Managing Your SBIR/STTR Award Effectively – Transcript and Chat Links

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Adam Sorkin: Good afternoon and thank you so much for joining us today. I am Adam Sorkin, the Small Business Policy Manager for the NIH Small Business Education and Entrepreneurial Development Office, or NIH SEED. And I will be your moderator today.

Some quick housekeeping as we get started -- slides and materials will be available in about seven business days at SEED.NIH.gov at our Events page, and you will be able to ask questions during the program. Please use the Q and A function in Zoom to submit them as we move along.

We do have a great program today. Following some brief updates from me, you're going to hear from a great panel of speakers who support our grantees and contractors during their SBIR and STTR projects, as well as from the HHS Office of the Inspector General. Next slide, please.

We're covering a couple of different topics related to award management, so I just wanted to set expectations at the front -- you're going to learn about best practices for working with NIH, what's expected of our recipients, who to reach out to with concerns, and how do I address those issues when they do come up? Then we're also going to discuss a very important topic, "Avoiding Fraud, Waste and Abuse," and really making sure that your federal funds get used appropriately into the benefit of the American people.

So, moving forward, if you've received an award over the past year, you've probably noticed some new requirements associated with the most recent program reauthorization. And specifically, for applications submitted for due dates on or after September 5th, 2023, NIH is required to assess security risk prior to issuing an award. Prospective awardees are also required to submit a disclosure regarding affiliations and relationships to foreign countries. We also have some new recent requirements for prior approval when changing a sub award, and you can find detailed information about all these specific requirements at our website. We really do have a great page regarding foreign disclosure and risk management, where you can find detailed information about how this process works. Next slide.

In keeping with the theme of today's webinar, did really want to make sure that our awardees were aware of specific reporting requirements during the award period, and so for awards covered by policy, and that's again if your competitive application was submitted for a due date on or after September 5th, 2023, recipients are responsibility for continued monitoring of the relationships with foreign countries of concern, and for any changes that may impact their previous disclosure made at time of award, or after time of award. So specifically, small business concerns receiving an award under the SBIR and STTR program, are required to submit an updated disclosure form to report any of the

following changes. This includes changes to any of the disclosures on your initial disclosure form. If you become aware of any material misstatements that pose a risk to natural security, and any change of ownership, change to your entity structure, any other substantial changes in circumstances to your business that could possibly pose a risk to national security. So, we do require that minimum, regular annual updates for grantees, at least, are required at the time at your annual interim and final Research Performance Progress Reports, or RPPRs. For any changes that occur between your RPPR submissions, updated disclosure forms are required within 30 days, using the SBIR-STTR foreign disclosure form request for additional material system in eRA Commons. And you can always reach out to the Program Officer and your Grants Management Specialist, or our office at seedinfo@nih.gov, if you have got questions about this process and what is specifically required of you. This is something we're always happy to discuss with you.

That concludes my comments at the front, and I am very happy to introduce you to our first speaker, Dr. Roger Miller, the SBIR-STTR Program Coordinator for the National Institute on Deafness and Other Communication Disorders. And with that, take it away, Roger.

Dr. Roger Miller: Thank you, Adam. So, it's my pleasure to talk to you today about some of the things the Program Officers are looking for throughout the lifetime of your SEED award. It's a little bit different whether you're in the recovery phase for Phase I, or for this Phase II SEED award, where you're actually doing the product development, so I'll give specific advice for both situations. The next slide, please.

If you have an NIH award, you're no doubt fluent in the use of the eRA Commons. You use that to download your Summary Statement, you use it to upload your Just In Time information, for the administrative review of your application. But now that you have an award, it's critical that you go in and verify your home email address so that our automated business systems will send you an email to the right address. That should match the email address on that face page of your application, but I've seen it blank a lot of time, and the PI wonders why they're not hearing anything from us. It's a good idea to go ahead and establish a .com email address that's appropriate for your small business, unless you have an STTR, in which case it's fine to continue using your .edu address. But now that you're in eRA, and you have a SEED award, it's time to download the Notice of Award. So go to the Status tab, as I show in that middle screenshot, and then in the bottom screenshot, you'll see there's some blue links on the left-hand side -- I don't know exactly what the system will look like when you go in to use it, but click on one of those links, download your Notice Award, and I've got test links here to help you navigate the system. Next slide, please.

