Got Funding? Tips for Efficiently Managing Your SBIR/STTR Award

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Moderator: Robert Vinson, NIH Small Business Program Manager

Panelists:

- **Artisha Wright**, Grants Management Specialist, NIH, National Center for Advancing Translational Sciences (NCATS)
- **Dr. Emily Caporello**, Program Director, NIH, National Institute of Neurological Disorders and Stroke (NINDS)
- **Jonelle R. Soeffing**, Operations Officer, HHS, Office of Inspector General (OIG)

ROBERT VINSON: Good afternoon everyone. My name is Robert Vinson. I'm the program manager for the National Institutes of Health small business office and I'm the moderator for today's event. I am delighted to be able to introduce three dynamic speakers. Our topic for today is Got Funding? Tips for Efficiently Managing Your SBIR/STTR Award. A few housekeeping rules before we get started. Please make sure that you're muted, and your cameras are off. Questions, you may ask them and place them in the chat. Direct them specifically to our speakers or panelists. Slides will be available within a week's timeframe. So, with that, I would like to introduce our speakers for the day. Doctor Emily Caporello, Program Director for the National Institute of Neurological Disorders and Stroke (NINDS), Artisha Wright, Senior Grants Management Specialist with NCATS, and our final speaker/panelist will be Jonelle Soeffing. She is from HHS, OIG's office. She's the operational officer. With that, let's go ahead and get started.

This is the agenda for today. Each speaker will introduce themselves. As I have mentioned we will have tips for efficiently managing your award, starting with program officer, Emily, then the grants management specialist, Artisha, and then the operational officer from OIG, Jonelle.

Then after that we will have questions and answers, so we'll have plenty of time to get to your questions. We will not be answering any specific questions to a grant or an award. Save those and contact the program official or grants management official to talk about those specifically. With that, let's get started.

EMILY CAPORELLO: Hello and thank you all for joining today. I'm Emily Caporello, program director for the small business program at NINDS. I'm going to talk today about the program officer side. Things you should be paying attention to after you have gotten an award. The first and most important thing to do is to read through that Notice of Award. There's going to be terms and conditions of that award that you need to make sure you are aware you have agreed to as the recipient organization for that award. You may see that some notices of award include requirements for data sharing, meeting attendance if you're part of a bigger initiative or program. You will also see the award for clinical trials may have specific terms and conditions that you must be aware of. The second thing to do is to note any restrictions that you may have on your award. Restrictions for funding and/or activities. That restriction will also be noted with the requirements that must be made to remove that restriction. It is very important that you do not spend those restricted funds or perform those restricted activities until you have that restriction on the Notice of Award has been removed. Oftentimes this will include activities related to animal research, if there are pending approvals needed at NIH or at the level. Human subjects research may be restricted pending IRB approval. You do not want to be in the case where, as the program officer, I'm reviewing your mid-year or final report and seeing that you went forward and conducted that research without the prior approval at NIH.

Make sure you are aware if you have any restrictions on your award and you're talking with your program officer and grant specialist to get to those restrictions removed before you perform any activities. Next, make sure you review the budget you were approved for. Make sure that aligns with your expectations and your planned spending for the project. If you believe your spending is going to be different by over 25 percent per category on the NoA, it's

something you will want to bring up with your program officer and grant management specialist in advance so you can make sure that your budget spending is aligned with your planned spending. Because, at the end of the day, you'll need to show that you spent in accordance with how you were approved to spend those funds.

Finally, note the key personnel that are listed in your NoA. Oftentimes, applications come in with a long list of key personnel and the program officers are advised only to put really essential people and list them as key personnel. You may see there is only actually a handful of names, less than what was in the application. Sometimes new people that you did not actually put as key personnel but the program officer, IC staff decided should be key personnel. Those people will be listed on the NoA. Their involvement in the project must be maintained. If it differs from what was proposed, and that also needs to be something that gets prior NIH approval. Make sure you know who those key personnel are.

As you are going forward and conducting your project, it is good to keep in mind when it is important to reach out to your program officer. We always love to hear from you. We want to hear how the research is going. We're happy to talk about that but there are certain times when the approval may be needed before you can actually move forward with making any changes. Generally speaking, it is great to let your program officer know if you plan on making any changes to your R&D plan, any changes to your team, your partners. It is good to contact us and let us know so we can make sure you're not changing the scope of your research. If it's a change of scope, or if it's any other kind of change that will require prior approval, it is important that we get that established and approved before that change is made in your report. Again, changes made in your report. So, at the end of the day, when your receive report and we look to what you did, we can say yes, this is what you were approved to spend that award funding on.

Things to keep in mind. Scope changes, changes to your key personnel, re-budgeting, changes to the ownership or eligibility of your small business, a change in foreign components. These

are all things you should contact your program officer about. The link on the page provided here give you more information about what might require prior approval at NIH and the eligibility criteria that relates to your small business. I will note here that generally, foreign work is prohibited in small business funding. If you have any inkling you may want to be working with a foreign partner, that is absolutely something you need to bring up to your program officer well in advance.

I will move on to some the fun stuff. So, what do you get as being an NIH SBIR/STTR awardee? You are now part of a very special group that gets access to a lot of resources at the NIH. Two programs I want to make sure you are all aware of are the I-Corps™ program and the C3i program. Both of these are programs that are open to Phase I SBIR/STTR recipients. I-Corps™ is a six week entrepreneurial immersion course which is really going to help you build out your business plan and test that business plan against your potential customers, users, distribution partners. And gain a lot of insights into the realities of that particular customer base or market. And get some real crucial feedback into the strengths and weaknesses of that business plan and help you change it so that you are moving forward with a strong tested business plan. In addition to being a great resource for your company, that can also be a really great piece of putting together a commercialization plan which you would use in building a Phase II application.

