NIH SEED Small Business 101 America's Seed Fund is Back - Powered by HHS-20260728_143018UTC-Meeting Recording

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Sorkin, Adam (NIH/OD) [E] 0:08
Good morning, everybody, and welcome to NIH SEED Small Business 101, Managing Your SBIR-STTR Award Effectively. I am Adam Sorkin, the Small Business Policy Manager at the NIH Small Business Education and Entrepreneurial Development Office or NIH seed as we call ourselves. Just a quick housekeeping at the top of the hour. Slides and materials will be available in seven to 10 business days at our website. If you're registered for any of our webinar series, you should get an e-mail as well once they become available and links to that website.

We will be using the Q&A function. So if you have any questions during our presentations, please just put them in the Q&A function and we will get to that at the end of the presentation.
And then as a reminder, our website remains a helpful resource for current funding information and opportunities, application and award information, and importantly, points of contact, like a lot of the people that you're going to hear from this morning.

And so we do have a great panel today and a great program where we at SEED do get to take a step back after the last two webinars to let you hear from some people who you might be interacting with when you're selected to receive an SBIR or STTR award. First, you're going to hear from some people in two roles who work together to issue and administer a grant award. Dr. Toyin Adeshafe, a program officer at the Eunice Kennedy Shriver National Institute on Child Health and Human Development, will be speaking from the program official perspective. So that is going to be the role who will be your primary scientific point of contact at your warding institute or center.

Then you'll hear from Artisha Wright, other Transaction Agreement Officer at the National Institute of Child Health and Human Development as well, who will speak to you grants management and preparation and administration of your award, making sure that you can access those resources responsibly and consistently with NIH policy. You'll notice that Toyin and Callie are going to speak to a few common elements, but from different and important perspectives. So pay close attention to that. Then we'll hear from Callie Persinos, who is the

Branch Chief and Contracting Officer from the Office of Acquisition and Logistic Management within the NIH Office of the Director, and she'll be speaking to SBIR contracts and what to expect when you negotiate and perform on a contract with us. I will also take the opportunity to note that this is particularly pertinent as the National Cancer Institute has recently released a new contract solicitation, which you can find from our webpage that I just linked.
previously.

And then lastly, we will hear from Janelle Suffing, Operations Officer in the Office of Investigations in the HHS Office of the Inspector General, who will talk to you about how to avoid fraud, waste, and abuse when using your federal funds, when working on your SBIR or STTR award what to look out for, some examples of fraud, waste, and abuse to avoid, and importantly, where to go and who to reach out to if you have any concerns about fraud.
And so, with that, I will hand things off to you, Toyin. See you at...

AT

Ajisafe, Toyin (NIH/NICHD) [E] 4:33
Thanks so much, Adam.

SA

Sorkin, Adam (NIH/OD) [E] 4:33
Discuss a word mention, basically.

AT

Ajisafe, Toyin (NIH/NICHD) [E] 4:37
Thank you. I'm thrilled to be here with everyone. As Adam mentioned, I'm Tony Ajafe. I'm a program officer in my primary role at the National Center for Medical Rehabilitation Research, and I also lead the NICHD's, the National Institute of Child Health and Human Development Small Business Program. Next slide, please.

So just to quickly orientate everyone, so we're all on the same page, this slide is really just... Reintroducing, I'm sure some in the audience may already know this, the different phases, at least phases one and two of the SBI-STTR program, and the respective goals of those phases that includes things like total cost as set by the Small Business Administration and durations. Notably here in phase one, you'll see that generally Phase one awards can go from six months to a year, but some institutes and centers at NIH allow more than one year. For example, the NICHD, which

is where my primary role lies, allows up to two years for phase one. The total cost doesn't change. However, we do allow up to two years, depending on the scope of the project. Phase 2, generally, so one will have established proof of concept, technical merit, feasibility, and now you're looking to further your research and development and depending on the type of project or product rather, you're now looking to start generating some evidence.

It could be efficacy, effectiveness depending on the design of the study. And you see that the budget reflects that increased scope of work. And generally, these can go from two to three years. And importantly, the phase two applications that require a commercialization plan.