Okay, looking at the Notice of Award, you see in Box 11 at the top right-hand side an Award Number. It's very important that you know this, because when you're communicating with NIH staff, whether it's Program Officers or Grants Management Officers, we want to make sure that we're looking at the same grant that you're looking at, and that Award Number is what we use. There's other numbers out there that you'll have -- please use the Award Number. At the bottom right-hand side of the Notice of Award, you'll see an end date -- you'll want to know that because it might be a little bit different from what you were expecting, based on when you submitted the application, and it's important to know when the end date is because you may need to ask for a no-cost extension to continue spending funds

under the award that remain available to finish out the award. A no-cost extension is possible for up to 12 months. It's granted by software, but it's actually reviewed again by staff, so it can be taken away. But it's important to know when the end date is so that you can go in before that date and request that no-cost extension if it's necessary.

Looking on the left-hand side of the columns where the red circles are, you'll see the PI and the AO. Hopefully, you know who that is. You'll also see the Grants Management Officer and the Program Officer noted. Please communicate with us with an email. In the best practices, the PI describes the situation and has it officially signed by the business by sending it to the authorized official. It's then sent to the Program Officer, the Grants Management Officer, both on the same email, and it has the Award Number on the subject line. That way, we can get a response back to you, upload that response in your initial query, into the initial grant files, so we all know what's what. Next slide, please.

Looking further down in the Notice of Award, you'll be very interested to know exactly what the award amount was. If you have a Phase I award, it's likely that it'll just be one year of funding, so you won't see numbers in multiple boxes. But if you have Phase II, probably you'll have dollars awarded, total dollars in different fiscal years. They'll also be subject to be availability of funds and satisfactory progress on the projects, so you'll want to know how to report that progress. And we'll go through that in a minute.

Reductions in the requested cost will be reflected here. So just because you requested for something, this is grant in aid, you need to understand what was actually awarded. And that might be your first contact with your Program Office and Grants Management person after the Notice of Award is out. If you had an indirect cost rate included in your application, grants management staff may or may not have used that. And this is where when you look inside the Notice of Award, just exactly what rate they did use, and what the total amount was. There may be conditions in the Notice of Award. If you have animal studies or human studies, NIH may have put the award out, but you're restricted by actually spending those funds on animal studies and human studies because there's some commissions that need to be met first. Those will be outlined in the Notice of Award. If you're using human subjects in a SEED award, it's very likely that this will be an NIH-defined clinical trial.

You'll figure all this out well before the Notice of Award, but if you have human subjects, the answer to the first question is Yes. Are they assigned to an intervention? Some people think that if everyone's assigned to the intervention, the answer here is no, but actually, you have assigned them to an intervention. Hopefully you're looking to show clinical efficacy of your innovations -- next box is Yes. And it's biomedically related, or it wouldn't be coming to NIH. So, it's very typically the case that you have a clinical trial. And it's important to know what you need to do now that you have a clinical trial, so you're using taxpayer funds; taxpayers should be able to see what the results of your clinical trial was, and that's provided by going to ClinicalTrials.gov. That'll also be in the Notice of Award, it's important to pay attention to that. Next slide, please.

Okay, the real meat of program engagement with PIs comes through the Research Progress Reports. You may file an annual, meaning at the end of one year of support if you have a multi-year award, an interim, meaning at the end of your Phase I SBIR or STTR Award, or a final Research Progress Report at the end of your Phase II. And this report will document the progress you've made with the grant

funding. It should show, or it must show, that you've complied with the terms of the award, and we'll describe what that means. And that is submitted electronically through the eRA Commons, you're seeing that that is a very important nexus of communication. In Section B.1 of this, you'll paste in a portion of the specific gains for your project. Don't make any changes in that -- just leave it the way it was -- you wrote it, the peer review system reviewed it, approved it, and now it kind of has a gold standard to it. These are short awards; we don't expect to see changes to the major goals of the project. The real meat of this report is in Section B.2; you can upload a PDF about two pages in length, and you can organize results but aims and milestones, so it's easy to scan over and see where you are in relationship to the aims which were noted in Section B.1. If there's no changes, which we're not expecting, go ahead and say there's no changes in either objectives or scope of the project.

It's a great idea to include photographs, a prototype, a circuit board, software that you've developed running on your device, so that anybody looking at the report can see what you've accomplished. It's easy for Program Officers to see the status of a project when we look at those photos. It's fine to see that we are on target to complete prototype construction, and then give a rough idea of when you expect to do that. Great idea to provide graphs with preliminary data acquired; we're program staff or scientists, we like to see those graphs. It tells us a lot and it takes a lot of effort to get them, so we can see that you're making progress towards your award. If you have challenges, go ahead and describe the challenge and the efforts to overcome those issues. Maybe you ran into some supply chain delays -- that's been a problem the past five years. Maybe enrollment of human subjects was slower than anticipated, for any number of reasons -- go ahead and tell us that, and what you're going to do to resolve that.

