

HHS Commercialization Readiness Pilot Program (CRP) Informational Webinar

December 2, 2015

Webinar Transcript

Betty Royster: >> Hi, everyone. Thank you for joining today's HHS Commercialization Readiness Pilot Program (CRP) Informational Webinar. My name is Betty Royster, and I will be your webinar moderator today.

This is a reminder that the slides, transcript, and recording will be posted on sbir.nih.gov (<https://sbir.nih.gov/engage#engage>) in the coming days. We will send a follow-up email to the listserv when they are available online. Today's first speaker is Dr. Matthew Portnoy, the HHS SBIR/STTR program coordinator. With that, I will turn it over to him.

Matthew Portnoy: >> Thank you very much, Betty. And good afternoon everyone, from cloudy and rainy Bethesda, Maryland at the NIH. My name is Matthew Portnoy, and I'm here with Stephanie Fertig to co-present this webinar with you. Stephanie is the SBIR/STTR Program Coordinator from the National Institute of Neurological Disorders and Strokes or NINDS. One of the 24 Institutes that has an SBIR/STTR program.

Today we'll be discussing this brand new program that HHS has called the Commercialization Readiness Pilot Program. We will first be discussing the statutory authority for the program and we'll be referring to it as the CRP throughout the webinar. We will then be discussing the basics of the CRP mechanism and how it works. We'll be discussing a pair of Funding Opportunity Announcements (FOAs) that we issued a short while ago about the CRP. And then we'll be answering some questions that were pre-submitted by you, our webinar attendees, and then we'll have open Q&A at the end. You can send your questions in through the question box on your webinar console. We may or may not be able to get all of your questions. If we can't, certainly feel free to follow up with an email to us afterwards.

And as Betty said, the slides, transcript and recording of this webinar will be posted on sbir.nih.gov within a few days, and we will send an email out to everyone to let them know they're there. The main website for finding the CRP solicitations is shown at the bottom of this slide.

<https://sbir.nih.gov/funding#crp>. The Commercialization Readiness Pilot program statutory authority comes from the SBIR/STTR Reauthorization Act of 2011, shown at the bottom of the slide, Section 5123 of the Act talks about a Commercialization Readiness Pilot program for civilian agencies.

As you may or may not know, a CRP was piloted prior for the Department of Defense. And that Department of Defense CRP program is now a permanent program.

The DOD CRP program, and the program I'm going to describe here today, are very different. So if you are familiar with the Department of Defense CRP program, pay particular attention to the differences here.

According to Statute, with the CRP authority, an agency can spend up to 10% of its agency SBIR program by budget. As you'll hear momentarily, both the NIH and CDC are participating in this CRP, and last Fiscal Year the combined SBIR/STTR program was a little short of \$700 million, so 10% means that we

can spend roughly up to \$70 million for CRP. This is up to - we are not required to spend up to that, but that's our maximum.

The two bullets, A and B, are the statutory description of the types of work that can be funded under the CRP. A) For awards, for technology development, testing, evaluation, and commercial decision assistance for SBIR and STTR Phase II technologies. B) To support the program of research, research and development and commercialization conducted under the SBIR/STTR programs to Phase III.

The statutory authority limits the amount of money we are able to award under the CRP to three times the SBIR Phase II budget guideline.

The current Phase II guideline is \$1 million, therefore a maximum CRP award that we are authorized to give is \$3 million total costs, direct costs, indirect costs and fee in all years.

The guideline is not the hard cap of \$1.5 million. The guideline is \$1 million, so the CRP max is 3 million. I want to emphasize this throughout that the CRP is a PILOT authority provided under the Reauthorization Act and the PILOT authority expires at the end of Fiscal Year, or on 9/30/2017 that is the last date that we as an agency can make a new competing CRP award. Excuse me. Bear with me a little bit. I'm working with a cold today.

So the ability for us to make new awards past this date will depend on either the extension of the pilot or if the pilot is made permanent in the next Reauthorization, which is coming within a few years.

Here are some of the basics about CRP here at HHS. We have issued two CRP grant Funding Opportunity Announcements called FOAs. We released them on November 2nd, 2015. We're going to emphasize this again over and over. It's incredibly important that you read the solicitations and all of the aspects of it. It's a pilot. You will note here and throughout that only some of the NIH and CDC Institutes and Centers are participating. Not all.

And so we have a small handful of Institutes and Centers that are piloting the program. We have two FOA solicitations, some Institutes are on one, some on the other, and some are on both. You have to read very carefully who is on what.

