Managing Your SBIR/STTR Award Effectively– Webinar Transcript

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Adam Sorkin: I am your moderator for today's program, Managing Your SBIR and/or STTR Award Effectively. My name is Adam Sorkin. I am the Small Business Policy Manager for NIH SEED, or Small business Education & Entrepreneurial Development, and thanks so much for joining us today. We're very excited to discuss what happens once you receive your SBIR or STTR funding and how to make sure you know what our expectations are and, more importantly, who to talk to when you need assistance, have to make changes or run into other issues managing your award. We'll hear a lot of different perspectives today, first from a Program Officer, a Grants Management Specialist, a Contracting Officer, and also from the HHS Office of Inspector General's Office of Investigations about avoiding fraud, waste and abuse, and I'll introduce all of our speakers a little bit more properly to you in just a bit.

I did want to cover a little bit of housekeeping before we get started. First, please use the Q&A function to ask any questions you might have for our speakers, and we will get to a Q&A session once each of them has had an opportunity to speak. And then, as my colleagues are noting in the chat, a recording and slides and materials from this presentation should be available at seed.nih.gov on our events page in about a week, give or take. And so with that, I am very excited to introduce our first speaker, Dr. Toyin Ajisafe. Toyin is a Program Officer at the National Center for Medical Rehabilitation Research within the National Institute of Child Health and Human Development. Toyin is also the NICHD SBIR/STTR Program Coordinator. And with that, I will hand things off to Toyin. Toyin, it's all yours.

Toyin Ajisafe: Thank you so much, Adam. I'm making sure I'm not ... that I'll be muted. As Adam said, my name is Toyin Ajisafe, and I will dive straight in. So I thought it would be useful to do a quick recap of the SBIR/STTR mechanism and specifically focus on Phases I and II. So for Phase I, just to remind folks that the goal of a Phase I is feasibility and to ... so often projects are coming in with looking to establish a proof of concept, and the cap, as set by the Small Business Administration, is $306,000 roughly, and the project period can range between six months to a year on average. And folks should be reminded that pilot data is typically not required for Phase I, where it is a requirement often for Phase II.

And so having said that, I'll jump straight to Phase II, but the goal of a Phase II project is full research and development, and it can include an efficacy or effectiveness trial, depending on the design of the study, but it doesn't have to include a clinical trial. They just generally tend to include that. The total cap in terms of costs will be $2,045,816. The project period can range from two-to-three years, and it's very important to remind folks that a commercialization plan is required for a Phase II. And again, if an applicable clinical trial, as defined by the FDA, so where you're looking at the effectiveness or efficacy of some device or technology, then it's really important that folks start to engage the FDA to figure out the regulatory pathway early on and potentially form their clinical trial in Phase II based on those pre-engagements and advisory meetings with the FDA.

I also wanted to go back a bit to pre-Notice of Award. So the Notice of Award is the official notification of funding, right? Prior to receiving that, there is no ... no matter what anyone may tell you from NIH, and until you get a Notice of Award, there is no guarantee of funding. And so prior to receiving Notice of Award, I think it's really important to remind folks not to overpromise in the application, and I'll touch on the reason I say that later on. I'll circle back to this point. All right. So it's possible that reviewers look at an application, maybe one that proposes sixty participants, for example, when in fact, based on their prior analysis, maybe thirty participants would sufficiently power that study, but they account for attrition and then go, for some reason, go to a general sample of sixty. And reviewers may not raise that as an issue, right, but then when it comes to the practicality of fulfilling or meeting that target over, especially, a one-year study, right, that could become challenging. So I'll circle back to

that point shortly. Now, following review, it's really important that applicants wait for their summary statement to be released, and once they have that summary statement, they can then get in touch with their program officer and to try to inquire about the odds of funding.

Now, different Institutes and Centers (ICs) in NIH have different practices, so some would publish pay lines, and others don't. So in that conversation with the program officer, I think it's useful to say, "Hey, can you tell me? Maybe you're not able to tell me pay lines, if your institute or center doesn't publish them, but can you tell me in recent history the range of scores that have been competitive, that the IC has funded?" That may then give you a decent gauge of whether or not your application will be competitive, and if it is competitive, based on your conversation with the program officer, it's advisable to then start to line up aspects of the project that could potentially mitigate delays if, in fact, your project is awarded. I'll give ... As an example is the IRB, right? Not waiting until you have a Notice of Award, as soon as you get ... have some indication that your application will be competitive, start looking at submitting your IRB protocols for approval.