In Section C.1, and I've got a screenshot of that over on the right-hand side of the slide, this is where you get to show off your publications. This is the gold standard for scientists. It's great to have publications -- the taxpayer paid for the study; the taxpayer wants to be able to see those publications. So, we have a process where you can show that you have uploaded a draft of the manuscript -- not a draft, the final manuscript -- to our system and made it available. If that is not in compliance with requirements, that will be an issue for you getting the funds for the next year. Human Subjects Enrollment Tables also provided in the Progress Report, and we want to see that enrollment's on track, you're enrolling subjects in about the rate that you expected to, based on your original application, or you explained why you weren't able to do that, and how you resolve that. And I've got some links there to help you read more about all this. Next slide, please.

Okay, so as I said, program staff are going to be very interested in seeing what you've done, and that it sort of follows the plans of what you originally planned. We call that being within the scope of the peer-reviewed application. If you get a Phase I award, we're not likely to see an Annual Progress Report, because it's probably a one-year award. It will be the Interim Progress Report that we see. The Phase I awards are short. They're limited funds, so we really want to see that you maintained the focus on getting the proof of concept necessary so that you could submit a successful Phase II application. Phase II awards -- these are where you're going to have lots of time and effort devoted to developing your product. And we want to see that your funds were spent as described in the application. If your application describes studies in mice, and see data from rabbits, we're going to want to talk to you,

because that's out of scope. If you had planned on doing your study on human subjects and we see studies on rabbits, we want to talk to you. We read animals weren't a part of your original project.

We're expecting that you'll have your product development complete at the end of Phase II, and you'll be ready to start selling your product, ideally. But that can be difficult. You might have put in a request for some technical and business assistance [INAUDIBLE] section for your application for that award, but I also want to highlight in Phase III, to bridge that gap from Phase II to Phase III, you might want to consider consultation with the NIH SEED innovators. Nevertheless, it's important to keep in mind that marketing costs are outside the scope of SEED funding, so don't include those. We don't want to see that you're printing brochures in Phase II, but we do want to see that you're working hard to commercialize your product. Next slide, please.

So, this is a new program that's been stood up in the last few years, and it's a terrific opportunity for PIs or scientists for making great progress on their technical achievement that need a little bit of advice, not quite sure what advice they need, or who to get it from on a number of different aspects. You see six different topic areas, I'm not going to go through them all right now, but they're here for you to peruse later. And then use the icon there if you have an award to request a consultation. This can be a terrific opportunity for an innovator to figure out what they need to do to work with the FDA better, what they need to do to work to get a patent better. And I encourage you to consider taking advantage of it. My final slide -- next slide, please.

I want you to understand how RePORTER.nih.gov works throughout the lifecycle of your award, and how what you're doing as you work hard as an innovator becomes available to the public. And use that to your advantage. You see the website there, you can search out different awards on different topics, and at the bottom of the slide I've got two links; one is for a sample application that we make available, and then the actual reporter, the outcomes from that study which are there for everybody to see. It's important to know that the description of your award is actually the abstract from your application; it goes right through, verbatim. So, understand when you're writing that abstract, you're telling the world what you plan to do. Over on the right-hand column, any publications that you happen to have, they appear right there under the award. It's very easy for people to appreciate the meritorious work that you've done. Click on the links and see the rigor and reproducibility of your science, based on those peer-reviewed publications.

Underneath the Publications tab, you'll see that there's a patents tab, so if you have any patents, it's easy for potential investors to see how well you've done in the ability to both publish and get patents. Underneath that there is a tab for clinical studies, and that's where your clinical trial results are linked to your recruitment efforts, and your clinical trial would appear. It's important to know that the outcome section is there. This comes from your interim or your final Progress Report, and it comes out verbatim. So, understand, what you're typing in that Progress Report will immediately come out on this website. It's a great opportunity for you to make your results available to the general public, but please don't include proprietary, confidential information or trade secrets, because that will harm your business. By all means, do include the standard development of your product and where you anticipate to take it next, because that makes it available to somebody else; if they want to fund your project and help your product if it's commercially for sale, they'll know the name of what it's for sale under.

And that concludes my presentation. Thank you, Adam.

Adam Sorkin: Great. Thanks so much, Roger. Next slide. Next, I'm happy to introduce Dr. Kari Ashmont, the Translational Team Lead at the National Institute of Biomedical Imaging and Bioengineering. Thanks so much, Kari.

Dr. Kari Ashmont: Thank you, Adam, and thank you, everyone, for attending. Next slide, please.