The C3i program is very similar in nature to the I-Corps™ program, except it is specifically focused on medical technologies. If you're developing a device, this is a program that is specifically made for your needs. It is held annually, and it is actually three separate parts. There's an e-C3i portion which is kind of the educational portion, the main C3i program, and a follow-up program as well. The links on the slides will give you more information about those programs and their solicitation timelines.

In addition, there are additional kinds of resources offered to you as an NIH SBIR or STTR recipient. There are supplement opportunities you may be able to take advantage of. I posted

a couple of these here. I highly recommend reaching out to your program officer at your specific Institute to see what supplement opportunities your Institute participates in. One is the TABA supplement. If you did not request technical and business assistance in your application, you may be eligible to request these services after you have received your award through the supplement opportunity.

TABA is a separate program that allows up to $6,500 in Phase I and up to $50,000 in Phase II for services that fall under this technical and business assistance umbrella. This may include things like market research, regulatory plan development. There's more information available in this notice that you can read through that may give you a better sense of the kind of activities that you can fund through the supplement.

In addition, many Institutes at NIH participate in the diversity supplement for SBIR and STTR awardees. This supplement opportunity will support diverse research staff hiring and training to have them participate in R&D that is related to your funded project. Many Institutes, including NINDS—the Institute that I'm representing today—have this program as a big priority. We're trying to increase the diversity of the workforce in the life sciences small business community. In addition, you have a wealth of opportunity and support available to you through the SEED office. There is free consulting available to you for regulatory reimbursement, IP, and company development topics. The NIH also sponsors SBIR and STTR awardees to attend partnering conferences such as BIO, RESI, MedTech. We will provide entrepreneurs in residence to give you some pitch coaching and developing your presentation and then sponsoring you to actually present at these conferences to facilitate interactions with investors and partners as you move your technology forward. I highly recommend taking a look at the SEED website that is here and some of the resources available to you as an SBIR and STTR awardee at NIH. From here, I will hand it over to my colleague Artisha Wright.

ARTISHA WRIGHT: Good afternoon. My name is Artisha Wright. I have been with NIH for 21 years and I'm currently at NCATS in the office of grants management. Being a recipient of a

small business grant is very exciting but if this is your first grant you may have questions or concerns regarding what happens next. Over the next few moments, I would like to discuss how communication with grants management is necessary for successful award management.

Before you begin any work, it is recommended you read the Notice of Award (NoA). The Notice of Award 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 the eRA Commons. The NoA 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 as well as the contact information for your assigned grants management specialist and program official.

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

In section four, you will find the special terms and conditions specific to the grant as well as the IC, or Institute or Center, that is funding them. These terms can include the Welcome Wagon letter for first-time NIH grantees, the subject funding opportunity announcement, the funding plan relevant to the fiscal year that your award is made in, any prior approval request –specifically, the process you would follow for that specific IC funding your award—anything pertaining to intellectual property, audit, final progress report requirements, funding recommendations or adjustments, other support issues, salary cap, administrative restrictions, and human or animal subjects restrictions. It is imperative that you carefully review and

understand the terms to avoid any noncompliance or violation of NIH policies and procedures which can result in adverse grant actions such a special terms being applied to your award and conditions for monitoring of funds withdrawal or possibly even grant termination.

Please note that the minute you request and draw funds for the Payment Management System, you accept the small business award and other applicable terms and conditions associated with it. If you have any questions or concerns, like I said, it is so important to reach out and contact you grants management specialist. My function is to manage the day-to-day functions and operations of your award and I want to make sure you are successful. If you have any questions or concerns, you want to reach out at the first sign of trouble.

After your in receipt of a Notice of Award, you're now in the stage that we call post-award because you've already submitted the application and been selected for funding. So now that is your post-award stage. You may find that things are not necessarily going as you expected. For example. You may have questions regarding the establishment and management of your grant funds and how they will be accessed. For the payment management system, it is utilized by NIH award recipients to access their funds and administered by the program support Center within the division of payment management. This platform is not something that your grant specialist would have access to or monitored by. 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 it's five months into the grant and everything was going well. Suddenly, a key piece of equipment that you need breaks down. So, you begin to do some cost comparisons you see that a replacement item, which is now more advanced and up-to-date, is going to cost you $28,000. This is more than the original purchase that you spent on the original piece of equipment that was approved. At the same time, your co-PI announces their departure, and the replacement needs to be identified. Is there anyone suitable to fill this position? Or is it more feasible for you as the PI to adjust your effort to kind of compensate for this? Because

this is a key personnel change. You're not quite sure if these actions require prior approval, and with everything being time sensitive, would it hurt if you just moved forward to purchase the equipment? Appoint a new co-PI and just maybe adjust your effort.

Before you do anything, you need to communicate with your grants management specialist as these are post-award changes to the grant that do require prior approval from NIH. Please note that if you move forward without receiving this prior approval, you are in violation of NIH policy and could face a restricted or 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. Does this size change impact your award eligibility? To complicate matters further, another co-PI decides they're going to move their lab and research to France which could potentially result in a new foreign performance site and funds may need to be allocated from your award to support this. Is it okay to just go ahead and add this site and conduct your research in another country? Or should you discuss with program and grants management beforehand? These two examples could impact your award eligibility. Failure to consult with NIH moving forward could result in special enforcement actions and or termination. When in doubt, you always want to make sure that you reach out. As the PI, we all know your focus is on accomplishing scientific gains and producing successful research. While program is focused on scientific management of the grant. My focus as your grants management specialist is on the day-to-day administration for compliance of the grant.