All right. Once you have the Notice of Award, it's really important that you download that document from the eRA Commons. Again, this is the official notification of funding, and so it's legally binding, and it establishes things like funding level. It establishes a period of support, terms and conditions of the award, and importantly it has the names of your Grants Management Specialist and your Program Officer, and these are two really critical people that you want to be engaged with across the life cycle of the award, which brings me to the Research Performance Progress Report.

So over the course of the award, the life cycle of the award, you would have to submit what we call an RPPR, which documents the accomplishments relative to the terms of the award. Folks would have to submit these documents electronically using ... There's an RPPR module in eRA Commons. And just to give you a sense of some of the questions that you would find on that RPPR, so it'll ask things like, "What are the major goals of the project?" And that's often very easy because you're just copying and pasting from your specific aims, right, in the application itself. Other questions are, "Have the major goals changed since the initial competing award or previous report?" This is really important, again, circling back to that point about not overpromising. So say, for example, the sample size proposed was

such that it was overly ambitious, and now the project is struggling to meet the enrollment target. Well, PIs, or principal investigators, cannot just make the decision unilaterally to decrease their sample size, for example, right? They have to reach out to the Program Officer and the Grants Management Specialist for what's called a prior approval. They may decide ... They may contemplate decisions around maybe an inclusion criteria, around maybe expanding that maybe to allow them to enroll more participants to be able to meet their target. These types of decisions and changes require what we call prior approval, so it's really critical to know that.

Additional questions from the RPPR, "What was accomplished under these goals?" All right. So as ... Again, as indicated in the original application, so how does one show that? One may leverage things like graphs, photographs of prototype if it's applicable to the specific project, listing any relevant publications in the appropriate section and making sure that those comply with the Public Access Compliance Report. And then the RPPR would also have a section that asks what folks ... what the awardee plans to do during the next reporting period to accomplish the goals. So those are some of the ... some examples of questions to expect on the RPPR.

And here I have linked the Office of Extramural Research RPPR web page that folks can go to see additional information about the RPPR, but I'll leave you with this. Really, really important that you engage early and frequently with your Grants Management Specialist and your Program Officer, and you don't want to wait until you're deep into issues with the award, right? You want to contact them early and often to mitigate any issues that may arise. And I'll pass it on to my colleague.

Adam Sorkin: Great, thanks so much, Toyin. Thanks so much, Toyin, and I will go ahead and welcome Mindy Bixby to speak with you all. Mindy is a Grants Management Specialist also at NICHD as well as the Grants Specialist Small Business Point of Contact for NICHD. And, Mindy, please ...

Mindy Bixby: All right.

Adam Sorkin: ... take it away.

Mindy Bixby: Thank you, everybody. I'm happy to be here today and answer any questions from a Grants Specialist perspective. As Toyin started to talk about, the most important thing you can do after you've gone through the pre-award JIT process is the exciting part, when you celebrate when you get

that Notice of Award. Don't forget to actually look at the Notice of the Award. I think that's one of the most common things I talk to with grantees and recipients about, is they forget to actually read their Notice of the Award. I know it's really exciting that you've gotten the award, but don't forget the read it.

On the Notice of Award, you will find things like the restrictions. You may have gotten your award, but maybe during the JIT process, you weren't able to finish or gather all the necessary documents that were needed. For instance, one of the more common restrictions could be you weren't able to get your IACUC for animal research, or you weren't able to complete the process with your IRB. If you have one of those restrictions, you're not able to do any animal work or human subjects work until you get the IRB or you get your IACUC and turn that paperwork to OLAW or, for instance, for human subject work, until you submit your IRB to the Grant Specialist or ... and to the Program Officer.

And then what happens is, you'll get a revised Notice of Award, and when that happens, you can start doing your human subjects work. Other things that you will find on your Notice of Award is your budget period, so for instance, when your award is. If you have a multiple-year award, it will tell you the start date of the award, the end date of the award, how much money is for each period. Also, as mentioned previously, it will have your contact for your Grants Specialist and your Program Officer.

Another important thing to look at in your Notice of the Award is information about closeout. That's going to be on every Notice of Award no matter what IC you receive your award from. So if you get an award from NICHD, from Aging, no matter what IC you get your Notice of Award from, it will have information on closeout. So it's important to read that information because when you accept the award, you're also accepting the terms of the closeout.

