2021 HHS Small Business Funding Opportunity Announcements Webinar

Tuesday, August 3, 2021

Stephanie Fertig, M.B.A., HHS Small Business Program Lead
Robert Vinson, Small Business Program Manager

Speaker: Valerie Virta
Welcome to the 2021 HHS Small Business Funding Opportunity Announcements webinar. I would like to introduce Stephanie Fertig, our HHS small business program lead, and Rob Vinson, our small business program manager. Go ahead and take it away.

Speaker: Robert Vinson
Thank you, Valerie. Hello to everyone. We're going to go through a lot of information. A large amount of information today. I encourage you to visit our website and please look forward to our new updated website coming in the fall of this year. Also, I want to bring to your attention that we're going to be doing a lot of myth busting today, a lot of SBIR, NIH myth busting today.

Next slide, please. We just recently had a virtual conference and I encourage you to visit our conference website to get more details and information about the review process and tips on successfully submitting applications. The link is located at the bottom of the slide.

Next slide, please. There are four operating divisions within the Health and Human Services agency. While we will focus today primarily on the NIH, in this discussion, we also have the CDC, FDA, and Administration for Community Living with us today for part of the Health and Human Services agency. They all have small business programs and are looking forward to being able to support innovation from small businesses. I want to mention that the CDC and FDA are both participants in our omnibus solicitation, grant solicitation. And we are looking forward to the upcoming year with these solicitations.

Next slide, please. The mission of the NIH is relatively easy or transparent. Primarily, we are a small business program to help NIH accelerate discoveries from bench to bedside. Essentially, we want to help get innovations from, into the hands of patients, clinicians, caregivers, and researchers that need them to go forward in commercialization.

Next slide, please. This is a congressionally mandated program, $1.2 billion that supports small businesses. The SBIR program has approximately $1.1 billion and the STTR program has $150

million. This slide is very important to understand and appreciate the benefits of NIH funding. We are the largest source of early-stage capital. This is not—the funds that we provide in the form of grants and contracts—they are not loans. It is non-dilutive funding which means we will not take a piece of your company or a piece of your business. The NIH is the final customer, unlike the Department of Defense or NASA, which typically purchases your innovation at the end of phase three funding. We do not do that here. Many awardees use the funding to de-risk the innovation to attract investors and partners that will help support bringing these innovations to market.

Next slide, please. This is our first myth that we will bust. In that it is easier and better for a company to just get investors and avoid all the working time to apply for the NIH grant. That could not be further from the truth. Companies that have developed their products with non-dilutive small business program money are very attractive to investors and strategic partners. This is important to remember that investors have a due diligence process in which they will take as much time, if not longer, to process or to go through the process of seeing if a company is worthy or if they want to invest in the company. Our process does take anywhere between seven to eight months but, in the end, this is something we have to do to make sure that the company goes through the review process and so that this is something we must do.

Next slide, please. Okay, we have a lot of success stories and we have stories that need to be told, that a lot of companies or individuals or people, applicants, potential applicants, need to be made aware of. We support innovation through targeting wide ranges of disease areas from cancer to minority health and health disparities. We have companies that have successfully leveraged their funding to get participating, or to get partnering and investors with success stories covering 35 states, 21 NIH Institutes, and we are involved about 20 minority and women owned companies that are in this success stories bank or website, or link, excuse me, that you can contact or lookup throughout the country, from Seattle down to Miami. We have a lot of success stories and a range of technologies, diagnostics all the way down to search tools.

Next slide, please. This is a phased program, the SBIR, STTR program are in phases, the first phase is feasibility and Phase II is full research and development. We want to make sure that you understand that sometimes what is somebody's feasibility and somebody else's research and development, that can be a little vague and not defined. We want to make sure that you understand there are three ways to enter a program. Significant support to help companies to get commercial, to get to the commercial market or to inflection points for investors and potential strategic partners as biomedical research may take more money and time, so we have these programs established that can assist you with that. We have the Phase I, of course,

and the Fast-Track which combines Phase I and Phase II awards, that is only NIH and does not include the CDC or FDA, or ACL, and we also have Direct to Phase II, again, this is only NIH and only SBIR. We also have, once you get to Phase II, we also have other programs, competing renewal awards and the CRPs to help get to that commercial marketplace or that inflection point that I mentioned. That is only some Institutes, not all the Institutes participate in the CRP or have Phase IIB competing renewals.

Next slide, please. The second myth that I'm going to bust is that it's much harder to get a NIH Fast-Track or a Direct to Phase II, so don't even bother applying. Could not be further from the truth. Although most new projects, about 74% are Phase I, we support many Fast-Tracks and Direct to Phase IIs. We encourage you to speak to the program officer to determine the best path for your project. The success rates for Phase I are approximately 13%, Fast-Track is approximately 16%, and Direct to Phase II is about 18%. These numbers have been fairly consistent, so it's still in a good range or acceptable range as far as receiving funding from the NIH.

Next slide, please. Our budget amounts are, and what I want you to realize about this particular slide, is that our budget amounts are much larger than people realize. We have waivers to exceed the SBA's guidelines. So, what you see here, $259,000 for Phase I and 1.7 million for Phase II, these are guidelines and suggestions. We have specific topics or waivers from the SBA so that we can exceed those particular topics and we encourage you to please reach out and talk to the program officer or talk with us about it prior to submitting an award.

Next slide, please. The third myth I'm going to bust, SBIR and STTR budget caps are too small to be useful. It is not worth the time or money in the end. As I just mentioned, the NIH can exceed the SBIR and STTR budget guidelines for many topic areas. A list of approved topics is published every year at https://sbir.nih.gov/funding. Please check with the specific Institute or Center because they each have their own specific budget guidelines.

Next slide, please. You're going to see this slide a lot during this presentation. We will walk you through the application and review process. Let's get started.

Next slide, please. I want to talk a little bit about eligibility. Most of you already know that fewer than 500 employees, with for-profit business, and work must be done within the United States. What is very important, that a lot of people do not realize or appreciate it, is that it is determined at the time of award. If you are several months out and you have not nailed down the specific aspects of your eligibility, please talk with us, but you don't have to have that locked down until you actually receive the award. The other thing I really want to mention is

that for SBIR only, you have to have more than 50% owned by multiple venture capital companies, or hedge funds, this is only for SBIR and something you should reach out and talk with us prior to submitting the application.

Next slide, please. This particular slide, we're going to talk about submission at this point.

Next slide, please. This will be my last slide before we transition to Stephanie. I want to mention very quickly that we have three receipt dates. Most agencies just have one annual receipt date, but we have three. The next one is September 7th. It is typically September 5th, January 5th, and April 5th, but the next submission due date, because of the holiday, is September 7th. We encourage you to look at our website, we want to make sure that our website, we want to make sure that you know the website is full of a wealth of information, including funding opportunities which are highlighted there in the circle. Also, if you are new to the SBIR and STTR program, we have a flowchart that will literally walk you through the process and that is highlighted at the bottom, on the side tab page. Again, the next submission date is September 7th. With that, I would like to pass the baton to Stephanie.

Speaker: Stephanie Fertig, M.B.A.
Thanks, Rob. As you all may know we have our new omnibus solicitations that have recently been released. Now, there are four solicitations—two for STTR and two for SBIR and they are divided up with regards to clinical trials not being allowed versus clinical trials being required. It's really important to read the updated program descriptions and research topic section. That has all of the specific information about what Institutes and Centers that fall within their mission and what they will allow with regards to clinical trials or not, what they accept, budget guidance et cetera.

So, when we talk about how many of these things are really dependent Institute by Institute, you can find a lot of that information in that program descriptions and topics section. We do have targeted solicitations. But it's important to remember that not all of these have a separate set aside or peer review and not all Institutes and Centers participate.

