

# NIH SBIR/STTR Presubmission Update Webinar

## Transcript

### **Betty Royster:**

Hi, everyone thank you for joining. We're about to get started. We have a full house with over 700 people that have already logged in. My name is Betty Royster and I am the NIH SBIR/STTR communications specialist and I'm also going to be the moderator on today's webinar.

You're going hear from Dr. Matthew Portnoy who is the Director of the NIH SBIR and STTR programs. He's going to talk to you today about the recent reauthorization and how that has affected NIH's SBIR and STTR programs as well as important presubmission webinar updates.

We will have a Q and A session at the end where we will try to get to all of your questions. We will do our best to answer them, and we are recording this and will post the webinar recording and the slides on our website at [SBIR.NIH.gov](http://SBIR.NIH.gov). And with that I'll turn it over to Matt.

### **Dr. Matthew Portnoy:**

Thank you very much, Betty. As she said it's our pleasure to be with you here today to have our first webinar. This is the first webinar that NIH has put on and so we are happy to be here today with basically a full house.

In addition to what Betty said about the webinar being recorded and available afterwards, you'll also receive a survey after the webinar and we really would encourage you to provide us feedback so we can continue to bring these to you and improve them and provide the type of content that you need for your SBIR and STTR program.

The agenda for today's webinar is shown here. I'll be discussing a high level overview of the NIH and the SBIR and STTR programs. I'll be discussing some registration and submission requirements for submitting grants to the NIH program. We'll talk about common submission errors and tips to get around them so you can ensure a successful, on time submission. We'll be showing you where you can find all of our SBIR and STTR solicitations and what to look for. And then we will switch gears a little bit and talk about some of the new items we brought online with the recent SBIR and STTR reauthorization. We'll talk about the budget hard caps and updates on that. We'll talk about participation of majority-owned venture capital small businesses in the SBIR program. We'll talk about switching between SBIR and STTR at Phase I or II. And finally, an interest I know that has gotten a lot of attention recently and quite possibly the reason you are here, is that we will discuss the new SBIR Direct Phase II provision and funding opportunity announcement.

I do want to say that this webinar today is not an SBIR 101 type of webinar. We won't be discussing the nuts and bolts of the program or how the programs work in general. If you're looking for that type of content, I would encourage you to go to SBA's website. Let me give it a second. The slide should be turning. I encourage you to go to this website for SBA's listing of webinars they did in the last year. There you will find SBIR basic webinars as well as agency specific webinars, including one we did last year about the nuts and bolts of the NIH, SBIR and STTR program.

And as Betty said, initially this webinar is currently being recorded and will be posted online, probably by next week, on our main homepage, SBIR.NIH.gov, probably near the bottom of it.

And we're just waiting for the slide to turn.

There we go.

So as a high level overview, the Small Business Innovation Research program (SBIR), and Small Business Technology Transfer program (STTR), are two congressionally mandated programs, whereby agencies are required to set aside a certain percentage of their extramural budget to fund grants and contracts to small businesses to engage in Federal research and development with the potential to commercialize the technology.

Currently, in fiscal year 14 the SBIR program is 2.8% of our extramural budget and STTR is 0.4%.

The main difference between the two programs is that STTR requires a cooperation between a small business and a U.S. not-for-profit research institution. Typically a university, but not necessarily.

Additionally, in STTR the principal investigator or PI of the project, may be employed either at the small business or at the not-for-profit research institution, while on SBIR it is required that the PI be employed by the small business.

The SBIR and STTR programs are Federal government wide across 11 agencies. Excuse me.

NIH is the second largest of the agencies involved in the SBIR and STTR programs through the Department of Health and Human Services, and takes up approximately 25% of the program based on dollars.

The National Institutes of Health is a complex organization made up of 27 Institutes and Centers.

And they're shown on the next slide.

These 27 Institutes and Centers are what we call ICs, and are your main point of entry for discussing funding decisions and all things about SBIR and STTR. All of these institutes are ones we will refer you to when we know what the specifics of your project are. And as you will hear soon, and you will hear throughout, we strongly encourage you to contact Program Officers in any of the Institutes where your technology may fit.

Our office, the coordinating office of the SBIR program, sits in the Office of the Director shown at the top of the slide. The mission of the NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life and reduce illness and disability.

Any SBIR or STTR application, be it grant or a contract submitted to NIH, must in some way meet this mission. And also the missions of one of our Institutes or Centers.

And so when you're thinking about submitting to NIH you need to keep in mind that we are focused on improving the public health.

Other agencies as well also, to some extent, overlap with this mission and you might find that the Department of Defense, National Science Foundation and in some cases the Department of Energy, may

accept applications on life science technology depending on what types of topics they're asking for in a given year.

This concludes the general overview of the NIH and the SBIR and STTR programs. Now we'll move on to registration and submission requirements for grants.

At the highest level you will be working with two main systems in order to submit and review your application. Grants.gov and eRA Commons. The process is if we start from left to right, you will find and download funding opportunity announcements, instructions on form packages, and we'll show you where to find those in a moment. You will prepare your application per our instructions and our guidelines. And then the Authorized Organizational Official or AOR also called the business official, also called the Signing Official (SO), will submit the application to us in Grants.gov. And we'll talk about Grants.gov in a moment.

Then the application gets transmitted from Grants.gov to the eRA Commons. eRA Commons is NIH's system that downloads the application and verifies compliance with a variety of system validations of which we'll talk about the most common ones in a moment.

Then the principal investigator, PI or business official, can check the submission status and view in the Commons; and from there with a successfully submitted, error free application, the application moves into our peer review process, which we will not be discussing the peer review process in today's webinar.

It requires registrations in several systems in order to be able to submit an application in the first place. It's a five step registration process. We encourage you to start early. Registration can honestly take six to eight weeks and many of the systems require that you register in the previous system in order to succeed. So if you are thinking about applying to our upcoming deadline on April 7th and you haven't yet started any of these registration processes, feel free to make an attempt, but you are unlikely to be successful in completing the registration in all these systems by the deadline.

It really does take six to eight weeks.

The first step after you have a company and you establish an EIN number from the I.R.S. is to obtain a DUNS number through the DUNS and website website. These are shortened by the bitly links, but you can also Google any of these and find the links as well. And of course these slides will be available to you in about a week after the webinar.

DUNS number - to obtain a DUNS number is free. There is no cost to you or your organization to obtain a DUNS number. Once you have a DUNS number, then you can go to register in the system award management or SAM. SAM is a Federal wide system for both grantee and contracting organizations to register their organization.

Once you have an active SAM registration - and I need to remind you that while you initially create a SAM registration, it must be updated and renewed annually. So please keep an eye on when your SAM registration will expire.

After you have a SAM registration, then your company can register in Grants.gov and eRA Commons simultaneously. You do not need one to do the other.

Grants.gov is a Federal wide portal to find and apply for Federal grant opportunities across all Federal agencies. And NIH uses Grants.gov for its grants processes.

eRA Commons and eRA, I should say, stands for Electronic Research Administration. eRA Commons is an NIH system that allows applicants, grantees and Federal staff to share application and grant information and eRA Commons pulls your applications in from Grants.gov.