I think that this is the most common question I receive from all new grantees, and sometimes it can be a little confusing, and so I really wanted to focus time on explaining to people the Payment Management System, otherwise known as PMS. You actually aren't really accepting your Notice of Award until you actually draw down funds, but you are not automatically enrolled into the PMS system. The PMS system is where all your money goes after you receive your Notice of the Award. You have to actually register for an account in PMS. The link here in the presentation, which also will be

provided to you later, is ... actually provides you with a PDF with instructions. Some people, my grantees, have a little bit of trouble applying through PMS, but they actually have made it a little bit more user friendly now. Like I said, there is a PDF and a YouTube video that you can watch to help you register. And for instance, the registration process is taking a little bit more ... a little longer than it has in the past, and so the system has provided you with a status module that you can check to see where your registration is in process. Part of the registration process is also completing a form called the SF-1199A. That form is pretty much your banking information, so where is your money going to go when you draw it down? You will send that to your PMS Liaison, and also that's a good person to keep in your Rolodex. That person with PMS will ... can answer any of your questions that you have.

So for instance, if you ever have any trouble with your PMS system with drawdowns or you hit an error, that's like your eRA Commons Help Desk. So the PMS Liaison can answer your questions as almost like a GMS on my side, and of course there's also a PMS Help Desk where you can just send an e-mail and say, "Help. Help me. I need help," and they can hopefully answer any questions. Unfortunately, your Grants Specialist, someone like me or anyone else within ... your Grants Specialist on your Notice of Award, they can provide you this information, but they can't help you speed up your account or, say, get you an account because we are not managing the PMS system.

It is managed by somebody else, just like the SAM system is managed not by NIH. It's managed by somebody else, so unfortunately we can't push the magic button to make it work. Just keep that in mind when you want to scream at your Grants Specialist. Don't scream at your Grants Specialist. We're trying everything we can to help you, but unfortunately we can't do magic in regards to the Payment Management System.

Okay, this was also talked about by Toyin, but I wanted to provide you a little bit more details. What you need to do if you ever run into something like a change, and we recognize that change does happen. You are doing a research project, and things don't always just go smoothly. Sometimes there's a little bump in the road, and you have to contact your Grants Specialist, contact your Program Officer and say, "You know what? I think we might need to change the PI," or "We didn't really complete everything on time after our first Cost Extension. Do you think we can get a second No Cost

Extension?" These kind of things are called prior approval, and to get prior approval, you have to send a formal request to your Grants Specialist and your Program Officer at least thirty days before it actually is going to happen. Now, since eRA is becoming a better system every day, a lot of these requests can be done through the Prior Approval Module, but some of these things are done through an email and a formal request.

If you ever have any questions about this, the first thing I would do is contact your Grants Specialist, say, "I want to maybe ... I have a budget question, and is this considered a prior approval request?" Sometimes a quick e-mail is a good thing to do because sometimes it might not be a change of scope, a change of scope regarding budget questions. Or sometimes, they will say, "Oh, you need to do a formal request if you're changing the model of your PI, if you're going to be adding a PI." And if you have a single PI, and you say, "I want to add another PI to the project," that is definitely a prior approval request, and they'll direct you to what you need to turn in and how you need to do it.

We're here to help you. We don't want you to be sitting in your office or sitting in the lab, which, you're already going, "Oh, what do I do? I don't want to get in trouble." Just give us a call, send us an e-mail, and that's what we're here for.

Adam Sorkin: Great, thanks so much, Mindy, very helpful. And I'm seeing a lot of good questions about your talk already. And so next, we will hear from Callie Prassinos, who is a Branch Chief and Contracting Officer with the NIAID Office of Acquisitions and is going to discuss SBIR contract management. Callie, all yours.

Callie Prassinos: Thank you, Adam. So, yes, let's change to ... Let's put it to contracts. So you've worked so hard on proposals and negotiations, and now you've been awarded an SBIR contract. So what do you do next? So this is the overview of what I'll be discussing, but I just wanted to let you know that every awarding component will do this differently. Every contract will be different in the awarding at each Institute or awarding component, so just keep that in mind moving forward. So a contract and its clauses, so a contract is a legal binding agreement between two parties, the organization and the government. There will be specific performance requirements in the Statement of Work and delivery schedules with details on due dates and expectations for performance. And usually a contract is set up

with these sections and will start with a cover page that will have your contract number, which is very important for billing and tracking. It will have the contractor's name, dates and signatures. And then you will find within the contract everything you need to know about those specific items, pricing, acceptance, period performance, deliverables within that contract, how to get invoice. So, please, when you get your contract, read through it.