Similarly, we also have a contract solicitation which is currently open, and we are going to have a separate webinar on the contract solicitations, so we won't be spending a lot of time on the contract solicitation today, but I encourage you to look at the contract solicitation. Again, only some Institutes and Centers participate in the contract solicitation so it's important to read it carefully and make sure to see if what you are doing falls within one of the specific topic areas.

Now, I love the myth busting as much as Rob does, so, this is one we get a lot. I should apply to a specific program announcement because targeted funding opportunities have their own dedicated funding. Well, that is just not true. The vast majority of NIH awards are made to applications submitted to the general omnibus solicitations. Not all targeted program announcements have specific set-asides associated with them. They might not even have specific review groups associated with them. So, it's really important to read the specific program announcement and reach out to the individual program staff that are associated with the program announcement if you have any specific questions.

But I do get a lot of questions about, I don't see a targeted FOA or funding announcement, does that mean you are not interested in what I am doing? Well, if it is within our mission, we are probably going to be interested. So, we really want you to look at the general omnibus solicitations and read the program descriptions carefully.

Okay. So, you may have heard me say that we have four different omnibus solicitations. Two for SBIR and two for STTR. The first question may be, what is the difference between SBIR and STTR? Which one should I go to? A myth that I do here is that the SBIR and STTR have a different scope, they actually have the same scope. SBIR, STTR is not earlier in the process than SBIR, the difference between a SBIR and STTR is partnering. SBIR permits partnering and STTR requires partnering with a nonprofit research institution partner. Which is a university. All the other differences listed here fallout of that big core difference. The differences are mainly associated with work requirement and the eligibility around the principal investigator. Whether or not, what their primary employment needs to be. At the end of the day, SBIR or STTR, it is important to know that the award is always going to the small business, even in the STTR. The academic partner in a STTR is the sub award.

Here is a big myth. You may remember that earlier in the slides the SBIR is a bigger program. People think, I have a better chance of getting an SBIR. That is not true. The size of the program does not correlate with the chance of getting an award. In fact, smaller programs such as the STTR or some of our smaller Institutes or parts of HHS may get fewer applications. It might be better to go to one of those other Institutes or to go to the STTR program. I generally tell people to pick what makes the most sense for you. Across NIH, and I know Rob gave some very specific percentages, these can fluctuate over time, the success rates of a Phase I, Fast-Track, or Direct to Phase II, or even the SBIR and STTR. But we found is that, over time, across NIH, the success rates of a SBIR and STTR are roughly identical, the success rate for someone coming into the program Phase I, Fast-Track, Direct to Phase II, are roughly identical, they do bounce around some. Overall, if you look across multiple years, they are roughly the same. The best thing for you to do is pick what makes the most sense for the

project you are proposing. If you need help with that, you can always reach out to a program officer. You're going to hear us say that a lot. If you take nothing else from today's presentation, it's really important and feel free to reach out to a program officer.

The other decision you have to make when looking at the omnibus solicitation is whether or not it is a clinical trial. Not all Institutes and Centers accept clinical trials as part of their SBIR or STTR programs. It is really important to note that the definition of what is or is not a clinical trial at NIH is different than you might think. Different than say, the FDA and their definition. NIH has a broader definition of clinical trials. I put the policy up here and really encourage you—if you're doing human subjects research—please go, utilize the decision tool and if you're still not sure, reach out to the program staff and we can help walk you through and help you determine whether or not you are likely to fall and be considered a clinical trial or not. This is very important, given that all Institutes and Centers except clinical trials as part of the SBIR or STTR programs.

This is one I used to hear a lot as a program officer. My project is so low risk and only has a few human subjects, so it can't possibly be a clinical trial. Well, I have to bust this myth. The definition is not the same as the FDA's, as I was noting, and it is not based on risk or number of subjects. That is really important, and I will say it again, the clinical trial definition is not based on risk or number of subjects. I encourage you to utilize that decision tool and reach out to us.

You're going to submit electronically. So, if you go and open the omnibus solicitations or any of those grant solicitations, you're going to see that you submit grant applications and contract proposals electronically. There are a number of required registrations and you see them here. Please do these registrations early. If, given that the upcoming receipt date, you should do them right now.

Also, it is important to note that coming soon there will be a requirement to have two-factor authentication to access eRA comments. Two-factor authentication shouldn't be that surprising to many of you as many systems now require two-factor authentication for additional security. We are going to use Login.gov at NIH, and the good news is you can use the same account for Grants.gov and SAM as well. You just need that one Login.gov account. There is a link in the slide deck, and we will be making these slides available online and you can look at the Login.gov and start that process.

Now, you can submit grants through ASSIST or Grants.gov, we strongly encourage you use ASSIST. We strongly recommend that. It helps reduce the number of errors you may receive an easier, cleaner way of submitting to the NIH. Regardless, it is very important to submit

early, I can't tell you how many applicants come to us on the last day and forever reason it didn't get processed or didn't get through and we have to tell them there is nothing we can do. It's very heartbreaking, very hard for us, so please submit early.

There are resources to help you submit. We do have an annotated form set that walks through and tells you what needs to be put in each section. We have application instructions, and you can search those application instructions for your specific questions. It's a wealth of information and I often tell people the little-known secret is I use those instructions; all of the program staff do. It is a great resource and I encourage you to do that as well. We have sample applications which are available on our researchers page and on several specific pages and you will have those links on the slides. We have several individuals who have allowed us to put their sample applications up on the web which helps you determine what the final proposal should look like.

The most important piece of advice, and this is something you will hear over and over again, is talk to a program officer at least a month before the deadline. Right about now is when you should be reaching out if you have not done so already. We do have a list of small program small business program managers on our website–I have highlighted it here–and I have the link which we also put in the chat for those who have not been looking at the chat. Lots of links are going into the chat.

If you are not sure who is the program officer, you can utilize our online reporting tools. RePORT.noh.gov. There's a number of different ways to look for a specific topic area or you can use the matchmaker tool. Plug in your technology, what you are planning to do, and it will tell you what similar awards have been made across NIH in your research area that can help you hone down to the one or two Institutes or Centers that may be most applicable. If you are still not sure, we understand, and you can certainly reach out to us at SEEDinfo@nih.gov and we help take a look at what you're trying to propose and try to match you with the appropriate Institute or Center.

Applications are submitted to a specific Institute, so I need to choose the Institute and study section for my application. This is a big one and I hear this a lot. I have to bust this myth. Applications are submitted to the NIH and then assigned to a specific Institute or Center and a study section. You can request a specific Institute or Center or a study section, but you don't have to. My colleagues at the Center for Scientific Review and the receipt and referral section, this is what they do for a living. You can request an area but, at the end of the day, they will look at what you have proposed and assigned you the most appropriate Institute and Center and study section.

Another myth, Institutes and Centers are actually not necessarily connected. And Institute and Center and study section are not necessarily connected, sorry. You can have assigned a study section and that study section might have multiple Institutes and Centers within multiple applications. An individual study section does not cater to just one Institute or Center which can be confusing. But it is important to remember that changing your Institute or Center does not necessarily change your study section. Changing your study section may not change your Institute or Center. It is important to keep that in mind.

Okay. As we're marching down the process here, we talked about eligibility, we talked about submitting electronically, and now we are entering the review process. As Rob noted, we say generally seven to eight, six to nine months, somewhere in there is the whole process from submission to actually getting an award. But you get feedback three to four months after submission from your study section. So, the good news is you will get feedback much earlier than the six to nine months which will help you determine whether or not you are likely to be considered for funding.

Now, how are you reviewed? For those who are familiar with the NIH system, these criteria should not look like a surprise. Significance, investigators, innovation, approach, environment are the core five overall scored review criteria that NIH uses. The difference is that, for a SBIR or STTR, the focus is on development of a product, development of a commercializable product and not on hypothesis driven research. Significance will talk about real problems for commercial potential. Investigators talks about the investigator and team but not just about how many papers have you published but, do you have the right team to take this forward and get this into the hands of the people that need them in the marketplace? Or, to that inflection point for an investor or partner?