The fifth system is the Small Business Administration or SBA company registry shown here. This is a new requirement instituted by the reauthorization last year whereby all companies must register in the registry and attach proof of registration to your application.

In order to register in the SBA Company Registry you only need a DUNS number. You do not need SAM or a Grants.gov or eRA Commons. So you can get to SBA registry relatively quickly, and that particular process is a few minutes.

Other processes can take several business days to a week or more, which is why it ultimately takes six to eight weeks to register.

As I stated, all SBIR and STTR applicants among all Federal agencies are required to register at the SBA company database, registry database, and that's shown here. This applies to all of our SBIR programs, STTR programs, the NIH, CDC, FDA, ACF and all Federal agencies. You are required to attach proof of registration in the Other Project Information, Other Attachments Section of your grant application. Every one of our funding opportunity announcements provides instructions in section 4.2 where we have application instruction on how exactly to fill out the registry and upload your attachment.

There are several help desks available to help you throughout the registration process and the submission process. The eRA Commons help desk is the NIH main help desk. This is your number one go to place to obtain help with registering in any of the systems or with submitting your application.

I will say the eRA Commons can help you with everything but the SBA Company Registry. The SBA can help you with that and we have information on how to contact them.

There's a website where you can go to put in an electronic help desk ticket or you can give them a phone call at the phone number here. The eRA Commons help desk is open Monday to Friday, 7:00 a.m. to 8:00 p.m. and these are the folks you want to talk to when you have snags on submission, they can help you very much and really help you with a successful submission.

If you're having submission issues and you have errors, and we'll get to those in a minute, and you don't know what to do, these are the folks you call, but you want to make sure you call them in a timely manner before the deadline. We'll come to deadlines in a minute, but the deadline is always April 5th, August 5th, December 5th typically, five p.m. local time of where your company is registered. So you want to make sure you give these folks a call before 5:00 p.m. and get a ticket number so they can help you out in order to prevent a late application.

On the right side, Grants.gov as well has a help desk number and you can see the number there. They're open 24 hours a day, seven days a week, except Federal holidays. They can only help you with registration and general submission that's used with Grants.gov. They cannot help you with the NIH system and they won't be able to help you with DUNS or SAM, but the Commons help desk can help you

with all of those, so the Commons help desk should really be your first go to choice with any questions you have.

So that covers the basic registration and submission requirements. Our SBIR application guide has much more detailed information for you about all of these steps and so that is also a good resource for you.

We will next move on to common submission errors and steps for your grant submissions. So at this point, I want to define what I mean by errors and warnings. So it's important to know that corrective submissions must be made before the submission deadline, and any application you send in to fix an error with a change corrected application overwrites your previous submission. And we do not have access to your previous submission. We only have the latest one you send in.

There are two types of indicators you will get from eRA Commons when you submit. Errors and warnings.

Errors stop your application cold. It stops it and it does not move forward and you must correct errors and then resend in your application through a change corrective application and work to clear all of the errors. This is where the help desk can be very helpful.

You must do this before the submission deadline.

You might also see warnings. Warnings do not stop your application process, however you do have the option to correct them if you want to. If you choose to correct them, they must be done before the deadline, 5:00 p.m. deadline on submission day.

Warnings will not stop your application. It will not affect the peer review or the funding decision of your application, but it's just for your information.

So if you're there very close to the end of the deadline and you see warnings, please let them go and allow your submission to proceed.

I will also say that the company registry, if you do not include the SBA company registry attachment, you will only get a warning. You will not get an error. The warning will not stop your application. And if needed, we can come and get the SBA company registry after the fact if you're going to be funded, although do attempt to try to get it in there in the first place.

Now we're going to talk about common submission errors. The top five most common submission errors we see for SBIR and STTR submissions account for approximately 80% of the total errors. So if you take a look at these errors on the next few slides and work to get the information in there correctly upfront, you really can greatly increase your chance of having successful submission the first time.

The most common error number one is that on the budget page, each senior and key personnel must be listed [and you] must include a value for effort of greater than zero, and it must be in calendar months or in academic and summer months. So it is okay to have zero dollars, no salary, but not zero effort. And this is for all key personnel.

So you may have someone working on the grant who is helping you out with some advice, may or may not be working too much, and you want to make them key personnel, that's fine, and you can list them as having no salary drawn from the grant, but you have to give them some minimum level of effort. And

then describe in the budget justification where the source of their salary is going to be for that portion of the grant.

Most common error number two is that all application attachments must be in PDF format, portable document format. You have to use simple PDF formatted files. The system does not accept Word files or any other type of file attachment other than PDF.

You need to keep it very simple. Do not use portfolio or any other similar feature to bundle multiple files into a single PDF. You want to also disable all of the security features such as password protection. Just generate a simple PDF, using adobe reader or adobe acrobat or other similar software. You need to keep your file names to 50 characters or less and only use only letters, numbers, underscores, hyphens, spaces and periods. Any other type of special character in the file name will cause an error.

Make sure you use meaningful file names so that you and the reviewers will understand what the file is because the file names are used to create the bookmarking for your application.

Do not include headers or footers within the files you convert into PDF, although within your main sections we encourage you to use headings as part of the body of the text, such as having specific aim section, background section and significant section, but do not put these into the header or the footer of the file.

Also, please follow guidelines for fonts and margins. So within your application instructions if you do a control F and search for fonts or page limits or margins, you will find the guidelines as well as at the bottom we've given you a resource to look up the PDF guidelines for all NIH electronic submissions.

Most common error number 3 is that the eRA Commons username must be supplied in the credential field and all senior key personnel who are listed.

If that field is not starred it, is not required for all Federal agencies because the forms you fill out for grants are used by all Federal agencies, but NIH requires the credential field. It's listed that way in our application instructions and in the annotated forms. You need to make sure you put the PI and their eRA Commons username in the credential field. If you're doing a multiple PI application, also for any other PI listed in your key personnel, you need to provide the credential as well and select PD/PI under the project role for them.

If you don't do this, this will again trigger an error.

Most common error number 4 is that you need to list the organization name for all senior and key personnel listed in the application. For the principal investigator, the organization name will be auto populated from the cover sheet, however, for any other senior key personnel you need to list the organization name and if not this will trigger an error. Again, the organization name is not starred, so it's not required by all Federal agencies who use this form, but it is required by NIH and our application instructions indicate this.

Lastly the number five most common error is about using the Federal Identifier which is in box 4A on the SF 424 R&R cover page. So this is shown on this slide.

Federal Identifier box 4A. If box 1, which is on the left, is application, and Box 8 at the bottom left is new, this is what you will be collecting for Phase I's for fast tracks and for our new Direct Phase II which

we'll come to in a minute, and then leave Federal Identifier blank. If you have to fix errors or warnings and box 1 is change to corrected and box 8 equals new, then in box.

Box 4A you want to enter the Grants.gov tracking number. This is an eight or nine digit number only and there are no letters in it.