Understand where to find these things, what the requirements are, what the regulations are, the FAR clauses are. And if you have any questions, reach out to your CO. So contract obligations and limitations, the mutual obligation of the government and the contractors are established by and limited to the written stipulations in the contract document. It's very important that you understand what's in the contract and what the limitations are because ... what the limitations are because the contract is very specific, and those obligations and limitations are hard requirements. So unless specifically authorized by the Contracting Officer, the contractor shall not assume any obligations or take any actions not specifically required or authorized by the contract.

When you get your contract, you'll get two primary point of contacts, government point of contacts. That will be the Contracting Officer and a Contracting Officer Representative. The Contracting Officer Representative, or the COR, is responsible for monitoring technical progress, recommending changes to the requirement. They are not allowed to make any specific changes to the Statement of Work, but they make recommendations to the CO. They interpret the technical performances. They perform required inspection and acceptances. They assist in the resolution and ... of technical problems that occur during the performance of the contract and, of course, not authorized to increase the negotiated costs of the contract. But the CO, or the Contracting Officer, is authorized to direct or negotiate any changes to the Statement of Work, modify or extend the period of performance, change the delivery schedule and change any terms and conditions that are found in the contract.

So the Statement of Work is an important document that you'll find in the contract. It defines the work to be performed under the contract and acts as the framework for what the cost covered under the contract. The contractor should be intimately familiar with all the details in the Statement of Work and understand if any changes that are needed in the Statement of Work during the performance of the

contract need to be approved in writing by the contracting officer. So if there's any ... If you're getting through your contracting, and you need ... you find a diversion from the Statement of Work needs to happen, please reach out to your contracting officer and your COR immediately. The contractor ... If the contractor receives a request from the government, anybody in the government, to perform a task or activity that will request ... that will change the Statement of Work, the contractor must inform the contracting officer before beginning that task.

Doing any activity that is not in a Statement of Work is a risk. So changes to the contract, any changes in the terms or conditions of the contract, including the Statement of Work, changes to the key personnel, the delivery schedule must be accomplished in writing in a modification. The contractor should submit their formal request in writing to the Contracting Officer for review as soon as they know. Thirty days before would be great. The Contracting Officer will review the request, obtain recommendations from the COR and provide consent, decline or request further information to make that change. And this is a page that is a sample of a modification, and they will have hard signatures on them to make that request or that change final.

So key personnel, prior to deriving from the individuals identified as key personnel under Article G of the contract, the contractor shall notify the CO in advance of replacing that key personnel. The request should include significant information, CVs, resumes, qualifications to authorize that replacement and avoid negative impact to the program or the contract. We would like those changes thirty days beforehand but understand that things might happen. So it's always the best practice to reach out to your CO as soon as you know something is happening.

If you can't get that qualification, you don't know who's going to replace that key personnel, but you are losing key personnel, reach out to them. Let them know. Let them know what's going on so that they can protect any negative impacts that might help to happen and results of those things. But understand no diversion shall be made to the contractor ... made by the contractor without the written consent of the CO, so you can't just replace a PI or key personnel without getting written consent and having it ... that changed in the contract.

So invoice submission and payments, so this will be outlined in your contract, exactly where...

where to send the payment, who's going to be authorizing those payments. But briefly, the government shall make these payments, invoices, contract financial payments by electric funds transfer. Payments on fixed price contracting may be made based on satisfactory completion, receipt and acceptance of the contract deliverables. Payment on cost-reimbursement contract may be made pursuant to receipt of proper invoices of allowable costs incurred, which may be submitted no more frequently than on a monthly basis, unless you get prior approval from the Contracting Officer.

And for all contracts, final payment will not be made until all reports and deliverables included in the contract have been delivered and accepted by the government. So reporting requirements and deliverables, satisfactory performance on a final contract shall be deemed to occur upon performance of the work described in the Statement of Work in the Section C of the contract and upon deliverable and acceptance by the Contracting Officer and the COR of any items in accordance to the articles in the contract. So each contract will have different deliverables and requirements for reporting, but some samples of that, some examples are a technical progress report, monthly progress reports, final report, a summary or salient results, and there will be additional reports that are less technical like the Small Business Innovation Research Program Life Cycle Certification, Final Invention Statements.