Because it's a new authority, we developed a new activity code for this mechanism called SB1. An activity code is a way in which we identify the type of activity. If you are familiar with SBIR/STTR, the activity code for SBIR is R43 for Phase I, and R44 for Phase II. STTR is R41 for Phase I, or R42 for Phase II. To note that a CRP is neither a Phase I nor a Phase II award. It is also not a Phase III award which is commercialization. Essentially the CRP is somewhere in between Phase II and Phase III, but we will be calling it a CRP award. A CRP applicant and award must be an SBIR eligible small business since we are using SBIR funding to fund the CRP program. Meaning that all of the rules about SBIR companies must be met with the majority owned by U.S. citizens or permanent residences, or owned by another small business that is SBIR eligible, or venture capital companies. The applicant and awardee is still the small business. Additionally, the CRP applicant and awardee must have received an HHS SBIR or STTR Phase II or IIB. A Phase IIB is a second sequential Phase II within the past three years. So it could be a current Phase II or IIB or could be one that was active within the past three years. This means that applicants with Phase IIs from other agencies are not eligible to apply to the HHS CRP program. Additionally, as we'll see in a moment, only Institutes that are participating in the CRP will accept CRP applications from Phase IIs within their Institute. We'll elaborate on that more in a moment.

I want to repeat, the website where you can find the funding solicitations. It's shown here (<https://sbir.nih.gov/funding#crp>). You can get there from the main page, sbir.nih.gov, click on the funding tab on the left and find it, or get through directly through here: <https://sbir.nih.gov/funding#crp>.

There are two solicitations. PAR-16-026 (<http://grants.nih.gov/grants/guide/pa-files/PAR-16-026.html>), and PAR-16-027 (<http://grants.nih.gov/grants/guide/pa-files/PAR-16-027.html>). The links are shown here and are on the website. The first one I'll be talking about is 026 and Stephanie will be taking over and discussing 027 and discussing other aspects of the CRP program in a few moments.

PAR-16-026 is called SBIR/STTR Commercialization Readiness Pilot program, CRP, Technical Assistance.

PAR-16-027 is called Technical Assistance and Late Stage Development. You will see in a moment when we get into specifics there is some overlap in the types of activities that can be funded by each of these and other differences and similarities as well.

For both CRP FOAs, they will use the standard SBIR due dates. These are January 5th, April 5th and September 5th.

These two FOAs will accept applications on those dates in 2016 and January 5th and April 5th, 2017. April 5th, 2017 is the last due date for the CRP. There will not be a September 5th, 2017 due date because the authority expires September 30th. These FOAs expire April 6th, 2017 and all types of applications are due on these dates, including AIDS. There are no separate AIDS dates. Both of these solicitations have an optional letter of intent. A letter of intent is simply a way to inform the agency that you might apply. And letter of intent is optional and it is also not binding. You are not required to submit a letter of intent. And if you do submit a letter of intent, you are not actually required to submit an application.

We use letters of intent to give us a heads up on how many applications may be coming in, and what types of scientific areas they might be in, so we can start to begin to plan the review, which we'll come to in a moment.

The solicitations indicate that letters of intent are due 30 days before each deadline. And letters of intent can be sent by email to the Scientific Review Officer in charge of the review. For both of these FOAs, we have two, Dr. Kristin Kramer and Dr. Gene D. Carstea, but Dr. Kristin Kramer will be receiving the letters of intent and her information is listed in both solicitations in the letter of intent section, both a phone number and an email address. But note letters of intent, again, are optional, not required, nor are they binding.

CRP submission. Applicants can use ASSIST, which is our new electronics submission system or they can continue to use the downloadable forms as with all SBIR solicitations. January 5th is the first date that ASSIST can be used for anything, and if you have questions about the ASSIST program, we did a webinar a month ago about the ASSIST system and you can go to our webinar events page and find that information there.

The Phase II predicate for the CRP could be a Phase II grant or a Phase II contract. If it's a Phase IIB, there will also be a grant since we don't offer Phase IIBs in contracts. CRP awards are all grants.

As I said, you have to be an HHS Phase II or IIB awardee to apply for a CRP. Because of the unique nature of this program, we have very special instructions in our solicitation. We will touch on this a little bit later, but specifically for submission, on the SBIR/STTR info form, if you're familiar with applying under program type, there are two choices, SBIR and STTR. You must check SBIR for the CRP submission, regardless of whether you are Phase II or IIB. Either way just check SBIR.

The next section talks about SBIR/STTR type on this part of the form. It says Phase I, Phase II or Fast track. You are required to check Phase II because CRP awards are follow-on awards for Phase II or IIB, and at this time we don't have a separate CRP button within that box. We are working on that, but it is not there yet.

You then answer the rest of the questions on the form and answer questions 8 and 9, which are specific to the SBIR program. Essentially, treat it like an SBIR grant for the purposes of the SBIR info form.