As Adam mentioned, I'm the Translational Team Lead at NIBIB, so I oversee our Small Business program, as well as I'm actually the Program Officer for all of the awards that come through NIBIB. In terms of sort of suggestions or best practices, I think one real big take-home message is, be informed. I know that Roger just went through the Notice of Award a little bit, but I wanted to re-emphasize it again, because I really do think that it is that important in terms of making sure that you are managing your award as effectively as possible. So, in addition to everything that Roger just went through, I wanted to highlight that if you do have a restriction in place in that Notice of Award, you cannot spend federal dollars on those activities associated with the restriction, until the restriction has been rescinded. That means that we have to receive the proper information, documentation, to have it reviewed and approved, and have a new Notice of Award revised that specifically rescinds that restriction associated with the funds that you are looking to spend before you are authorized to use those dollars.

So, it's very important to make sure that you're reading through that full Notice of Award so you know about these sorts of things, and you're not by chance making the error of spending dollars that you really should not have been. Additionally, another piece that's very important in that Notice of Award is that closeout information, so once you get towards the end of the award, what do you have to do to actually wrap things up and put a nice little bow on it, and close it out properly?

The final thing that I wanted to mention related to the Notice of Award is, how that Notice of Award is accepted. So, this is a legally binding document. So, what do you do in order to say yes, you agree to it? You actually draw down funds. So, there's no signature that you send back to us, or anything like that. But by drawing down funds via the Payment Management system, you are accepting that Notice of Award with all of the Terms and Conditions that are in it. Importantly also is that everyone's human, sometimes there are small mistakes in the Notice of Award, so if you are looking through it, and you notice something that doesn't seem quite right, or that you're not sure of, reach out and have that discussion and get it addressed as quickly as possible.

Now in terms of the Payment Management system, I'm actually not going to go into it in detail, because it is not my area of expertise, as a Program Officer, but I did want to just note that it is the system by which you draw down dollars. You do need to have an account via the Payment Management system, and if you have any issues or questions about how to get access to it or creating that account, you should reach out to the PMS Help Desk, or locate your PMS liaison to help address those questions.

Some additional documents that are also very helpful in terms of making sure that you are informed about managing your award are the Welcome Wagon letters that you will receive when you actually get the award. This is basically a summary of a lot of the key requirements, some referrals from

important sources of information. And it also helps to identify some offices within the NIH and HHS that are responsible for certain functions.

Then last, but not least, is our favorite NIH Grants Policy Statement, which is, as the name suggests, it basically lists all of the policy requirements associated with the award. All of these are really great resources to make sure that you know what you need to know, when you need to know it. Next slide, please.

Okay, so you get your Notice of Award, you've done your due diligence, and something changes. Uh-oh, what to do now? Well, there are some changes that as an awardee, you can actually effectively make on your own. For example, say you had a staff engineer, and that staff engineer took a new job. If that staff engineer is not a key personnel associated with the award, you can replace that person without having to get prior approval from your Program Officer or Grants Management. You will need to make that report available once the RPPR comes in, but you can execute that change without reaching out to us ahead of time. However, there are a number of changes that do require prior approval; meaning that you have to reach out, you have to inform us that you plan on making these changes.

And then we have to give you a formal approval before they are effective. This would include things like a change in scope, a change in budget, so any rebudgeting that would amount to more than 25 percent of your overall award does require prior approval. And then things like animal model, level of effort of key personnel -- so if you're changing a key personnel, you do need prior approval. Or organizational status -- and we'll talk a little bit about that in just a moment. All of these pieces of information are available again via your grants policy statement, as you can see on the screen here.

Now, okay, so you know you need prior approval to make this change. How do you go about getting that? There are two ways, as of right now, to make this change. First, you have the prior approval module. This is restricted to only a certain new types of changes that need prior approval, you can see them on the screen here. For all other changes, as of right now, the change request needs to come in via email. And that needs to be sent from the Authorization Organizational Representative, AOR, to your Grants Management Specialist. And it's always good practice to make sure your Program Officer is in the loop as well. This request needs to be submitted 30 days before the proposed change actually takes effect.

Now all of this can be a little bit confusing. Sometimes the change isn't clearly something that needs prior approval or not. So, at the end of the day, if you have an anticipated change and you're not sure -- reach out. Reach out to your Program Officer and your Grants Management Specialist -- they will help you decipher whether or not you need to go through the prior approval process or not. But this is something where you don't want to act now and ask for forgiveness later. You really do want to make sure that if you need that prior approval, you are going through those proper channels. Next slide, please.