These reports and deliverables are very important to the contract completion, so please be familiar with what reports need to happen throughout the contract. Not delivering these reports and these deliverables can put the contract in risk for payment. So ... and each contract has an evaluation for contract performance, and that's found in Article G, a Post Award Evaluation of Contract Performance. If your contract is only a year, then you will only get a final evaluation. If your contract is longer than a year, then you'll have interims that are done annually, and they will be prepared in accordance with the FAR, and they'll have these ... They'll be based on these evaluation factors, technical and quality of the product or services, cost control, schedule and timelines, management of business relations and regulatory compliance.

All evaluations will be provided to the contractor, and they will be provided 30 days to review the document and submit any information or rebut any statements that are done on these evaluations. The copies of these evaluations, the contractor's responses and any additional comments are retained

in our systems and will be used by Contracting Officers for future award decisions. So it's very important to look at this document, understand how you can perform these tasks and how they'll be evaluated in the system moving forward.

So then you get to the end of the contract, and if you get a Phase I contract that's not a Fast Track contract, you will be informed of the opportunity to apply for Phase II from the awarding component after or close to the expiration date of the Phase I contract. Phase I awardees will be provided with the Phase II proposal submission requirements. This will detail the due dates, the content, the submission requirements of the Phase II proposals. Just keep in mind that usually those requirements that are found in the Phase I Omnibus is what we'll go on, right? So if the Phase II has requirements ... If there's Phase II requirements under those topics, that's what will be the base work of how to move forward from a Phase I for ... to a Phase II proposal.

There only will be one Phase II award that may result from a single Phase I SBIR contract. And then if you're awarded a Fast Track contract, so that means that you have a Phase I with a contractual option for a Phase II, the government is not obligated to fund that Phase II portion until the con ... the awarding con ... exercises that option at the end of Phase I. But don't do any Phase II work in your ... until that option is exercised because the government is not obligated to exercise that option. So thank you very much, and congratulations on your contract award, and if you have any questions, definitely reach out to your Contracting Officers.

Adam Sorkin: Great. Thanks so much, Callie. And I see a lot more good questions about contracts and grants as well. And with that, I will hand things off to our final speaker, Jonelle Soeffing, who is an Operations Officer within the Office of the Inspector General Office of Investigations. Jonelle, all yours.

Jonelle Soeffing: Thank you, Adam. Good morning, everyone. During my portion, I will wrap up the key messaging from my fellow panelists, and I'll share some helpful information towards protecting your award by avoiding fraud, waste and abuse. OIG's mission is to fight fraud, waste and abuse in Medicare, Medicaid and more than one hundred other HHS programs. Grant and contract fraud investigations typically involve conflicts of interest, theft of government funds, embezzlement or failing to properly support the use of funds. We want to encourage an understanding of fraud, waste and

abuse to ensure that any violations made against HHS can be properly reported. Fraud is intentional. It's an intentional or deliberate act to deprive another of property or money by deception or other unfair means. That is intentionally submitting false information to the government, which includes situations in which you should have known the information was false to get money or a benefit.

Waste involves practices that directly or indirectly result in unnecessary costs such as overusing services and misusing resources. Abuse is the intentional or unintentional thoughtless or careless expenditure, excessive or improper use of government resources including one's position and authority. There's a moving fraud scale displaying actions that could be considered an honest mistake versus you should have known better versus intentionally deceiving. This fraud scale assists prosecutors on the charging spectrum from no action needed to administrative, civil or criminal action. On the next few slides, I will cover fraud schemes and indicators. Fraud schemes essentially boil down to actions that involve lying, stealing and cheating.

Here is an overview of certain fraud schemes that could lead to fraud investigations. Applying false information on applications, proposals and documents; creating fake records; accepting or offering kickbacks; using funding for unauthorized purposes such as personal expenses and personal travel; not doing any work but billing as though you did the work; theft and embezzlement, bribery, and the list goes on. Remember that lies by act or omission both count. Do not use grant money on one research topic or project to pay employees working on completely different topics or projects and then charge it back to the grant. Ensure that eligibility requirements are fully met. The most common eligibility requirement that awardees appear not to meet is a requirement that Principal Investigators must be primarily employed by the awardee. Some awardees do not meet the SBIR size requirements. Awardees must have fewer than five hundred employees, including affiliates.