The last case is if you are doing a resubmission for what we call an A1 or you're applying for a Phase II or Phase IIB and you have a prior NIH grant number, then you will use the NIH Institute Code and serial number. So while you may be aware that full grant numbers go something like 1R43CA 98764 01, in the box you would only put the two letter Institute code, CA, and the six digit serial number, 987654. We describe how to do this in your application guide, and if this particular box isn't filled in correctly this also triggers an error. And those sum up our most common top five errors that account for 80% of our errors.

And so I stated this a little bit early on, but I want to reiterate it here and you will see this throughout the remainder of the webinar. The most important piece of advice that we can offer you is to talk to an NIH Program Officer about your application and please be sure to submit early.

And by early, I mean days before the deadline and not hours and certainly not minutes. We do have lots of data showing that there are unfortunately a large number of applications that come in literally in the last minute before 5:00 p.m. You can save yourself a lot of time, a lot of heartache and a lot of trouble by just submitting a few days early. This gives you plenty of time to work with the eRA Commons help desk to work out your errors and get everything in safe and secure error free well before the deadline.

All of our solicitations in the bottom section, section 7, always have all of our program officers listed that are responsible for that solicitation. And in the Omnibus solicitation, we have a large table which has all of our Institutes and you can always find a Program Officer to contact on all of our solicitations.

Program officer contacts are also found in your eRA Commons account where you can also find your Program Officer, Science Review Officer and Grants Management Specialist contact.

We also have these posted on our website as well as in our solicitations.

If you don't know who to contact and you're not sure which Institute is right for you, please email us in the central office at [SBIR@od.nih.gov](mailto:SBIR@od.nih.gov) and just talk to us for a few minutes, send us a short abstract of your project and we will refer you to the appropriate Institute or Center for further guidance.

So moving on, on where you can find our SBIR and STTR solicitations where you find them and how you can download them. Our main website for NIH SBIR is [SBIR.nih.gov](http://SBIR.nih.gov). You can also Google NIH SBIR and you will find us. Right below the top of the page that has our news flashes you will see a table that looks like this. This is our main table for all of our funding opportunities.

At the top is where we post our grant Omnibus solicitations. You will see two. One for SBIR and one for STTR. And below that we have also our program topic description document.

Below that we've added just last month a new section to put our pilot SBIR direct Phase II solicitation. Below that, a link that links to all of our other targeted funding opportunities. And I'll show you that in a minute, but we do issue many targeted funding opportunities beyond our Omnibus and I'll show you that in a second.

And at the bottom is where we post our annual contract solicitation. Our annual contract solicitation typically comes out in the summer with the receipt date in the fall. The contract solicitation itself is also posted in FedBizOpps.

But if we go up one and look where we post our other funding opportunities, that particular page looks like this. Where we have a table that lists all of our funding opportunities, including the Omnibus, and we currently have over 60 Institute specific targeted funding opportunities. Some of these will be by one Institute, some will be by several. Some of them will use our standard due dates, which I'll come to in a minute. Some of them will use a custom date. If you look at the top link in here for the RFA you will see it has custom dates. Within every single funding opportunity it also lists the dates.

Additionally, we cross post all of our funding grant and contract funding opportunities on the SBA's main SBIR website, SBIR.gov and you will find a link back to the solicitation. NIH uses three standard due dates throughout the calendar year, April 5, August 5 and December 5.

If you are proposing a project that works on AIDS or AIDS related topics, your due dates are one month later, May 7, September 7 and January 7 of the following year. For those of you interested in the upcoming April 5 deadline, because April 5th falls on a Saturday, the deadline will actually be Monday the 7th, five p.m. your local time. Keep in mind that the NIH eRA Commons help desk will not be open on the weekend, but they will be open of course Monday to Friday.

So our office gets many types of questions along the lines [of what's] shown on the next slide. Applicants would like to know which funding opportunity announcement, which solicitation is best for them. Should they apply for the Omnibus? Should they apply for one of the targeted funding opportunities, should they apply for an RFA? We also get questions like should I apply for SBIR, should I apply for STTR? What's the main difference? What is better? Should I play for a Phase I or fast track or this direct Phase II, should I apply for that?

The main piece of advice we can give you on all of these questions is we can certainly provide general advice, but you really want to speak to an NIH Program Officer in one of our Institutes and we are happy to provide the contact information and refer you to them.

Since the Institutes make all the funding decisions, and have all of the authority to make the awards they'll be your best source of advice on what is the best route for you and your technology.

So now we've kind of covered a lot of basics about registration, submission errors, finding our solicitations and talking to us. I now want to switch gears and talk about the Reauthorization and some of the provisions we've implemented in the past year, and as recently as a month ago that are new flexibilities and opportunities available to you.

And I'm going to go through them one at a time, starting with the budget hard caps. So as many of you may have heard or understand, the guidelines for the grants in Phase I is 150 thousand dollars. In Phase II is one million dollars. The Reauthorization allows applicants and agencies to make awards up to 50% above that. So what we call now is a hard cap is \$225,000 total cost for Phase I and \$1.5 million for Phase II - total cost and this includes all years of the project. So a two year Phase II is \$1.5 million.

However, agencies can get the authority and apply to SBA for a waiver for certain topics to make awards over these amounts where appropriate and where the science dictates it. And it is our role as NIH and the agencies, not you as the applicant, to apply for this waiver from SBA.

And so I'm happy to tell you we have done so. We've applied to SBA and received a waiver for an approved topics list which allows us and the agency to make awards for projects in excess of these hard caps as long as the project topic is on this list.

This topics approved list is posted in our regular topics list in Appendix A. So if you go to our main topics doc, which if you have seen it before, you know it's about 150 pages. And it includes topics of interest for all of our Institutes and Centers. This year there's an appendix that has around 30 pages of topics which the SBA has approved for budgets over the hard cap.

And so we encourage you to take a look at this.

Now, this approval that we've gotten from the SBA is good for any topic on the list that you apply for using the Omnibus SBIR and STTR solicitations, and any FOA that we issue. So any of the 60 that we have, as long as the topic is on the list it's okay, including the Direct Phase II FOA, the topics are approved for that as well. And we will update this award list annually and we get it approved by the SBA.

Now, even though you may look at this list and you see definitely and clearly see a topic that you know you're going to be working on, we still strongly encourage you to contact a Program Officer to discuss your application, especially if your budget is going to be over the hard caps. You definitely want to make sure to get advice on if the Institute is interested in the application in that area, and interested in an application over the hard caps and if they feel it is on the list in order to allow you to submit.

And so that is the hard caps. And we do get a lot of questions on that.

The next item I want to discuss is about venture capital participation in the SBIR program. The slide will turn in a second.

There we go.

So a new authority provided by the Reauthorization allows agencies to opt in to allow small businesses that are majority owned by multiple venture capital operating companies, hedge funds or private equity firms to apply and receive SBIR awards.

So NIH has opted in and opened up last year, if you look at the notice in the middle, this announced our opening up of the SBIR program to majority owned small businesses by multiple venture capital companies.

So as of our August deadline of last year, these types of companies have been able to come in and apply and compete for awards. In order to do so and so that we know that your company is a venture capital backed company, you're required to submit a certification with your application that your company is venture backed and we post instructions in all of our SBIR solicitations and a link to the form on how you fill this out and how to attach it so we can correctly track which companies are VC backed and which are not.