So, I've noted here some pre-award considerations that I think potentially could set one up for success in the post-award phase. And what are some of those considerations? I think it's important that applicants don't over-promise in an application. It may
It may bode well in review, because generally reviewers may like a bit of over ambition compared to under ambition. But you want to be very careful on what you're promising. For example, I think you want to give a lot of thought to the technical development trajectory involved in the project. And are you thinking about potential pitfalls and alternative strategies? And what do those alternative strategies look like? How practical are they? Because I'll be preaching to the choir that some of these hiccups can in fact stall a project. Importantly, also, you want to think about the sample side. If, for example, if you're recruiting or proposing to recruit human subjects for that research project, are you being practical, right? Are you thinking about what it may take to actually recruit and enroll the subjects that will be from your target population? For example, if you think of people, say children with cerebral palsy as an example, have we really thought about what it takes to recruit and enroll that population, because why am I why am I honing in on human subjects? Because this is a common source of a lag in project milestones that we that we see.

You also want to think about regulatory approval. Are there things you can start to tackle even ahead of getting a notice of award. For example, IRB approval. As you know, NIH cannot sanction and give an award that allows engagement with human subjects without IRB approval. Again, assuming the project involves human subjects.

You also want to think about the type of product. Is it a drug? Is it a device, for example? And if the product is regulated by the FDA, you want to think about the types of regulatory approvals that are necessary to even do the work, right? You may need an IND investigational new drug,

you may need an investigation or device exemption. For example, again, depending on that type of product that you are looking to bring to market. Next slide, please.

On to the notice award, so what's the notice award? This is the official. This is an official document, right, that informs you of your funding status. Now you have your notice of award, you know that officially you are being funded. And it's very important to review, carefully review the notice of award because it has a few important details. One, is it asserts the funding level, it asserts the period of support, it tells you what the terms and conditions are. I previously mentioned the IRB and whether or not one has approval. If there is no IRB approval, you will notice that the notice of award would stipulate that all human related, human subject related activities are cannot move forward, right? They're restricted until there is our approval. And I know someone may say, well, you're free to conduct other aspects, other activities on the award except human subjects. So you want to look out for such restrictions on the notice of award. It also specifies the reporting frequency for your progress and milestones. And this is also very important. And very critically, It has the contact for your grants management specialist and your program officer. These are two people that you will interface with across the lifecycle of the award and people that are in your corner. We're always rooting for you. We want the award to succeed. Not only are we investing in your project, we ultimately want what you want, which is to be able to deliver a product that helps improve lives and serves the mission of the NIH. Next slide, please.

Now, I mentioned reporting milestones. Well, how does the PI, the investigator and their team communicate that to the NIH? It's via what we call the Research Performance Progress Report, the RPPR.

Importantly, you want to note the frequency, right? So you annually submit this big research progress report, the RPPR. But if your study or your project involves what's called a clinical trial, Depending on the risk classification for that clinical trial, the reporting frequency may actually vary. For example, we have what's called a low risk clinical trial, medium risk and high risk. A medium risk clinical trial would require two touch points across the budget period, across the year. which means there will be, in addition to the main RPPR, there will be an interim progress report, which your sign-in official would submit to the grants management specialist. Onto the RPPR and the interim progress report, the types of question you will see and you would have to Answer are things like, what are the major goals of the project, right? That's a light left, because you simply have to copy and paste when you're for your main application, but on to questions

like, have the major goals changed? This is really important, right? So, as a team, as a PI. You should never just decide that you're going to change the scope of the project without having previously consulted with the program officer and the grants management specialist. And how do you seek permission? That's called a prior approval request. And depending on the timing, sometimes you may work out such that you're able to put this request in the RPPR, but if you're looking to make such a change of cycle and so of cycle with the RPPR, you would use what's called a prior approval module to submit a prior approval request where you're saying, hey, where are we considering the sample size, for example.

And here, here's why. Here's the justification. And here are the pivots we're making in terms of statistical analysis to still ensure that we have the power to make the appropriate interpretations from the data we collect. So this is really important. You don't want to you laterally make a decision and change scope, and then we find that later on. So again, critically communicate with your program officer and your grants management specialist. Next slide, please.

There are other questions you will see on the RPPR, things like what have you accomplished under the goals of the project? And here again, you want to give NIH a good sense of the progress you're making. So you would know things like your progress on human subjects recruitment and enrollment applicable. You want to include things like graphs and data to again help capture the progress you're making. Are there any relevant publications? You want to list those. And then there's a question that asks what you plan to do in the next reporting period. Again, to help accomplish these goals. You want to make sure you're answering those questions judiciously. There's a link here to get you to that, to the RPPR webpage. And it has a ton of information related to things you should know prior to preparing your RPPR.