Communication amongst all three parties is so vital when faced with situations like the ones mentioned above. If you do not communicate and you move forward on your own, you could definitely face some adverse reactions. You could be in violation of policy and be noncompliant with all of the NIH terms and conditions. You just want to make sure that everybody is involved. We all want to work together. Another thing you want to make sure is that you have timely submission of requests that come from your grants management specialist when it comes to prior approval request. You also want to make sure that you are submitting your progress reports 45 days prior to the start of the upcoming budget period if

you have a multi-year R43 or are in a Phase II R44. When in doubt, like I said, always reach out. The communication does not stop with program and grants management. Momentarily you will hear from our colleague at OIG with how you need to be in communication with them. At this time this concludes my portion of the presentation and you will now hear from Jonelle Soeffing.

JONELLE SOEFFING: Good afternoon. I'M Jonelle Soeffing. I'm an operations officer within the investigations branch for the Department of Health and Human Services, Office of Investigation. I will cover tips for efficiently managing your SBIR/STTR award. OI's mission is to protect the integrity of HHS programs. OI conducts criminal, civil, and administrative investigations in the area of fraud, waste, abuse, and misconduct. Fraud, waste, and abuse typically fall into one or more of these three general categories: conflicts of interest, theft of government funds or embezzlement, and failing to properly support the use of funds.

I will give some basic overviews for the definitions of fraud, waste, and abuse. Fraud is intentionally submitting false information to the government or a government contractor for money or a benefit. Waste is practices that directly or indirectly result in unnecessary cost such as overusing services and misusing resources. Abuse is the intentional or unintentional thoughtless or careless expenditure, consumption, mismanagement of government resources or excessive or improper use of government resources including misusing or misrepresenting your position or authority. The bar located at the bottom of this slide shows a spectrum from mistakes, negligence, to fraud. For not necessarily a direct interaction but to the actions that you could face. From administrative to civil to criminal action.

We understand there is a difference between an honest mistake versus you should've known better versus intentionally deceiving the program. You have a requirement to be presently responsible with your SBIR or STTR award. If you're not presently responsible, when there is a lack of program business integrity or honesty, a willful failure to perform in accordance with

the terms of your award, or a serious and compelling cost that directly affects your present responsibility.

Now I will cover some fraud schemes that could impact your award. Some common fraud schemes include false information on grant applications or progress reports, creating any false records, fabricating your company and invoices, using your funds for unauthorized purposes, Not doing the work that you claim to do within your award, extending kickbacks to others to generate additional business, allowing your investigators to have outside employment, or exceeding the award company size requirements—going over 500.

Here are some specific examples of what not to do. Please do not operate outside of your residence or will do not operate outside of your authorized location. Do not use grant funds for personal expenses. Do not pay others to do all of the proposed research when your award dictated otherwise. Do not pay institutions who did not do the proposed work but still draw down on your funds. Do not lie to us, including on your application and Biosketch. Please bear in mind, a lie is both by action and by omission and both count.

We certainly want you to have an awareness of fraud. Without understanding what fraud, waste, and abuse looks like, you could inadvertently commit it and be on the radar of HHS OIG or of another federal agency. Fraudsters utilize SBIR/STTR funds that could otherwise be given to legitimate awardees such as yourself. In essence they are stealing from all of us. Please use your grant money for what you say you would use it for. No more and no less. Certainly, there will be no resulting problems. The big factors if you see a problem, please bring it forward. Use common sense. Do not be afraid to ask questions of HHS OIG, even if you simply have questions on whether or not a particular expense is allowable. Please do not hesitate to call HHS OIG and to report any suspicious activity. OI investigates thoroughly and confidentially. If there is a wrongdoing found, the report was justified, and you helped to protect the program. There is no fraudulent activity identified, the case is closed and there is no harm done.

An important element for you to remember is to maintain good record-keeping. Always maintain your required documentation to include but not limited to timesheets, related financial receipts, and invoices. Again, we understand there is a difference between mistakenly using grant money for one single personal purchase or from using your grant money to buy groceries for your family the entire time of your award. There are consequences when you misuse your award. The consequences could include criminal prosecution, civil prosecution, or administrative action.

There are various fines associated with these criminal statutes, the ones listed here on the slide. 18 USC 641 Criminal Embezzlement and Theft of Public Money, 18 USC 1001 False Statements. Some of the fines could go upwards of $250,000 for certain violations involving these statutes. You could face imprisonment of five years, 10 years. And wire fraud, which is not included here, could have a sentence of upward to 20 years.

We want to show you the need to be presently responsible for your award. Outside of the actual prosecution that could result from criminal or civil wrongdoing, there is administrative action that HHS OIG has the option to endeavor upon. These are powerful tools to make sure our government funds are protected. The administrative actions goes against individuals who are not presently responsible or inappropriately handling their government funds. Just to explain the suspension is an immediate action. It is done to immediately protect federal funds. It is a temporary disqualification, and it stays in place until the suspension is lifted or until debarment is issued. Debarment is a disqualification for government contracts for a specific term, typically three years. And it's from all government interactions, not just within the awarding agency, in this case HHS OIG.

An exclusion is something that is done within HHS OIG. It is administrative action that affects payments from HHS. Any individual or entity that has been or who is irresponsible with their award can be expected to be suspended and/or disbarred.