So I want to take a moment here to kind of discuss a scenario, a venture capital scenario and go through it with you so everybody can kind of understand and be on the same page about what we're talking about.

So we have a case where a small business is 54% owned by a single VC company and is 12% owned by another VC. So they are not majority owned by multiple, however one owns more than half.

In the coming months this small business expects to lower their 54% ownership to below 50% by raising some equity or some other type of mechanism. So the question I would pose to you and then I'll answer on the next slide, is this company eligible to apply for the upcoming deadline? So with this particular case the answer is, it will come up in a second, I should say the slides are turning a little bit slower.

So yes, as long as this small business meets the eligibility requirement of being less than 50% owned by a single VC by the time of award, not submission. So eligibility for the program is always determined at time of award.

And if they can demonstrate they are not majority owned by a single VC by time of award, then they can be eligible. However, currently as is, with 54% owned by a single VC, this company is non-eligible at the moment, but could be if they either get a second VC and the ownership is multiple, where each doesn't own more than 50% or they come in below 50%, either way. Our SBIR solicitations since last year have descriptions and definitions of what we mean by a VC firm and what the rules are.

The last question that's part of the scenario is would this company need to fill out a venture capital certification form as is if they are in the case of 54% owned by a single VC. The answer is, as soon as the slide turns.

There we go. No. They don't submit the VC certification form since the company is not majority owned by multiple VC firms. So the general rule is you only fill out a VC certification form with your application if your company is majority owned by more than one, two or more, VC firms, hedge funds and/or private equity firms. However, if our example company or any company goes under 50% owned, then the company would have to reevaluate their equity distribution to see if they are now majority VC owned or if they would fall under the regular eligibility criteria which is greater than 50% owned by U.S. citizens or permanent residents.

Another new feature from the Reauthorization that we implemented with the launch of this year's SBIR/STTR Omnibus is the ability to switch between SBIR and STTR, between the phases. This is something that was not allowed previously, but now is allowed.

With the launch of the Omnibus in January, and for the upcoming deadline and all future deadlines, NIH, SBIR and STTR applicants may now switch at Phase II or Phase IIB to any active SBIR or STTR solicitation and this essentially comes in four flavors. As seen here in the bullets.

Current Phase I STTR awardees may now apply for NIH SBIR or STTR Phase II. Prior to this, they were only allowed to apply to STTR Phase II. They couldn't switch to SBIR. Now they can choose.

The second case is that a Phase I SBIR awardee may now apply for NIH SBIR or STTR Phase II. They were only limited to SBIR before. Now they can switch.

This carries forward from Phase II to IIB. The third case is a Phase II STTR awardee may now apply for an NIH SBIR or STTR Phase IIB, and lastly, a Phase II SBIR awardee may now apply for NIH SBIR or STTR Phase IIB. I do want to make a note about the Phase IIB program that not all of our Institutes and Centers accept Phase IIB applications. You need to look at our Omnibus topics in the front and it talks about which ICs do accept Phase IIB. And as always this is something you definitely want to discuss with a Program Officer.

So some helpful tips when thinking about switching between SBIR and STTR is that you have to follow the program rules of what you want to apply for. This includes where the PI is, the percent effort, the subcontracting, etc.

So for instance, if we have a Phase I STTR awardee and now they want to apply for a Phase II SBIR, well in a Phase I STTR, the PI could be at the university or the small business or proper non-profit research institution. When they apply for Phase II SBIR, the rules are with that program that the PI has to be employed as a small business. So if you're going to switch from one or the other you have to make sure you are following the rules for the program you want to apply for and use the appropriate funding solicitation. If you apply to an STTR solicitation for Phase I, you got a Phase I STTR award and want to switch to SBIR, you have to apply to an SBIR solicitation that accepts Phase II now.

Beyond making sure you use the right solicitation and use and follow the program rules, there are no special instructions or requirements from applicants. You just need to apply to the program you want to apply for. We also posted guidance on this in the notice shown here, NOT-OD-14-048 when we launched the Omnibus and as always you should talk to your Program Officer if you're thinking about switching well in advance of any date so they can give you advice.

And so lastly, we come to discussing the new provision about SBIR Direct Phase II. The Reauthorization allowed a few agencies, one of which is NIH, to offer to applicants the ability to apply directly for a Phase II and skip Phase I.

This is for small businesses that are ready for Phase II development and bypass Phase I, however, the company must have already done essentially a Phase I equivalent or Phase I type work, either develop a prototype, feasibility, concept, done proof of concept in order to move directly to a Phase II under the new solicitation and we will ask you in the Phase II application to describe what you've done to establish feasibility. Essentially provide a Phase I like progress report within your Phase II.

I should also reiterate that the direct Phase II is a pilot by Congress. It is time limited. It is available through fiscal 17 and so we've issued a pilot solicitation a few weeks ago and it's a separate funding opportunity announcement, it's PAR-14-088. You can find it on our main website. You can find it in SBA, SBIR.gov and you can find it if you Google it. This solicitation only accepts Direct Phase II applications. It does not accept regular Phase II's. It does not accept fast tracks. Conversely, our Omnibus and all regular solicitations do not accept Direct Phase II. This solicitation at the moment, and this one only, will accept Direct Phase II solicitations.

Also, not all of our Institutes will accept Direct Phase II's. Only the ones listed in PAR-14-088 will accept. I think we have currently have 18 or 19 out of the 24 that are on there, but you have to make sure you're responsive to an Institute's mission that is on the solicitation.

Also you cannot apply for a Phase II and a Direct Phase II for the same research project.

So the key distinction here is if you have a Phase I award in a technology area, be it at NIH or be it at another agency, you cannot apply for the Direct Phase II to continue that project. But you could apply for a regular Phase II.

Also, all of the Institutes and Centers listed in our Direct Phase II solicitation will accept technology on anything within their mission, with one exception. So this is very much like the Omnibus in that as long as you're proposing something within one of our Institute's missions they will accept it under the Direct Phase II solicitation with the exception of NINDS (National Institute of Neurological Disease and Stroke). They have a few exceptions of things they will not accept under Direct Phase II and the solicitation lists these very explicitly. So certainly for Direct Phase II as with everything, we strongly encourage you to talk to a Program Officer before applying to find out whether the Direct Phase II might be for you.

Lastly on this particular part of the topic, while at the moment we have a single Direct Phase II FOA with most of our Institutes. Some of our Institutes may choose to issue their own separate Direct Phase II FOAs in the future, and if they do, we will post them in all the places I've discussed recently.

Some important tips about the Direct Phase II, the Direct Phase II is not a Phase IIB. A Phase IIB is a second sequential Phase II. This is not. This is an initial Phase II. And so while you could probably get a Direct Phase II and possibly apply for a Phase IIB, a Direct Phase II is not a Phase IIB. Secondly we currently will not allow any applications past the standard due date of December 5th, 2016. This is because the Direct Phase II is a pilot, and we're not allowed to fund awards past the end of fiscal year 17, which is September 30th, 2017. And finally on this topic, the Direct Phase II is only for SBIR. It is not available for STTR and is only for NIH. It is not available for the CDC, the FDA or the ACF SBIR programs. And the reason is relatively simple - this is the way Congress wrote that piece of it in the Reauthorization law. It says NIH and it says SBIR.