Again, I'll note this, engage with your program officer and grants management, especially early and often to mitigate any issues. Next slide, please.

Now, the foreign risk assessment, again, I'm preaching to the choir. I'm sure many in the audience know what this is by now. Initially, this was only applicable to new awards. But what's changed is that this is now applicable to non-competing awards. And what do I mean by non-competing awards? Say you have a three-year grant, right? You get a notice of award for each budget period. So it's no longer the case that you say, well, I got my first year award. I can breathe easy and not have to worry about my foreign relationships. That's not the case anymore.

So each new budget period, the foreign risk assessment will be conducted. So I want to strongly recommend that awardees, if you get an award, you want to keep track of those relationships and continue to monitor implications. Thankfully, the SEEDA office has many, many helpful resources related to the foreign risk assessment process. And importantly, they have these case studies that can really help you get a good sense for the types of implications and interaction that may trigger and cause a potential pitfall when it comes to the foreign risk assessment. So I would highly recommend that you go through these case studies so you have a a good knowledge of the breadth of the types of issues that could arise during the forward risk assessment. Next slide, please.

So, that concludes my talk. If I, if there is a take away from today, it's please talk to your program officer and grants management specialist. These are two people in your corner. Our job is, of course, oversight and stewardship, but we want the same end goal that you want, so it's... Very important that you communicate early and often. Thank you.

Sorkin, Adam (NIH/OD) [E] 17:31
Thanks so much, Toyin. And that is a great lead-in to our next speaker, who will be speaking about the grant management role. And with that, I will hand things off to Artisha.

Wright, Artisha (NIH/NICHD) [E] 17:48
Hi, good morning. As Adam stated, my name is Artisha Wright. I am a Other Transaction Agreement Officer and Grants Management Officer at NICHD, and I'm very excited to speak with you this morning. Next slide, please. So receiving an NIH small business grant is a significant and exciting achievement. However, if this is your first grant, you may find yourself with questions or uncertainties about the next steps in the process. It is normal to feel this way, and there are many aspects on managing an award that require careful attention and understanding.
So before commencing any work on your NIH-funded project, it's essential to thoroughly read the Notice of Award or NOA. And Toyin touched on that earlier, but I do want to go over it again. So the NOA serves as the official legal document confirming that your organization has received an award.

This document is issued for the initial award period, and it's sent via e-mail to the address your organization provided during the registration process in eRA Commons. The NOA contains critical details, such as the budget project and period start and end dates,

the name of the organization, the name and address of the signing official, your project title, the funding commitment amounts, all applicable terms and conditions, and the contact information for both the assigned grants management specialist and the program official.

In section 3 of the NOA, you'll find the standard terms and conditions, such as the life cycle certification requirement. There are two different times when you would have to submit that. So for your phase one, when you're receiving that final payment, or in that phase two stage when you're at 50% of the payment, 50% of the award and at the final stages. Also too, you're going to notate if you have carryover authority, if you're subject to SNAP, which is the streamline award, streamline non-competing award progress report, if you have closeout requirements for that one year phase award.

And in section 4, this is going to contain the IC specific award conditions, such as your clinical trial indicator, if you have any restrictions. So like if you have delayed onset for human or animal subjects, and you haven't received those IRB or IACUC approvals at that time.
If you have restrictions for personnel cost or total funds, so let's say, for example, in fourth quarter, we're working judiciously to get your awards out. And there may be part of the just-in-time information that you miss, such as the other support for a key personnel, or we may see that somebody is overcommitted, we will put an administrative restriction for that person as opposed to holding to continue to have you meet the needs to rectify that situation. Also, we will indicate the notice of funding opportunity that your award applied to. The welcome wagon term will be there if you're a first time NIH grantee if there are any funding reductions or adjustments that were made during the time of our workup, if we applied the salary cap, if you have that consortium, and then the SBIR, STTR specific terms that go over intellectual property, audit, and the final research performance progress report additional requirements. if this is the closeout final year.

It's very imperative that you carefully review and fully understand the terms and conditions outlined in your NOA. Doing so will ensure that you are in compliance with the NIH policy and procedures. Any violation or non-compliance could result in adverse grant reactions, including special award conditions, monitoring your funds withdrawals from PMS, grant termination, and impact future funding eligibility. Once you request or draw down even $1 from PMS, you officially accept this small business award along with all the applicable terms and conditions associated with it. Next slide, please.