This slide we'll be talking about some of the similarities and the main differences between a CRP and the SBIR program.

So the small business concern applicants must meet and continue to meet the SBIR company eligibility requirements related to the number of employees, the ownership structure, et cetera.

Like an SBIR, the CRP Principal Investigator must be primarily employed at the small business at the time of the award and during the award. The primary employment, which is defined as greater than half time employment is not related to the effort of the PI on the grant. The PI may have any effort that's appropriate for the grant, less than 50% and that's fine, but the employment must be majority.

Here's the key difference between a CRP and an SBIR. If you are familiar with SBIR, you are aware that there are subcontracting limitations on SBIR. SBIR companies can subcontract out a maximum of up to one third in Phase I, and half in Phase II, calculated as a percentage of budget. We helped conceive the CRP program to allow SBCs to subcontract a substantial portion of its CRP award to third parties, though both consultant and sub-contractual arrangements. In a case where a small business is contracting out to a CRO, this could be done with the majority of the budget. However, the small business must still perform a substantial role in the conduct of the planned research and oversight. They need to provide and demonstrate both in their budget and budget justification they have appropriate oversight of all scientific, programmatic, financial and administrative matters related to the grant. And it cannot merely serve as a conduit of funds to another party or parties. So what this means is that you cannot sub out 100% of the grant. We're not providing specific guidance on a percentage, on a maximum percentage, but there needs to be a certain amount of effort done at the company to oversee the CRP. And a certain amount of money, whether that's 10 or 20% or some other appropriate amount, that's up to you and that will be evaluated both by peer review in the budget section and by program staff and Grants Management staff prior to award.

But the 50% limitation in Phase II SBIR is not here in the CRP. All right, now I'm going to spend a few minutes talking about the first solicitation, PAR 16 026 called Technical Assistance.

What's shown here is from the funding opportunity announcement, and that I just want to draw your attention to the red text which says this type of award will provide additional support for technical assistance not typically supported through Phase II or IIB grants or contracts. This may include preparation of documents for the FDA, development of intellectual property strategy and/or planning

for a clinical trial. Not conducting a clinical trial. That's an important distinction. This solicitation is for technical assistance only. I already see some questions in the box that we'll be addressing. The link is again shown here for this. You can also just Google PAR 16 026 and you will find it. This is the list of Institutes and Centers that are on the solicitation. There are eight NIH Institutes and one CDC Center.

NINDS, NHLBI, NIA, NIAAA, NIBIB, NIDDK, NIEHS, NCATS and the CDC National Center for Chronic Disease Prevention and Health Promotion or NCCDPHP. These Institutes and these Institutes alone will accept CRP submissions. As such, the predicate Phase II or IIB must be from these Institutes. So if your Phase II or IIB is from another federal agency, or from an NIH Institute or CDC component not on this list, then you are not eligible to apply to this CRP solicitation.

I know that's obviously going to be unfortunate for some of you on the line. And not all Institutes are on this. This is a pilot program. And so we are piloting it with some of our Institutes and Centers.

What happens in the future will depend on how the pilot goes. So keep that in mind. Also, you will note when Stephanie gets to the other solicitation, you will see an overlapping, but slightly different list of Institutes.

Budget specifics for PA-16-026.

While the CRP maximum is \$3 million, this solicitation limits total costs to \$300,000 for technical assistance. For the project period, regardless of number of years. The three Institutes below, NHLBI, NIDDK and NIEHS has set limits under the 300 cap, which are up to \$50,000 for NHLBI, NIDDK up to \$150,000 and NIEHS up to \$200,000, the maximum budget period is two years. And so you'll see in a moment why this limitation with the other solicitation that you will hear about goes higher. Types of activities that are supported under this solicitation include, but are not limited to: development of regulatory strategy; designing and planning for a clinical trial; development of an intellectual property strategy; technical assistance often associated with manufacturing and other technical assistance offered through a third party assistance provider, including some types of market research. Essentially what the intent of this solicitation is for the company to bring on a technical consultant or assistance to give them advice they need in various different areas of their project, specific to the needs of their project.

So these are the types of activities that are encouraged under this solicitation.

With that, I'm going to try to go over to Stephanie Fertig from NINDS to take over from here and I'll be back in the end to help moderate the question and answer session. Stephanie?

Stephanie Fertig:

>> Stephanie Fertig: Thank you, Matt. As Matt indicated, we do have two CRPs and the second CRP program announcement is for both technical assistance and late stage development. And, again, we put the purpose of the funding opportunity, the program announcement, up, and as you can see, we've highlighted in red the major differences between either the major components of this CRP and the other CRP.