For an innovation, is this new or improved? Is this better than what is currently available and on the market? For the approach, is it feasible and the research design make sense for the next step along the process? And finally, environment, do you have the right facilities and resources? There are additional review criteria, there are some application-specific considerations, depending on the phase, whether or not you are Fast-Track, Phase I, Direct to Phase II, protection of human subjects, et cetera. They're not scored individually but they do factor into the score. I want to point out that, in the gray box on the screen you'll note what additional review considerations are not factored into the score but reviewers comment on them, things like foreign components, justification for doing any foreign work outside the United States, as Rob noted, most work should be done within the U.S. There are some very

rare circumstances where we do allow that, but you need to make sure it is justified in the application.

Budget and period of support. Those are not given a score but are additional review considerations where review can comment on it. Now, there's more information at the Center for Scientific Review. In addition, you go back to the first couple of slides where we have a long set of specific talks on this during our conference, and there is even a link to a mock study section on our YouTube and I encourage you to go and, if you are unfamiliar with our review process, there is a lot of information out there about it, and certainly we can talk and answer questions here as well.

Okay. My application did not get discussed or funded the first time. It is a waste of time to try again. Well, I am going to bust that myth. It is very competitive. Only about 14% of new projects are funded. But our resubmissions have a higher rate. My comment is, persistence is key, read your summary statement, every grant application, regardless of if it is discussed, only those in the top half are actually discussed during the review meeting, if it is discussed and gets a score or not discussed and does not get a score, in the bottom half regardless, everyone gets a summary statement. Read that carefully. Your program officer, their name and information are on the top corner. Reach out to them by email, contact them, ask to discuss your summary statement. Here is a big one, offer to be a reviewer. There is no better way to get a good idea of what the review process is like that offering to be a reviewer. Not sure how to be a reviewer? Email us at SEEDinfo@nih.gov with your CV and we can help pass your name to the Center for Scientific Review.

I wanted to put some quotes from actual entrepreneurs who have successfully navigated the process. It's really important to hear from people who have been there. Who have gone through the journey and may have gotten some difficult reviews and persisted. I think that both of these individuals will tell you that they were able to take the feedback, take that criticism, correct what needs correcting as was indicated and resubmitting. Dr. Carter is actually, she has been a reviewer before and she will even tell you, she has said this on several panels, even she has to resubmit and go through the process. It is important to know that persistence is key.

Another myth, novice applicants to the program are almost never successful at getting an award. I have to tell you that that is not true. 25% of all of our SBIR and STTR awards last year went to new investigators. We strongly encourage new applicants, particularly from underrepresented innovators or parts of the country that normally have a lower number of SBIRs and STTRs. We do have an Applicant Assistance Program. Not all Institutes and Centers

participate but a number of them do. If you have never had received a SBIR or STTR from NIH, I encourage you to look at that Applicant Assistance Program. Again, while NCI is the one with the website, other Institutes participate. I encourage you to look at the program and they can help you with that submission process.

I want to talk a little bit about our fairly new office, SEED, Small business Education and Entrepreneurial Development. Now, you guys know SBIR and STTR is America's seed fund. The SEED office helps support the NIH innovator community through funding with the SBIR program as well as resources to help our innovators make that transition and get things into the hands, get those great innovations into the hands of the patients, clinicians, caregivers, and researchers that need them.

Now, this is a big myth, that the small business programs only provide money. We have to bust that myth with this new SEED office. We provide technical business assistance, education, partnering opportunities and commercialization support to our small business awardees. We do have a number of new programs and new support for awardees, and I do want to touch on these briefly. Specifically, around the technical and business assistance which you can request technical and business assistance in your grant application but there is a centralized service, a centralized technical and business assistance program for those new Phase Is. We also have education through the I-Corps program. We have C3i programs, funding, and support such as the Commercialization and Readiness Pilot program that Rob mentioned, as well as regulatory and development, business development consultants and partnering and investing opportunities.

While I noted you can ask for TABA funding as part of your grant, that is technical and business assistance funding, that is allowed to take advantage of either doing some of those technical and business things that you need to really bring something to market. Many of our new companies or companies that are a little earlier in the product development pipeline do not really know what their next steps are. They don't know what they need on that business side. We have a new needs assessment program that helps businesses identify those product development needs.

The TABA Needs Assessment Program helps validate requests for further TABA funding in the Phase II and helps companies think about what they really need to put into their commercialization plan. You do need to have an award to submit to the needs assessment program, but I encourage you to look at the website and see if the needs assessment program is a good fit for you. I did mention TABA funding. We do allow for companies to ask for technical and business assistance funding within their application. For a Phase I, that is $6,500

per year and Phase II, $50,000 for the whole project. If you have specific questions on that, we do have frequently asked questions on our website around TABA funding and TABA support and we did have a webinar that is on our website specifically focused on TABA and TABA funding.

Beyond TABA, as I noted, we do have innovator support that is outside of the technical and business assistance program. We provide regulatory and business development consultants, entrepreneurs in residence, regulatory and reimbursement experts for our awardees. We also have partnering and investing opportunities. Again, since we recognize that many of our projects will utilize the small business program to get to an inflection point to do further investment and partnering. We really want to make those opportunities, make that available to our companies and so we provide opportunities at different events called the Company Showcase. It used to be across the nation but now it's virtually across the nation but at a number of different conferences and events throughout the year.

With that, I will end and make sure we have plenty of time for questions. I encourage you to get connected, subscribe to our listserv. Follow us on Twitter. Look us up on LinkedIn. Definitely email us if you do have any questions and feel free to read our success stories and you can see the breadth of things we do support. We support of a number of different technologies and we encourage you to come and see the different things we are interested in and submit a grant application. With that, there we go, I would encourage you to ask questions. I am seeing some questions in the chat box. We encourage you to put the questions in the specific Q&A located in Zoom. Zoom has a specific Q&A box which makes it easier for us to track. I will turn it over to Valerie who will help us with the questions and pushing them over for Rob and I to answer.

Q&A Moderator: Valerie Virta
Excellent, Stephanie and Rob, I am going to try to go through these chronologically and we will see how many we can get through.

Question: The first question is, can a small company use any awarded resources to buy equipment?

Stephanie Fertig: Rob, do you want to take that one?

Robert Vinson: I am not sure. Are they saying, would you read that again, I am sorry?

Valerie Virta: It seems to have disappeared.

Stephanie Fertig: I think the question was around equipment and whether or not you can purchase equipment as part of your grant application. You can't As part of the grant you can put equipment cost, supplies, salary, all that can be part of the application. That is part of the budget section. Small business grants do have detailed budget information. You would put a detailed budget description as well as justification for that request.

Question: Is the SBIR transition grant open for applications again this year?

Stephanie Fertig: I will take this one because I know this funding opportunity announcement well. This is the SBIR TT, a specific funding opportunity put out by a couple of different programs at a few different Institutes and Centers. When a program announcement expires, there is an opportunity, and sometimes NIH will reissue that program announcement. We can't talk about a program announcement unless it has already been issued or there is something called an intent to publish. Unless there is an intent to publish or it is active and out there and available to the public, we can't discuss any plans or any potential applications or proposals that will move forward.

Question: Okay. The next question is, what about, if you are a minority or a woman-owned business, how does that affect scoring or funding decisions, and does it help to promote that you are a woman or minority-owned business?