So after understanding the purpose and contents that the notice of award contains, I do want to tell you how you are going to access this document to review the relevant information. So to locate the NOA, you want to begin by logging into your Commons account. Once you've logged in, you want to navigate to the Commons landing page and select the status option.
This will direct you to the area where award statuses are displayed. Next slide, please.
Alternatively, you can access the status section by clicking the apps icon located in the upper left-hand corner, and then you will use the drop-down menu to select the statuses. And once you do that, next slide.

Once in the status section, you're going to locate the specific award number which you wish to review the NOA for. The status information screen is then going to appear. And in this section, you want to look for the other relevant documents and click that icon to expand this area. Here, you're then going to find the latest NGA or Notice of Grant Award, you want to select the date relevant to the NOA that you wish to review. And once you do that, then you're in a separate window, you're going to be able to view the Notice of Award, which is found on the next slide, please.

And here again, as you also saw in the prior presentation from Toyin, we have a sample of the notice of award and information that I talked about earlier is found here. So like I said, you're going to see the award number, the unique federal award identification number,
It's going to give you our amount, the federal award project title. You're going to find the specific funding amounts for this year, your project period start date and end date. And then in the column to the left, it's going to be the recipient information. So the name, the business address, your payment management system identifier number, the awarding agency, your program official contact, as well as grants management.

Next slide, please.
So after you've received your notice of award, you now enter into your post-award phase of the grant. At this stage, it's very essential to remain in close contact with grants management to ensure that everything continues smoothly and we can address any questions or concerns that may arise. Effective communication with grants management is especially important.
when it comes to establishing and managing your funds, as well as understanding how to access them. So the payment management system, which is administered by the Program Support Center within the Division of Payment Management, is the official platform that NIH grant award

recipients use to access their grant funds. Grants Management does not maintain or monitor this system directly, but your assigned specialist can provide you with the necessary contact information, such as the phone numbers and the website for customer service that you can get assistance and guidance from. By reaching out to Grants Management, you can ensure that you have the resources and the support that you need to navigate through the payment management system and manage your funds appropriately. So eligibility is a big thing. There may be organizational changes such as a merger or acquisition, and that can significantly affect your company's eligibility for NIH grants awards.

So let's say, for example, your organization does undergo a merger or acquisition, and your number of employees rises from 350 to 600. It's essential for you to consider how this change in your company size may impact your current award eligibility. And once you are ineligible for an award, then we have to go into a process of bilateral termination and we have to end your awards because you are no longer eligible as an SBC to receive those awards. So any alteration to your organization structure or employee count should be brought to the attention of the grants management specialist and the program official to ensure that you're still in compliance and avoid jeopardizing the award status. Additionally, there may be changes in the research location sites that could affect your grant. So let's say, for example, you have a co-PI that decides to relocate their lab and the research activities to France which would result in a new site and a foreign consortium. Supporting research at a new location may also require you to reallocate your funds to support that new site. But it's a foreign site, and it's also a site that wasn't there previously. So now, before you proceed with doing this research, you have to reach out to grants management and program to make sure that everything is okay and this is appropriate because otherwise you're moving forward and you're taking a risk and it could lead to special enforcement actions and or award termination.

Next slide, please.
So let's say hypothetically, five months into your grant, your research is on track, everything is good, you're achieving your project goals, and suddenly a critical piece of your equipment breaks down. So now you're doing cost comparisons, and you do discover that there is a piece of equipment that you want to use, and it's a more advanced and updated model. However, it costs $48,000, which is significantly higher than the original purchase amount. And at the same time, you have a co-PI that announces that they're going to depart, making it necessary that you have to now identify a replacement. You may consider whether there is a suitable candidate to fulfill this role, or would it be practical for you to adjust your effort and compensate for this

change in key personnel? You're faced with these unexpected developments, and you may wonder, well, do I need the prior approval from NIH? I have the equipment. I've identified it. Should I just go ahead and do that purchase? Can I just appoint somebody as the new co-PI to that may not have the same qualifications as my departing colleague, but we can just get it done. And it's very tempting to move quickly because you're trying to resolve all these issues. But it's very critical that you communicate with grants management and program before making any changes, because these do require prior approval from NIH. And if you move forward without obtaining these approvals from us, you are violating the NIH policies and procedures, and it could result in adverse reactions, with your award being restricted or even terminated. Next slide, please.

