipient must comply with. And lastly, we have the NIH guide to grants and contracts. The NIH publishes new policy requirements in this guide, typically on an annual basis around this time of year, NIH revises the NIH Grants Policy Statement to incorporate the policy changes from these guide notices that were issued throughout the year. If you do not already subscribe to this publication, we encourage you do so, so that you can keep abreast of the different and latest policy changes and requirements. Now we'll move on to our discussion on common compliance pitfalls. In this section, we will cover excessive cost transfers, allowable costs, administrative and clerical costs, and debarment. Cost transfers, with cost transfers recipients must maintain documentation of cost transfers and must make them available for audit or other review. Cost transfers should be supported by adequate explanations and justifications and must also be certified by a responsible official. As with any other charge, you want to ensure that the transfer meets the test of allowability with the charge being reasonable, allocable, consistently applied and conforming. Now I'll pass it over to Alesia to talk about allowable costs.

Alesia Brody: Thank, Philip. Let's talk a bit about the allowability of office entertainment and meal costs. We'll start with office supplies, if the office supplies are not specifically allocable to the grant, they are considered general office supplies and should not be charged as a direct cost to the grant account. What about entertainment costs? Well entertainment costs are unallowable. Lastly, are meals allowable? Well it depends, meals are allowable when they are provided to subjects or patients under study provided they do not duplicate the participant's per diem or subsistence allowance. Specifically approved as part of the project activity in the NoA, are an integral and necessary part of a meeting or conference, such as working lunch where business is transacted to disseminate technical information. Meets the test of reasonableness, no filet mignon lunches and consistent with the terms of award. No I'm going to turn it back over to Philip so he can share info about other types of costs.

Philip Smith: Next we'll cover administrative costs and clerical costs. Generally these costs are charged as indirect costs or otherwise known as F&A costs. NIH policy does allow for the direct charging of these costs if all the following conditions are met. One, administrative or clerical services are integral to the project or activity. Two, individuals involved can be specifically identified with the project or activity. Three, such costs are explicitly included in the budget. And four, the costs are not also recovered as indirect costs or otherwise there is no double-dipping in direct and indirect costs. Such charges also must meet the criteria for allowable costs as described in NIH Grants Policy Statement Section 7.2. Prior approval is generally not required when re budgeting direct charged administrative and clerical costs, as long as the conditions and the NIH Grants Policy Statement Section 8.1.1.5 are met. However, prior approval is needed when requesting additional funds for the position or the incurrence of the cost constitutes a change in scope. For Modular grants, direct charging of these costs will require that the person's name, percentage effort and role be included in the personnel justification. The justification will also need to address how the costs satisfies the four conditions laid out in the NIH Grant Policy Statement. Now I'll pass it on to Alesia to talk about debarment and suspension.

Alesia Brody: Thanks, Philip. 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. Which means that use of these tools is based on an assessment of entities current and prospective capabilities, not their past misconduct. So what is the difference between debarment and suspension? Debarment is a final exclusion decision for a specified period of time, generally as a result of a conviction or finding a fact in results in the imposition of a set period of time decided on a case by case basis. Suspension differs from debarment in the purpose and duration of exclusion. Suspension is a temporary action, immediately effective to protect public interest, pending the completion of an investigation or legal preceding. When it is discovered that a debarred individual has involvement on your award, you should immediately report the situation to your Office of Compliance if you have one or to your Office of Sponsored Research. And you should notify each involved NIH funding component. Any organization or individual that has been suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants or be paid from NIH grant funds, whether under a primary or lower tired transaction during the period of suspension, debarment, or exclusion. Any charges made to the NIH grants for such individuals are unallowable and must be returned to NIH. What are your responsibilities as a recipient? Prior to drawdown of fund for each grant award, recipients must report to the NIH funding income if the recipient or any of its principals are presently excluded or disqualified. Have been convicted within the preceding 3 years of any of the offenses listed in 2 cash flow 108.800(a) or had a civil judgement for one of those offenses within that time period. Are presently indicted for or otherwise criminally or civilly charged by a governmental entity with commission of any of the offenses. Or have had one or more public transactions terminated with the preceding 3 years for cause or default. Per 2 CFR 180.995 principle means an officer, director, owner, partner, principal investigator, or other person within a participant with management or supervisory responsibilities related to a cover transaction or a consultant or other person whether or not employed by the participant or paid with federal funds who is in a position to handle federal funds, is in a position to influence or control the use of those funds, or occupies a technical for professional position capable of substantially influencing the development or outcome of an activity required to perform the covered transaction. Now I turn it back over to Philip.