Stephanie Fertig: We encourage women and minority-owned businesses to apply. We are very interested in having a diverse perspective and companies come to the program. You do not get a scoring benefit for identifying as a woman-owned or a socially or economically disadvantaged business. NIH changed its policy on how we identified women owned or socially or economically disadvantaged businesses. While we used to have individuals identify in the application itself, there were two checkboxes and you would check one, you no longer do that. We actually pull the information from your SAM registration. We do that because we want to make sure that the information was not visible to the peer reviewers. We utilize the program for tracking, we utilize the designation for tracking purposes which helps us with our planning a better understanding to make sure we are doing the appropriate outreach and making sure that we are out there and speaking to all the individuals across the country. There is no specific benefit from a scoring perspective, but we do encourage you to appropriately self-identify in SAM. Again, the Applicant Assistance Program, one of its goals is to increase participation by those who have historically underrepresented in the program. If you are a new applicant who has never applied before or never received a NIH SBIR or STTR, I encourage you to look at that program.

Question: Thank you, Stephanie. How do we tell which institutions offer Phase IIB and/or commercial readiness pilot programs, and how do we tell what the funding levels would be for those?

Robert Vinson: The best way, Valerie, for an individual to determine that, is to contact the Institute itself or the Center itself and talk with the program official. We could help you get to that particular institute or program official by contacting the SEED office if you are not sure which Institute to reach out to. It is important to understand that not all Institutes participate in particular programs. It is best to reach out to us prior to making the assumption or thinking that a set Institute does participate.

Stephanie Fertig: It is also important to remember that, on each program announcement, whether it is CRP or any targeted program announcement, you can see a list of the participating institutions right up at the top. I know there are three CRP program announcements, they do have varying funding levels and amounts. You can go into the program announcement itself and see what is the allowable budget. With regards to Phase IIB, again, I would also start with the program descriptions. When in doubt, always contact the program officer. Rob is spot on. At the end of the day, when in doubt, contact the program officer. You can look at the descriptions document which has a wealth of information too.

Question: My next question, I have generalized from several questions that touch on this topic, the question is, how do I choose my collaborators, when do I decide to collaborate with someone from academia, and how does this affect whether I choose a SBIR or an STTR grant application?

Robert Vinson: I can tell you that, typically, we do not pair up or match up individuals with collaborators. We do have a system, RePORTER.com, with that, you can look at all of the awards we have funded, it has filters on it so you can break it down by specific areas of research, specific areas of the country, states, and you can start there and determine if this individual who is doing similar research or research that is connected or could be connected to yours, would be someone you would be interested in partnering with. We do not say that you need to go to ABC Corporation to do X, Y, and Z. That's just not something that we do. We can make it known that we'll help you look at specific industries or specific areas of research and you can take it from there. It is not something we normally mix-and-match, companies together.

Stephanie Fertig: I am not a matchmaker in my personal or professional life, but you do have a lot of flexibility with regards to who you ask to be on your team. I put up that specific

information about eligibility and I'm going to roll back, this is why I keep the slides up, because I can use them to chat. When I go back to the SBIR versus STTR slide, which I have, by the time I talk about it, I will not find it. There we go. That whole question of employment, that employment question is really focused on the contact PI. If you have a multi-investigator grant, those other investigators can be, they don't have to follow these specific rules. For example, if you have a SBIR, the primary contact PI has to have primary employment with the small business greater than 50%. However, if there is another investigator, part of a multi-PI application, that other investigator they do not have to be majority with the company. They could be with another university, they could be with another nonprofit, they could be with another company, they could be with any number of places. Again, the primary employment rule, that is again for the contact PI. You do have some flexibility with regards to your team. What's really important is, this is at the time of award. You do not have to have primary employment at the time of application, you just have to be able to meet this at the time of award. You can hire someone as an employee or even say you're going to hire someone as an employee in the application, but you do have the flexibility there to decide what makes the most sense in regards to academic partnering. I hope I answered the question. I see a number of academic partnering questions here so hopefully we helped address that.

Valerie Virta: Yes, there are. I would like to emphasize that this slide is very helpful for trying to figure out how you arrange your collaborators and how that informs your decision of whether or not to apply for the SBIR or STTR grant. So, thank you.

Question: The next question, if you have never submitted a SBIR grant before, does it matter if you try to apply for a Phase I or a Direct to Phase II?

Stephanie Fertig: Good question.

Robert Vinson: Yes, the key thing about applying for a Direct to Phase II is that you need preliminary data to show that you can actually skip the Phase I, the feasibility portion of the program. We also have, not just the Direct to Phase II, but we have the Fast-Track, and that mechanism is very effective because it does combine Phase I and Phase II, you apply once and once you complete the Phase I portion of your project, it is reviewed, a progress report is submitted to the program official, and they say that you have met all the tasks or all of your targets. Milestones excuse me. And you proceed to Phase II. Again, I do not want to harp on this, but these are the type of conversations that are very important to have with a program official because they may think that you do need to submit a Phase I to get into the rhythm of dealing with the federal government, reports, and progress reports and things like that. And then you can go to a Phase II or you may need to submit a Fast-Track. Or they may suggest

Direct to Phase II. It depends on how much information or how much you have already preliminary data that will help make that decision.

Stephanie Fertig: I would like to add, as a program officer, we will make recommendations at the end of the day it will be up to you to how you want to proceed. But, oftentimes when someone is brand-new to the program, the Phase I can be easier since it is a shorter proposal and does not have the commercialization plan, the Fast-Track is more tricky because there is an expectation of preliminary data even though it is not required. If you're cramming a lot into that application. You are putting a Phase I and a Phase II into the same age limit that the standard Phase II has. You have less space to make a bigger case. Direct to Phase II requires that solid preliminary data. It is dependent, I have seen new applicants come in with a Direct to Phase II and be successful, but it really depends on the project. These are questions for your program officer, 100 percent.

Question: Thank you very much. The next question is about how to write the grant. I will generalize again from a few questions. Essentially, I have a great idea for a health intervention, but I have never written a grant. How do I find resources on preparing my grant application?

Stephanie Fertig: I will flip to the resources, but you can speak while I do that, Rob.

Robert Vinson: Again, you want to make sure that you start early in the process. I know, for individuals who have never written a grant before, we have a list of links and resources that will literally walk you through the process. You want to make sure that, like I said, you start on time, you submit your registrations in a timely fashion, the worst thing that most people do who are new to the program is that they wait until the last week or last month prior to submitting or starting the application process. Even now, you have 32 days before September 7th submission date. It will be tight if you have not already started. The main thing you want to do is give yourself enough time to write a decent application or write your best application the first time out, even though you may have to resubmit. Take advantage of these sample applications that we have. Take advantage of the ASSIST program that walks you through the process and if you have information in a block that is not correct, or if you skip something, it will let you know right then and there and keep you from going further. To me, that is the best advice you can have. I would not suggest, I hear it all the time, should I get somebody, a professional grant writer? I don't think that is necessary. You are intelligent enough to put this research together or intelligent enough to follow our very basic instructions on submitting the application. By all means, you can, but we do not suggest that you do that if you don't have to.

Stephanie Fertig: I think it really depends. For those who know me know that I refer to this whole enterprise a lot, I reference home-improvement a lot when talking about scientific grants. Putting together, it is a little like home improvement, sometimes you hire a contractor to help you with different components of doing basic home improvements, sometimes you want to change out the light fixture yourself and sometimes you want to hire someone. It really does depend. Some people feel more comfortable having someone, that is great, some people feel more comfortable doing it themselves. It's important to note that grant writers will not write the scientific portion for you but what they can help you with, oftentimes the best they can do is help you through the overarching process. Now, some grant writers may help put together that research component, but, at the end of the day, you will have to be the one that goes through and makes sure that it is accurate and appropriate. They will not do all the work for you, even the best grant writer will not do that. For many people, they find them very helpful, and it is a personal decision. I will state that, again, the Applicant Assistance Program for those who are brand-new, is a great service that the NIH does provide, and you can apply and request to be a part of the program if your area falls under one of the Institutes or Centers that participates. That is another place to look for help.

Question: Thank you for the answer. The next question builds on this. In my grant application, how much focus do I want to place on science versus my commercialization plan?

Stephanie Fertig: Good question.

Robert Vinson: For a Phase I, you do not have to have commercialization plan. You might want to mention it, but it is not required in your Phase I application.