Here are some specific HHS OIG case examples, recent case examples within the last year. One of the top involves the individual named Owen Hughes. Owen Hughes agreed to a settlement resolving allegations that despite his certifications he had no financial policies in place. As a result, he could not substantiate how he had actually used the federal funds that he used. The settlement also resolved that he co-mingled his grant funds into his personal account then used the co-mingled funds for his aviation hobby; for paying for an aircraft hangar, rental fees, and for buying aircraft parts. This is a clear example of somebody who violated the use of their award.

The example on the bottom involving William Rosellini who entered into a settlement agreement and agreed to pay $50,000 and agreed to be excluded based on allegations that his company drew down funds from the HHS Payment Management System and funds that were sent to an overseas affiliate without NIH approval. They were in violation of NIH SBIR requirements and based upon quotes and other potential costs that were never incurred and co-mingled among various affiliates and used for unallowable costs unrelated to NIH SBIR awards. This concludes my portion. I will turn control back to Rob Vinson. Thank you all for your time and attention to my portion.

Q&A

ROBERT VINSON: Thank you Jonelle, Artisha, and Emily. I'm sure you have answered a lot of questions through your presentation. We do have a number of questions in the chat that I'm excited that we will be able to address. We have plenty of time. Please feel free to send your questions and answers to us. Let's get started with some the questions.

QUESTION: How soon and frequently should a small business concern contact program officers after an award? Let's go with Emily with that of course.

EMILY CAPORELLO: Unless your Notice of Award or program officer has told you about any requirements for interim phone calls or interim reporting, you're not necessarily required to

contact your PO unless one of the situations I brought up before like a change in research plan, a change in the team, something like that comes up. The typical requirement is that you are going to send your annual report in when it is due before the end of your first project period. Typically, 12 months or six months. That is typically the first time you going to the report but different programs and program officers at different ICs may have different policies. We always love to hear from you. We always love to hear updates so you shouldn't hesitate to let us know how it's going. We are certainly always there for questions. You should look at your Notice of Award in terms of required reporting and reach out to your program officer to see if they have any specific requests or requirements in terms of staying in touch.

QUESTION: We might as well stay with you for this particular question. Does foreign partnership exclude individual contractors for software development?

EMILY CAPORELLO: That is a great question. The important thing to keep in mind is in the SBIR/STTR case, generally foreign work is prohibited. If you do have a consultant or a partner that is going to be conducting their work in a foreign location, this would count as foreign work. It is something you should definitely bring up with your program officer and grants management specialist. You can discuss how you may be able to manage their involvement.

QUESTION: Thank you. Artisha, we have one for you. Is a small business concern allowed to change equipment vendor outlined in the budget. If so, what is the process to request approval?

ARTISHA WRIGHT: Sorry, Can you read that question again?

QUESTION: Is the small business concern allowed to change the equipment vendor outlined in the budget? If so, what is the process to request approval?

ARTISHA WRIGHT: Are we talking about the special line item? Under TABA?

ROBERT VINSON: Special line item. Typically, the grantee who would need to request that type of change from the grants management officer and as long as from what I recall less than 25 percent of the budget, you can re-budget that particular item. So, that is going to be the best way to address that.

QUESTION: I have another one for you though, Artisha. If we were not able to attend the conference listed for travel in the budget, can we request to attend another one and if so what is the process to request approval?

ARTISHA WRIGHT: That would be a prior approval request. Just an administrative change that you would want to submit to your grants management specialist and your program official. I would say you will follow the procedures outlined according to the Institute that is funding. We do have a special mailbox that all prior approval request should be sent to. You would list the specific type of prior approval request. You say you wanted to attend this conference; it didn't happen. You would state the reason why it did not happen. For example, we know we're in COVID and a lot of travel have been impacted by it. You also want to make sure that you are following their specific organization travel policies and procedures. Then making sure that there is not an impact on your award financially.

So hopefully, it is easy transition and substitution from one to another. No additional cost would be needed. And if so, if you'd be willing to re-budget to cover those expenses, like if it was an increase. You're also going to identify how you plan to reallocate or re-budget those funds. You would send it to the grants management and program official. We would review it and provide you with a response. Typically for prior approval request, it is a 30 day window that we allow for submission, review. If we do need additional documentation, we do ask that you submit that to us at your earliest convenience so we can provide you with that response. You also want to make sure that you are doing this before the conference and not the day of or the two days before. Giving us advance notification, that always helps.

QUESTION: Can we start a study or start a grant before the Notice of Award and then reimburse someone from the expenses before the date of the notice?

ARTISHA WRIGHT: You do have that 90 day pre-award wiggle room. You do enter into that at your own risk. It is the pre-award spending that you can utilize. What you do receive the Notice of Award to the reimbursements. You do enter at your own risk doing so. Right now, we are currently under ACR which is a continued resolution. We do not have actual budget. Right now, realistically speaking, it would not be recommended for you to enter into any pre-award of activity for a new grant. It is a little different if you're in that noncompeting stage. You do have the funds to cover that. Those are not brand new awards. If you're trying to get a new Phase II and you've already had that Phase I and now you're thinking on getting that Phase II, you do take a risk. If it is a two-year Phase I or two-year Phase II and you're waiting on that, that would be it.

QUESTION: Emily, we have one for you. Emily. This is for you. Are the resources mentioned, I-Corps, and C3i, available only during the funding period or beyond?

EMILY CAPORELLO: It is good to check with the links I provided to look at eligibility information. To my knowledge, both the I-Corps and C3i programs are open to Phase I recipients while their award is active.

QUESTION: Also, Emily. This was a question. Could you elaborate on the resident example.