As I mentioned, related to organizational status -- so oftentimes as a small business, we see things that are legal actions that may change the status of the organization. For example, a merger, an acquisition, or a successor in interest. If any of these happen and your small business is no longer an eligible small business, then not only can your company no longer receive new awards, but your company can

actually no longer receive additional funds from existing awards. This would include non-competing continuation awards and supplements to the award. So, it's important to understand that if you do go through one of these types of changes, if the new organizational status does not meet the eligibility of a small business, then you definitely need to be having a conversation about how to basically move forward and halt receiving any additional funds. Next slide, please.

The last piece that I wanted to make sure to highlight is, lifecycle certification. So, we have a lot of reporting at the very front end of the award, but it's important to recognize that a lot of this has to be continuous throughout the life cycle of the award. So, the lifecycle certification is basically an attestation that confirms that the award continues to meet program-specific requirements. So, these would be things such as the PI employment status. For an SBIR, is the PI employed greater than 50 percent at the small business concern? That has to remain in effect not only at the time of award, but throughout the duration of the award. Work requirements -- is the proper amount of work being taking place at the small business concerned, versus on a subaward -- those sorts of things. These certifications are required.

Like I said, throughout the award, you can see Phase I has a specific requirement at the time of receiving final payment. Phase II at the time of receiving more than 50 percent of the total, and prior to the final disbursement, and we also do require these associated with the submission of the final RPPR as well as interim RPPRs which, as noted before, are due in eRA Commons prior to the end of the performance date. And you should note that these will actually go into Section G.1, where you should not be saying that you have nothing to report, because indeed you do via this lifecycle certification page that needs to be filed out.

I believe that may be my last slide, but next slide, please. Thank you.

Adam Sorkin: And indeed, it is. Thanks so much, Kari, very helpful discussion, as always. And next I'd like to introduce Callie Prassinos, the Branch Chief and Contracting Officer in the Office of Acquisitions at the National Institute of Allergy and Infectious Diseases. Thanks, Callie.

Callie Prassinos: Hi, everybody. As Adam said, my name is Callie Prassinos, I'm a Contracting Officer at the National Institute of Allergic and Infectious Diseases. And you've been awarded an SBIR contract, and I'm here to talk about what's next. So, the next slide.

So, some of the things I'm just going to briefly go over is, the contract and its clauses, talking about obligations and limitations, all the way through the different aspects of a contract to evaluation, and moving from Phase I to Phase II and Fast Tracks. So, next slide.

So, a contract and its clauses -- a contract is a legally binding agreement between two parties, your organization and the government. There's specific performance requirements in the Statement of Work and the delivery schedule of the contract, which details the due dates and expectations of the performance. Usually, a contract is set up with a cover page that has the Contract Number, and it has signature from both parties, and it goes through all of the sections where you can find different regulations and requirements throughout the contract. Here are some of the sections if you need to look at things within it. So next slide, please.

Callie Prassinos: The mutual obligation of the government and the contract are established by, and limited to, the written stipulations in the contract document. 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. The contract is a legal document, and it's set with certain requirements and stipulations that limit the contract, and also obligates the Contractor to certain things. So, make sure you read your contract document thoroughly. Next slide.

So, there are two very important individuals that you'll be working with in a contract, the Contracting Officer and a Contracting Officer Representative. They have two different jobs. The COR is responsible for monitoring technical progress, recommending changes to the Contracting Officer, but the COR cannot make changes to the Statement of Work, or the reporting requirements -- only the Contracting Officer can do so. They interpret the technical performance requirements. They do inspections and acceptance of that performance. They insist that any technical problems that may occur during the performance, but the COR is not authorized to make any changes to the cost of your contract. This is only the responsibility of the Contracting Officer.

They direct and negotiate any changes to the Statement of Work. They modify the contract either in cost or peer performance, or delivery schedule. So, if anything needs to be changed, please reach out to your Contracting Officer; they're the only ones that are authorized to make any changes to the contract. Next slide.

So, your Statement of Work is a very important document in your contract. It defines the work that needs to happen under the contract. It acts as that framework for the cost. The Contractor should be intimately familiar with all of those details in the Statement of Work. Any changes to the Statement of Work, anything that needs to be changed, or is not right or is not accurate, please provide written documentation to the Contracting Officer so that it can be updated. If the Contractor receives a request from the government to perform a task, if the government changes the Statement of Work, they will provide the Contractor with an updated Statement of Work, and negotiations will happen to change those activities through modification, or change. Thank you. Next slide.

So, changes to the contract -- so if there's any changes to the Statement of Work, any changes to key personnel or delivery schedule, that will happen in modification to the contract. The Contractor should submit a formal request for any changes in writing to the Contracting Officer. The Contracting Officer will review it, they will discuss it with the COR, and then they will move forward with either a modification or additional communications to ensure that the changes are needed. Next slide.

