

Funded? Top Tips for Effectively Managing Your SBIR/STTR Award Webinar Transcript – November 2022

Adam Sorkin: Great. Well, hello, everybody. And thank you so much for bearing with us while we're dealing with a couple of small technical issues. But I want to welcome you all to our webinar today. I am Adam Sorkin, Small Business Policy Manager for the SEED office, or Small Business Education and Entrepreneurial Development office here at NIH. I will be your moderator for today's program, where the topic is Funded, Top Tips for Effectively Managing Your SBIR and STTR award. Like the title suggests, we're here to discuss how you can effectively manage your SBIR or STTR award once it's issued. So, this includes things like making sure you're using your funds for the purpose that they're actually awarded for, communicating effectively with NIH staff when necessary to avoid common pitfalls, and in general, when communication is appropriate, how to- learning how to watch out for and avoid fraud, waste, and abuse and stay out of trouble.

And one thing I do want to emphasize is that you're going to hear about both grants and contracts today from different NIH staff. Please keep in mind that these are award instruments that are administered differently, and different policies may apply, depending on the kind of award you have. So just try and remain conscious of that, and we will kind of try to highlight that as we speak through different topics today.

And just a bit of housekeeping as we get started. First, please try and enter your questions in the Q&A box on Zoom. Panelists will answer them during the Q&A period after each one of them has had a chance to talk. We will not address questions regarding specific awards or applications, but please reach out to your program officer to discuss any issues you might have specific to those issues. And if we don't address your questions today, or you'd like to discuss your project or just get further information about our programs, please feel free to reach out to us at seedinfo@nih.gov. So today, we'll be hearing from Dr. Roger Miller, Small Business Program Manager from the National Institute on Deafness and Other Communications Disorders, Artisha Wright, other transaction authority lead at the Eunice Kennedy Shriver

National Institute on Child Health and Human Development, Christine Biser, Contracting Officer at the National Cancer Institute, and Jonelle Soeffing, Operations Officer at the HHS Office of the Inspector General. And with that, I will hand things off to our first speaker, Artisha Wright. So, thanks so much Artisha, and it's all yours. Artisha?

Artisha Wright: Yes, I'm here.

Adam Sorkin: Okay. Please go ahead.

Artisha Wright: Okay, sorry. Good afternoon. Being a recipient of an NIH small business grant is very exciting, but if this is your first grant, you may have questions or concerns regarding what happens next. So, over the next few moments, I like to discuss how communication with grants management is necessary for successful award management. So, before you begin any work, I recommend that you read the Notice of Award. The Notice of Award, or NoA, is the official legal document that notifies the grantee and others that an award has been made. It is issued for the initial award period and sent via email to the address entered by the organization during the registration process in eRA Commons. The Notice of Award contains the budget and project period start and end dates, the name of the organization, the name and address of the signing official, the project title, the funding commitment amounts and all applicable terms and conditions, and the contact information for the assigned Grants Management Specialist and Program Officer.

NoA has two sections where the terms of award are described. And in section three, you will find a list of the standard terms such as the grant program legislation in the program regulation, the Code of Federal Regulations and regulatory requirements as applicable, the federal award performance goals, the lifecycle certification requirements, the NIH grants policy statement in effect at the beginning of the budget period, and any applicable references to carryover authority and SNAP, which is the Streamlined Non-competing Award Process, and close-out requirements if applicable.

In section four, you will find the special terms and conditions specific to the grant, such as the Welcome Wagon letter for first time NIH grantees, the subject FOA, or Funding Opportunity Announcement, the funding plan relevant to the fiscal year the award is made in, prior approval

request, intellectual property audit, final progress report requirements, funding reductions and or adjustments, other salary support issues, the salary cap in human and animal subject restrictions. It is imperative that you carefully review and understand the terms to avoid non-compliance or violation of NIH policy and procedure which could result in adverse grant reactions such as special terms and conditions, monitoring of fund withdrawal or grant termination. Please note that the minute you request and draw funds from the payment management system, you accept the Small Business Award and all applicable terms and conditions associated with it.

So, after receipt of the Notice of Award, you are now in the post-award stage of the grant, and may find that things aren't necessarily going as planned. So, for example, you may have a question regarding the establishment and management of your grant funds and how they will be accessed. The payment management system is utilized by the NIH award recipients to access their funds and is administered by the Program Support Center within the Division of Payment Management. The PMS system is a platform that is not maintained or monitored by your Grants Management Program. However, your specialist will be able to provide you with the phone number and website for customer service assistance and guidance.

So, let's say five months into the grant, everything is going well with your research, and you begin meeting some of the aims and everything, but suddenly a vital piece of equipment breaks. You begin doing some cost comparisons and see the replacement item, which is more advanced and up-to-date costs \$28,000, which is more than the original purchase. And at the same time, your co-PI announces their departure, and a replacement will need to be identified. So, is there anyone that's suitable to fulfill this position? Or is it more feasible for you to adjust your effort to satisfy the change of key personnel request? You're not sure if these actions require prior approval, or if it's okay for you to just go ahead and deal with it. And with everything being so time sensitive, will it hurt if you just move forward with purchasing new equipment and appointing a new PI who may or may not be as skilled as the one that's departing? Before you do anything, please, please, please communicate with your Grants Management Specialist and Program Officer as these are post-award changes to the grant that

do require prior approval from NIH. Please note, if you move forward without receiving prior approval, you are in violation of NIH policy and could face a restricted or a terminated award.

But what if your company has experienced a merger or acquisition and the number of employees increases from 450 to 600 as a result? You want to know does this size change impact your award ability? And to complicate matters worse, another PI decides to move their lab and research to France which could potentially result in a new foreign performance site, and funds may need to be reallocated to support this new site. Is it okay to add this site and conduct the research in another country? Or should you discuss this with grants management and program beforehand? These two examples impact your eligibility, and failure to consult with NIH prior to moving forward could result in special enforcement action or termination. So, when in doubt, always reach out. As the PI, your focus is on accomplishing scientific aims and producing successful research, while program is focused on the scientific management of your award. And my focus as the grants management specialist is on the day-to-day administration and compliance of your grant.

Communication among all three parties is so vital when faced with situations like the ones mentioned above, because we all work together, and we want to ensure that the proper procedures are followed. Later on, you'll hear from program regarding communication, but right now you're going to hear from my colleague, Christine Biser, as it relates to managing your small business contract. Thank you.

Adam Sorkin: Thanks so much, and actually, quick correction, we are going to first proceed with Dr. Roger Miller's comments from the program officer's perspective.

Roger Miller: Thank you, Adam. Thank you, Artisha.