EMILY CAPORELLO: The entrepreneurs in residence that I talked about. This is part of the SEED office's innovator support team. There are a number of different consultants with various expertise including a cadre of experienced entrepreneurs in residence who are available to help consult with any SBIR or STTR awardee at NIH on anything related to business development or fundraising plans, market research. Not to do the entire research but to help

you figure out basically what kind of help you need to set you in the right direction. Where to get additional assistance. They're not available to become part of your company or work for your company but they are available to consult with to kind of help point your needle in the right direction over a course of a few meetings. If you have any further interest in that, I highly recommend checking out the website listed in our slides. They were made available to everyone and you will see more information about the innovator support team at NIH through the SEED office and the kinds of consulting support they can provide. It's a really wonderful resource and I advise everyone to try to take advantage of these consulting opportunities.

QUESTION: Jonelle, we have one for you. If there is an allegation, does the individual have the chance to appeal the allegation or is that it? Once someone alleges something, how does that process go from there?

JONELLE SOEFFING: There certainly is an appeal process that is available on the suspension and debarment side. Certainly, there is a judicial process that is included for several criminal prosecutions. Essentially, it really comes down to a case by case situation. But absolutely, there are different parameters in place.

QUESTION: To follow up on something similar to that. When an allegation is made, is it necessary for an individual to give their name? I know there's a certain amount of anonymity, but do you take more stock more credence in the fact that someone is giving the name and contact information as opposed to someone who just called in and makes an allegation.

JONELLE SOEFFING: That is a terrific question. If you do not mind going back. Just for that proper reporting for HHS OIG hotline complaint. I highly encourage everyone if there ever is a moment where a complaint needs to be filed, even if it is just suspicious activity, something you're unfamiliar with. I highly encourage you to report this activity. It is most helpful if you include your name and your contact information. That does allow us to take the complaint to the highest level possible. If you're only in a position to file in anonymous way, I will not

discourage you from filing a complaint. Again, if there is a true benefit to having contact information included with the complaint.

QUESTION: Have a question concerning overlapping support. Could you address that particular question? Artisha, could you address that particular question?

ARTISHA WRIGHT: Yes. What was the question?

ROBERT VINSON: Overlapping support.

ARTISHA WRIGHT: Are we saying there is the issue with? Or committed? Are they have duplicates of scientific because there is a distinction.

ROBERT VINSON: Let's go with both of those examples.

ARTISHA WRIGHT: If there is an overcommitment. If you have more than 12 calendar months, that is the area for grants management. When we are reviewing your other support, we want to ensure that nothing exceeds 12 calendar months which is also 100 percent effort. And when we are reviewing that other support, we notice that you are overcommitted, we're going to send a message to the PI and AOR are asking that you submit updated other support that does not exceed the 12 calendar months. If it is duplicative scientific, then that is the area for program because you have to have that resolution. Can I take that to Emily for input?

EMILY CAPORELLO: Absolutely. Part of our pre-award due diligence is looking to see if there is any scientific overlap with any projects that have already been funded. If we do identify those being touched to figure out if and how it can be resolved. That is something your program officer would work with you on.

QUESTION: Can you elaborate more about supplemental grants for the diversity program?

EMILY CAPORELLO: Sure. The diversity supplement program is intended to support the hiring and training of an individual with a diverse background at your company to help work on the R&D that is related to the project you are funded for. There are a few different components. You need to identify the individual you're planning to hire. You need to describe the research and development they would be doing related to your project. You also need to have a very strong mentoring plan. How will you train them? How will they learn about being part of a small business? The applications go to each individual Institute that participates. Each Institute may differ on their specific guidelines in terms of budget timeline and review process. I recommend taking a look at the supplement notice or supplement funding opportunity and looking at the contact of the Institute that is awarding your award and reach out to them to get further information and talk to you about your specific case.

ROBERT VINSON: Okay. Thank you. Thank you very much. Some of the questions we are getting our overlapping or redundant or duplicative. Kind of putting some the responses together with some the questions together. We are not going to be able to answer all the questions that have been placed. We will keep track and respond to them later. If we do not respond to your question right here and right now, please do not hesitate to reach out and talk to us or send us a specific email. You can send an email request to us at SEEDinfo@NIH.gov. If you need to contact us about general questions about the program, about anything in regard to SBIR and STTR we are more than happy to answer those questions at that point and time. Another question that came in. This is probably going to be for Artisha.

QUESTION: Where and when is the budget submitted? Is that on PMS? Do people typically use an accountant for this? I guess they're asking primarily is an accountant needed to submit the application or can they submit the application themselves?

ARTISHA WRIGHT: You mentioned PMS. Just to clarify. PMS is a Payment Management System that the grantee utilizes to access their grant funds. For that, you specifically do not

need an accountant. I'm just trying to make sure that I understand the question. Just in terms of the budget that you would submit with the application, you want to ensure you are paying specific attention to the FOA, which is the funding opportunity announcement that you are applying under. You want to make sure if there are caps that you are adhering with those caps. The costs that you're requesting needs to conform to the NIH cost principles which are reasonable, allocable, allowable, consistent, and necessary for your award. They would consist of personnel cost, travel, materials, and supplies. Those are the direct costs. Also included with the consortium cost and then you would have your indirect cost. Hopefully you answered that question. In terms of needing an accountant to put it together, not really sure about that. When it comes to that accountant, if you have the financial systems in place which will be part of your eligibility review that we will be looking for, you will fill out the financial questionnaire forms. You would want to have an accountant just to ensure you have the proper recordkeeping and everything is fine. For putting together your budget, I do not think you would need that.

ROBERT VINSON: Thank you. We have a general question that has come up a couple of times. Will there be a certificate for attendance of this particular program? No, there will not be a certificate for your attendance today, but we greatly appreciate you spending some time with us. Another question. I think Emily, this is going to be more for you.