So in conclusion, before I move forward, one of the things that I definitely wanted to emphasize to you is when you're faced with uncertainty during the management of your NIH small business award, it's always essential to reach out for guidance. As A principal investigator, your primary responsibility is to achieve the scientific aims and produce successful research outcomes. The program official is dedicated to the scientific management of your award. While my role centers around the day-to-day administration and ensuring that you are in compliance with the grant requirements, open communication amongst all three parties, the PI, the PO and the GMS is vital, especially when dealing with the complex situations like I described above. By collaborating, we can ensure that all the actions that you're taking are proper and in accordance with NIH policy and procedure. This communication does extend beyond program and grants management. And in a moment, you're going to hear from my colleague who is going to talk to you about effective management of contract management. So at this point in time, this does conclude my presentation and I'm now going to turn it over to Callie.

Prassinos, Callie (NIH/OD) [E] 30:40
Next slide, Adam. Thank you. So congratulations. You've been awarded a SBIR contract. So now what do we do next?

So a contract is a legal binding agreement between two parties, the organization named on the contract and the government. There will be specific performance requirements in the statement of work and in delivery schedules, which will detail the dates, the due dates and expectations for performance. Usually contracts are organized by the following sections. So if you have any questions on specific requirements, please look in your contract at these sections.
So you might be able to find the answers. They should outline pricing, payment schedules,

inspections of invoices, period of performance and delivery dates, all the FAR clauses and terms and conditions, and also attachments, including the statement of work.

Next it, next slide.
So the contract is a mutual obligation of the government and the contractor as established by and limited to the written stipulations in the contract document. Now this is very important because 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.
Next slide.

So the roles of the contracting officer and the contracting officer representative are as followed. The contracting officer representatives will handle mostly all of the technical requirements. They're monitoring technical progress. They'll recommend changes to the contracting officer if needed, but the Corps is not allowed to make any changes to the statement of work or the reporting requirements. Only the CEO may do this. They interpret technical performance requirements. They perform the inspection and acceptance of invoices and assist in resolution of technical problems. But the Corps is not authorized to negotiate any cost or change any anything that might incur costs in the contract whereas the CO, the contracting officer, will direct any changes to the statement of work. They'll work with the core on what needs to be changed in the statement of work and will work with the contractor. But they're the only ones that can officially change the statement of work. They'll modify or exchange the period of performance. They'll change, they can change the delivery schedules, and they can change any of the terms and conditions of the contract.

Next slide.
So the statement of work found in your contract defines the work to be performed under the contract and acts as the framework for what costs are covered under the contract. The contractor should be intimately familiar with all the details of the statement of work. And if there are any changes to the statement of work, it must be provided in writing by the by the contractor. If there is a chance that something needs to be changed in the statement work, please contact the contracting officer so those changes can be made.
Yes, and if the contractor receives a request from the government to perform a task outside of the statement of work, please give us a heads up so that we can negotiate with the COR and the contracting officer those changes can be made. Thank you. Next slide.

So if there are changes that are changes to the terms and conditions of the contract, including the statement work, or if a key personnel needs to be changed, or there's going to be a delay in delivery, these need to be done in writing. The contractor should submit their formal requests in writing to the contracting officer the contracting office will review it with the core and those changes will be either made or negotiations will happen further. And please note that, you know, in the attachments or if any changes, look at the contract and make sure that any changes can affect any of the terms and conditions, including the disclosure or foreign affiliation of relationships. So if there is a key personnel change or if there's a subcontractor change, please look at that document because that document needs to be resubmitted and recertified and it will need to go through foreign review disclosure again and approval again.

Next slide.
So key personnel, if there is any change in key personnel that is identified in section G of the contract, please notify the contracting officer in advance. Now we can understand that timing and advance might not always be the case, but as soon as possible. This request should include Who? The proposed person to take on as new key personnel, any qualifications and any timelines and any impact to the contract that might happen because of the change. But please note that any deviations must be done in writing to the contract before any actions are happening.

Next slide.
Invoice submission and payments. The government makes payments through electronic funds transfer. The instructions to do such should be found in your contract. Payments on fixed price contracts may be made based on the satisfaction completion, receipt, acceptance of the contract deliverables found in the contract. Payments on cost reimbursement contracts may be made pursuant to receipt of proper invoice of allowable cost incurred, which may be submitted no more frequently than on a monthly basis unless otherwise negotiated into the contract. For all contracts, a final payment will not be made until all reports and deliverables included in the contract have been delivered and accepted by the government.