Adam Sorkin: And we'll get his slides queued up just... All right.

Roger Miller: Okay, thank you. [CROSSTALK] So my name is Roger Miller. And I want to share with you some of the common pitfalls that come to the fore when a PI is managing a grant award in general and the SBIR/STTR SEED funding in particular. And the point I want to make is much in keeping with what Artisha just said, is that it's important to communicate at certain points along the project to ensure the overall success. These SBIR/STTR, and SEED funding in

general, these awards are quite short. So, we hope that you as the PI will lay out the foundations of what you billed within and stay within that scope. And it's the program officer's job to make sure that the work as it progresses remains within the scope, and that takes a scientific understanding of what you're doing to really know whether or not this is a big change or a small change. And program staff always work in close concert with grants management staff as you'll see as we go along.

So, my advice to you is to understand the program before you start, so you build- you lay the foundations of a successful project, these are short, Phase I is really focused on getting the pilot data you need for Phase II. So, keep focused on that, work within your scope, because you don't have a lot of money, and you don't have a lot of time. The idea here is to get the preliminary data so that you can put in a full Phase II application, which builds on the best parts of the preliminary data that you got in Phase I. And you have that maneuverability between Phase I, which you laid out, you did the work, you got an increased understanding, and now you can tune your Phase II application based on that without any need to involve program staff, because you're going back to the peer review system. And that's the way we like to do it. We like to give you the funds, you work within the scope of your application, and then you can retool, change directions, go back to the peer review with the full benefit of that input after they reviewed what you're looking to do.

Phase II is really where the bulk of the work is done, you have a lot more money, you have two years. And we hope at the end of that, that you're keeping track of the end goal, which is that you should have something to sell at the end of Phase II, perhaps it's an IP licensing strategy, perhaps you'll sell the product yourself. And this is where scope becomes very important. If you've set out your specific games, well, you'll have the latitude to work within that foundation to build the structure that you can sell. And don't step outside of the requirements of this program and end up in commercialization that's outside of scope for the NIH's SBIR/STTR funding. Grants management and program staff will helpfully go through your application before the award and remove those costs, that counts against if you submitted it and under that cap and your actual award amount will go down, but that'll keep you within the legal requirements of the program.

So, there are so many different technologies that people might be working with in the SBIR/STTR across NIH mission, I wanted to start with just a simple example. Let's say you as the PI have great experience sailing the open seas and want to take that skill and move it forward into bringing your product to market, sailing up the canals. This is a task-based approach. I don't recommend it, but it builds on your past experience. You submit your application, you get funded, and your award starts out quite well. You look around to see that other people are also moving forward in this area. The currents are carrying you in the right direction, the winds are moving, some people have all their sales up, some people no sales, there's a variety of different approaches, all goes well at the start of the program, at the start of your project.

So many times, however, so many times, new problems emerge unexpectedly. Here, we see the navigation obstacle has come into place, the wind is no longer moving the boat in the direction, or the project is not going in the direction that you'd like to go. So, you're not getting the traction that you'd hoped with your technology. Currents are going against you. This is a good time to throw out an anchor, stop spending money and just communicate with your program officer. So many times, projects can be helped by asking or letting us know that you're going to need a no-cost extension, a little extra time, and that's something we can consider to save your project, save your crew and allow you to figure out how to move forward. Maybe the bridge was up out of the way, maybe the currents change. And many times, I've seen PIs use a no-cost extension to their great advantage to save their project.

Perfect storms do emerge however, sometimes things just don't go your way, problems occur, and you need to figure out how you're going to move forward. If you have good specific aims, you can still work within those aims. Hopefully, you budgeted for a couple of failures and even told the reviewers that, you know, one of the problems might be that you'll need to replace your mast, there'll be clearance problems. And you've already got that included within your budget. Don't, at this point, come back to NIH and hope that you can change your scope and say, "You know, this really isn't working out, so we're going to reduce what we deliver, innovation, we're still going to stick with the original technology, but we're not going to go very far inland." That's not what you promised in the application. That's what we would call a

change in scope. And we want to work with you as program staff so that you have the room to innovate and actually accomplish our mission areas.

Here's an approach where somebody has maybe gone through a couple of Phase II SBIR/STTR awards, and they've innovated in different areas of the project, perhaps they had a separate application looking at defective currents and came up with hydrofoil technology, perhaps they came up with a different propulsion system, or a low-profile vessel so they can move forward. The best approach is to make it very clear what you're going to try and innovate so that if you need to come back for a new award, it's not overlapping with your previous award, and you can ultimately come up with something new, potentially disruptive. And that's the best thing about the SBIR/STTR program. If you use them effectively, you can come up with very disruptive technologies which help NIH with its mission areas.

So that's kind of a contrived example, let's get a little bit closer to the actual science, and look at aims well-constructed from this sample application. You can see here there's a link to the NIAID website. Here's the name of the PI. We have a number of different grant applications and summary statements on the NIH website, so you can look at these different funded projects and see what worked well. Here, the scope was well-mapped out by what I've shown here in bold, there's a mouse animal model that's laid out, if you wanted to change this model to a different animal, that would be a change in scope. The compounds are laid out and aim one is to perform for analogs of that compound, if it's a very different compound, that will be a change of scope.

In two and three, layout exactly what the essays will be. If you wanted to say an aim three, you wanted to change the time points, not just two ages, you want to do three or four ages, that'd be a conversation to have with your program officer to see whether or not that still is so similar that it's considered within scope or without scope. Every project is different. This is a conversation you need to have with project officers- program officers. However, you need to understand how NIH takes your information in and shares it back with the public because as a government agency, we do that on a consistent basis. You need to understand that when your application is funded, the abstract from your application comes right out and it's published in our reporter.nih.gov website. You can use this as a valuable resource to see how to structure

your reporting, what other people are working on, and find where your project fits in the marketplace.

It's important to understand that as you make publications, you need to report those to NIH, you need to acknowledge funding in your publications, and share them so that the public can go in and look without cost at those publications. That's one of our terms and conditions of award. If you have any patents- this particular project didn't have any patents- but if you have them, you need to cite them and go through the iEdison reporting process so that your company can use that and also show compliance with our reporting requirements. When your project is finally finished, you'll need to report your outcomes in your final progress report, and it's important to understand that everything that you've written there in the final progress report just punches straight through and comes in the outcomes. Now, however, you understand that there's this very valuable resource here of example applications and descriptions of other projects available to you as a PI, and when you want to structure your project, you can look back to see who your potential competitors and collaborators are.