QUESTION: Does the U.S. based company that is paying taxes here but has an outsourcing model okay? They are listed as a third-party vendor on our grant.

EMILY CAPORELLO: Is okay to assume there is a foreign one? We're kind of getting into a couple things. One is if you're a U.S.-based company but have a virtual model, outsourcing all of your work. Generally, no, that's not going to meet the work requirement. Again, that maybe something want to discuss specifically with your program officer. If the question is your U.S.-based and you have a vendor who is foreign, that is going to count as foreign work. If there are direct costs associated in your SBIR or STTR award that are going over to do work at a foreign

location. That likely is going to count as foreign work and needs to be discussed with your program officer to make sure that you're staying within the policies of the SBIR program.

QUESTION: The question is if a complaint is filed, will I deal with the same special agent or individual for OIG or will I have to tell my story numerous times to get my point across and get some action for my particular allegation?

JONELLE SOEFFING: First, I want to again thank everyone for always considering the complaint filing option. If you ever come across the need to file a complaint and again, the more information that you include in your complaint, the more we can do with the complaint. Thank you for your consideration. I am not in a position where I can verify or confirm that you will be dealing with the same special agent throughout the process of your complaint filing. I will say that we of course would do our best to not take up any additional time from you. Again, we just want to make sure the program is protected. We just appreciate you taking the time to follow the requirements for your awards. And to report any wrongdoing when you do come across it. Report to the HHS OIG hotline.

QUESTION: We have a question concerning should the tax and shipping cost of equipment be part of the budgeted direct cost or may be considered within the indirect cost? They're asking as far as the tax and shipping cost of equipment be part of the budgeted direct cost. Or may be considered within the indirect cost.

ARTISHA WRIGHT: That would be included in the equipment line item.

QUESTION: Emily, what is the best way that you would suggest for a potential applicant or someone who is new to the NIH who wants to get in contact with the program official. What do you suggest and how should they go about doing that?

EMILY CAPORELLO: The ideal thing to do is to have a project summary. Ideally a draft specific aims page that describes what is your technology, what do you plan to do with grant funding, what are you seeking specifically? How do you plan on doing it? There are a number of sample applications that are available, SBIR and STTR applications that have examples of specific aims pages you can use to make that document. The reason that is really important to have the initial contact with the program officer is because the first thing we're going to do is make sure you're talking to the right person. I want to review that project and make sure this is, in my case, the NINDS mission space. I want to make sure that I'm the right program officer and not one of my colleagues in a different portfolio in the small business space.

If it is not me, I'm going to help facilitate work with my colleagues and send that specific aims page around to find you the right person to talk to. That is my recommendation. Reach out well in advance of when you want to apply. Ideally six weeks plus in advance of the deadline. With the draft aims page and make sure your first talking to the right person. Then you can have a longer conversation with him about your application. Tips for the FOA, the budget and all those things to keep in mind for that specific Institute that you would be applying to.

QUESTION: If we have a 12 month Phase I award, can we start applying for the Phase II? Can we start applying for the Phase II if we finish prior to the first year?

EMILY CAPORELLO: Yes you can. There is no restriction as to when you can apply for your Phase II. You do not have to be complete with the project period for your Phase I award. However, you're likely to be most competitive for that Phase II funding if you can demonstrate you have met the aims that you put forward in your Phase I. I do recommend you wait to you're able to show success with your Phase I award before applying to Phase II. You do not have to wait for that phase or project period to officially end before you start with this Phase II application. That also may be something you want to talk to your program officer about to see if they have any guidance or suggestions about when the right timing for your Phase II application would be.

QUESTION: When submitting the other support document. Is the effort listed for the remaining year or is it for the entirety?

ARTISHA WRIGHT: When you reflect your other support, it should be for that entire project period. So, whatever awards are actually active at the time of your application submission. Let's say you have 10 grants. Five are active, 10 are pending. You want to list the five active. There is an active section then there is a pending section. You want to make sure you're capturing everything. Whenever you receive the actual Notice of Award, is live, you want to make sure that your listing that in the amount of time that is remaining on the award. So, if there's two years left, you do want to reflect that entire two years remaining. Hopefully, that answers the question.

QUESTION: Emily this question is specifically for you. Who can be considered as a good candidate for diversity program?

EMILY CAPORELLO: Again, I direct you to the language of that diversity supplement funding opportunity because it's going to have very specific language that categorizes what diverse means in the life sciences small business community. I hesitate to try to regurgitate that off top of my head in fear of miss identifying the groups. That information is well described in the funding opportunity. I encourage you to go to that one.

QUESTION: In the Payment Management System, what is the difference between FFR cash transaction and the federal financial reports. Are they both required?

ARTISHA WRIGHT: Can read the question one more time?

QUESTION: They want to know the difference between the FFR cash transaction and the federal financial report. Are they both required?

ARTISHA WRIGHT: Depending on the type of award that you have. These are small business awards. Typically, your FFR would not be due until the end of that phase. Unless you're under a special condition then you would have to have a yearly submission of the FFR. FFR is the Federal Financial Report. Like I said that would be submitted at the end of the phase. I think the other one, the federal cash transaction, that is a different type of report that would be submitted in different segments. I know with other transactions; we would have them submit that. You're not doing that yearly submission of that FFR. If you do have questions or concerns, another source that I recommend is reaching out to PMS because another thing that has changed, that is where the FFRs and FSRs do go now. They no longer come to OFM, the Office of Financial Management.