If you're interested, I think also DARPA and the Department of Defense is also exercising a Direct Phase II although their solicitation recently closed.

So based on some questions you've sent in before, and since we've launched, we get a lot of questions about how the Direct Phase II is different than a fast track. That's a good question. As you may know a fast track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together as one application, although it uses the Phase II page limit. And we initiated this program 10 years ago as a way to reduce or greatly eliminate the funding gap between Phase I and II, so Direct Phase II is different in that this eliminates the Phase I portion altogether and you can go directly to Phase II. You may have done some work and you're not sure if you should apply for our fast track or you have enough to apply for a Direct Phase II, you basically should talk to your Program Officer at an Institute and get advice on this.

How will these Direct Phase II's be reviewed? So as you may be aware, all of our grant applications go to the NIH center for Scientific Review and most of our SBIR and STTR grant applications are reviewed within small business study sections within CSR or Center for Scientific Review. A small number of our phases are reviewed at the Institute, but most is reviewed at CSR. The Direct Phase II's will also go to CSR and be reviewed in a standard small business study section, and the link shown on this slide is the link where you can view all of the standard SBIR study sections. They will be reviewed in regular SBIR panels alongside standard Phase II applications, Phase I and fast tracks.

However, we will be giving review staff, reviewers and SRO's guidance on the Direct Phase II and what makes it a little bit different than a regular Phase II so the reviewers will have necessary information in order to review Direct Phase II's alongside standard Phase II's.

And so perhaps the biggest question on your mind and our mind for that matter is what does this mean? What are my chances and how many people are going to put in for this? And it really is too early to know. The first deadline that will accept Phase II's is upcoming on April 7<sup>th</sup>, and we won't know the volume of applications we get, how many do well in review, and what the success rate will be until we make funding decisions on these.

I will say within an Institute, these Direct Phase II's will compete with their other SBIR projects in the award pool. They'll be competing against regular Phase II's and fast tracks and the Institutes make their funding decisions based on a number of criteria. One of which is going to be the outcome of the scientific peer review or the score, the summary statement. Another factor is the available budget. Another factor is programmatic priority and balance of Phase I versus Phase II's versus Direct Phase II's. All of these decisions happen within the Institute. And as you may know, within an Institute, success rates can vary depending upon the Institute and the particular volume of applications and their budgets. So we just don't know yet what the volume success rate is for these. We will of course collect that information and have that available once we start to see.

Based on early indications what we've been getting in the central office, I do think there's a lot of interest in the SBIR Direct Phase II, so we will have to see how that goes. And for that matter, [I want] to reiterate it is a pilot. We will see how it goes.

So as we have come to a close of this portion of the webinar, we will open it up for a Q&A relatively soon. If you haven't already, I will just say here, you can ask questions and answers in the chat box that will go to Betty, who is organizing it. And we'll open it up for her to kind of repeat the questions and we'll answer them. We may or may not be able to get to everybody's questions. We know that. There are now over 950 of us on the webinar. And if we don't get to your question, please follow up with us afterwards or send us an email. So to summarize, I think that you can appreciate that because of the Reauthorization and all of the things that we've talked about, the SBIR and STTR programs are getting more flexible. You have more opportunities to be flexible with the program. But necessarily it's also become more complicated, as a result of the Reauthorization. And you also know, agencies are required to increase their percentage of set asides every year for the next couple of years, so we'll be spending more money on the program.

As mandated by Congress, so times are good to provide innovative ideas to develop life science based technology and come into it in a variety of different ways to commercialize your technology.

We have put up a Reauthorization website, that's the link shown on the next slide here. On all of the changes that we've made to the program in response to the Reauthorization. If you have questions, certainly obviously contact your Program Officer or contact us in the central office at the link on the slide or [sbir.nih.gov](http://sbir.nih.gov). I also want to draw your attention to the fact that there are organizations in most of your states, if not all, that are there to exactly provide you with the advice, guidance and resources for SBIR/STTR. These are sometimes called SBDC or (Small Business Development Centers), sometimes they're called Economic Development Corporations. They go on many names, your state may vary, but the link shown there goes to [SBIR.gov](http://SBIR.gov) and SBA with a list of these by state. Some are probably on the

line today for the webinar. Please reach out to these folks, they can really help you out quite a bit. Additionally you can also contact your SBA district office. Before I open it up for questions, I do want to address a few things that we heard about based on what you sent in before the webinar started. You probably noticed we asked you when you registered to let us know if you are a women-owned small business or a small disadvantaged business. I want to spend a moment telling you what they mean, why we asked it, and what we do with that information.

So a women-owned small business is a definition that comes from the SBA. A firm that must be at least 51% owned or controlled by one or more women, primarily managed by one or more women who all must be U.S. citizens. The firm must be small as defined by the SBA, and companies self-certify that they are women-owned when they apply to NIH and frankly every other federal agency. There's a check box on every agency's firm are you a women-owned business, and the link there links to an SBA page.

We did get quite a number of companies telling us they were unsure if they were an SDB. An SDB is a small disadvantaged business, also called a socially and economically disadvantaged business. This used to be called minority owned business, but now the definition has become a bit broader, which is shown here. The firm must be 51% or more owned or controlled by one or more disadvantaged persons, the disadvantaged person must be socially and economically disadvantaged, small by the SBA standards. Business must self-certify by registering your business in the System for Award Management (SAM). Also, they all have a check box as well, usually next to the women-owned check box that's asking if you are an SDB. Your company could be both. It could be either, none, or both. The link at the bottom goes to the SBA website on SDBs, and also has the definition of an economically disadvantage person as well. What do agencies use this for? You will note that we didn't talk about veteran owned small businesses or service disabled veterans owned organizations. We didn't talk about 8A or a H.U.B. zone for that matter. All of those are important designations, however the SBIR act requires us to collect information just on women-owned and socially and economically disadvantaged businesses.

And so we collect this information, solely for tracking purposes. And so we report this information in aggregate to the SBA and to congress every year. And whether you check that you are a women-owned business or a socially economically disadvantaged business does not affect your peer review one way or the other. Does not affect the funding decision. This is used merely for tracking purposes. But a goal of the SBIR and STTR program is to increase participation in the programs by women and disadvantaged persons, so we use some this of type of information to allow us to help coordinate and target outreach to increase participation among groups of businesses of this sort. And you will start to see some more of this coming centrally, both from NIH and centrally coordinated from the SBA. So we strongly encourage you to one, certainly find out if you are a women-owned business or a socially economically disadvantaged and then please fill out those check boxes on our applications. Please do it consistently from application to application. This will help us help you in quite a number of ways.

But I do want to say that while the status of your company in this regard did not affect your funding decisions, does not give you an advantage nor disadvantage in SBIR grants or contracts, of course, these types of designations can help you when you are putting in for federal government service contracts and so there can be advantages in service contracts with the Federal government, just not in SBIR and STTR, it's no tracking purposes only. And so now to close, I want to tell you about a couple of ways in which you can be connected with us and make sure that you are up to date.