Stephanie Fertig: You cannot put a commercialization plan in your Phase I. It is much less of a focus.

Robert Vinson: Correct.

Valerie Virta: That is really helpful and helpful for people trying to decide if they should apply for a Phase I or Phase II.

Stephanie Fertig: I want to encourage people to look at the sample applications as well. If you are not sure, that is why the sample application exists, to see how people leave in questions of commercialization and how they put it into their application.

Question: The next question is, I understand that there is contact information for program officers but what if my idea spans different specialties and I'm not sure which program officer to reach out to, what should I do?

Robert Vinson: This is where our office comes into play, the SEED office comes into play if you are not quite sure. There is no harm in reaching out to several at the same time. A lot of the awards that we fund have a primary and secondary Institute listed and there is a lot of collaboration between the Institutes. When you are reaching out or trying to contact, if you are not sure, there is no harm in reaching out to several at the same time.

Question: Thank you. The next question is, when looking at application types, what is the difference between U applications and R applications?

Stephanie Fertig: A U Is cooperative agreement. That means it has more interaction by the NIH. We will be more involved in the grant when it is running versus a standard R designation. U is A cooperative agreement.

Question: The next question, there is another webinar next week about contract solicitations. What will be discussed in that webinar that will not be discussed in this webinar?

Stephanie Fertig: Contract solicitation.

Robert Vinson: It will focus on our contract solicitation. The contract solicitation is once a year also and there is only one submission date. That will be a major difference. Only about a handful of Institutes that will participate in that webinar or be able to participate in the webinar. You will also have the CDC taking part in that or being a part of that. It is enough difference that it will be worth your while to check it out if you're interested or thinking about contract as a mechanism to receive funding from the NIH or CDC.

Stephanie Fertig: You might want to look at the contract solicitation and look at the specific topics and see what you are working on within the specific topics. If it does, I encourage you to tune in. We talked more broadly and focused more on the grant process that there are significant differences with the contract process. I encourage you to reach out as it will be about the contract solicitation but there will be some basics but a lot of it about the contract solicitation and differences and some of the things to consider and you will hear from the specific Institutes and Centers that are involved and about their topics.

Question: Thank you. Essentially, this webinar covers the grant funding mechanism and the one next week covers the contract funding mechanism which leads into my next question, I attended the HHS virtual conference in April, are the information in this webinar in the next webinar, are they different, do they supersede any information we got in the April virtual conference?

Robert Vinson: First of all, thank you for attending the conference, the virtual conference. We wish we could have been there in person. But the information should be the same. We have more updated information as far as our website will be released in the fall, the solicitations are out. And so that will be the difference. The information will be the same other than being more current with our information.

Question: Thank you. The next question is, for the general omnibus solicitation funding, is the funding based on pay lines set by the various NIH Institutions?

Robert Vinson: Yes.

Stephanie Fertig: Yes and no. It is not a yes or no question. I will myth bust that, yes, it's set by the various Institutions, but no, there is not necessarily a pay line. Individual Institutes and Centers do have, may determine who may pay based on a variety of different factors. One of the myths that I hear is that study section makes funding decisions. In study section, reviewers are told that funding is a word they cannot say, and that information they provide is provided to the program staff and to Institute leadership and they take that into consideration and may or may not fund straight down by score. They may do sliding pay, and many of them do.

Question: This is great information, thank you. My next question is, can you apply for a SBIR and STTR grant simultaneously with the same project? How about a Phase I or a Fast-Track Direct to Phase II? Could I apply for all of them to hedge my bets? I simplified the question.

Stephanie Fertig: I understand there is confusion. Because this is a question that comes up a lot that is a great question because we do get that a fair bit. The answer is, unfortunately, no, you do have to pick, you cannot submit an application that is duplicative to the NIH. This is where it is important that the question about submitting to the NIH overall versus submitting to a specific Institute or Center. Since you are submitting to the NIH overall, and CDC overall, you can submit one kind of application. You cannot have duplicative applications that are one going to say NIAID or NINDS but if you submit to the NSF and NIH, because HHS is different than NSF, you could submit those at the same time, but you cannot submit to us at the same time. It is a great question. It is a complicated one. I am glad you asked.

Question: Thank you. I have a couple of questions about clinical trials and human subject research. For ideas including clinical trials, do we need to have a collaborator who is a strong clinician? And at what point would I need to bring them into the process? Do I hire them if I get the money, or should they help me write the grant?

Robert Vinson: Again, I am only speaking from a budgetary or administrative perspective, but I would think that, if you can hire someone, a clinician, from the outset to help you write and prepare the budget or prepare the grant, that has to be a good idea, as opposed to bringing them in afterwards or to be determined. If that is the only way, then sure, fine. But, to me, it would be prudent to have someone, a clinician involved in the writing of the application from the outset as opposed to coming in afterward.

Stephanie Fertig: I think this is a great question. I agree with Rob. I think it is generally good to have a clinician as part of the writing process, even if they are not an employee. Maybe they are a collaborator or partner in the early stages of the grant, and when you transition to doing clinical work, you may bring them on board. Again, the individuals you list in your grant do not have to be employees or they don't have to, you don't have to start paying them at the time of application, it is at the time of award. It may make sense to have a good collaborator and the importance of the team, that is something, when people asked us, what are some of the big mistakes that you see people make, oftentimes it is not having the right team, not bringing in that disease expertise, if you have a platform where you don't have that expertise that the clinician will bring, you will want them to look over that application. I agree with Rob, it is good to have that person involved, even if they are not your employee, just providing that expertise for you.

Question: From the human subject angle, will I need to involve my institutional review board at my research institution in my grant application?

Robert Vinson: Yes.

Stephanie Fertig: Yes, you will. It depends. Obviously, if the work is being done at the research institution. But, obviously, wherever the work is happening, I can see the question. I can see one of the questions that went on by, whether or not we fund animal research, we do, and depending upon where the animal research is occurring, you need to make sure you have the appropriate assurances in place. All of the rules associated with animal work or human subject work, that comes into play with regards to a SBIR or STTR grant. But we still do find both human subjects as well as animal research in our grants.

Robert Vinson: Again, please do not wait until a month out, that process with review boards, they do take some time and, from what I remember, they are scheduled at certain times, maybe once a month, or whatever come at the University, so you may want to start the process earlier or as soon as you realize this is what you are doing, animals or human subjects.

Valerie Virta: Thank you for answering the animal model question because that was going to be the next question. I saw the human questions clustered together and I decided to ask that one first. I am looking through, some of them may be seen a little bit specific in terms, one question we have…

Question: If collaborators are a mix between a profit and nonprofit company, they are asking about specific percentages, but I think the question is understanding what will be required in the grant application in terms of the work requirements and the division of labor.

Stephanie Fertig: I saw questions about the work requirements. All of these are very good questions because it can be, again, there is a lot of information in the slides. I appreciate everybody asking all of the questions today. We are trying to get to as many as possible. I put back up the SBIR versus STTR because it talks about the work requirement and your right, I will state that I did not go into detail with regards to the work requirements. For a SBIR or STTR grant, there are requirements that a certain percentage of the work be done by a company, not by a partnering organization. Whether for-profit or not-for-profit. In the SBIR, a small business can outsource 3% in a Phase I or 50% in a Phase II. With the STTR, a minimum of 40% has to be done in a small business while 30% has to be done by research Institute partner. That means that, really what we are trying to make sure is that the company does a good portion of the work for either the SBIR or STTR. There are some nuances with regards to the work requirement. What is considered outsourcing is a little bit complicated because there are specific kinds of things that are considered to be for service. If you have questions about your specific situation. I found, as a program officer, those can change, what is considered outsources, these are things you can ask the program officer about. They can help walk you through how best to think about what is done within the grant and outside of the grant. I would encourage you to reach out to your program officer if you have questions around the work requirements and are not sure if you will meet the core requirements. Don't immediately say that you should not apply, there may be flexibility. There are things that people do not consider. I would encourage you to reach out to a program officer and they can assist you in talking through what makes the most sense for your grant application. It is complicated, really, it is.