Philip Smith: Thank you all for joining us. This is it for the first half of our presentation. We hope to see you at the case study and Q and A session immediately following this segment.

Philip Smith: All right, welcome back. Now we're going to discuss four case studies where we will give you an opportunity to test your knowledge. We're just waiting for the slides to come up and as soon as they come up we'll begin. All right, next slide. All right, for the first case study, a University employee transfers expenses from one account to another account and annotates the cost transfer "to correct an accounting error." Internal take exception, why? Next slide, please take a moment to answer the poll, please select the four options on your screen. Okay, it looks like we may not have the polls available so we'll just go ahead and move forward. So the answer to this question would be four, all of the above. Cost transfers should be completed within 90 days of when the error was discovered. With cost transfers, recipients must maintain documentation of the cost transfer and must make them available for audit or for other review. Cost transfers should be supported by adequate explanation, justifications, and be certified by a responsible official. And with that, I'll turn it over to Alesia for case study number two.

Alesia Brody: Thank, Philip.

Philip Smith: Next slide. Hold on 1 second, Alesia. Mike, could you go to the next slide after this, thank you.

Alesia Brody: Thank you. Okay, so for the second case study, you are asked by a PI to stop at an office supply store on your way to work and pick up a few items such as pens, envelopes and paper clips. The PI also asked you to get some donuts for a lab meeting that morning. When you arrive at work, the PI tells you that all of the items should be charged to the grant. Your Departmental Administrator tells you that these purchases must come from the Departmental funds. Why? Please take a moment to answer the poll, the question should appear on your screen, hopefully. And the options are, because these costs do not apply direction to the grant or because meals are never allowed to be charged to a grant. Or because donuts are always overhead costs or because this cost couldn't be down without more pens. So let's see what everyone chooses. Wow, it looks like an overwhelming number of folks chose number one which is correct, because these costs do not apply directly to the grant. And just as a reminder, F&A costs are necessary costs incurred by a recipient for a common or joint purpose, benefiting more than one cost objective. And some examples of F&A costs include research facilities, utilities, administrative salaries, and general office expenses which are normally treated as F&A costs since it would be difficult or impossible even to allocate such costs to each individual project. And now onto case number three, I'll turn it back over to Philip.

Philip Smith: Thank you, Alesia. And for this case we want you to kind of keep in mind that the grant application or the grant in question is a single project, non clinical trial research grant, such as an RO1. Case study three, 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? Next slide. Please take a moment to review the four options on the screen and provide us with feedback.

Alesia Smith: For anyone not able to view the poll pop-up, you may want to just enter your response in the chat whether one, two, three or four just to get a sense of what people responses are.

Philip Smith: Great suggestion. All right, looks like the majority of everyone said the answer was number four which is absolutely correct. So, salaries of administrative and clerical costs are normally treated as F&A. However, direct charging may be appropriate only if all the following conditions are met, one it's an integral part of a project. Two, can be identified with a project or activity. And three, included in a budget or have written prior approval if applicable. And four, the cost is not covered in your indirect cost pool. And with that, I'll go ahead and turn it over to Alesia for our last case study.

Alesia Smith: Thank, Philip. Case study number four, you recently learned that a post-doc working on an NIH grant had not disclosed that she was debarred for defaulting on her student loan. Unfortunately, you determined that this situation has gone unreported for a period of 3 years and during that time her salary has been paid by NIH grants funds, now what? Okay, so hopefully everyone can see the pop-up questions in the poll on their screen. I will read the options just in case, so do not allow her salary to be charged to the NIH award going forward. Or number two, make sure all funds for that individual are paid with University and not federal funds. Or three, immediately report the situation to your Office of Sponsored Research and the NIH ICs. Or four, tell that individual they owe the NIH money, let's see how everyone responded. Excellent, overwhelming 92 percent chose immediately report the situation to your Office of Sponsored Programs which is the correct response. And just as a friendly reminder, as the grant recipient it is your responsibility to immediately report the situation to your Office of Compliance or Office of Sponsored Research. You should also notify, of course, each involved NIH funding component, meaning if you have different grants from different ICs, be sure to notify each IC. Also, just to point out, while checking [Indistinct] is not a requirement, all NIH grantees must have a system in place to determine whether the institution or any of it's principles is excluded or disqualified from participating prior to drawing down any of the grant award funds. And grant recipients may decide the method and frequency by which they determine if whether it is any of it's principles is excluded or disqualified from participating in a cover transaction prior to entering the cover transaction. And with that, I will turn it back over to Philip.