So this provides additional support for technical assistance and later stage research and development, not typically supported through Phase II or Phase IIB grants or contracts. And this can include

independent replication of key studies, IND enabling studies, clinical studies, et cetera. And we'll go into exactly what it covers in a few minutes.

So if we go to the next slide, apparently there's a slight delay on my end, there we go. This is for technical assistance and late stage research and development. So it covers more than the other CRP. And we have put the link to this specific program announcement here. Now, there are nine NIH Institutes and Centers that are participating. NINDS, NEI, NIA, NIAAA, NIAID, NIAMS, NIDCR, NIDDK and NIMH. As Matt noted, this is a different list than the other program announcement. In order for you to apply to this specific program announcement, you have to currently have or have had a Phase II or Phase IIB from one of these specific Institutes and Centers. If we can go to the next slide.

So we're going to be looking at the budget now. So the budget as Matt noted for this program announcement is much larger than for the other program announcement. We allow for budgets up to \$3 million in total funding support, direct costs, indirect costs and fee for the entire budget period. Now, some Institutes may have different budget guidelines. For example, NIAID says that the budget may not exceed one million total funding support in any year.

NIAMS states that the budget may not exceed \$400,000 total funding support in any year. NIDCR says you can't exceed a million in total funding support in any year. NIDDK doesn't allow you to exceed a million overall, over the entire budget - over the entire project. And for NEI, budgets may not exceed \$500,000 total funding support in any year. So I think this is a great point to again emphasize the importance of contacting your Program Officer, contacting the individuals who are on that program announcement and asking if what you are planning to propose is appropriate for the CRP. Communication with program officials is critical for both of these announcements.

The maximum budget period for this CRP program announcement is three years.

Next slide.

And so what exactly is covered in this program announcement? Well, similar to the other program announcement, you can ask for technical assistance, and we have the same technical assistance activities that were in the prior CRP that Matt read previously is in this program announcement, so I'm not going to go through them in detail. But again it really affords you the ability to work with a technical assistance provider, or a contractor or contract resource organization to give you some of the technical assistance necessary to move your device or your product or your drug to market.

So next slide we're going to discuss the research and development components of what might be allowed through a CRP.

And what you can see here is - this is the first slide of three slides where we gave a lot of examples in the program announcement of what could potentially be included. Now, this isn't meant to be an exhaustive list and, again, this is why it's important to contact program staff prior to applying.

But this program allows you to do some of the later stage research and development activities that you might not normally find in every Phase II or Phase IIB.

For example, you can do independent replication and confirmation of key studies. You can do the activities to ensure compliance with applicable, you know, FDA requirements and good manufacturing practice standards. Everything from, looking at some large animal studies that are GLP compliant and if

you go to the next slide, I'm not going to read every one of these because I think we want to leave plenty of time for questions and this can take a while ... but as you can see, we include, independent replication of key studies, Investigational New Drug other IND enabling studies, looking at process optimization and synthesis, and if we go to the next slide, you can see that it can include optimization of delivery, manufacturing of the clinical trial supplies, and in some cases clinical studies and clinical trials. Now, the clinical studies and clinical trials is an important thing to note for this CRP program announcement.

Not all Institutes who are listed will accept clinical trials through this program announcement. Now, that's clinical trials as defined by the NIH. Which is different from the FDA definition. So it's important that you talk to your Program Official if you are planning to propose human studies as part of your CRP.

Because you want to make sure that the Institute that you are applying through will accept the clinical study that you are proposing. Specifically, NINDS, NIAID, NIDCR, NIAMS, NIMH and NIAAA will not accept clinical trials through the CRP. If you are planning to do a clinical trial again, it's critical that you contact program staff well in advance of your application.

If we can have the next slide, we can talk a little bit about how the CRP differs from your standard SBIR/STTR grant application. If you look at the program announcement, you will see that there's specific section about the application. And there's additional component there that are not in the standard Omnibus solicitation program announcement, or maybe another more standard SBIR program announcement. Now, similar to the standard SBIR, you do need to have the SBA, SBC Registry PDF. You need to have registered with the SBA and you need to provide that PDF document in your application. If your small business is a venture capital owned business, so it's majority owned by multiple venture capital firms, you do need to still provide that certification. Again, exactly like a standard SBIR grant.

The budget is different and as Matt noted, the small business will actually outsource much more of the CRP than in a standard SBIR grant. However, you have to be able to provide appropriate oversight of all scientific, programmatic, financial and administrative matters related to the grant. So, yes, you can outsource the majority of the work here. But you really do need to be providing and, you know, providing that substantive role. In addition, we don't allow the filing fees associated with the file of patents or FDA submissions to be part of the budget. So you can't include those as part of your CRP.