Next slide.
So reporting requirements and deliverables found in the contract. Satisfactory performance of the contract will be deemed once we receive all of the reporting requirements that are found in the statement work or in Section C, and they are accepted by the contracting officer and the

core. You'll also find deliverables and article examples of these deliverables are monthly progress reports, final reports, summary of salient results, the NIH Small Business Innovation Research Program Life Cycle Certification, and the final the final statement.

Evaluation of contractor performance, which we call a CPARS. The CPARS is detailed in Article G of the contract and is the evaluation of the contractor performance. These are done annually. So if you have a contract that is that is the period of performance is over a year, you'll have interim evaluations and a final. The evaluation factors are technical and quality product or services, the cost control, schedule and timelines, management and business relationship, and regulatory compliances. All evaluations will be provided to the contractor within the system, and you'll be allowed 30 days to review these documents and submit any responses. The copies of the evaluations are very important because once they are finalized, they'll be retained in our systems and can be used to support future award decisions.

So moving to phase two, once you have the phase one contract and you're getting close to being to the end, we want to think about moving to phase two. So phase one contractors that do not get a fast track contract will be informed of the opportunity to apply to the phase two from the awarding component after or close to the expiration date of phase one contract. The phase one awardees will be provided with the phase two proposal submission requirements with details on due dates for the proposal, the content which needs to be submitted, any submission requirements of the phase two proposal.

Only one phase two award may result from a single phase one SBIR contract. And this differs from a fast track contract wherein the phase one contract will have an option for that phase two. That gives the government the ability to exercise that option into phase two because the proposal, the original proposal has already been for phase two has already been evaluated. But that doesn't mean the government is obligated to fund the phase two option at the end of the phase one, but the option is there for it to move faster into phase two.

Next slide.
And thank you very much. And if you have any questions, please feel free to reach out to me. Thank you very much.

Sorkin, Adam (NIH/OD) [E] 40:43

Great, thanks so much, Kelly. And hopefully everybody is getting a feel for sort of the differences between these two mechanisms. And just as a reminder, I'm seeing a couple of questions come in, but if you do have any questions for our previous speakers, you can use the Q&A function in Teams to submit those and we will get to them after our next speaker. And with that, I will hand things off to you by Janelle.

Soeffing, Jonelle R (OIG/OI) 41:06
Thank you, Adam. Good morning. I am Janelle Sofing, an operations officer within HHS OIG Office of Investigations. During my portion, I will wrap up the key messaging from my fellow panelists, and I will share some helpful information towards protecting your reward by preventing fraud, waste, and abuse. HHS OIG's mission is to fight fraud, waste, and abuse in Medicare, Medicaid, and in more than 100 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 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, 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. 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, 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, cheating, and stealing. 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 purchases and 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 a completely different topic or project and then charge it back to the grant. Ensure that eligibility requirements are 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 500 employees, including 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 in determining whether affiliation exists. HHS OIG has found some awardees that were affiliated with organizations much larger than 500 employees. For example, one awardee company that was itself well under the 500 employee limit was owned by a larger company that had over 7,000 employees which is improper. Another important requirement is that any and all work associated with an SBIR/STTR award must be done in the United States. If SBIR/STTR award work is done outside of the United States, award recipients become ineligible For the SBIRSTTR program. 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 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 is no need to hesitate calling HHS OIG to report suspicious activity. HHS OIG 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 grants officials is also key. There are consequences to fraud that involve criminal prosecutions and civil and administrative actions. Here are some common criminal statutes, such as 18 United States Code 641, embezzlement and theft of public money, 18 United States Code 1001, false statements, And on the civil side, 31 United States Code 3729, false claims. 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. In the first example, two biotechnology companies and their co-founder 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 involves a researcher at the University of Montana who was owner and CEO of an 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 to four years probation and restitution, totaling $165,446.

And lastly, 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 are allegations and are treated with privacy and discretion. A hotline complaint is an allegation. We investigate independently and hotline complaints can provide helpful information to criminal, civil, and administrative investigations. After receiving my overview, the strongest take away to consider is to keep awareness and to keep 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. Thank you, Adam.