Okay. All this meets- the rubber really meets the road, as Artisha said, with the Notice of Award. It's legally binding, it lays out the duration of the award, it lays up the dollars and it lays out a lot of the scope, although it doesn't show the specific aims. You need to download that from the eRA Commons and realize that eRA Commons now is going to become an essential place for you to go to manage your award. It lays out inside the Notice of Award who the grantee is, the principal investigator, and key personnel. If you want to change any of these three things, maybe the PI wants to take the award to a new grantee that's also a small business, or the grantee, the small business, wants to hire in a new PI. All those are official requests. After you have an award, I think it's important to go ahead and establish an email address that has a dot com and it's related to the business. Then go into eRA and update your home email address so the NIH knows how to email you to get in contact with you with regards to this particular award.

The Notice of Award will tell you who the program officer and the grants management specialist is, that can change over the duration of the award, but when you want to make an official request, changing one of these things or the other items that Artisha described, you will

need to send an email, include both the program officer and the grants management personnel on that email, include the grant numbers so we know exactly what you're talking about, write it to your business official, so it's an official request, and then get the approval. That approval will go into the official grant file, and it's there for years later, if anybody wants to know whether or not you really had approval to make that change.

The funding levels established in the Notice of Grant Award, understand that this is a grant in aid, it's not going to cover every single cost. It's completely appropriate for you to find other sources of funding, perhaps in my previous example to pay for that broken equipment, the new mast, and understand that that's something that the PI has to navigate and with careful management of the award budget. Understand that extensions can be granted, and they can be used to good effect. So, if you need that, and during the COVID-19 pandemic, many people needed to make use of that flexibility, by all means, ask it. Understand that animal studies, if you requested them and got them approved, that'll be noted, those approvals will be noted in the Notice of Award. But if you change animal models, that's something that's a change in scope, you need to get that approval, try not to do it. These are short awards. Human studies, if you didn't request them, you can't use grant funds to do them. That's something that you'd want to do outside the award, and vice versa. So, the scope is made clear, and especially clear for human studies.

Don't get caught up by changing the scope as your project is moving forward. On the face page of your progress report, which you'll need to file with NIH every year to get continued funding, you're going to say, again, but I'm not sure you had human subjects involved in vertebrate animals, and especially here, inventions, patents, if you have them, report them, it's critically important to you down the road when you go to commercialize. When you're asked what are the goals of the project, if you have good specific aims, I mean, they're in the application, just cut and paste and leave them there. And in the next section, when they ask you have you changed them, the answer we typically want to see here is no. You should have laid out at scope, so you're working with those aims so you can work within it.

When you go to talk about what's accomplished under the goals, it's a good idea to keep this about two pages, talk with your particular program officer to make sure you understand what

their impression of your project is. Include graphs to show your progress, and it's nice to have a photograph of your prototype to show how you've made progress and how you've spent those funds. Typically, when you talk about what you're going to do in the next reporting period, if you have good aims, you can just say that you're going to focus on and to prepare data for an FDA submission. Understand that you're going to have to report about your publications to NIH, this isn't so much of an issue with SBIRs sometime, or STTR awardees, but if you do have publications, understand that your next year funding, you're going to have to have fulfilled your public access compliance requirements to get that second year of funding.

And that wraps it up for me. NIH staff wants you to be successful, program staff especially want to see you move the project forward without getting hung up in any of these [INAUDIBLE]. It's critically important that you create aim- include aims that go through peer reviewing your project that allow you to do all your work without changing the scope of those things. Thank you, Adam.

Adam Sorkin: Great, thanks so much, Roger. Great comments. And with that, we will hand things off to Christine.

Christine Biser: Hello. I wanted to speak to everybody about contracts. A contract is what you will receive typically after several weeks of negotiations, and you will receive this document that's maybe 30 to 80 pages long. So, it can be a little bit daunting if you've never seen a contract before. So, I wanted to just sort of introduce the contract format to my audience and go over some of the sections. Next slide. Oh, I get to do it myself. Oh, there we go. Okay. So, this is a picture of the face page of a contract. It is referred to often as an SF 26, and there are a number of items on it that are extremely important. It will tell you your contract number in box number two here, right under that word "award/contract." It will also state the effective date, and I'll get into a little bit later why that's important. And you will also see at the bottom, where the signature is on the right side, who your contracting officer is. And that is an important thing to take note of because you want to include that person in any communications regarding your award as things progress and if things change especially.

So, Section B is there's a title named Suppliers and Services. And for SBIRs, it's as often services. So, there will be a description and maybe three, four sentences about what you as a contractor are going to accomplish for the government. And directly underneath that section is an item called Prices and Costs, and you will see very important information about the pricing and the costs of your particular contract. So, I wanted to point out that there are two types of contracts. The first one is called a firm fixed price contract. Those are very often used for Phase I SBIR contracts. And in those contracts, there is a negotiated schedule by deliverable. So, there's a kickoff presentation, quarterly progress reports, a draft final report, a final report, there might be a few other deliverables, and those are tied to a specific amount of money. So, when you submit that deliverable, and it's accepted by the government, you submit your invoice, and that amount of money is paid for your invoice.

Cost reimbursement contracts are used oftentimes in Phase II. NCI has been phasing them out for Phase II, we use firm fixed price contracts for Phase II as well, but they are still used. And in this payment is your work on objectives and the statement of work are paid on a usually monthly basis. So, you will have costs like direct labor, fringe benefits, other direct costs, overhead GNA fee, the rates have all been negotiated, but the amounts are not necessarily known upfront. And I wanted to point out that with cost reimbursement contracts, it's very important to stick to allowable and allocable cost categories. So, let's say the contract did not allow for travel. Well, if you go on travel and you submit travel expenses, that would not be considered an allowable cost and it will not get paid. If there's a particular reason why that travel was necessary, that can be discussed, but it's not to be assumed.

Underneath the prices article is one called advanced understandings, and that is where all of those assumptions are going to be made. So, there will be certain text about SBIR certifications that you have to remain eligible for the SBIR program throughout the period of performance on a contract. Any kind of subcontracts that you've proposed will be included in this section. Travel, as I said, indirect cost rates, anything else that- equipment, for instance, might be included in there. So, if you go under contract administration and you expect to incur a cost and it's not covered by your contract, you would need to contact the CO and make arrangements to have that included.

The next section includes the statement of work, and Dr. Miller did a terrific job on discussing the statement of work. A lot of the aims and goals are similar for contracts as they are in grants. This statement of work is typically included as an attachment. Sometimes it is included in the contract itself and it's just included in text, but oftentimes it's an attachment. The statement of work is going to list all of the technical contract, the endpoints that the company has negotiated with the government to deliver. So, everything that you as a business owner needs to do will be included in that statement of work. There is typically also milestones schedules, when you're going to have these things done, so, you know, month one, month two, month three, through the end. It is important sometimes to keep those up to date. If you're falling behind for whatever reason, you need to notify the government that that's happening.