So if we go to the next slide, we can see some of the research plan is also different. And there's some additional instructions for significance, innovation and approach that are part of these applications. The letters of support here are really important and that makes sense if you are outsourcing more of the grant, it's really important to get the letters of support from those individuals who will be performing some of the work.

But there's other components of the significance, innovation and approach that are different as well. It is really important that you read the instructions in the FOA very, very carefully. Again, this is different from a standard SBIR grant. And if you have any questions about those, please contact program staff.

So for the information form, make sure that you read carefully as Matt noted, and make sure that you follow the instructions for the checking the SBIR and Phase II boxes. And there are additional instructions for the commercialization plan as well, not just the research plan. Read through that

carefully. It includes, for example, a fundraising plan so that's an important component that you need to include. Again, answer questions 8 and 9 specific to the SBIR. Next slide.

So a little bit about the peer review of the CRP. And we do today have the Scientific Review Officers who are associated with this program with us, so they'll be able to address questions that you might have about the review. But there will be a special review panel convened by the Center for Scientific Review. As Matt noted, the Scientific Review Officers contacts have changed. And the contact information is now in the program announcement.

The review criteria, which is in Section V of the program announcement, has also been changed and it's specific for the commercialization readiness pilot or the CRP.

Now, that review criteria is critical and I would encourage anyone who is interested in applying to the CRP to read through it very carefully. Those are the questions that reviewers are going to be asking themselves as they read your application. So it's really important that you think about those questions when you are writing your application. Some additional review criteria on the commercialization plan and fundraising plan are located in those specific review criteria. It also includes progress on your Phase II or your Phase IIB, so you should note what progress that you have made to date.

I can't emphasize this enough as we're moving to the next slide, you have to read these program announcements carefully.

So the other thing that I can't emphasize enough, if you take nothing from the presentation today, please talk to your NIH Program Officer about your application. Talk to us well in advance of applying. We can help determine if the CRP is the best program for you, make sure that that's the right place for you to submit, or there might be other programs at the specific Institute that you're, you know, calling that may be a better fit for you. So contact us. We can help guide you through the process.

And submit early. Not in hours and minutes, but days early. You can find the Program Officer contact information on the specific program announcements, on those CRP program announcements, you can also find it at sbir.nih.gov, a great website and a wealth of information. If you are not sure who to contact, the NIH SBIR Office of the Director has an email address, sbir@od.nih.gov. They do answer all of those questions, and can make sure that you get to the appropriate contact.

So we had some questions that were submitted in advance. I'm going to try to go through those now and then we're going to open it up to other questions. As I'm reading these questions that were submitted in advance, if you have additional questions, please ask those questions in the questions box that's on the GoToWebinar console, and we'll try to answer as many of those as we possibly can. One question that we've been getting is: Does the Phase II have to be funded before the CRP application can be submitted? Or another one is do you need to have a Phase II in order to apply for the CRP? And the answer is yes. You have to have either an active Phase II or have had a Phase II in the past 36 months. So you do need to have a Phase II or have had an active Phase II and that CRP is going to be about that Phase II that you either have active or had at one point in the recent past.

So can the Phase II and the CRP be active at the same time?

Yes, it can. This is one of the distinctive differences between the CRP and the Phase IIB. They can be active at the same time, so you can apply for the CRP while your Phase II or Phase IIB is ongoing.

Are the CRP and the Phase IIB mutually exclusive? The answer is no. However, if you have a Phase IIB right now and you are considering applying for a CRP, or you're not sure whether you should apply for the Phase IIB or the CRP, I would encourage you to talk to your Program Official. They can help you make decisions, they can help you with the strategy there and potentially get you information about, you know, the benefits and drawbacks to both of the programs so that you can make an informed decision on how best to proceed.

If I have a Phase II from an NIH Institute/Center or another agency that does not participate, can I come in for a project under an Institute and Center that does? Unfortunately, you cannot. You have to have a Phase II or a Phase IIB with one of the Institutes or Centers that's currently participating.

So you know, right now as Matt indicated, this is a pilot program. And you need to have a Phase II or Phase IIB with one of those participating Institutes and Centers.

Could the CRP be submitted by the same PI, but from a company, also a small business, other than the company that was the recipient of the original Phase II funding? The answer here is yes, actually. You can have a situation where the small business may change between a Phase II and a CRP.

And this can happen if the company either changes significantly or branches off, or has the PI join another company. And it's similar to what can happen between a Phase I and a Phase II. However, this is a complex situation. I would encourage you if you have this kind of situation to talk to program staff before applying. The other company would have to be willing to allow you to do that, allow you to kind of take over the Phase II.

So you really need to talk to us in advance before you apply, if you are in this specific situation.