Key personnel -- prior to any deviation for individuals that need to be changed, please contact your CO, your Contracting Officer in advance for replacing any key personnel. In the contract there will be a listed key personnel. If there needs to be a change to that key personnel, please let them know as soon as possible with the updated CV, with the replacement, who needs to be put in place for that key personnel change. Then the Contracting Officer and the COR will negotiate and ensure that those changes take place before that key personnel change is made. Next slide.

So, Invoice Submission and Payment -- the government shall make payments, including invoices and contract financial payments by electronic funds transfer. Payments on fixed-price contracts may be made on satisfactory completion of receipts and contract deliverables. Payments on cost

reimbursement -- contracts may be made, but when a proper invoice is received. Usually, these invoices are received on a monthly basis, but please, that will be outlined in your contract and can be discussed with your Contracting Officer. For all contracts, any final payments that are made will not be made until we receive all of the reports and deliverables made within that contract, and that they're found acceptable by the government. Next slide.

And in the contract, reporting requirements and deliverables -- in the contract there will be a section that outlines which Progress Reports and deliverables are requirements under the contract. They will either be found under Section C or Section F of the contract. Some examples of these deliverables are Progress Reports, a final report, the Small Business Innovation Research Lifecycle Certification, and any final Invention Statements. But please read your contract and ensure that you know what deliverables are required under your contract, because final payments will not be made until those deliverables are received and accepted by the government. Thank you, next slide.

And then evaluation -- so contracts are evaluated on an annual basis. The Contractor performance is evaluated. These details will be in Article G of the contract, and the factors that are evaluated are technical in quality of the product or services, cost control, schedule and timelines, management and business relations, and regulatory compliances. All of these evaluations will be provided to the Contractor through the CPARS system, and the Contractors are allowed the ability to respond to the evaluations within the system. This is very important, because these evaluations are used by other contracting officers in the government for future awards. So please be aware of evaluations being done on an annual basis and watch out for those CPAR emails so you get the chance to respond within the system of those evaluations that are provided. Thank you. And next slide.

Lastly, moving from Phase I to Phase II, and Fast Tracks -- so Phase I Contractor that did not get a Fast Track contract will be informed of the opportunity to apply for a Phase II by the awarding component. Usually, you get a Phase I award, and coming to the end of that expiring contract, the Contracting Officer will send out invitations, or will start discussions about Phase II. Then you'll have the opportunity to provide an additional proposal that will be evaluated that will go through the same process as the Phase I award did. Then you'll get an additional -- if found acceptable and best value by the government will get an additional award for Phase II. This is different than a Fast Track, where a Fast Track was awarded at the time of Phase I.

Usually, the Fast Track Phase II is an option in the contract. When you get to the end of a Phase I proposal, the option will be exercised, so there's no gap in between the Phase I and the Phase II. But if you have any questions about Phase Is and Phase IIs, please discuss that with your Contracting Officer. They'll have more information about that, and how they do that, and how they'll invite for Phase II proposals. Thank you very much. Okay, next slide.

Adam Sorkin: Great, thanks so much, Callie. And I will now introduce our final speaker, Jonelle Soeffing, Operations Officer at the Department of Health and Human Services, Office of Inspector General. Thanks, Jonelle.

Jonelle Soeffing: Thank you, Adam. Good afternoon everyone. During my portion, I will wrap up the key messaging from my fellow panelists, and we'll share some helpful information towards protecting your award by preventing fraud waste and abuse. OIG's mission is to fight fraud, waste and abuse in

Medicare, Medicaid, and in more than one hundred other age-adjust 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 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 that the information was false, in order to get money or a benefit. Waste involves practices that directly or indirectly result in unnecessary costs, such as overusing services, and misusing resources, whereas abuse is the intentional or unintentional thoughtless or careless expenditure, excessive or improper use of government resources, including one's position and authority.

There is a moving fraud scale displaying actions that can 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 or 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, cheating.

Here is an overview of certain fraud schemes that could lead to fraud investigations. Some are applying false information on applications, proposals and documents, creating fake records, accepting or offering kickbacks using funding for unauthorized purposes, such as for personal expenses and personal travel. Not doing any work, but billing as though you did the work. Stealing, theft and embezzlement, bribery, and the list goes on. Remember, that lies by action or omission both count. Do not use grant money on one research topic or project to pay employees working on a completely different topic or project, 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 the 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 500 employees, including all affiliates. The Small Business Administration's definition of affiliates does leave some room for interpretation, but it considers factors like ownership, management and contractual relationships, and determining whether affiliation exists. The OIG has found some awardees that were affiliated with organizations much larger than 500 employees. For example, one awardee company, though was itself well under the 500-employee limit, was owned by a larger company that had over 7,000 employees -- that is improper.