Valerie Virta: That is why it is so important to start a dialogue with the relevant program officers early and throughout the application process.

Question: Building on that idea, one question is, if I'm collaborating with the research institution to write a STTR, do I need to include that in context with my program officer?

Stephanie: I don't quite understand that. For blending the research institution and program officer.

Question: Sorry, the question is, say you are writing a STTR application, and you have a research institution as a collaborator, when you are establishing a relationship with the program officer, do you need to include the research institution? Do you need to coordinate the communications with the research institution, or can you manage the relationship on your own?

Stephanie Fertig: You do not have to. Many people do and you can. Here is the important thing to know. This is actually the bigger and most important thing, the NIH, once you apply for a grant, the people that we can talk to are: the investigators, the principal investigators listed on the grant, investigator or investigator's, the business official from the company, and that is it. If the CEO of the company is not one of those people, we cannot talk to them about the grant. Similarly, if you are part of an academic institution and partnering with a company and you are not the PI or the business official, we cannot talk to you about the grant as you are considered a sub awardee. Make sure that communication across parties is set because that is very important.

Robert Vinson: In addition, it is your responsibility to manage or control or handle the relationship between you and the sub awardee or the subcontractor. We do not, as the NIH, as an agency, we do not get into that relationship as far as making sure things are going swimmingly or if there is a problem. That is your responsibility to handle or manage that relationship.

Valerie Virta: We have some questions around percentage of ownership. Of the business associated with the PI applying for the grant. Those questions center around citizenship. And also stakes by venture capitalists.
Question: One question is, how important it is, does the person, percent ownership apply to SBIR and STTR?

Stephanie Fertig: Yes, the eligibility criteria you see here apply to both STTR and SBIR. With the exception of, and this is important, the individual ownership is the one we get the most questions on and I bet that is the other question you got. A company can be either owned greater than 50% by individuals, or owned 50% by other business concerns that fall under that category that are SBIR or STTR eligible. For SBIRs, there is a third option - and that is the multiple investing company. Those three you see under individual ownership are not an AND, they are an OR. You can either be owned by individuals, owned by a company that is SBIR eligible, OR for SBIR only, there is an option for multiple venture capital ownership. Those are the OR.

Valerie Virta: Thank you, that covers our ownership questions. Scrolling back, we also have some questions around rejections and re-submissions.

Stephanie Fertig: I do have one question and the question you asked, I am trying to remember, it was about, the question about citizenship, and you do need to be, it needs to be owned by U.S. citizens or permanent resident aliens. The principal investigator has to be able to work in the United States. We do get some questions around individuals who are not U.S. citizens. I encourage you to go to our website where there is a wealth of much more detailed information on eligibility, including the SBA eligibility guidance requirement has a lot of information around eligibility of different companies.

Valerie Virta: Thank you for the clarification patient about citizenship requirements because that is one of the questions in percent ownership. We have some questions about rejection and resubmission. I will kind of clump them together again.

Question: We did a resubmission and we thought we answered all the questions, but our score was worse, not better. What can we do about that? Building on that question, how long do we have to resubmit after we get a rejection?

Stephanie Fertig: That is really hard. That was the most difficult call when I was a program officer. Trying to speak with somebody who had resubmitted and trying to review the summary statement and try to figure out how to move forward. A lower score is better, the lower the score, the better the score is. A 10 is the best score and a 90 is the worst score. I think both Rob and I do that, we will say, it is a lower score when you really mean it is a worst score. I will assume you mean you got a worst core, which does happen, reviewers are told to review the application in front of them and not consider the prior score. Things may have changed, and you may have different reviewers. We don't guarantee that the same reviewers are viewing applications. I would encourage you to reach out to your program officer. That is

the time when you can reach out to your program officer and talk to them about your summary statement and figure out the best option to proceed. That is when the program officer is valuable.

Question: This build into a relevant question, I did reach out to my program officer and I asked to discuss my summary statement and they said they did not have anything to add. So what is next for me?

Stephanie Fertig: I think in that situation, if you have a specific question, I would read through the summary statement and, if you are not sure how to best take the summary statement and apply it to changing your grant application, or take the summary statement and, I am not sure how to proceed, I'm trying to decide from X to Y. I don't know your specific situation or program officer, but it was better when I was program officer if they came up with a specific question. If you have a question about the following two things and I'm hoping you can answer or address them. Or based on this feedback from the summary statement, this is what I plan to do in the grant application, and I want to discuss that with you. It's not always just talking about the summary statement but walking through and talking about the specific items. Or, if you have already utilized - you only get two shots on goal, you do get a first submission and a resubmission, at the end of the resubmission, you may want to tell them you need to find out the best way to move forward and to find out the next best options.

Question: The next question is, if I have a patent on my technology, how can I leverage this in my grant application?

Stephanie Fertig: You can mention the patent. You can discuss the patent. It is something the company has. You can reference the patent. It is important to note when a company has a patent, and you can mention that in the application.

Valerie Virta: If you have a patent, don't assume that reviewer will find out about it, you need to mention it in the application?

Robert Vinson: Yes.

Stephanie Fertig: Absolutely. You cannot assume the reviewers know anything. You cannot assume they will know any of your papers or patents.

Question: Another question is around the criteria for the decision-making process. After the study section. How do we know what happens after our proposal is discussed in the summary statement is written?

Stephanie Fertig: That is very Institute and Center specific. Different Institutes and Centers have different processes, internal processes for doing due diligence on the applications and determining what their funding plan will be. In general, if you are in the range of consideration, the program officer will reach out to you with regards to your application and may ask you questions or have you submitted a response to the critiques in the summary statement. When I was a program officer, I would always ask for, how did I put it? I said, "I am giving the applicants and the last word so you can give me a couple of pages and tell me, provide a response to the summary". Different program officers and different Institutes have different ways, different processes. I would encourage you to come if you are in the zone of consideration, you can reach out your program officer and ask if they need anything. You can be proactive. Here is the big thing. Rob, as somebody who worked in grant management, it was always amazing how many times I sent out an email and get no response. I would encourage you to make sure, if you do, sometimes there is a quick turnaround there for some of the items, so be on the lookout for the NIH email and you may want to respond to it. Sometimes it is not your program officer, it may be the grants management specialist or someone working with your program officer who is asking for that information.

Robert Vinson: Please check your spam filter. A lot of our emails will go there. I highly suggest you make sure that you check those spam emails.

Valerie Virta: Okay, thank you. So, skipping around just a little bit, because I do not want to spend too much time in a narrow area,

Question: In terms of physical requirements for a separate space, some people have been working from home during COVID, others have not least space because they're waiting for a grant. How important is it to have a separate physical space to do the work? When you are writing the grant?

Robert Vinson: When you are writing the grant?

Valerie Virta: Yes.

Robert Vinson: That is a tax question as far as being able to deduct a portion of your home for your taxes or as far as a business expense. You don't have to have a physical location until the time of award.

Stephanie Fertig: Yes, I think that is a personal decision in regard to how you run your company prior to the award. But you need to show, in the application, that you have the adequate resources and a place to do the work you are proposing. You do not have to have the lease signed but you should be able to show proof that you can get the last space necessary or get the location and access to resources that you need. You don't need to have those at the time of application, so that is a personal question, at the time of application, but you can show you will have access to those at time of award.

Question: If I get an award, do I get indirect costs as a small business? If I have an academic collaborator, and do they get indirect cost as far as the subcontract?

Stephanie Fertig: All you, Rob.

Robert Vinson: Yes. For Phase I, you can get up to 40% without an agreement already in place. The subcontractor will get their indirect cost rate but is built into the award. So, yes.