Underneath that section, the statement of work, is reporting requirements, which will list those technical reports that you need to submit to notify the government where you're out with your project. As I stated before, there's often a kickoff presentation, there are quarterly reports, with Phase II, there are sometimes monthly reports, there's draft final reports, there might be commercialization plans, there might be any number of things. You will find those described in Section C. So, if you win the award, and you're not quite sure what to put into your quarterly report, you would consult Section C of your contract.

Due Dates for those deliverables will be found in another section, those are in Section F, which I'll get to. The entire contract is going to be peppered with references to the Federal Acquisition Regulation. We call that the FAR. You will see I've given the URL for the FAR here, you can look up those regulations, they do change over time, they sometimes change. Some of the FAR is referred to- the FAR is also included in the US Code of Federal Regulations. And I have the URL for that, too. So, it may be referred to differently by different organizations. And the Cornell University had put together a very nice website for looking up USC regulations, and that is below here.

In Section D, the Section D is generally very short, it tells you how to mark your deliverables or your correspondence regarding your contract. So, it is very common to be asked to include your contract number and your contractor name on all of your communications. We have hundreds and thousands of contracts, and so when you send in your contract, we have to know that

we're matching it up with the correct contract. And as many previous contractors may know, you may have several contracts. And so, it's very important to specify which one you're referring to.

In Section E is an item on how your deliverables will be accepted, inspected, and accepted. So, the COR will often do that. The COR is the Contracting Officers Representative. That is, they're also referred to as the project officer. So, they will review your deliverable and they will say whether they accept them or not. Sometimes in this section, it will tell the business owner whether they can assume that the government has accepted their deliverable. So, for instance, we often say if you have not heard an objection from us within 30 days, you can assume that your deliverable has been accepted. That means that you can now submit your invoice if you haven't done so already.

Section F is as promised, the part where we have the deadlines for the deliverables. So, the first section is described as a period of performance that states your contract starting date and your expiration date. The starting date is important because that is the first day on which you can incur expenses that can be reimbursed by your contract. So, you may not hire someone, for instance, for your contract and have them start, if they start before your period of performance, your contract will not pay for them. You may have to pay for them out of pocket, but the government will not see that as acceptable. You will also see the expiration date, that is the date by which you have to have all deliverables submitted. They don't have to be accepted yet, but they do have to be submitted. After that, you also may not incur expenses related to that contract, the funding will not cover it. Section F2s has all of the lists of deliverables, and it states when they're due and whom you send them to and what the address is. So sometimes they are email addresses, sometimes they are websites, sometimes it's a physical address, that varies.

In Section G, you have contract administration data. You will have- the first item in here will name your contracting officer's representative. That is this COR that I had mentioned. There will also be- if your proposal included key personnel, those persons will be listed under this section. And it will also include language that tells you what is specific, what the government specifically requires of a key personnel. So, one of the things is that if your key personnel gives notice and

has determined not to continue working on your project, there is a 30- the government wants 30 days' notice. And we would like to see who the next proposed person is and accept that person. So, there are specific requirements for key personnel that you might propose. There are instructions on what to include in your invoices, where to send them to, when they're due, what you may put in the invoices, so what the naming convention is, they're often submitted as an email attachment, so what you name that file and where you send it to. And it will also give information on how your contract performance will be evaluated by the government. That will be in there.

For Section H, this is a long section, this has quite a bit of boilerplate language. And it will cover specific items to your contract, such as human subjects, vertebrate animals, publications, there are many, many things that can be in here. So, for instance, an example of in terms of human subjects, let's say you were to prove to have, you know, there hasn't been an approval of your use of human subjects, let's say you're waiting to have an FWA number assigned to you, or you are anticipating approval of your IRB review. Language like that would be located in this item here. It is a long section, and this would be- you need to read all of your contract, but this is a good one to read.

Then there is a long section called Section I, it has contract clauses. Here you'll see those URLs, again, for the Federal Acquisition Regulation, and the US Code of Federal Regulations. There is also HHS as an agency has its own additional regulations that apply on top of the Federal Acquisition Regulation. Other agencies have their own versions, and you will find all of those clauses listed in this section. They're divided into four subgroups. So, there are some- many of the regulations are grouped by a type of contract or a particular use. So, section I will typically for Phase I, it will typically include a whole list of clauses that are specific for firm fixed price contracts, there is a separate set for the cost reimbursement clauses. So, you will find those listed. It's only going to include the number, the date that it was revised and the title. You would be expected to go to the FAR website and look it up.

The second section is if there are substitutions for certain clauses, sometimes there's an alternate that will apply depending on a particular prescription in the Federal Acquisition Regulation. So those exceptions will be included in section I-2. You will see, you know, this

section, blah, blah, blah, the FAR regulation is deleted in its entirety, and the following is substituted for it, and you will see that, so that would help you figure out what part of the Federal Acquisition Regulation applies to you. Item I-3 is additional clauses that sometimes are, if something falls through the cracks with these two, I sections above, they would be included here. Those are also listed only by number and by the date that it was revised and the title. And then there are certain clauses that the government determines has to be included in full text and those will be included in this last section.

And Section J will include the list of attachments that come with your contract. So, the first one is typically the Statement of Work, and there may be contract invoicing instructions. NIH currently has several, we're transitioning our invoicing. And so, there are instructions for the old system, and we're using a new system. And there are the instructions for the new system, and there are lists on what to include in it, and there are also instructions on how to email it and submit it properly to the correct website. There are- oftentimes the government has forms. This applies if your contract includes a government property, there's a form for reporting property, there will be templates for deliverables. NCI has a deliverable called the Contract Outcomes Report. So that would be attached. There are the SBIR certification forms come attached. So, there are whatever we need to attach to give you as part of the contract. And those attachments are incorporated into the contract, they count as the contract.

The final section is Section K, and oftentimes, you'll find the SAM.gov representations and certifications in there. There is a clause in the contract that states whether NIH can use the SAM.gov record as applicable to this particular contract. If you had SAM.gov reps and certs that were different than on your SAM record, you would attach those here in Section K. And you will also see various clearance data. I had mentioned the human subject. So, you may see the FWA number there specified and which IRB approval applies, you might also see the assurance numbers for vertebrate animals, and whatever else we need to attach to the contract.