The Small Business Administration's definition of affiliates does not leave room for interpretation, but it considers factors like ownership, management and contractual relationships in determining whether affiliation exists. The OIG has found some awardees that were affiliated with organizations much larger than five hundred employees. For example, one awardee company that was itself well under five-

hundred employees was owned by a larger company that had over seven thousand employees.

Without understanding what fraud, waste or abuse looks like, you may inadvertently overlook fraud indicators, essentially taking award opportunities away from legitimate individuals. Awareness of fraud is ever important to safeguard federal funds. Use common sense. Use your awards appropriately. Don't be afraid to ask questions of the granting agency if you have questions on whether a particular expense is allowable. There's no need to hesitate calling the OIG to report suspicious activity. OI investigates thoroughly and covertly.

If you see an issue, say something. Your reporting of a possible problem is justified, and you've helped to protect the program. Disclosure and communication with HHS Grant Officials and the OIG is key. There are consequences to fraud that involve criminal and civil prosecutions and administrative actions. Here are some common criminal statutes, 18 United States Code 641 Embezzlement and Theft of Public Money, 18 United States Code 1001 False Statements, and on the civil side, 31 USC False Claims. Administrative actions involve civil monetary penalties, exclusion from HHS programs and government-wide suspension and debarment. And fraud consequences are made public. Here are two OI case examples. In the first example, two biotechnology companies and their co-founder entered into a civil settlement agreement to pay more than $10 million back to the United States to resolve allegations under the False Claims Act.

They engaged in improper billing through federal grants. The firms mischarged federal grants by billing for costs incurred by another business and by billing for compensation in amounts exceeding authorized federal limits. The settlement also resolved allegations of backdating services and cost-sharing agreements by knowingly presenting a backdated agreement to the United States. The other example involves a civil settlement to resolve allegations of false statements to obtain grant funds. The SBIR awardee made false certifications and false claims, did not accurately report disbursement, used their grant funds for personal expenditures, made drawdowns after the performance period of the grant and failed to mention and maintain a financial management system as required by the NIH.

And finally, I want to emphasize the importance of reporting any suspicious behavior or activity. If you see or learn of anything that seems wrong, please say or do something. Please report complaint

information through the HHS website or by calling 1-800-HHS-TIPS. Hotline complaints are allegations and are treated with privacy and discretion. Hotline complaints provide helpful information to criminal, civil and administrative investigations. After receiving my portion of the overview, strongest takeaway to consider is to keep awareness and communication lines open by asking questions, making inquiries and referrals and by reporting any complaints. By doing so, you are doing your part to protect HHS programs and the public. Thank you.

Question and Answer Session

Adam Sorkin: Wonderful. Thank you so much, Jonelle. It's very helpful. And thank you very much to all of our panelists for some very informative presentations. And now we'll move into the Q&A session. We've got a lot of great questions coming into the Q&A module through Zoom. Please feel free to keep on adding your questions, and we will get to as many as we can. I do want to note that any questions that we receive for OIG regarding fraud, waste and abuse, we will defer and pass on to them to follow up with later but will not be answering today. And with that, let's get started. And I do see we've got a number of good answers already in the module. I may ask some of our speakers to address some of the things that they've [Indistinct] so everybody can benefit. And with that, I will start with Toyin. I do see we've gotten a lot of questions about RPPRs, so I wonder if you wouldn't mind discussing briefly just, when are RPPRs required and ...

Toyin Ajisafe: Yeah ...

Adam Sorkin: ... and where ...

Toyin Ajisafe: Yeah ...

Adam Sorkin: Oh, please.

Toyin Ajisafe: Yeah, and so I've attempted to answer many of them, but generally ... so many of the questions are around ... related to when they're due typically. Generally it would be towards the end of each budget period, and if you think of a budget period as a year essentially, but there are cases where, if the project, for example, includes a clinical trial or involves recruiting and enrolling participants who maybe are stroke survivors, for example, and the risk level depending ... based on the

intervention type and setting is deemed to be more than low, so either medium or high, the number of touchpoints then increase. So instead of a yearly RPPR, then it may be quarterly, right, for a high-risk trial, or it may be twice a year for a medium risk. So those are the only ... Those are for the risk profile of the study, is primarily the factor that would change the ... what would normally be a yearly due date for the RPPR.