Question: Okay, thank you. One question, someone pointed out that they went to the link for the Applicant Assistance Program and the deadline had passed. Are there other future deadlines for the Applicant Assistance Program, and, building on that would it be helpful to speak this situation over with my program officer?

Stephanie Fertig: Always helpful to speak your program officer. Rob and I are laughing because, if we are ever given a choice between, talk to your program officer and not talk to your program officer, we will always go with talk to your program officer, 100%. That said, you are correct, the Applicant Assistance Program have specific deadlines attached the receipt date, and they are not open all the time. They do tend to collect specific; they tend to do applications based on specific receipt dates. That is generally how that program is run.

Robert Vinson: Again, if you are just looking, sorry, but if you are just looking at the Applicant Assistance Program 32 days before submission, that is pushing it. You have to give or allow yourself enough time to submit the best application you possibly can the first time out. Give yourself the time to submit a great application. That means contacting the program officer also but getting into the application assistance program too.

Stephanie Fertig: That is right.

Valerie Virta: One question that has been asked a couple of times. Sorry about this.

Question: One question that people have asked, would it be helpful to write specific names for my grant before I contact my program officer and share those specific goals with the program officer?

Stephanie Fertig: Yes. In fact, it is helpful when you contact us to determine which program officer, even if you just give a brief description of what you're planning to propose, that helps us determine where you will likely be assigned. I will also tell you to not worry about the specific aims being perfect. I have people who were concerned that I would judge the written quality of their specific goals, but I was not looking for that and wanted you to follow the scope of the program and if there were specific programs that were more applicable. Program officers cannot pre-review your application and they cannot preview your specific aims, but what they can do is help make sure that you are not going to, you will not submit a clinical trial to something that is a non-clinical trial option. You will not be asking for a budget that is way outside of what the Institute normally allows. They can help you make sure you follow the parameters.

Robert Vinson: You want talking points when you connect with a program officer. You want to say, have something to bring to the table as far as what you are doing and how you want to do it.

Valerie Virta: Yes, it sounds like having specific aims to discuss can only be helpful on multiple levels.

Question: Are Institutes in Puerto Rico eligible as collaborators for the STTR program?

Robert Vinson: Yes. And we have done a number of roadshows and events in Puerto Rico to try to get more collaboration, to get more applicants, to get more people involved. So, yes!

Question: Thank you. We have some TABA questions, what is the Phase II TABA ceiling?

Stephanie Fertig: $50,000 for the entire project. I knew there would be TABA questions. I know it is complicated and I want you to look at our frequently asked questions on the web about it. If you have additional questions, talk to your program officer. I know it is a

complicated program and if you had not asked questions on TABA, I would have been very surprised. I am glad to see we are getting to those.

Valerie Virta: Here is another one, I will just read this verbatim because it is complicated.

Question: Is there an opportunity to partner with the NIH TABA program to provide regulatory expertise to the STTR or SBIR awardees in order to get their products to market successfully if there is a gap identified in the market area?

Stephanie Fertig: I do get these questions a lot, Rob and I both do, we get this a lot, individuals interested in working with our applicants or individuals interested in becoming a contractor to the NIH, to perform the service. The SBIR and STTR programs and the specific funding opportunities are focused on developing a product, doing the research and development in order to develop the product and the vast majority of cases, unlike some of the other agencies that are out there, we are not the final purchasers. Rob mentioned this at the beginning of the presentation that I think it is worth mentioning that we tend not to be the final purchasers is of the technologies. It is individuals working in the healthcare space that are the final purchasers of the technology or researchers in the biomedical field. That question of partnering with us. If you are interested in providing TABA services to applicants, you are going to have to work with companies, companies can put specific TABA services and their proposals and ask for TABA funding. And they can name who they want to use to perform the services. You can work with those individual companies, we are not matchmakers, you can work with companies and provide those services to them, but, at this time, we don't have contract specifically for services.

Question: Thank you. One more TABA question, can you tell us more about the company showcase portion of the TABA program?

Stephanie Fertig: The company showcase is not part of TABA, and this is a question we get a lot. The TABA program is specific, right now it is the needs assessment program and TABA funding. In addition, our office supports, provides support for awardees using funding, specific funding for this that allows us to provide expertise. Again, some of that EIR and regulatory expertise, as well as supporting companies to go to different showcase events throughout the country. That is not technically part of TABA, that is important, even if you get a TABA needs assessment or ask for TABA funding, you can still participate in the company showcase. That is why I am pointing out it is not part of TABA. But there is a request to be part of the company showcase that is available on the SEED website. We generally open that up. If you have gotten an award, you will generally get an email associated with potentially being part of the

company showcase and taking advantage of those if you are eligible. We do send those out during different periods throughout the year as different showcase events occur. This is why it is equally important, based on what Rob said, equally important, even after the award, to make sure that you are not, no NIH emails are getting caught up in your spam filter, because, not only will we talk to about running and managing or grant, but there may be additional opportunities sent to you and you can miss them if your spam filter is on.

Valerie Virta: That is helpful.

Question: One more TABA question, are transiting costs included in the total budget cap for the grant?

Stephanie Fertig: This is a really good question.

Robert Vinson: Yes.

I would state to you, it depends -- when we talk about caps, it is important to note that individual Institutes and Centers have different budget guidelines. If you are talking about what we report to the SBA, no, it was not part of what we report to the SBA, we report how many things went over the cap, that budget guideline that you see, or cap, that budget guideline on the previous slide. However, individual Institutes and Centers have different budget guidelines. Those could be even less then the SBA guidelines that you saw on the slide deck. It is important to reach out to a specific Institute or Center and talk about your budget. Because they may or may not fund your application at a specific level. Again, even the SBA guidelines, Institutes do not have to fund that amount. They can cut your application for any reason, including that they may not allow for applications above that.

Valerie Virta: Okay. Thank you.

Question: We have more questions about how long does an applicant have to resubmit an application. The answer to that was unclear. Building on that, what is the advantage of resubmitting an application versus submitting a new application?

Stephanie: I will take the resubmitting versus a new application. The resubmission includes that additional page that allows you to respond to the reviewers. So, in a resubmission, you can respond to reviewers and kind of talk a little bit about what you have changed in your application and how you have responded to their concerns. That is really helpful for reviewers because they can look at the review and can kind of go, okay, yes, they have responded to this

concern and thought about it and this is how they want to proceed. That can be helpful when you're actually trying to reviewers

Robert Vinson: The timeframe is three receipt years, 36 months, essentially. That is from the last time you submitted to the next time or the timeframe you have to submit, the timeframe is 36 months.

Stephanie Fertig: And generally, interesting, overall, NIH uses 36 months. If you are wondering, that is for a variety of reasons, that is what we do. With that said, it is always helpful, you can go…. there is some policy documentation on resubmission of applications that I will try to put that in the chat. And that will hopefully provide general guidance on the resubmission process.

Question: How many times can you resubmit your application?

Stephanie Fertig: Once - I joke you get two shots on goal, the initial submission and the resubmission.

Robert Vinson: It is imperative you submit your best obligation possible the first time out. That includes, like we have been saying, speaking with a program official. You can get that under your belt and make sure you are on the right path because there is nothing worse than counting on having a second shot on goal and that may not be the best advice that I would give anyone. The first time out, make it your best application.

Valerie Virta: Thank you. Speaking of first time out, our new investigators,

Question: Are there new investigator awards for SBIR and STTR awards? And is there a higher pay line threshold for new investigators?

Robert Vinson: I think Stephanie covered that as far as, it is like a 25% as far as new or novice investigators. But there is no separate mechanism like the new investigator award for research projects, not from the SBIR.

Stephanie Fertig: Specific Institutes and Centers may have specific programs. When you are talking about the overarching program, we don't have specific, something specific for new applicants but specific Institutes and Centers may take into consideration new applicants when they are determining the funding pay lines. They may have specific program

announcements targeted for transitioning investigators from the academic institutions to a company. Again, I would encourage you to look at your specific Institute and Center and reach out to the program officer as they will know the programs available at their specific institutions.