And finally, I wanted to say when a contract goes for a year or two years, things change, as Dr. Miller mentioned. And so, this first graphic is the contract itself, which I covered in the first slide. And this second larger graphic is what we use to modify the contract. You will again see the contract number, you'll see an effective date, you will see the modification number, the

sequence number, you'll see the authority by which we are modifying the contract. And then it will stay in this box here on the bottom, that's about a third of the way down, you will see a text description of what is being modified in the contract. So sometimes, for instance, those FAR clauses change, and we determine that we have to update the contract. Normally, the contract is awarded, and those clauses go with that contract till the expiration date, even if they are updated by the FAR Council.

However, sometimes we determine that we have to update that FAR clause. And then we will do that with the modification just as you see here. And we will explain what we're changing and why and where it is located in that, all those sections that I just went over in the contract. I would definitely like to recommend that you read through your contract. And if there are any questions to always, always ask your CO and include your COR, ask your COR, but always CC your Contracting Officer. Sometimes you will have a contract specialist assigned to you, and that person will see to it that the CO is notified of any changes, but you might have a Contracting Officer, a Contract Specialist and the Contracting Officer's Representative. And that concludes my tour through a contract. Thank you very much.

Adam Sorkin: Wonderful. Thank you so much, Christine. And with that, I will hand things off to our final speaker Jonelle Soeffing.

Jonelle Soeffing: Thank you, Adam. Afternoon. In my portion, I will wrap up the key messaging from my fellow panelists and I will share helpful information towards protecting your award by avoiding fraud, waste and abuse. OIG's mission is to fight fraud, waste and abuse in Medicare, Medicaid, and in more than 100 other HHS programs. Grant contract fraud investigations typically involve conflicts of interest of government funds or embezzlement and failing to properly support the use of your funds. We want to encourage the 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 a property or money by deception or other unfair means. That is intentionally submitting false information to the government, which includes situations in which you should have known the information was false to get money or a benefit. Waste involves practices that directly or indirectly result in unnecessary costs, such as overusing services and misusing resources.

Abuse is the intentional or unintentional thoughtless or careless expenditure, consumption, mismanagement of government resources, or the excessive or improper use of government resources including your position or 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, administrative, or civil or criminal action. On the next few slides, I will cover fraud schemes and indicators. Please remember that fraud schemes essentially boil down to lying, stealing, and cheating.

Here is an overview of certain fraud schemes that could lead to fraud investigations, applying false information on your application, proposal, or document, creating fake records, accepting, or offering kickbacks, using funding for unauthorized purposes such as personal expenses and personal travel, not doing any work but billing as though you did the work, after an embezzlement, bribery and the list goes on. Remember lies by act or omission both count. Do not use your grant money on one research topic 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. Most common eligibility requirements that awardees appear not to meet is a requirement that PIs 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. Even though the definition of affiliates may leave room for interpretation, it allows for factors like ownership management and contractual relationships in determining whether affiliation exists. We found that some awardees are 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.

Without understanding what fraud, waste or abuse looks like, you may inadvertently overlook fraud indicators, essentially taking award opportunities away from legitimate individuals and by stealing from all of us. Use common sense, use your awards appropriately. Don't be afraid to ask questions of NIH, if you have questions on whether a particular expense is allowable, there is no need to hesitate in calling the OIG to report suspicious activity. OI investigates thoroughly and covertly. If you see an issue, you say something, your reporting of a possible problem is

justified, and you've helped to protect the programs. There are consequences to fraud that involve criminal and civil prosecutions and administrative actions. Here are some common criminal statutes, 18 USC 641, which is embezzlement and theft of public money, 18 United States Code 1001 false statements, and Civil Code is 31 USC, there are so many different statutes that could apply to fraud or wrongdoing. We want to make sure that all awardees stay away from this realm and also administrative actions that involve Civil Monetary Penalties, exclusions from HHS programs and government wide suspension and debarment.

Fraud consequences that I just mentioned [INAUDIBLE] are made public and here are two case examples. The top civil settlement to resolve allegations, false statements to obtain grant funds, SBIR awardee made false certifications and false claims, not accurately report disbursement, use their grant funds for personal expenditures, made drawdowns after performance period of grant and failed to maintain a financial management system as required by NIH. The agreement and exclusion at the lower section of this slide, the SBIR awardee sent SBIR funds to an overseas affiliate without NIH approval in violation of NIH SBIR requirements, made draw-downs based upon quotes and other potential costs that were never incurred, commingled among various affiliates and used for unallowable costs unrelated to the NIH award, and also made draw-downs that were not supported by adequate documentation to ensure that the funds were used for allowable costs in accordance with the terms and conditions of the awards.

Finally, I want to emphasize the importance of reporting any suspicious behavior or activity. If you see or learn of anything that seems wrong, please say it, or do something. Please report complaint information through the HHS website, or by calling 1800 HHS tips. Hotline complaints are allegations and are treated with privacy and discretion. Hotline complaints provide helpful information to criminal, civil and administrative investigations. After receiving my overview, the strongest takeaway to consider is to keep awareness and to keep communication lines open by reporting any complaints, referrals, inquiries, and by asking questions. By doing so, you're doing your part to protect HHS programs and us all. And I will now hand control back over to Adam.

Thank you.

Question and Answer Session

Adam Sorkin: Great, thanks so much, Jonelle. And now we will be happy to take questions for any of the panelists you've seen here so far. And we've got a lot of questions teed up in the Q&A section already. So, anything that we don't get to you today, we'll be happy to answer offline. So please feel free to reach out to us. We have seen a number of questions about whether or not slides will be available, and the answer is yes, slides and the recording should be available in about seven days or so. And you should be notified once those are available. We've got a number of questions already answered, but I'm going to ask our panelists to revisit just a couple of these, because I think they can be helpful for you all. Let's see. I've got one question that Artisha covered, about the Welcome Wagon, noting that the Welcome Wagon is quite a bit of information overload with numerous links to sites, what's the most important information to pay attention to?

Artisha Wright: Hi. I would say you definitely want to pay attention to everything because all of the information while it is overwhelming, is very applicable, and it guides you with setting up accounts and everything, and if you're not sure about something, please don't hesitate to reach out to your grants management specialist. And we're happy to help you work and navigate through that whole process. But if you're an SPC, and you as the PI are the sole, you know, like the AOR, definitely reach out to us if you have somebody who has gone through the experience, and has, you know, set up the process, that is your first line of defense as the AOR. But like I said, you can always reach out to us, and we will be happy to help you with that. But never overlook anything.