Adam Sorkin: Great. Thanks so much, Toyin. Let's see. Lots of questions. Oh, and I did want to clarify. I do see a little bit of confusion in the Q&A module between grants and contracts. Please keep in mind grants and contracts are two separate funding vehicles. You would get one or the other. If you apply it to the Omnibus Solicitation, you get a grant. If you apply to the ... submit a proposal to the Contract Solicitation, you would negotiate a contract. You wouldn't ... You shouldn't expect both. Let's see. So, Mindy, I'm also seeing a lot of questions about the PMS. Would you mind talking a little bit about when it's appropriate to draw down on funds? How often should awardees be doing this and when?

Mindy Bixby: Of course, I'd be happy to. That's actually common question. The rule of thumb is you draw down funds when they're needed. So you can make as many drawdowns as you need, but the rule of thumb is not to draw down funds too far in advance because you don't want to have the large amount of cash on hand. It's expected that you might have some cash on hand, but for instance, if you have a $1 million award, you don't want to draw down $1 million all at one time. That would be an audit red flag. So for instance, if you have to do payroll, draw down the money that you need for payroll, and maybe that's $4,000. Draw that $4,000 down and do that payroll. But just, for instance, say you know you're going to have to do a ... You have a fee-for-service for $15,000. The total cost of the fee for service is $15,000. It wouldn't necessarily be the right thing to draw the whole 15K down right at the beginning of the grant period if you're going to be paying that 15K in increments, maybe each month. Does that make sense?

Adam Sorkin: Very much, thank you. Let's see. All right. And another question, I think, for Mindy. How long before the end of a grant should a No Cost Extension be submitted for a Phase I award, and what's the maximum time for an extension?

Mindy Bixby: Good question. So, everybody, your first No Cost Extension, guess what? It doesn't

require our prior approval. The first No Cost Extension could be done in eRA Commons. The trick is, though, you have to do it before your grant period ends. So that date that's on your Notice of Award, you have to do it before that date ends. Otherwise, you'll have to get prior approval from your Specialist, and they might be nice and say, "Okay. Sorry you missed the deadline," but they could say, "Nope." Hopefully they'll be nice like Toyin and I, but you never know.

So, make sure you don't let that date lapse because then you don't need prior approval to get that first No Cost Extension. The second No Cost Extension is not guaranteed, and it does require prior approval, and you have to do it thirty days before your grant period ends. And you need to do that request in the Prior Approval Module, and if you have questions about what you need to submit, you can contact your Grants Specialist.

Adam Sorkin: Perfect. Thanks so much, Mindy. And following up with a similar question for Callie, how would somebody go about changing key personnel on the contract? Are there specific forms, or is it just something that they would reach out to their Contracting Officer about?

Callie Prassinos: So, yes, I would reach out to your Contracting Officer and see if they need a specific form filled out. I would usually just take the e-mail but requesting the change but ensuring that you submit all of the formal documents, a resume, a commitment letter, anything else that will help make those determinations on that key personnel that is attached to that e-mail. But reach out to your Contracting Officer and see if they have a specific form that needs to be filled out as well.

Adam Sorkin: Great, thanks so much, and I ... Hopefully you're noticing a theme emerging. Stay in close contact with all of the contacts for your award, be that your Program Officer, GMS, your Contracting Officer, your COR and what have you. We're here to help and sort of clear up all of these issues before they become a problem. So we want to help you. We want you to succeed, so please don't be shy. We're very nice people and happy to help. Let's see. Lots of questions. Another question about prior approval, so where do we find the information on where to submit these requests and changes? Is that in the Notice of Award, on a website? What should our awardees be looking for?

Toyin Ajisafe: For prior approval?

Adam Sorkin: Uh-huh.

Toyin Ajisafe: Yeah, there's a Prior Approval Module in eRA Commons. So that's where they would submit any counsel, especially if they can't find it. It's always helpful if you just shoot a quick email to the Program Officer and Grants Management Specialist and say, "Hey, I'm thinking about possibly making these changes or proposing these changes. How do I go about that?" But, yeah, that's ... They would use the Prior Approval Module to submit the requested or the proposed changes. And generally we would ask them, in addition to what's been proposed, for example, if they are proposing to change the sample size, we would ask for justification and why they're proposing that.

And hopefully it doesn't come to us as a surprise because they will have been engaging previously. So we are up to date on whatever struggles the studies may be experiencing, so, again back to Adam's point, engaging frequently and early helps mitigate some of these issues.