QUESTION: Typically, how long is the process for allegation to come from start to closure, start to finish?

JANELLE SOEFFING: The duration of time varies from case to case. I can say with all transparency that we will professionally and efficiently handle any complaints that are filed to HHS OIG. It just depends on the nature of the complaint and what is involved with the investigation to show how long the investigation will take.

ROBERT VINSON: It is hard to kind of determine that. Each case is going to be unique. Certainly, the allegations.

QUESTION: Give me one or two pieces of advice that you would strongly urge the applicant or anyone who is applying to us or anybody in the federal government basically to heed what to be aware of. Two things you think really stand out that is either going to help that individual or prevent them from going to jail or keeping them on the right path and cupping them with a decent award. Let's start with Emily.

EMILY CAPORELLO: From my perspective, I would just say really read your Notice of Award. Make sure you are aware of what you're obligated to do. In particular those restrictions. Please pay attention to those restrictions. It happens when people do not pay attention to those restrictions and they end up blasting forward in their project. When I go to open that report, it's a big fire, a big issue. So please look at your Notice of Award. Please note if you have any restrictions and make sure you that act on resolving those restrictions before you do any of those activities or spend any of those funds that are restricted.

ARTISHA WRIGHT: The one thing I would say. Paying attention to any changes. If there's any changes you want to make. In the examples. If you want to have a change in key personnel. A piece of equipment breaks. If you know that could potentially be an addition of a foreign site. When in doubt, always reach out. Do not do any changes before you consult with grants management and with program. You can definitely be in violation of the terms and conditions associated with your award. You are excited. This is brand-new. You have that award. You want to keep the lines of communication open. We know you're so focused on the science. We wanted to be successful because this is the small business program. We understand. Do not ever think there is a question that is stupid. If you're not sure about something, communicate. We are here to help you. Don't think you're bothering us. Just reach out. We're on your side and we want to help you.

JONELLE SOEFFING: My two key recommendations are to always follow the requirements of your award. Never deviate from that. Always follow the law. Always follow the rules. Secondly, to report any wrongdoing that you may have done, report any suspected fraud that you encounter. So, it's always good to follow the rules and report any wrongdoing when it becomes known to you.

QUESTION: What is Max money?

EMILY CAPORELLO: I do not know. Unless you're talking about the budget limits that are part of the program. There are limits to the SBIR STTR funding amounts. There is SBA wide limits. Also limits set by individual Institutes. So, if you're interested in knowing what the budget limits are for particular SBIR/STTR funding opportunities, I recommend you enter the contacts of the individual ICs because they vary widely.

ROBERT VINSON: Generally, for the NIH, we have $150,000 for Phase I. $1 million for Phase II. Those are guidelines. We also have waivers. We have topics or research that is above those amounts. We certainly can look at those awards. Making those awards above those limits or above those guidelines. We have what they would do what you would call considerate for Phase I award up to $259,000 for Phase II award, 1,000,000.7. Again, those at the waiver topics. They would have to be looked at closely.

EMILY CAPORELLO: There are some waivers that can actually see those higher limits. I really encourage you to talk with the program officer. You can start with this. This is the work we want to do. We think it is going to cost whatever that is. $500k, a million, or whatever it is. Then start the conversation with your program officer and their advice might be, you're really at the Phase I level. We really thinking about feasibility here. These are the limits you need to work with. You may just look at the first year that you would do. That is what you actually apply for. I think start with what is the plan for your research and development over the next year, two years, three years. Talk to your program officer and work with them on strategizing the funding opportunities that make sense and how to work within the budgets that are available to you under that Institute and the FOAs you're going to apply to.

QUESTION: We have a question for you concerning indirect cost. Individuals currently using a provisional indirect cost rate. What would happen if the actual length is different?

ARTISHA WRIGHT: That could be subject to the particular Institute that you have received funding from. Their policies and procedures. Also, it depends on the time of year within that

particular budget period. That indirect cost proposal has been approved. If it is one month remaining, they probably are not going to give you that new rate. Just because of the amount of time. It also depends on funding availability as well. Like I said, it is different. It is IC specific, and you can find it in the grants policy statement. Just because a rate became approved at a specific time, if the IC does not have the funds available to cover it within that particular budget period, they may not revise the award. Moving forward for future budget periods, you will get the new rate in effect.

QUESTION: My program officer requested additional development under one of my aims to satisfy concerns before awarding my Phase I. This will incur additional cost. Should address the re-budgeting based on what I anticipate those will be? Or reimburse as they occur?

EMILY CAPORELLO: You should definitely address this beforehand. How your funds are going to be spent. It is not uncommon for us to see that there was a potential concern raised in the review and the funding is contingent upon re-budgeting to address that concern due to additional activity. That is not unheard of. You should reach out to your program officer to work out what that might entail. Obviously, you have the budget you have. You may have to reallocate funding. There is also times when a discussion may involve not getting to the last stage aim. Maybe that's something to work through with your program officer. There may be other, potentially other ways to solve it such as administrative supplements. It really depends on the Institute, whether they participate in the supplements to fund additional R&D. Based on the input of reviewers. It is something you should talk about and solve first. You do not want to go spending and doing activities that there's no clear approval for you to do a budget to spend on those activities. If you want to handle this beforehand and work out a plan for what funding is going to go to that activity and make sure that is approved before you start going down the R&D and the activity.

QUESTION: Is there a threshold or a minimum that the OIG will look at prior to looking into an allegation?