Adam Sorkin: Great, thanks so much. And let's see, I do see another comment. Are these grants mainly focused toward academia or small business? It sounds pretty scary just trying to apply for one of these if you're a small business person. And, you know, as Artisha does note, you know, today's focuses on small business. So, these applications are always made to a small business, or these awards are always made to a small business, whether or not it's an SBIR and STTR grant or an SBIR contract. So, we do have a number of resources available to help you get your arms around this process at seed.nih.gov. We encourage you to review those resources

and those do include application assistance program, in the cases that can help you approach this program and help you figure out how to engage with us and move forward. Let's see. We do have questions regarding contracts. How long does it take for an agency to pay an invoice for an SBIR contract? We have been asked to use IPP. Christine-

Christine Biser: I'll take that one. The process generally takes about two weeks for us to approve it, it may take another week or so to receive the payment. So, there's a number of steps, you submit your deliverable and the invoice, the COR takes a little bit of time to review those, a couple of days usually, to review those and accept them, then a CO will go in and approve the associated payment, that goes to through NIH. And the NIH sends that direction to the Treasury, and you will receive your payment from the Treasury. And that is direct deposited into your checking account. And if you need to change that, that would be done through SAM.gov. So typically, two weeks, sometimes when you're first getting a contract, you have to sort of send a practice invoice. And typically, what I do is I have the first invoice, I'll review it and have them make changes. If changes are needed, they resubmit, and then we know how to submit them. And that's often the process.

Adam Sorkin: Great, thanks so much, Christine. Very helpful. Let's see. We've got another question, perhaps for Artisha, does a change in TABA or technical assistance vendors require prior approval by NIH?

Christine Biser: I'll take that. I'm not aware of it. I am not aware that you need prior approval, I believe that the CO, during negotiations, would approve the involvement, that would be done through the proposal. So, I would certainly mention it, if I was a contractor, I would mention it to the CO that you're planning to use this certain vendor, and then the government would take care of evaluating that.

Adam Sorkin: Great, thanks so much. Artisha, is that consistent with how you approach grants? Or is that-?

Artisha Wright: So, to be quite honest, I've never had that situation, and I was going to actually kind of defer it to Roger to see if you've had anything like that happen.

Roger Miller: Yeah, since it went through a peer reviewed with a particular person providing those services, I'd want to make sure that the new group or person had the same skillset. So, I wouldn't really be too happy to see that change, although sometimes it's necessary. And when it's necessary, we'll certainly consider it. But I'd certainly want it to go. If I was the awardee, I would want to have that official approval in the grant file report, because those funds would have been spent.

Adam Sorkin: Great. Thanks very much all three of you. Okay, so we have a question, perhaps for- we can start with Roger, but Artisha and Christine may have some feedback as well. A collaborator has reduced their commitment. Is it okay to seek out an alternative? How do I communicate that and get approval?

Roger Miller: And I think for the last round, we just saw that it really depends on the project, and that's why I advise awardees to send in the request. If it's a grant, send it to both the program staff and grants management staff. If it's a contract, Christine will advise this, but I think it goes to the contracting officer, get that into the official file. And it would really depend if that person was a key personnel, right? And PIs will send in an application, and they'll fill out paperwork on different people that they call key personnel, but they're not necessarily listed on the award as key personnel. So that's where you would go back to the Notice of Award. If this person's name was in the Notice of Award, you definitely want to have an official request to make the changes. If it was a smaller, lower level position. It's nice to go ahead and have that official request made to NIH staff so they're aware of it when it happens, and we're not surprised when we see the progress report and come back to you to ask what happened and then have to figure out whether or not this was really within scope or not. So, my advice would be to send in the official request.

Christine Biser: I would corroborate that. It may require a contract modification. I had just gone over the contract modifications. So, you would see in the advance understandings and the final proposal revision how much that collaborator is going to be doing in terms of schedule and price. So, who's going to be doing what? And if that changes to a great degree, definitely get your contracting officer involved before or after award. That is true even during negotiations. Let the CO know that things have changed and rebalance your budget.

Adam Sorkin: Great, thanks so much. Let's see. You know, here's an interesting question about disclosing patents. And since Roger, I believe you brought this up during your discussion, I'll ask you first, do patent applications that were submitted before the project start date but were updated during the duration of the project, are those required to be disclosed as well? Is there an NIH legal contact that is available for other IP questions?

Roger Miller: So, we do have some resources to you to ask questions about business development here at NIH, but I think that's an area where a particular company is probably better served getting their own legal advice about the strategy they want to pursue and then documenting the reasons for that carefully within the company in case questions come up a couple of years later. It really would depend on the significance of the change in the patent, I wouldn't think that there would be any harm in attributing the additional value that came out of the SEED award along with the patent application that links the patent with your award. And this all speaks to your proudness and past successes as a PI. NIH does not dilute your value of the company by taking proceeds from the SEED award. So having that link with your patent in iEdison, I don't see how that would hurt you, but that's, again, is where you'd want to get your own legal advice.

Adam Sorkin: Great, thanks very much, very helpful, and I think very astute advice. Let's see. A question Artisha may be able to have some insight on. It's a question about it looks like a budget planning, actually. Do we allocate indirects and profits monthly as a percentage of direct expenses paid, or is there another method?

Christine Biser: So, for contracts, so the indirect rates are going to vary with each vendor's business, they are very much a reflection of the number of projects you have and how expensive those projects are. So, we're not in a position to tell a vendor how to allocate indirect costs because it varies so much. There is a notice that applies to contracts and grants, I think actually also, where below a 40% indirect cost rate, we will not ask you to- ask the contractor to submit a package to the division of financial advisory services to negotiate a formal indirect cost rate agreement. However, the indirect cost rates still have to reflect the vendor's actual expenses. And those do vary over time from year to year or sometimes maybe even less. And as your company grows, they will change quite a bit. So DFAS, the Division of Financial Advisory

Services has a very good worksheet, it has some instructions that come with it. A link can be found, if someone really wants to find it, it's on- if you Google NIH division of advisory financial services, you're sure to come up with it. And it will allow you to calculate based on the company's own income statement, what they should be charging for indirect cost rates. So, I would- and we ask to have those when we get a contract proposal, if they haven't been submitted, we ask the vendor to submit that and fill it out and we discuss it. I have had many memorable, long, interesting conversations about indirect cost rates with vendors.

[CROSSTALK].

Adam Sorkin: Please, Artisha, would you like to add?

Artisha Wright: No. And for grants, like pretty much similar, we use your rate that's in effect at the time of the award. So, for Phase I, you would not negotiate a rate, you can request up to 40% if your organization does not have a negotiated rate. During Phase II, that is when you would submit your package to DFAS to be negotiated, but also, whatever you request, if it's up to that 40%, that's what covers that budget period. So, you wouldn't have anything that you're reporting to profit wise on a monthly basis, we would just give you that one lump sum that you will be able to expend in that budget period for your indirect cost calculation.