Philip Smith: Thank you. If you have any questions that we weren't able to get to today, please feel free to reach out to us at the information on the slide here. And now we'll move into, actually our Q and A portion of the presentation and try to answer some of those questions. And again, if we can't get to them, please feel free to reach out to us.

Alesia Brody: Philip, I guess I'll take the first one, the first question.

Philip Smith: Sure, let me pull it up here. Let me get it situated. All right so, Alesia, the first question is, is prior approval required for re budgeting? For example, when reducing the amount of budgeted for salary and increasing the amount of equipment?

Alesia Brody: Per the NIH GPS, the Grant Policy Section, there's a section on prior approval requirements and I believe that's Section 8.1.1.2, we use it a lot. There is no prior approval requirement for re budgeting unless of course the re budgeting of the funds results in a change of scope, then NIH prior approval is required. A change of scope is a change in the direction, aims, objectives, purposes or type of research [Indistinct] identified in the approved project. The recipient must make the initial determination of the significance of a change and should consult with the grants management officer named in the notice of award as necessary. Further, there may be specific terms of award included in the NoA that may require that you obtain prior approval for actions that would modify the approved budget so you want to make sure that you read the NoA carefully, especially Section 4 and consult with your GMO on those specific circumstances. I hope it addresses the participants question.

Philip Smith: Okay, so it looks like I got another question here and I'll go ahead and take that one, it's in regards to cost transfers. It goes, I understand the cost transfers need to be documented, can you provide a template for this documentation that is acceptable to NIH? And the answer to that question is, no. There is no template that NIH provides for documenting cost transfers, again as we covered in the presentation the documentation must be consistent with the requirements of the NIH Grants Policy Statement, which you can find that, the requirements for the cost transfers within I believe Section 7.5. Again, as we covered previously the transfers must provide justification for why you're transferring it and they must be approved by a responsible organization official. And then also, you'll want to make sure that, that documentation is available if requested by your NIH funding IC or by any NIH entity. And with that, let me grab another question here. One moment, please. Alesia, I'll throw this one your way, okay.

Alesia Brody: Okay, sounds good. I'll give it my all.

Philip Smith: Right. All right, it goes as, it looks like it's in reference to meals. It goes, I spoke with my program officer about the allowability of meals on my research grant and she said, that they are never allowable so what should I do?

Alesia Brody: Well meals are allowable for subjects and patients under study or where specifically approved as part of the project activity, provided that the charges are not duplicated in the participants per diem or substance allowance as we went over during the presentation. But please remember that you should always direct your administrative and financial questions to your office of sponsored research and they can respond on behalf of your institution. If however you need to contact NIH, you should contact the grants management specialist on the Notice of Award. The PO is responsible for the scientific and technical aspects of the award and the GMS or GMO is responsible for the financial and administrative aspects of the award, so hopefully that addresses your question.

Philip Smith: Thanks for that, Alesia.

Alesia Brody: You're welcome.

Philip Smith: So we have another question here and I'll go ahead and take this one. And it's in reference to a reduction of effort and the question goes, I have a question regarding effort requirements of key personnel. The grants policy statement says that reduction of effort by 25 percent or more applies to key personnel, if someone is listed as key personnel on the application but not [Indistinct] of award, but the Notice of Award does not specifically name them, are they still subject to the 25 percent rule? And so the answer to that is the requirement to obtain NIH [Indistinct] approval for that, for key personnel where that have an effort change of 25 percent or more decrease an effort in 25 percent or more only applies to NIH, or to senior or key personnel named on the notice of the awarded regardless of whether the applicant organization designates the individual as key personnel. It's really those individuals that are named on the Notice of Award. The institution they can be named by either name or position, the institution can designate other staff as key in the application but the individuals ... But if the individuals name is not on the Notice of Award we really don't consider them subject to that requirement. And we have some more time, so we'll definitely go through some more questions here. Looks like we have another question in regards to prior approval and this one's actually in reference to the increase of effort. I'll go ahead and throw this one to you, Alesia. It says, do you need prior approval for a PI that increases effort?

Alesia Brody: No, prior approval is not required for increases in effort unless of course it results somehow in a change of scope.