JONELLE SOEFFING: There are certain thresholds. Again, it is very case-by-case. The totality of the complaint situation. I would again just encourage proper complaint filing and to let the rest lie in the hands of the HHS OIG office of investigations because one complaint could comingle with another complaint. There are certain thresholds. There are certain rules that we take into account along with our local, state, and federal prosecutors. And ones we take into account with our office of counsel for administrative action. Again, please follow the rules. Follow the requirements for your SBIR and STTR awards. Report any wrongdoing.

QUESTION: Is there any particular type of fraud that you see more frequently than another type? Kickbacks, or not doing the work. Is there something that you see more often than any of the others?

JONELLE SOEFFING: A few of the ones that were listed on the fraud scheme slide are ones that we see in a revolving way. I would say out of the ones that were listed, outside employment for a PI, misusing your SBIR and STTR funding. Essentially, for most individuals when they decide to encounter fraud, they are doing so to have a financial benefit. It typically stems from having employment outside of your award and/or misusing your award funds. I would say those the top ones. Again, a variety of different fraud schemes. Anytime you cross the line outside of your requirement, your entering into the area where administrative civil or criminal action could be taken against you. I think I have reiterated enough the importance of following the requirements and reporting any wrongdoing by yourself or by anyone within your realm.

QUESTION: We have a lot of work being done while waiting for actual clinical work to start. While a prior approval request is being reviewed for some changes to the clinical protocol, can we still start drawing down on funds for the grant work being done now?

EMILY CAPORELLO: Is that one to me? Sorry. Look at your NoA. It is not unusual in this case for there to be a restriction just on the clinical portions. That would be identified in the NoA. It

is just on the clinical activity and the funds for clinical activities. Look at your NoA and see what the restriction is for. It would not be uncommon for that to happen. You want to check and make sure the whole thing is not restricted. If the whole thing is restricted get in touch with your program officer or grants management specialist to let them know you like to work on the preclinical components and see if they can work with you on that. It is not unusual for us to partially restrict just the clinical activities.

QUESTION: What is the level of spending detail reported to the NIH in the final progress report?

EMILY CAPORELLO: I should probably go to Artisha on this. We look at the progress report which is going to really be the technical progress. There is not too much financial information in that progress report. The financial reporting is really going to go to the budget.

ROBERT VINSON: Absolutely. The question was the level of spending detail reported to the NIH in the final progress report. I am not quite sure what they're asking as far as the level of spending.

ARTISHA WRIGHT: I am not following that either. I guess like as a specialist, I'm going to look at that financial report and the amount of funds looking at the obligated balance. That is going to give me a picture and also looking at PMS so I can see your draw downs. In terms of the level of detail. I'm not sure. We will be able to see if you're fully expended all of the grant funds associated with that award if you spent 50 percent. In terms of level of detail. I'm not sure about that.

QUESTION: Can an unpaid foreign advisor be included? There asking about pro bono.

EMILY CAPORELLO: There's a few ways you could involve a foreign consultant in your work without paying them through direct funds which is what is prohibited. Using SBIR and STTR

funding to support foreign work is not allowed. There are ways people can still get that foreign consulting work involved. One is yes we could compensate them through non-SBIR funds. In the working pro bono or working with equity. The determination from your company. They're paid outside of those direct funds. You can use the fee that you get with your award. That is consider profit to the company. There are not restrictions on how that fee can be spent. That is often a way that companies will fund foreign-based consultants. Or you can use separate funding outside of the award. There are a number of opportunities or ways to get that expertise to your company. What's restricted is using direct funding from your SBIR/STTR award to support any foreign work.

ROBERT VINSON: A couple of questions regarding taxes and reporting of grant funding or award. It's income. Questions like that should be addressed to your tax accountant. Someone who is familiar with grant funding or reporting federal income. As far as grants or contracts. Make sure you get a good accountant or CPA that can address those issues. Those are the types of questions we're going to stay away from. Only because they are out of our realm at this point. I did not have any other questions that needed to be responded to at this time.

QUESTION: What if you obtain FDA funding approval for a human study well ahead of the grant and funds were to be used for animal studies.

EMILY CAPORELLO: Maybe you proposed to do additional animal studies thinking that would be needed to get your IND or IDE or to get your approval for human use. It turns out the FDA approved it. You did not need to do that additional animal work you are funded for. That is actually something to bring up with your program officer. That would be considered a change of scope. Those would be activities not originally part of your award. It is a change in scope to not do that animal work you proposed and instead to the clinical work. If I have the situation right. It depends on the Institute. It depends on what process they have for change of scope. At NINDS it would be a decision made among multiple subject matter experts. Whether that change in scope can be approved. Something you want to bring up with your program officer

because it does require prior approval from NIH to use those funds for this new activity. Especially because this new activity is going to be clinical research. That may not be possible under the award made to you. It is possible you can't add in a clinical trial component. Something you definitely want to bring up with your program officer well in advance.

ROBERT VINSON: We are just about out of time. I want to kind of wrap up or give a take-home message that seems to be prevalent through all of our panelists and their presentations. Please talk to us. We are not going to bite you. We're not going to do anything that is going to hurt you. We encourage you to reach out to us. Talk to us prior to submitting application. Talk to us prior to an event or an action that you think may cause a problem. It is going to save you a lot of time and aggravation. We can help you make sure you're going down the right path. Please reach out and speak with us. Our contact information is available. You can easily reach out to us and talk about your grant concerns or anything as far as the small business program is concerned.

I would like to personally thank our panelists Jonelle Soeffing from the OIG's office, Artisha Wright from NCATS, and Emily Caporello from NINDS. I cannot thank you ladies enough. I greatly appreciate your time and I know we will be doing this again next year. Expect that telephone call or email. Again, thank you all and thank you for participating in this particular webinar.