Without understanding what fraud, waste and 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 your common sense. Use your awards appropriately. Don't be afraid to ask questions of the grantee agency if you have questions on whether a particular expense is allowable. There is no need to hesitate calling the OIG to report suspicious activity. We investigate thoroughly and covertly. If you see an issue, please say something. Your reporting of a possible problem is justified, and you've helped to protect the program within HHS. Disclosure and communication with HHS grant officials is key.

There are consequences of fraud. There are consequences that involve criminal and civil prosecutions, and administrative actions. Here are some common criminal statutes, such as 18 United States Code 641, Embezzlement and Theft of Public Money. 18 USC 1001, False Statement, on the civil side -- False Claim Statute. Administrative actions involve civil monetary penalties, exclusion from HHS programs, and government-wide suspension and debarment.

Fraud consequences are made public. Here are two OIG case examples, and the first example, two biotechnology companies and their cofounder entered into a settlement agreement to pay more than 10 million to the United States to resolve allegations under the False Claims Act that they engaged in improper billing to 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 second example here involves a researcher in the University of Montana, who was owner and CEO of their own LLC, which conducted neurological disorder research, who admitted to charges of falsifying documents related to grant funding from the NIH. The researcher-owner was sentenced last month to four years' probation, and restitution totaling $165,000, approximately. And on to the last slide.

I want to re-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 or allegations and are treated with privacy and discretion. A hotline complaint is allegation. Hotline complaints are treated confidentially. We conduct independent investigations, and hotline complaints can provide helpful information to criminal, civil, and administrative remedies. After receiving my overview, the 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're doing your part to protect HHS programs and the public.

Thank you, and I'll turn control back over to Adam.

Question and Answer Session

Adam Sorkin: Great. Thanks so much, Jonelle. And thank you to all of our panelists. Now, we've got a bit of time left to address some Q and A. If we don't get to your questions, please know you can always send questions to us at seedinfo@nih.gov, and we'll be happy to answer them. We're going to be focusing on questions specifically for the post-award processes and management, and I do want you to note that we will not be answering questions regarding fraud, waste and abuse presentation live, but are happy to take any questions you have back to our colleagues at OIG.

And with that, I know that we do see a couple of questions about the foreign risk management process that we didn't want to address at the front end. First, we received a question about whether or not these requirements are for applications submitted after September 5th, 2023, or for awards that were given after September 5th, 2023. And to be abundantly clear, this applies to competitive applications that were submitted for due dates not after September 5th, but for the September 5th due date and

after. Additionally, we have a question about whether or not the CEO, a change in CEO would need to be disclosed. Keep in mind we do require an updated disclosure form for any of the initial disclosures on the form, which should include covered individuals in your project -- so that's typically any key personnel named in the project application, as well as any change of ownership, change to energy structure, or other substantial changes in the circumstances of your business. So, I believe in most cases, that would likely include a CEO.

Let's see, and then we've got a number of other great questions. I did see a couple of questions about prior approval and projects. So, I wonder if either Kari or Roger would like to discuss the flexibilities our awardees have in rebudgeting, what is prior approval required, when is prior approval not necessary?

Dr. Kari Ashmont: I think we're playing a game of chicken of who is coming on here first. [LAUGHS] So could you read the specific question, Adam? I thought there was something about -- there was some specific information in it that I can't find right now.

Adam Sorkin: Let's see, well, I think -- I did lose my question --

Dr. Kari Ashmont: Is it between categories? Is that what the question was about? Really, so I guess if you're moving money between categories, so say from equipment to salary, or something like that, if it raises to the level of being greater than 25 percent of your overall award, then it requires prior approval. If you are below that 25 percent threshold, then you do actually have the authority to make the rebudgeting on your own, but you should make sure that you are reflecting that change in your Progress Reports that are submitted. If you have a question about whether or not you are reaching that 25 percent threshold, it's always a good idea to reach out and have a conversation with either your Program Officer and/or your Grants Management Specialist. Roger, do you want to add anything to that? You're welcome to. No? Okay.

Adam Sorkin: Thanks so much. We did see a related question about spending prior to award -- and so you do have some flexibility to spend up to -- budgeting costs up to 90 days in advance of the start of your award, but please keep in mind that all of that spending is at your own risk until the Notice of Award is issued.

Let's see. Different question -- what is a carryover request?

Dr. Roger Miller: I believe that's a no-cost extension request. Am I wrong, Kari?