Philip Smith: That is correct. And got another one here, it says I forgot to submit my first no cost extension before the end of the project period. So yeah, that can be an issue if you forget to submit your no cost extension, that can be an issue definitely. And unfortunately once you pass the end of the project period, that no cost extension automatically becomes a prior approval request and you'll need to submit that via either the prior approval module or via e-mail to your grants management specialist. And with that said, we also recommend that you please reach out to your grants management specialist for guidance on exactly what's needed for that request. And now I'll go ahead and answer, grab another question here. Okay, so it looks like there's some issue taken with, something I guess we had in our presentation in regards to changing scope. It says, I thought re budgeting had to be within 25 percent of the budget in addition to changing scope? So that's not always the case, really that 25 percent change in budget is really just a guideline. And it might be an indicator of a change in scope and then that's why we would want you to reach out to us at NIH to verify if there's a need for a prior approval request. Do you have anything to add on to that one, Alesia?

Alesia Brody: Nope. I just wanted to just point out really quickly that I saw a comment that my e-mail was wrong in the presentation. And so my e-mail I put it in a chat but just in case it's my first name alesia.brody@nih.gov. So I just wanted to, sorry about that, but that was a great catch.

Philip Smith: Yes, thank you for catching that. And we'll definitely make sure that the slides that are posted to NIH are updated with the correct version. There's one in the chat here that just came up it says, can we reiterate that the request the GMS should be through the AOR via eRA Commons? Yes, that is probably the most appropriate way to submit prior approval requests. Those should go through your AOR and through eRA Commons through the prior approval module, that is the most appropriate way to submit a prior approval request. Give me a moment, I'm trying to find another question here.

Alesia Brody: Let's see.

Philip Smith: Okay, so here's one. I'm going to give you this one, Alesia. What happens when the budget for a project is not exhausted after a no cost extension is granted?

Alesia Brody: Well the funds if you would do all your close out and you would do your final FFR and you would submit all your required close out reports and then it would eventually be returned. If there's still a balance on the FFR it would eventually be returned to treasury.

Philip Smith: Right, right. And that balance on the FFR would be, is what we call the unobligated balance and that would be returned as soon as your FFR is accepted and your grant is closed out.

Alesia Brody: There's an anonymous attendee who mentioned, can you please repeat the answers again. Is there anyway to know which answers you're referring to? We would be happy to, I'm just not sure to which question you're referring.

Philip Smith: Yes, please repeat that or tell us what answers you are looking for. In the meantime, I think we have a really good question here as far as for debarment and suspension. So the question is, where can we find debarment or suspension information on researchers? And with that, typically which the system that you can check is SAM, which is the Systems for Award Management, where you will find records for entities for individuals that have been excluded from federal awards, that is a good place to look. And that is the central place to look but with that said, your institution may have other systems to check that, you might, you will probably will want to check with your sponsored research office if you have one to ensure that you're using the correct systems to check. And let me see if we can pull another one here.

Alesia Brody: There's another, Philip, I just saw another question regarding debarment and suspension. If an investigator is from another institution is it sufficient to have it in a sub awarded or other contract that the sub recipient does the checks? It is ultimately the primes responsibility to make sure that everyone on the grant is eligible to work on the grant, meaning they are not debarred or suspended in the system for any reason. So how your individual institution would like to ensure that is something [Indistinct] that should be addressed in it's internal processes but from our standpoint it is part of the responsibility of the prime recipient to make sure that everyone on the grant is eligible to work on the grant.

Philip Smith: Okay, it looks like we have time for a couple more. Let me see if we can find one that's a good one here. So this one is in regards to the allowability of cleaning supplies, it said would any cleaning supplies be allowable on an RO1 and with that yes, typically probably as an indirect cost but however, if maybe there's some type of cleaning supplies that is specific to a piece of equipment that is specific to that award then you could probably charge that as direct. And if you really don't, you're unsure, I definitely recommend that you reach out to your Grants Management Specialist to confirm if that's a chargeable cost or allowable cost on your award. And let's see here if we can find another one. This is a good one, all right great, we can wrap it up with this one, do cost transfers need or need to be approved by someone other than the preparer? Now, I guess for that, yes I would say the person that prepares the cost transfer typically should not be the individual that certifies the cost transfer just for internal control purposes. You'll definitely want to have a separation of duties when doing that action. And with that, we'll go ahead and wrap it up. Let me ... Thank you for joining us for our session. If you have additional questions please visit our exhibit hall staff for a chat and one-on-one opportunities or you can always find contact information in the help section of our grants.nih.gov site. Your feedback is very important, please take a moment to let us know what you thought by clicking on the session feedback button located with the description and presenters on the auditorium list of sessions. When you are completely done with the seminar, please also complete the overall survey form in the navigation bar at the top of the page. Again, thank you for joining us and have a great day.