Adam Sorkin: Great, thank you so much. Let's see. I will actually take a step back. And Artisha, we'll ask you first. Well, the question is, what are all the reasons why funds might be withdrawn? But speaking generally, in what situations might NIH withdraw grant funds?

Artisha Wright: So, are you saying withdraw the award?

Adam Sorkin: Yeah, essentially.

Artisha Wright: Or terminate the award?

Adam Sorkin: Terminate the award or take back funds.

Artisha Wright: So, if you just, let's say, we issued you the award, and it just comes that you're not going to be able to complete the project, you're returning it, you know, you want to terminate, a self-termination, then that's when we will take the funds back. If for any reason,

like it was just an egregious offence, and we had to terminate the award for non-compliance, that's an instance where we will take the funds back.

Adam Sorkin: Great, thank you so much. Let's see. We've got a lot of great questions. Let's see. Questions. Okay, here's another question about reallocation of funds. Can we reallocate funds to a different category without prior approval if it is below 25% of the total approved budget for a budget period?

Artisha Wright: Yes. So, if you're budgeting less than 25%, you can do that on your own accord. If it's greater than 25% budgeting, then you would have to seek prior approval from your grants management and program officer. And that is actually outlined in our NIH grants policy statement.

Adam Sorkin: Thanks so much.

Christine Biser: I would just like to add in terms of contracts, for Phase II cost reimbursement contracts, there might be ceilings. So, there might be ceilings for subcontracts, for instance, or equipment. And so, a contract, you will not assume a 25% cushion, you need to get in touch with your contracting officer and either realign your budget or find some other way to fund unanticipated change in costs.

Adam Sorkin: Great. Thanks so much, Christine. Let's see. Here's a question for Roger I think, what part if any of the RPPR is in the public domain?

Roger Miller: For your annual progress reports, none of them punches right through like I noted for the abstract or your final, but also be aware that anyone can request information from the government through the freedom of information requests, so it is possible that it would get out. Now, you can highlight the areas where you have IP or confidential information, and that's a good idea to do when you file your report, and that way, if it might come up under a Freedom of Information Act, you have already keyed in on the areas that you would want to withhold.

Adam Sorkin: Great, thanks so much, Roger. And we'll stay with you for a couple questions. Getting a couple of hands, we've seen in the Q&A. When is it appropriate to request an administrative supplement? How can you add funds if necessary to an SBIR grant?

Roger Miller: It's always fine to submit a request to discuss that with your program officer. There are just a wide range of situations that, let's say a hurricane comes through and destroys some of your key equipment, when that's a wide scale events, sometimes you'll even see NIH put out a notice of an NoA telling you that it's okay to, you know, we're conscious of the situation, and we're willing to consider these requests. But you have to understand that there's a limited amount of funds. Every IC is trying to balance the ability of particular projects to go forward which have already received substantial amounts of funding with new projects that won't go forward at all because they've received no funding. So, you have to understand that you've had your bite at the apple, and you'd have to have a very compelling case of what would be possible with an administrative supplement. Thank you.

Adam Sorkin: Great. Thanks so much, Roger. And I think one more question. When is it appropriate to pursue a- When is Phase IIb a good option?

Roger Miller: Phase IIb is something that NIDCD participates in, and that to people that don't maybe know the nomenclature, that is an opportunity to submit a second Phase II application. When you look at the application instructions for the SEED funding, you'll see that some ICs participate in that, some do, some don't. NIDCD does, but only for a very particular set of circumstances. So, you can ask for follow-on funding, which goes through peer reviews, this is a nice pair, Adam, with the previous question about administrative supplement which doesn't have peer review, and this request that does have peer review. And we have other notices, the CRP program, which is Commercialization Readiness Pilot program is another opportunity for you to get follow-on funding to get over specific hurdles to commercialize your product. It's much easier to get additional funding through a peer review process with one of these other either Phase IIb or the CRP programs. But the scope really narrows down from what we have available to people for a Phase II, that initial opportunity to get non-diluted funding from NIH to develop your product, and then for follow-on funding, it's a much better approach when you're kind of thinking of how do I get additional funds to build out a big project, like I kind of indicated in mine, taking a simple idea. And there's multiple levels of innovation needed to really disrupt the commercial marketplace. It's better to focus on multiple Phase IIs, some

maybe that are preceded by Phase I, maybe some of them are directed Phase II, to focus on different aspects of innovation. Thanks, Adam.

Adam Sorkin: Thanks so much, Roger. Looks like we have perhaps an interesting question for Jonelle. And I will paraphrase a bit. It looks like we see somebody who has concerns that a PI may have been taking support while unable to actually work towards the project as described in their award. How might somebody take that up with you and present their concerns?

Christine Biser: I'm sorry, Adam, can you repeat the question? I heard about- I'm not sure if it was directed at a CO.

Adam Sorkin: No, it was actually directed towards Jonelle. Somebody expressing concern that somebody accepted support while actually unable to work towards their project.

Christine Biser: So, in the instance of a Phase I-

Adam Sorkin: Oh, I'm actually asking Jonelle for- about somebody.

Christine Biser: Oh, okay. I'm sorry.

Adam Sorkin: No. No worries.

Jonelle Soeffing: Well, interestingly enough, I would probably defer anyone bringing that information forward to their contracting officer or to their program manager just to make sure, and I think even Roger touched upon this a few times over the importance of documenting certain areas that are affecting your award and being transparent about your work. So, to me, every situation differs, and it would depend on the amount of work that is possibly languishing or the amount of work that's being put back in during another month's time. So, I think there's just too much to go into play with that question. But I think being transparent and open and asking questions and bringing awareness to these, you know, possible issues is the most important piece for me, for us.

Adam Sorkin: Great, thanks so much. Very helpful. And Christine, if you do have a comment, you're certainly welcome to.

Christine Biser: I would concur. The reason has a lot to do with how we would handle that. So, if someone has had an illness, you know, and they can't work on it, then probably the best

solution is a no-cost extension and just allow them time to recover and go back to work. And if there's- very often it requires a modification to the contract, you have to add time, you change the Statement of Work slightly. In a Phase I, it might not necessarily matter as long as you can get the deliverable in, which is what was negotiated, you would be able to invoice for that and the deliverable. For Phase II, it would be much more likely to involve some communication with your CO and the COR.

Adam Sorkin: Great, thanks so much. So, here's an interesting question for Artisha, I believe. Is it allowable to pay a success fee from the grants? And if so, can that funding only come from the fee or also from indirect costs? So, I've seen this is like a contingency fee for somebody perhaps helping to prepare a grant, can you pay them a fee from the award if you're successful receiving it?