Obviously, a lot of you find out about the webinar, we're all happy that you are here, some of you probably find out about it through the listserv. I encourage you to sign up for the SBIR listserv, shown in the first bullet here, very easy to sign up. We don't overly use this. So you are not going to get a lot of spam from us on it. We use it really when we have something very important to tell you. If you want to keep in touch with what is coming out of NIH in terms of funding opportunities, new SBIR solicitations, you want to sign up for the NIH Guide for Grants and Contracts weekly listserv. Also, you want to follow us on twitter @NIHsbir. We use it daily and are slowly and steadily increasing our twitter following. We use this to put out lots of short pieces of information for you. Certainly visit our website, SBIR.NIH.gov. Hopefully by the summer you will see a brand new looking NIH SBIR website that's going to be very snazzy, very intuitive, very user friendly, lots of new features, we will continue to build on that new features for the community in the next year or two. Certainly you can contact us at the central email below.

I do want to give a heads up to save the date. We have as of this week locked up our dates and location for the 16th Annual NIH SBIR/STTR annual conference. It will be this year, October 21 to 23, 2014, in Albuquerque, New Mexico, we are pleased to work with as host the University of New Mexico, Health Sciences Center. So please stay tuned. We will have details to come on our website through twitter and through our listserv when we launch the registration website with much more specific information about the conference and this will be our 16th annual conference. We are looking forward to seeing hopefully as many of you as we can. This conference will allow you three days to come and work with us and learn really about the nuts and bolts of the program and all of the different aspects of the NIH as well.

So finally I want to thank all of the great people I have on my team here in the Office of the Director at NIH working on the program. They are all here working both in front of the scenes and behind the scenes today. Lenka Fedorkova, Robert Vinson, Betty Royster your moderator for the day, and Julie Beaver our new SBIR reporting and statistician.

So now I would like to take the time to open it up to questions. Because it's a webinar, you will have to ask your questions in the chat box and Betty and Rob will do their best to read your questions, we will try to get through as many as we can before 2:30 Eastern Time comes along. Certainly, if we don't get to your questions, feel free to send us an email and we will get back with you as well. With that I'm going to stop, thank you for your attention and then open it up for Betty to come online and do the Q&A portion. Thank you very much.

**Betty Royster:**

Great, thank you, Matt, for a wonderful webinar. We have several questions that have come in and they keep coming in. The first one we wanted to start off with deals with the No. 5 most common submission error. I think there might have been a little bit of static on the phone when you were explaining this, we were wondering if you could go over the scenario that you discussed. About when you would enter a grant number.

**Dr. Matthew Portnoy:**

All right. I'm going to flip back to that slide. There's a little bit of a delay on the webinar. So I'm going to flip back to case No. 5.

This is about filling in the Federal Identifier, box 4a. It's a little complicated, the blue box on the right kind of goes through it. If you are submitting a brand new Phase I, a brand new fast track and brand new Direct Phase II, the first time it stays blank. If you are submitting any of those and you need to correct errors, so then in box 1 on the upper left, you are going to be flipping at the change corrected application, but it's still the first time submission for those, then you are going to put the Grants.gov tracking number, that's the number you will get from Grants.gov. The last case is where you are coming in either as a Phase II, you have a Phase I or you are coming in as a resubmission, which is your second attempt which we didn't discuss today. But you do get two tries to send your application in if it doesn't get funded the first time.

For those cases you are going to put your previous NIH grant number. Just using the two letter Institute Code and the six digit serial number. You will not use the full grant number. That's what usually triggers the error there. I think that's the best way to describe it. If you have questions, ask the eRA Commons help desk. You will be able to help work you through that.

**Betty Royster:**

Great thank you, our next question is can a revised Phase I grant be submitted as a Phase II?

**Dr. Matthew Portnoy:**

So to clarify, I think that question is if someone submitted a Phase I they were not funded, can they now submit that as a Direct Phase II? The answer is yes, they can. You cannot submit a Direct Phase II if you have a Phase I award. But if you submitted a Phase I application, it was not funded and in the meantime you basically have done the equivalent of the Phase I work at the company, you could submit a Direct Phase II. As always, you want to call the program office for guidance.

**Betty Royster:**

Great. The next question is: Does an FDA approved Phase I clinical trial qualify for a Direct Phase II SBIR?

**Dr. Matthew Portnoy:**

So the answer is does a Phase I clinical trial qualify for Direct Phase II? It could. But you want to talk to the Program Officer.

Some, many, but not all Institutes accept clinical trials through the SBIR program. Some don't and have specific clinical trial funding opportunities, even for small businesses. So the answer is, as with many answers, you need to call a Program Officer and get advice at the Institute where the clinical trial would be funded if they recommend a Direct Phase II or another mechanism.

**Betty Royster:**

Do universities subcontractors on the application also need to register with the small business registry?

**Dr. Matthew Portnoy:**

They do not. Only the applicant small business needs to. Also, for the case were a small business is collaborating on a subaward with a second small business, that second small business does not need to register either, only the applicant small business needs to register at the SBA company registry.

**Betty Royster:**

If I'm employed by a university and own a small business, do I need two distinct eRA Commons names for each entity?

**Dr. Matthew Portnoy:**

This is a very good question. And a very common one. So as a PI, no. Any individual only needs one eRA Commons PI account and it will follow you throughout your career from if you have an F31 or F32 pre or post doc, to all the way through to a university or any other organization you might work for. And that PI on the eRA Commons account could have multiple affiliations both with the university and with the small business. However, the small business will need its own organizational eRA Commons account that a small business official at the small business needs to have a separate organizational eRA Commons account for the small business.

**Betty Royster:**

The next question is, for resubmission, which didn't get funded the first time, can you change from fast track to Direct Phase II?

**Dr. Matthew Portnoy:**

The answer is very similar to the last one, the answer is yes. If you have an unfunded fast track, can you apply for Direct Phase II? Yes. You want to call a Program Officer for advice on that.

**Betty Royster:**

If a company is majority owned by multiple venture capitalist firms, does this give the company any strategic advantage?

**Dr. Matthew Portnoy:**

No. It is not included within the peer review process nor the funding process. The projects are evaluated on the scientific merit of the project. We only use the venture capital status to track award dollars.

**Betty Royster:**

Can SBIR Phase II awardees from other federal organizations apply for NIH Phase IIB as long as the specific aim of the project aligns with the mission of the ICs?

**Dr. Matthew Portnoy:**

So this is a good question. When we get it a lot and the answer is yes. If the NIH Institute with whom you would apply for is interested in receiving a Phase IIB. In the case where you have a Phase I or a Phase II from another agency, and you want to apply for Phase II or IIB at the NIH, you have to get buy in from a Program Official ahead of time and they have to accept it, and you do a little internal paperwork within the CSR to make sure that the application can be submitted successfully. But you definitely have to talk to a Program Officer for that in advance.

**Betty Royster:**

Can you apply simultaneously for a Direct Phase II FOA, as well as a Phase I FOA that does not support the pilot program?