Would the regulatory assistance and clinical studies needed for the CPT code application be qualified as CRP costs?

And I'm going to bundle that in with the one right under it, which is would the review prioritize FDA regulatory costs over the reimbursement submission costs? So the reimbursement submission costs, while not specifically listed, are allowed. And we're not prioritizing one type of technical assistance over another. But please keep in mind it is technical assistance and this kind of leads into the next question, which is marketing work allowed? Again marketing, if you are looking at say market research or trying to understand what other components of your product may need to reach the appropriate market, that's fine. What we can't cover is sales. We're not going to help you build your sales force or increase sales of your product. So that kind of work, the commercialization itself, Phase III component is not covered here. It is prior to that Phase III commercialization.

Does the CRP follow SBIR policies associated with work in foreign countries?

Yes. It does. Similar to the standard SBIR in a CRP, the work should be done in the United States unless there is a clear justification as to why it cannot be done in the United States. And has to be done overseas. Again, this is something that if you are in this situation, you should definitely contact your Program Official well in advance of applying to see if it is possible for you to do that work overseas and what you would need to do in order to make sure that the appropriate approvals are done in that specific Institute.

And finally, if an Institute, NINDS, NIAAA and NIDDK participates in both FOAs, which one do I apply to?

Well, all three of those Institutes have decided that if they are participating in both FOAs, that if you are asking for only technical assistance, you should come in through the technical assistance only program announcement. However, if you are asking for both technical assistance and late stage research and development, or just late stage research and development, you should come in through that second CRP that I was discussing, which includes both technical assistance and late stage research and development.

And, again, this is another situation where contacts your program official is critical.

And with that, I'm going to pass it back over to Matt, who is going to read through some of the questions that you hopefully have been typing and I have it open and I see a number of questions that have come in, more than several. So let's start answering those.

>> Matthew Portnoy: All right. Thank you very much, Stephanie.

So I'm going to ask Gene and Kristin on the line to unmute themselves and stand ready. We do have a number of questions about review. I'm going to go through some other questions first, and there are a lot of them. We do have some time, but I doubt we'll get to all of them. So I apologize for that and certainly feel free to follow up with us afterwards if your questions aren't answered.

And these are in no particular order, although I'll try to go through in general the order in which they were submitted.

This is a good question. Does the CRP replace or supplement the Phase IIB or Bridge program?

>> Stephanie Fertig: I guess that I can take that. It does not replace the Phase IIB or bridge program. I believe when we're talking about the Bridge program, we're talking about the NCI Bridge Program. So the National Cancer Institute is not participating in the CRP at this time. So if you have a grant with the NCI, you should go through their Bridge program and certainly contact your Program Official. So this is not replacing the Phase IIB program, but can be used in conjunction with the Phase IIB. Again, it's important to contact your Program Official if you have a Phase IIB, and you are thinking about submitting a CRP or you are not sure if you should do a Phase IIB or a CRP.

It's important to talk to us ahead of time about that.

>> Matthew Portnoy: Great, thank you. Stephanie, also you are making a little bit of an echo, maybe I'll answer a question or two, or maybe you can either dial in or switch over to the mic or something.

>> Stephanie Fertig: Okay.

>> Matthew Portnoy: Is the \$3 million a hard cap? Yes, it is. It cannot be exceeded. No waivers. Nothing. It is a hard cap. As also are the limitations that the other Institutes have placed on their programs, so the Institutions that have listed lower limits, those are hard caps for those Institutes. Please keep that in mind. Is there an electronic application package available? There is, go to the FOAs, you will have two buttons to either apply using ASSIST or using downloadable forms, either way you'll be fine.

We got this question a number of times, what about a Fast-track, we have been awarded a Fast-track and we come in for a CRP. The answer is yes, you have to be in the Phase II or completed the Phase II portion of the Fast-track within the past three years. If you are still in the Phase I portion of the Fast-track, do not apply to the CRP until you get to the Phase II portion.

Do you have to complete the Phase II before applying to the CRP, can you apply while still in the middle of Phase II, the answer is yes. You can apply during Phase II, but the Phase II must be awarded.

So some questions about NCI, and questions about other Institutes who aren't on the solicitations. Questions related to will they come on later, why aren't they on, what happens after 2017. So the Institutes all had the options to be on or off, one or the other. And they have a variety of reasons why they chose not to be on or not. And what can you do if they are not on it? You can discuss your grant with them. It's possible that you still can apply for a Phase IIB if you haven't already, and the ability they have the option to sign on within the time remaining, if they choose, and what happens after 2017, it will be up to Congress. The program expires by law after 2017, so it has to be renewed for that.