Artisha Wright: I've never heard of that before. So, you're basically asking if they've written your grant, and you submit it, and it's- I would not use NIH funding for that. You can pay your own funding, but it is not recommended that you're using the NIH funds given to pay for that grant writing. That is something, you know, those funds are specifically allocated for the use of, you know, accomplishing your aims and goals scientifically for that purpose. And that would not be an allowable cost.

Roger Miller: Can I ask a follow up on that, Artisha?

Adam Sorkin: Please.

Roger Miller: Would it be possible to use funds based on the fee, the profit from the SBIR/STTR award, and for something like that?

Artisha Wright: So, I would look at the grants policy statement regarding that fee, because there is some leeway, but again, just my personal assessment, I would not utilize the NIH funding to provide and pay somebody that, you know, wrote your grant.

Adam Sorkin: Okay. Thanks so much for Artisha. Roger, shifting gears a little bit, we've had a couple of questions about no-cost extensions. Are they available to all SBIR Phase I awardees? And I'll ask Artisha first. How does somebody go about requesting one?

Christine Biser: Oh, I'm sorry.

Adam Sorkin: Please, start Artisha first.

Christine Biser: [CROSSTALK]. Go ahead, Artisha.

Artisha Wright: So, under the no-cost extension in comments about 30 days prior to the project budget period end date, that button will be available so that you can do the no-cost extension, the very first one on your own. If you do miss that timeframe, then you would submit a prior approval request to your Grants Management Specialist and Program Officer to review, and then we would go into the system and process that on our end. But everybody can have that first no-cost extension, you know, on your own, with no questions or concerns.

Adam Sorkin: Great. And Christine.

Christine Biser: That's also true for contracts, so they're available to any SBIR contract. What one would do is look at your Statement of Work, look at whether you need more time, and how you can stretch out the money and contact your either contract specialist or contracting officer. It requires a modification, so it also requires about 30 days advance notice. In September, when we are extremely busy, it would be greatly appreciated if we're given a little bit more time because we're awarding lots and lots of contracts, and we're definitely overworked at that point.

Roger Miller: Adam, could I pop in here, please?

Adam Sorkin: Please, Roger.

Roger Miller: So, you can request that first no-cost extension, and it can be for up to a year, but please correct me, Artisha, if I'm wrong, and the system software will approve it. But it's good that your program officer knows to expect that because if I see that the request has gone out and it's been approved, and I have concerns, then I'll reach out to my grants management partner. And we'll go back and ask for additional information. So, it's kind of a software approval at first, but that's for the first no-cost extension. So, if you asked for that first no-cost extension for two months, which I don't recommend people do, and you decide you need another month, then you have to go through the more formal work process. And you can

request a second no cost extension in some cases, again be in contact with your grants management staff and your program staff, if necessary, through a more rigorous process.

Thanks.

Adam Sorkin: Thanks so much, Roger. Artisha, and I think Christine as well, we've got a question about whether or not it's possible to spend funds before they're received but after the Notice of Award has been issued. Artisha, can you talk a little bit about pre-award spending for grants?

Artisha Wright: Yes. So, with grants, you do have that 90-day pre-award spending capability, but please note that you do enter into that at your own risk, because until you receive that Notice of Award from NIH, you know, signifying that we have issued your award, that is our legally binding document. Again, you can enter into that 90-day pre-award spending at your own risk. And that is in the beginning, you know, prior to that first budget period occurring, so that year one of the award.

Adam Sorkin: Okay. Thanks so much. And Christine, is pre-award spending feasible for contracts?

Christine Biser: There is no such thing in contracts as pre-award spending. So that effective date that I was mentioning and the expiration date, so if you are in negotiations for a contract, and you have to assemble the personnel, you do not want to be making a firm employment offer. You want to make it contingent on receiving the contract award, because that effective date is the first day that you're allowed to spend money, you will not be reimbursed for any expenses prior to that. So definitely, I would recommend a contingency letter.

Adam Sorkin: Great. Thanks so much, Christine. Let's see. A lot of good questions, and we are running short on time. Let's see. Okay. Well, a question, I will start with Roger, and perhaps we can discuss with Artisha as well. What happens if a Notice of Award does not reflect a budget waiver request made in the application? Is this something that you can go back and request the full amount for?

Roger Miller: You got me stumped on that one. I would defer to my grants management colleague, and you can see how closely program staff work with our grants management fellows.

Artisha Wright: So sometimes there are reductions to the budget. And there will be a term of award in the NoA to indicate why that particular category may not have been included because it could be an unallowable cost. It could also be that on the summary statement, the council recommended moving those costs. So, it would not be uncommon, but also one of the standard practices is during the adjusting time negotiation process. Grants management will let- we will indicate if there aren't unallowable costs, and you may need to re-budget or revise your budget accordingly. So, we will let you know more times than not, it's not a surprise with us removing it beforehand, but we do like to make that information known but it's not uncommon.

Adam Sorkin: Great, thanks so much. Let's see. Perhaps one more. And this is I guess most likely for Roger and Artisha again. For a no-cost extension for a fast-track award, how does this affect- if you get a no-cost extension for the Phase I, how does this affect the timeline of the Phase II?

Roger Miller: It's a great question. When you request that no-cost extension, let's say you go for the maximum period of time, you get that extra year, and then you say, "Oh, great, I finished up in six months, so I'd now like my money for Phase II earlier than I had anticipated." That's a difficult dance for us to accommodate. You asked for a no-cost extension, we allowed for it, so we're expecting your final progress report- not your final progress report, but the report that shows that you've met all the milestones which were written in stone when that fast-track was awarded. So, we have made budget plans based on the fact that you won't be coming in earlier, so that's a difficult request to accommodate.

Adam Sorkin: Great, well, thanks so much. Unfortunately, we are about out of time for today's program. I just want to extend my thanks so much to all four of our panelists: Artisha, Roger, Christine, and Jonelle. And thanks so much to my colleagues, Vicki, Laura, and Duran helping on the backend. And thanks so much to all of you for joining us today. As Vicki has noted, these materials will be available likely, in seven days, give or take. So, look out for those in about a

week or so. And, you know, certainly feel free to reach out to us at seedinfo@nih.gov with any questions we didn't get to today, and there are certainly a good amount. And check out seed.nih.gov for general information about the program and a great FAQ that addresses a lot of the things that came up today. So, with that, I will end the program. And we'll look forward to speaking to all of you soon. Thanks so much.

Roger Miller: Thanks everyone.

Christine Biser: Bye-bye.