**Dr. Matthew Portnoy:**

You could. And if you were successful, you certainly could not accept both. However, if you have already done the feasibility for a Phase I, you really don't need a Phase I grant.

At best you might be looking at a fast track application, so it might be fast track versus Direct Phase II and again that's a Program Official discussion.

**Betty Royster:**

Okay. So this is a bit of a longer question. But with a Direct Phase II, if the work of the Phase I equivalent was done at an academic institution and then the small business licensed the IP, can the new company apply for a Direct Phase II even though technically the company didn't do the feasibility work?

**Dr. Matthew Portnoy:**

That could be allowed. That would be allowed. It will be up to the company to work with the university to sort out licensing and intellectual property.

**Betty Royster:**

Okay. If we have a Phase I that did not receive a Phase II award, submitted twice, can we refocus it from the diabetes to heart disease, for example, and use the Phase I results as feasibility to apply for a Direct Phase II?

**Dr. Matthew Portnoy:**

I think I've got it. This is a case where they have a Phase I award. And they've attempted to get a Phase II twice, and it has not been successful in one or more Institutes. And now they want to refocus it to another Institute and try for a Direct Phase II, essentially skipping the Phase I. It would have to be for a different technology and a new project. If refocusing it to a different disease will in many cases require in some cases starting from scratch or being a different project that could be allowed, but depends on the project has to be [substantially different], it cannot be the same project that has the Phase I and was not successful at Phase II.

**Betty Royster:**

How far into a Phase II can one apply for a Phase IIB?

**Dr. Matthew Portnoy:**

So typically, it's going to be near the end of it. Because as part of a Phase IIB application, you will have to describe what you have done in the Phase II and demonstrate that Phase II is successful and worth continuing. So there's no minimum certainly. Maximum is within two years of the end of the Phase II, but there is typically, I would say most folks apply in the second year of their Phase II, it's something you can also talk with a Program Officer about because certain Institutes have separate Phase IIB solicitations, specifically NCI and NHLBI and NINDS have separate Phase IIB solicitations. The other

Institutes that participate you can apply to from the Omnibus so you can talk about the timing with your Program Officer.

**Betty Royster:**

Great. Can we apply for a Direct Phase II based on data published by others or by one of the applicants but not during their tenure with the current employer?

**Dr. Matthew Portnoy:**

So there's very little advice I can give on this much beyond what has already been said. The law is very vague and it basically says the company has to demonstrate feasibility. I think one would have a very hard time commercializing technology based on published work from other groups because there wouldn't have intellectual property protection. But ultimately the company has to demonstrate the feasibility. And it's relatively agnostic on how that occurs.

**Betty Royster:**

Okay. The PI on an STTR is automatically entered into the main budget page, even though they are a university professor. They belong on the subaward budget. We have been entering zero dollars on the main budget and reentering with correct pay on the subaward. Is this correct?

**Dr. Matthew Portnoy:**

Yes. That is absolutely correct. And that is the way it is for STTRs because of the way the forms work. So when you put the PI on the very, very front page, it auto populates the PI in all of the forms where it belongs. As a consequence it populates the top line of the project budget form, which is the small business with the academic PI. So that is correct. You put zero for dollars and then you relist them on the subaward budget page with the appropriate effort and dollar amount for salary.

**Betty Royster:**

What are the resubmission rules covering the Direct to Phase II applications? Can they resubmit as a Phase I, fast track or another Direct to Phase II?

**Dr. Matthew Portnoy:**

So the Direct Phase II does allow resubmission, and if you are applying for a Direct Phase II and are not funded the first time, you can resubmit the Direct Phase II. If you are going to decide based on the advice of the reviewer that you need to do more feasibility work and you have to kind of switch it to a Phase I that would not be a resubmission. That would be a new Phase I submission because the scope of a Phase I is so much smaller than a Phase II. Conversely, if you were to jump from a Direct Phase II and you were deciding to resubmit as perhaps a fast track, obviously you would have to use a different funding opportunity, that would probably be considered a resubmission because the scope is relatively the same.

**Betty Royster:**

Are SBIRs reviewed by people with business experience and not just academic experience?

**Dr. Matthew Portnoy:**

Yes, they are. As I said earlier, we have special SBIR and STTR review panels, so at the first level these are not reviewed in our standard academic study section, so they are not reviewed alongside R01 and R 21s and etc. In the first review panel, they are reviewed with other SBIRs. The makeup of those panels is both academic folks and industry folks. Typically the PIs on SBIRs and STTRs from the company. And CSR aims to have around 25 to 50% representation on the panel by industry. Now, even the academic folks on the panel are very familiar with the SBIR and STTR programs as they are frequently collaborators with small businesses on an SBIR and STTR. So everybody on those panels has a really full and robust knowledge about the programs.

**Betty Royster:**

Our company recently just went public. Does that affect our ability to apply for SBIR or STTRs?

**Dr. Matthew Portnoy:**

So by and large it doesn't. Public companies are eligible and can be eligible but they have to make sure that they are greater than 50% owned, U.S. owned and operated by U.S. citizens or permanent residents, which when you go public does start to include your shareholders. SBA has guidance at their website about publicly owned companies and how to estimate or rough this out to determine if your public company would still be eligible.

**Betty Royster:**

Should consultants be under the consultant section in the budget or key personnel?

**Dr. Matthew Portnoy:**

So they are not exclusive. So consultants should be listed under the consultant section of the budget form under other direct costs. And it is up to the PI to determine if that consultant is or is not key personnel. An important determination, they could be key personnel, but not necessarily. An important determination is anyone you make and list as Key Personnel, their effort can't change substantially on the grant without prior approval, so plus or minus 25%. You have to get NIH approval to change the effort of someone in the middle of the project period.

**Betty Royster:**

Is SAM the only registration that's annual? For example, do we have to worry about the other registrations also expiring?

**Dr. Matthew Portnoy:**

That's a very good question. And that is correct. SAM is the only one that must be renewed annually, meaning you have to go into SAM and do something to renew your registration. The other DUNS, Grants.gov, Commons and Registry are one time unless you happen to have changes. So if you are a business, changes address or moves to a new location, you will have to go into all of these systems and changes your company's address, etc. But that's only under those circumstances.

**Betty Royster:**

Okay. May the time limit as well as the hard SBIR cap be exceeded if the Program Officer gets SBA approval for an approved topic?

**Dr. Matthew Portnoy:**

So I'm going to answer that in two parts. The time limits on SBIRs and STTRs - six months or one year for Phase I and two years for Phase II, can be exceeded if appropriate, you should always talk with a Program Officer, but agencies and applicants do not need SBA waivers or permission to exceed time limits if it's appropriate for the project.

Budgets, if it's over the hard cap, NIH has already received a waiver with a long list of topics, and if the topic for the project is on that list, then the agency would be okay to make an award over the hard cap. But this is something an applicant, even if they think their topic is on the list, they do want to call a Program Officer to make sure that it's okay.

**Betty Royster:**

Does the switch between SBIR and STTR have to happen during the application for the next phase?

**Dr. Matthew Portnoy:**

By and large, yes. We occasionally administratively switch, but it's very rare. Ultimately we're talking about the next competing phase applicants can switch.