Can you apply simultaneously apply for a CRP with a Phase II resubmission? Well, the answer is probably no because if you are resubmitting a Phase II you haven't been awarded a Phase II, and you have to have an active or previously awarded Phase II in order to apply for a CRP.

All right. Gene and Kristin are you there?

>> Yeah, we're here.

>> Matthew Portnoy: I'm going to cherry pick out some of the review questions that we got through the list here, okay?

>> Okay.

>> Who will compose the review panel?

>> Okay. The review panel will be made up of the appropriate experts based on the topics covered by the application submitted. There will be a heavy emphasis on reviewers from industry because of the emphasis on commercialization readiness.

>> Matthew Portnoy: Great. We covered this, but we want to address what section will review the proposals, we had another question, will they be reviewed in SBIR panels?

>> They will not. Largely SBIR like, but it will not be a current panel. There will be special emphasis panels that are designed and assembled specifically for this topic.

>> Matthew Portnoy: So they will not be reviewed alongside Phase Is and IIs and Fast-tracks, they will be in their own panel.

>>> That's correct.

>> Do you use external or internal.

>> Always external. Members of the specific community, members of the industrial community. Experts.

>> Matthew Portnoy: Great. Let me just scroll through here. Real quick about review questions.

>> Matt while you're scrolling, I know we are actually hearing an echo now, but one of the questions that I did see is the question of if I was awarded a Fast-track am I eligible? The question here is are you in your Phase II? Is the Phase II component active? A Fast track as some of you may or may not know, is

when the Phase I and the Phase II are all part of the same application. But when it's awarded, we award the Phase I component first, and then it goes through an administrative review instead of the standard peer review between Phase I and Phase II and after that administrative review, the Phase II is awarded. So once you are in the Phase II component of your Fast-track, you then have a Phase II grant and can come in for the CRP.

>> Great, thank you. I just want to note to everybody, we know there's a bit of echoing, the GoToWebinar technical team says there are some audio issues, so hopefully it's nothing that we're doing, but it may be a little bit more system wide, so please bear with us.

I didn't quite see any other review questions, but if we come across them, we will definitely ask them again.

Is assembly of documentation for FDA approval allowed?

>> Assembly of the materials required to get FDA approval is allowed as part of the technical assistance and often it's important to have consultants or others that have worked with the FDA previously to help you get those materials available. So that would all be part of the technical assistance component of the CRP.

>> Matthew Portnoy: Great. Currently, the PI of an STTR award does not need to be employed by the small business. If a CRP award is to follow-on to a Phase II STTR, are you saying that the PI must now be employed by the small business? And the answer is yes. We are. Because we are following SBIR rules using SBIR funds and when we get down to this commercialization stage, really it's the realm of mostly company work.

Can you apply to a different Institute than the one that you receive the Phase II from, say from NINDS to CDC?

>> So as the program announcement is currently written, you are applying for the CRP to the Institute where you got your Phase II (if the Institute allows). You can't, as Matt noted in his example, go from say NINDS to the CDC. And that's because the CRP is linked with the Phase II that you've gotten. So in theory, it should be on the same scope, the same kind of thing that you were doing in the Phase II.

>> Matthew Portnoy: Right. Are these CRPs available if the parent Phase II is a no cost extension, additionally what does it mean by the three years. So certainly, yes, if there's a no cost extension it's fine to apply for the CRP if you are in Phase II. Also, the three years is from the active award, so if the Phase II ended, let's say two years ago, you're fine. If the Phase II ended three years ago, you're fine. If the Phase II ended three years and one day ago, then you're not fine. That's based on your submission date.

What types of marketing plan assistance will be included?

>> Stephanie Fertig: So as we noted, we listed some examples in the program announcement itself and I would encourage you to read through the slides and read through some of those specific examples. And, again, you know, contact program staff if you are concerned that your specific example or what you are thinking about proposing isn't within scope. You can contact us, and we can talk to you about if the CRP is the best fit.

>> Matthew Portnoy: Okay. Great. More questions about switching Institutes, I think we've established that you have to go to the Institute where you got the Phase II from if they're on the CRP.

The caps per Institute are hard caps. We got a few questions about NHLBI on the technical assistance one, the 50k. If you read the solicitation in the budget section you will not see them listed. That is because they issued a Notice a few days after it went out to clarify their budget position of \$50,000 total costs. So near the top of it, there's a link to an NHLBI Notice. Also a link within the slide set that you will have within a day or two indicating that.

>> Stephanie Fertig: That is a correction. So please follow that correction.

>> Matthew Portnoy: That's correct. We already covered our filing fees. The FDA application covered? They are not. Those are unallowable costs at the agency, let alone the CRP. Let me go here. Does the technical assistance manufacturing 027 include costs for technical assistance, automation and scale up?