Valerie Virta: Okay, thank you very much.

Stephanie Fertig: I do see in the comment, I want to jump in, it is important to note that, as a new investigator, you still have to show that you are able to perform the work in the grant application. Again, if you had a situation where the reviewers are calling, looking for the investigator component, that would be something you could talk to a program officer about and see how can I build my team and make sure that there are no gaps for this project. Again, your specific case, it is hard to talk about specific cases and reviewers dinging specific questions, but, overall, these are all good questions to talk with the program officer about.

Valerie Virta: Okay. Let's see. Sort of as a time check, we have a little bit less than 15 minutes left. I wanted to check in with you, are there topics that you noticed we have not covered yet? Because there are still 25 questions and I don't think we will be able to answer them all in the time that we have left. In terms of prioritizing, I see one question that has a concern about reviewer bias.

Question: The question is geared around overcoming reviewer bias but perhaps we should make it more general and ask what is NIH doing to address reviewer bias?

Stephanie Fertig: That is a great question. I would encourage you to take a look at our recent conference. We specifically touched on the specific questions around diversity and inclusion and talked about some of the NIH activities focused on diversity and inclusion. In particular, I would encourage you to take a look at the new UNITE initiative that is the, that is the NIH UNITE initiative, hopefully we can get that in the chat for everyone to take a look at. There is a specific interest in really trying to identify and address structural racism within the NIH supported and greater science community. We are looking at the specific things and taking them seriously. I know that, from a reviewer perspective, we work very hard to… the scientific review officers, work extremely hard to provide a fair and unbiased review.
I know there is guidance, specific guidance to reviewers provided in the specific area. The other thing I would encourage is that we are very interested in making sure that our reviewers reflect the broader United States. We want to make sure that we have diverse individuals participating in the review process. I do encourage you to reach out and ask to be a reviewer as we are happy to have you and are always looking for reviewers. We love to have people

participate. Again, this is something the NIH is taking seriously and something we are looking at. It is one of the reasons we removed the women-owned and socially or economically disadvantaged checkbox from the application as we wanted to make sure we reduced the potential for bias in our reviews. It is something we are taking seriously.

Valerie Virta: Thank you and thank you for sharing a link to the UNITE work that is being done by NIH. I wanted to switch gears about a question on study sessions because we have not addressed them yet.

Questions: The question is, are the study sections, standing rosters, ad hoc, how does that work for how study sections are constructed for reviewing the grants?

Stephanie Fertig: Great question. They are ad hoc for the most part. They are put together for the specific grant applications that we received. I am glad we are touching on study sections. This is an area we should definitely touch on. I would point you to the specific, we had a number of specific sessions on the review process that are available online because we will not be able to cover all of the nuances of the review process in nine minutes. It is unfortunate but we just can't. If you are not sure if your specific question is answered, I encourage you to go there as well.

Valerie Virta: Thank you very much. I was attempting to quickly answer one of the questions by typing, let's see, building on the study section part…

Question: What sort of training does NIH provide to study section reviewers?

Stephanie Fertig: That is a great question.

Robert Vinson: That is a very good question. The best thing to do is contact the Center for scientific review. They can kind of fill you in. I am not sure of any type of specific training they provide --

Stephanie Fertig: They do provide specific training and you can look at the specific review information online. There is frequently asked questions, guidance templates, all of that is online and how to become a reviewer. I will pop that link in the chat as well. This provides you the specific orientation, the resources, we try to make it as transparent as possible so you can see the kinds of things the reviewers are given. I will give you another not so secret. In the bottom of the Omnibus solicitation, the general solicitation, we have the specific questions we ask reviewers under each of those different review criteria. If you want to know what

reviewers are supposed to consider when they're talking about significant approaches, you can see all of those questions in the omnibus. You can see the different questions and what we want them to consider. It is at the bottom. I think sometimes people do not get there, but it is a great, I would read through those because they can be really helpful when you're thinking about your application and what they will be thinking about.

Valerie Virta: Thank you very much. One question I accidentally skipped over, but one other person has echoed, I am at a specific phase in my product development process, this person specifically had completed Phase I clinical trials, but other people will be at other phases during their development processes..

Question: They want to figure out how can they find out more specific funding opportunities for their situation? How can they narrow down the results and where do they go to do that?

Stephanie Fertig: officer is a great place, particularly if you are further down the pipeline to see what could potentially be available to your specific project. The other thing you can do, we do have a page that specifically links to all available funding opportunities and you can look at those specific funding opportunities and some of the later state funding opportunities as well. It is Institute by Institute specific. Very Institute by Institute specific and that is why I am tempted to say, that is a question for the program officer.

Valeri Virta: Great. We have five minutes left and we may only get to a couple more questions.

Question: But one that has not come up yet, who owns the intellectual property that emerges from these SBIR or STTR grants?

Robert Vinson: You do as your company.

Stephanie Vinson: The company does. The STTR and SBIR follows Bob Dole act. Read through it, if you have questions, you should get an intellectual property attorney to discuss your situation because there are specific clauses within the Bayh Dole act, specific rights within rights to intellectual property developed as part of the grant. Again, it is in general, we do not take intellectual property but we do follow the Bayh Dole act, it is a little complicated and I encourage you to read through that and if you have additional questions you can reach out to us or reach out to the SBA. It is always best to have an intellectual property attorney if you have specific questions about your specific case.

Valerie Virta: Thank you very much. With less than five minutes left, I want to help reemphasize that, for further questions, don't hesitate to contact the SEED office. I apologize that we are not able to get to everybody's question, but I want to choose a final question to go out on.

Question: This is about how many hours should I plan to spend on the application process in order to prepare a high-quality submission?

Stephanie Fertig: That is hard.

That is a really hard question - a great question. In part because the last time I was part of an application submission it was not electronic. It has been a couple of years. I would state, and it really does depend on your specific situation, how strong of a writer you believe you are, some individuals just feel stronger in that area than others. I would encourage you; you need to give yourself, not just enough time to go through the whole application process and some of it depends on if you are submitting a Phase I versus a Fast-Track versus Direct to Phase II. You should also give yourself enough time to have people read your application. Have other people read your proposal, I say give it to the most critical person you know, give them a red pen and go to town. You really want somebody who has not been eating, sleeping, and breathing your application, eating and sleeping and breathing your technology, say, do you understand where this is coming from, do you have any questions? Make sure it is understandable. Sometimes you work on something for so long, you fill in the gaps by accident and you will skip over a key point where you are filling it in, and your brain is naturally filling it in, but any other individual may need additional information in order to follow the same logic. I would encourage you to give enough time to have somebody right, read the application and give that feedback to you. I don't know how many hours it takes.

Robert Vinson: I will add to the fact that you want to make sure that you are following some very basic things, like page limits, font sizes, that you are following the directions or instructions in the FOA. Little things like grammatical errors in spelling, things like that, you want to make sure to tighten that up and not have those issues or have those count against you in the application process.

Stephanie Fertig: That is a good point, make sure it is all visible. If someone cannot read your chart, that information is lost. I have been part of many reviews or somebody cannot read a chart, somebody cannot see the figure. They don't understand what is happening here and there was probably valuable information, in many cases there was valuable information in the chart or in the figure but unfortunately the reviewers could not take advantage of it.

Valerie Virta: Thank you very much for the thoughtful answers. It sounds like each person needs to budget their time and how much they will need other people and not just the hours spent writing the application, but the calendar time needed for feedback and for getting information from other people and things like that.

Robert Vinson: Absolutely.

I hope that was a good question to finish on and thank you so much to everyone who attended and for your time and for all of your really great questions. Please reach out to the SEED office with any other questions that you have.

Stephanie Fertig: Thank you everyone for attending.

Robert Vinson: Goodbye.