**Betty Royster:**

And this is just a reminder to everyone still on the phone that we will be posting the webinar recording as well as the transcript and slides to our website.

Our next question is: How frank will a Program Officer be if there is really no interest in a company's project?

**Dr. Matthew Portnoy:**

So it depends. I think if you are proposing a project that is not within the mission of the Institute, meaning you kind of got the wrong Institute, they will be very frank with you and say you are not at the right place, why don't you try this Institute. In some cases, they may say the NIH isn't the right place, you want to try another agency. And, the Program Officers are really good folks and they are going to be as frank with you as they can. We can't tell you, a Program Officer can't tell you that you can't apply. You can't do this. We won't accept it. They can give you advice and you can choose to accept the advice or not. But they always give very good advice.

**Betty Royster:**

Can an applicant switch between Phase II STTR to SBIR once the phase II was initiated (ie: for the year two.)

**Dr. Matthew Portnoy:**

So this is a question where the STTR award is out the door and on the street, and can they switch? This is a question and discussion that you want to have with a Program Officer. It would really depend on the circumstances to a very, very large extent.

**Betty Royster:**

We currently have an SBIR Shift Phase I; is there still an SBIR shift Phase II available?

**Dr. Matthew Portnoy:**

So this is in response to one of our funding opportunities that NIAID put out. The shift funding opportunity expired, however, you can take that Phase I award from any of our funding opportunities, regardless and apply to any other appropriate FOA that accepts Phase II, you could apply for the Omnibus in Phase II or there might be a different FOA. I recommend that you call your Phase I Program Officer and see which FOA they recommend for Phase II.

**Betty Royster:**

Great. We're going to combine two questions into one. Talking about does it ever hurt you to self-identify as a woman owned business and on the same note, what are the advantages of registering as a Native American owned business?

**Dr. Matthew Portnoy:**

So the answer is that it never hurts you nor helps you in terms of the peer review process or a funding decision. It's neutral. It's information that we collect to report on statistics of awards in this area. And to the second question, we don't collect information down to the level of Native American owned business. This would probably fall under the socially and economically disadvantaged business, although you can check the website links that I provided to see if that qualifies under there. And this is also would provide neither an advantage nor a disadvantage. It's a tracking, it's for tracking purposes and outreach purposes as well.

**Betty Royster:**

Can you please clarify if a tool for clinical research that requires substantial statistics to convert the tool for diagnostic is in the frame of an SBIR project?

**Dr. Matthew Portnoy;**

The answer is that it could be, and this is a discussion that you want to have with a Program Officer to get their feedback on whether they think that would make an appropriate project and if it's within their mission. I realize I'm not deflecting your answer, but by just always say call a Program Officer, but they are really the ground level NIH staff who manage your projects on a day to day basis. They are in the best position to advise you on specific aspects of science for your technology.

**Betty Royster:**

Great, and on a similar note, is there anything that you cannot talk with your program officer about?

**Dr. Matthew Portnoy;**

So this is a good question because this gets into a little bit about the differences of grants and contracts. So by and large, NIH does grants, but we do do a little bit of contracts, but in terms of grants really no. You can call us and the Program Officer to discuss anything you want. There's no blackout period. You can discuss pre review, post review, they may not have information they can share with you at certain points if nothing is available. But certainly you are not barred from calling a Program Officer at any time.

If you are applying for our contract solicitation, however, that is a little bit different like all contracts at all agencies with the contract, your point of contact that you are allowed to ask any question of is the contracting officer.

**Betty Royster:**

Okay, this person is asking, they have not started the registration process yet. Do you believe that they should try to apply for the April deadline?

**Dr. Matthew Portnoy:**

So I will never tell people not to try. And not to make an attempt. However, the likelihood of being successfully registered in all of these systems, because most of them require the former, and having time to submit days early and clearly address of your errors is not good. Because if you are not registered, you will not be able to submit and you'll get blocked from submitting because let's say your SAM isn't up to date or your Grants.gov isn't up to date or isn't in there. Even if the final system registration happens the day after the deadline and you submit, that's considered late. And while NIH has a late submission policy, and that is listed in our guidance, not starting the registration process early is not an acceptable excuse to allow a late submission. That's typically submitted to illness of the Principal Investigator or members of the family or natural weather disasters.

**Betty Royster:**

Okay. Great, we have time for two more questions.

Do you have a limitation for the PI's percentage of effort?

**Dr. Matthew Portnoy:**

Can you say that again, is there a limitation on the PI's effort?

**Betty Royster:**

Yes.

**Dr. Matthew Portnoy:**

So I'll answer that two ways. On STTR, the PI has a required minimum effort of 10%. There is no maximum effort. SBIR has no minimum requirement nor is there a maximum. PIs need to propose effort on the grant that is appropriate for their effort on the project.

And we see the range. I would say most efforts probably fall within the 20 to 60% range on a project. But it really does run the gamut from the range. And of course it can't be zero because you have to have a greater than zero effort.

**Betty Royster:**

Where can you find the list of preapproved topics for the SBA waiver again?

**Dr. Matthew Portnoy:**

Great. So the topic list can be found, if you go to our main site, SBIR.nih.gov and you find the Omnibus research topics list. So it's posted below the Omnibus grants solicitation on the main site. It's also linked out of within our Omnibus solicitations and I'm pretty sure it may link out from the Direct Phase II, although I'm not entirely sure at the moment. But it is the Appendix of our standard topics document we post every year. So the 2014 topics list, there's a bookmark in it, it's Appendix A, that's where it can be found.

**Betty Royster:**

Great, and this is our last question. Is there any new activity in phase 3 that you support, so the valley of death?

**Dr. Matthew Portnoy:**

Phase 3 is the portion of the SBIR and STTR program where agencies are not allowed to spend SBIR and STTR funds and where some agencies provide phase III awards with their non SBIR funds. As a matter of course and practice, because NIH is not going to be the primary customer or acquirer of your technology, we want your technology at NIH to go into the open marketplace, NIH does not fund Phase III. This is where you would typically go out to find angel investment, venture capital, or strategic partner. We certainly provide technical assistance programs at NIH both through our niche assessment program and our commercialization assistance program, especially for Phase II that can help you work to strengthen the ability for you to find these Phase III resources on your own.

**Betty Royster:**

Great, thank you, Matt. We still have several questions left. But unfortunately we are running out of time. So as Matt said, if you have a question that wasn't answered on today's webinar, please contact your Program Officer or email us at [SBIR@od.nih.gov](mailto:SBIR@od.nih.gov).

**Dr. Matthew Portnoy:**

I will just put up the last slide real quick with that email address on it again. Give it one second to catch up.

All right. Well, thank you.

**Betty Royster:**

Also, we want to remind everyone that you will be receiving a feedback questionnaire tomorrow about the webinar. And we encourage everyone to fill that out. It will be in your follow up GoToWebinar email. Your feedback will help us improve future webinars, and as a final reminder, we want to let you know that the webinar recording will be posted on SBIR.NIH.gov.

And with that, this is the conclusion of the webinar, thank you so much for joining.