Adam Sorkin: Great, thanks so much, Toyin. All right. Let's ... I've got, a think, a question for Mindy, and I think we're taking a couple things for granted, but we do have a lot of new awardees who aren't familiar with our processes. What is the role of a Grants Management Specialist?

Mindy Bixby: The role of a Grants Specialist is to help you through the award process pre-award, during the JIT process, during award, post-award, and the closeout specialist will help you with closeout, but it is also possible that the GMS may help you through the closeout process if you have questions about the documents as well. Depending on the IC, they may help you with the questions when you're applying for an award. For instance, at NICHD, where I work, I help small business awardees or people that are applicants that are going to apply answer questions regarding the application process. So if they have trouble, kind of like a liaison with SEED, helping them just so they don't bug Adam as much.

So, it's possible that your GMS, with doing small business awards, you can maybe contact them and say, "Would this be a topic that your IC might be interested in?" So it's possible that your GMS could direct you to someone within the agency. For instance, if you're applying with Aging, you could ask the GMS, "Can you direct me to someone within your IC to see if this would be a topic that you'd be interested in funding?"

Adam Sorkin: Excellent. Thanks so much, Mindy. And I will take that opportunity to plug our help desk. I am very happy to be bugged if you do have questions. You can reach out to us at seedinfo@nih.gov with your questions, and we're happy to answer them or help connect you to the people who can resolve your issues. So if you're having trouble, don't be shy. Please reach out. I think a question for Toyin and then perhaps Callie, what are the options for supplemental funding? What happens, say, if you're halfway through your project and your deep freezer breaks? What can NIH do to help and maybe provide some additional funding?

Toyin Ajisafe: Yeah, so there's something called an Administrative Supplement, which I suspect is what you're alluding to, and these are considered on a case-by-case basis, and they heavily depend on funding. Many may be aware that we are currently under a continued resolution, and so many of these factors determine or influence the degree to which your awarding Institute or Center may be able to accommodate requests such as the one the attendees are alluding to. But generally there's a mechanism called the administrative supplement through which you can submit such requests, and then they would have to be considered at the level of the IC, and one hopes for the best then.

Mindy Bixby: And Adam ...

Adam Sorkin: Great.

Mindy Bixby: ... if I could chime into that question ...

Adam Sorkin: Mm-hmm.

Mindy Bixby: ... a little bit, too, just say it's not a huge expense. The recipients are given a little bit of latitude as far as some budget modifications. Just say, for instance, they had budgeted to go to travel to a conference for presenting, and the expense was maybe $2,000 or something. And they now see that they don't really need to go to this conference, and they need the supplies rather than going to the conference. That's a budget modification that would not require our prior approval, and so they are able to do that without contacting the Grants Specialist. So that is obviously you're not going to be requesting a supplement for $2,000, and they can do that change without talking to GMS or PO.

Adam Sorkin: And so I believe the threshold for that is, what, 25 percent ...

Mindy Bixby: Correct.

Adam Sorkin: ... within the cost category?

Mindy Bixby: Yeah, and if it's not a change of scope, so ...

Adam Sorkin: And if it's not a change in scope ... and I'll move over to Callie. How does something like that work for a contract? What kind of flexibility do our contractors have to access additional funds or make changes, small changes, to their budget?

Callie Prassinos: Yeah, so in contracts when you have a fixed price contract, that is the fixed price to complete the Statement of Work. So if any ... There is not really any flexibility to get any changes to that fixed price to complete that work when you have a fixed-price contract. When you have a cost reimbursement contract, and usually those are Phase II contracts, those, you can get adjustments to. They do have a prior approval. You need to get those approved by the CO. They will negotiate those costs when you have a cost reimbursement contract, but when you have a fixed price contract, that is a fixed price to complete the Statement of Work. And if there is adjustments that need to be done within that fixed price, just ensure that you're not going to get any more to complete that Statement of Work and will be held accountable to complete the Statement of Work.

Adam Sorkin: Got it. Thanks so much, Callie. And let's see. We are very quickly coming to the end of our hour. So unfortunately it does not ... We've got a lot of questions we haven't been able to get to. I think rather than try and quickly get through something, please feel free to reach out if your question wasn't answered either to SEED, and you can reach us online at seed.nih.gov or ask questions by email at seedinfo@nih.gov. You can also reach us at social media as well or reach out to the lovely people that have been speaking to you for the past hour or your very own contacts on your award. Thank you so much for joining us today.