Adam Sorkin: Well, I believe it's --

Dr. Kari Ashmont: So, this is -- I believe what they're referring to is for a multi-year award, if they have dollars that are left over from Year One --

Dr. Roger Miller: Okay.

Dr. Kari Ashmont: -- and they want to request to be able to use those in Year Two, for example. How would they get authorization to do that? And that is via a carryover request. In some cases, I believe you do -- I think the small -- don't we have carryover authority for small amounts of carryover funds, meaning that it does not have to be a separate request, but in other cases, you do actually have to submit a formal request to carry over those funds. In those scenarios where you do have carryover

authority, it is handled through your RPPR, the details of the funds that are going to be carried over and what they will be spent on in the subsequent year.

Dr. Roger Miller: That's right. So that's a question -- thanks, Kari -- so that is reported in your RPPR. And don't be afraid of spending your funds wisely and having the carryover request. Go ahead and justify it. If you see that's happening, you want to reach out to your Program Officer in advance. We can't approve it in advance, but just to get a good idea of whether or not what you're doing seems reasonable -- that's fine. But I kind of got into that a little bit when I was talking about knowing when your end date award is. And if you have something that's slowing you down, go ahead and note that in your Progress Report. Say that you anticipate submitting a no-cost extension, and you're going to pay for that with the funds that are remaining. And that would be part of your carryover.

Adam Sorkin: Great. Thanks so much. Let's see -- I am seeing a couple of questions about what happens if your company is sold, or you go through a merger and acquisition? What happens? I'm happy to comment on that a little bit -- so we do have some mechanisms available to transfer your application to either a new organization, or a successor in interest. Always a very good idea to reach out to your Branch Management Specialist as soon as possible if you believe that one of those transactions is going to occur. They can examine the grant, see how much funding is left on your existing award, and develop a plan to either wind down the grant if you're close to the end of it, or make plans to help you transfer that award to a new organization, so long as the successor or acquiring organization remains eligible for the SBIR or STTR program.

Let's see. We are quickly running out of time. I am seeing a couple of questions about the COR -- Callie, I was wondering, can you just clarify the role of the COR, and differentiate that from the other people working on the project?

Callie Prassinos: Yeah, absolutely. So, your COR, that Contracting Officer Representative, is going to be your technical point of contact. They're the government official that will help with technical progress and acceptance of the deliverables, any technical issues that you might have, working through the Statement of Work and those requirements. They are not able to make any changes like the Contracting Officer; the Contracting Officer is more of the person to turn to for any changes, any deviations, any cost questions. But the COR is mostly for the technical aspect, the technical point of contact for the contract.

Adam Sorkin: All right, thanks so much, Callie. And let's see. A couple -- we're getting a lot of questions. One more question for Kari and Roger. What happens if, for some reason, your PI is no longer available to the project, or you need to make a change in personnel? What's the best practice for working through that with NIH?

Dr. Roger Miller: So, you want to let us know as soon as possible. You have some authority to carry on, but really, you want to let your Program Officer and Grants Management person know. What I like to see is a CV from a replacement PI that matches the capabilities of the PI that was outgoing. These are short awards, so we're really not expecting to see that. It's troubling when someone comes in as the PI on an award, and two months into a six-month award or a two-year award, they decide that they're going to pursue a career in academia. Program staff really have to look carefully at this to see whether

or not it's likely to succeed. So really, if you submitted the application as the PI, we're expecting that you'll fulfill that obligation. And in the case of NIDCD, we've looked at the change in structure and decided it just doesn't make sense to continue.

Adam Sorkin: Great. Thanks so much, Roger. And that has very quickly brought us to the end of our hour. As I mentioned, if you have unanswered questions, please reach out to us at seedinfo@NIH.gov. Most importantly, if you have questions or concerns about your specific situation or award, you can always reach out to your Program Officer and Grants Management Specialist to really work through those issues and resolve them. A big thank you to all of my panelists, Callie, Kari, Roger and Jonelle today for joining us. And please reach out to us with any follow-up you may have about today's program. And thanks so much to Vicki and Audrey for working behind the scenes to make sure everything went smoothly today.

Helpful Chat Links

Foreign Risk

Foreign Risk webpage

- Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries
- NOT-OD-24-029: Clarification of Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-award and Post-Award Requirements
- NOT-OD-24-149: Prior Approval Requirement for Changes to Domestic Subawards for the SBIR and STTR Programs

eRA Commons

- Tutorials
- Navigation
- User Guide
- No-cost extension

Innovator Consultations

- Request a consultation

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- Visit NIH RePORTER

SBIR/STTR

- Eligibility
- Grants
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