>> Stephanie Fertig: For the larger commercialization readiness pilot program announcement, we would allow for, you know, potentially allow for manufacturing technical assistance. But the research and development is really supposed to be later stage research and development. So if there's research and development associated with the manufacturing, that would potentially be included.

I don't know if you want to add anything to that, Matt?

>> You know, capital equipment. So that's a challenging situation. I don't think we look favorably upon, you know, a \$3 million equipment request in and of itself. I think there needs to be more to it than that. More R&D to do, more work to do.

>> Stephanie Fertig: But I think there is often research and development, once you get to the point where you are trying to, you know, manufacture, say, a device, it's often very different than what might have been occurring in the lab. If there's specific development or research activities that you need to do in order to appropriately scale up, and get the products to the point of manufacture, that could certainly be included.

>> Matthew Portnoy: Great. Please define the difference between replicating studies and clinical trials for the Institutes who don't support clinical trials.

>> Stephanie Fertig: Ah replicating studies. So what we're talking about there are animal studies potentially that may need to be replicated before you can move to the next step. Now, as many of you know, the NIH is really looking at rigor and reproducibility as a critical thing to look at when you are moving something through the translational process. Often to reproduce something, it has to be done in an independent laboratory. In this situation, given that the CRP allows us to outsource more than within a standard SBIR, it would allow you to get independent replication of your studies so that you can move forward with confidence to the next step in translation.

>> Matthew Portnoy: Great. Does the CRP require matching funds similar to some Institutes Phase IIB programs?

>> Stephanie Fertig: No, it does not. However, obviously if you have matching funds, that would be great to hear. And it does have a fundraising plan component as part of the commercialization plan, so

it's important to have a plan for you to move forward after the CRP, after your Phase II or in your Phase IIB and to really know what the plan is for fundraising after the NIH funding ends.

>> Matthew Portnoy: Great, great. More questions about patent fees. How can you pay for patent fees? How do companies pay for patent fees or filing fees? The company could use its fee for part of that. The fee is an unrestricted type of funding through the company, but they cannot use the direct or indirect costs. Within the CRP awards, it's limited to the fee and other company resources.

>> Stephanie Fertig: Again, just to emphasize the point that Matt made earlier, that \$3 million is a hard cap and it does include the fee. So it's direct, indirect and fees all have to be under \$3 million for that technical assistance and research and development CRP.

>> Matthew Portnoy: Yes, yes. Here's a good one: While clearly beneficial, does this program take away from the funding for a regular SBIR Phase I and II awards? The answer is necessarily yes, we have the authority to use up to 10% of the SBIR set aside. This is at the discretion of the participating Institutes. So they have the authority to spend up to 10% and how much they spend on any one award in total is up to them, so long as they don't go over 10%. Obviously it's, you know, the Institutes, as always, make funding decisions based on the available budget, program balance, scientific merit and balance of the portfolio, Phase Is, versus Fast tracks versus CRPs. This will be at the discretion of the Institute to establish that. But these are important but do come from SBIR set asides, up to 10%.

Here's a very interesting one. How far can you deviate from the original program goals? For example, if my Phase II was for indication A, but the technology also supports indication B, can we propose CRP for development of indication B?

So I would say that the CRP is like a IIB, it is a follow-on to a Phase II for the same project, for the technology, for the same indication. If you've got another indication that you are looking for support for, that would be essentially be in a new proposal at the beginning of the program or perhaps later depending on how you do it.

>> Stephanie Fertig: Also, that would be a great instance, again, to talk to the Program Official, ask them about your specific situation, and ask them what advice they could give, what is the best strategy to move forward.

>> Matthew Portnoy: Great. Do you know why clinical trials are not allowable by many of the funding Institutes under CRP?

>> Stephanie Fertig: Well, I can answer that for NINDS. We have specific program announcements for clinical trials through the SBIR program and actually through our standard R01 program as well, and we allow clinical trials only through those specific program announcements. As the CRP is a pilot, we chose not to write a separate CRP program for clinical trials. So at this time, the CRP for us doesn't cover clinical trials. That said, if you're planning on proposing a clinical trial or you're at the point of a clinical trial and you're at NINDS, I would encourage you to contact me. If you're with one of the other Institutes, contact those other Institutes and in the program announcements several Institutes actually had links to their specific clinical trials program. So look at the program announcement. Go to maybe one of those other programs or contact your Program Official and we can help potentially find another program that will work for you.

>> Matthew Portnoy: Great. A question on dual assignments. If a funded SBIR Phase II has a funding assignment through an Institute not listed in the CRP announcements, but it had a secondary or a dual assignment with an Institute that is on the CRP, could they apply to the CRP? The answer is no.

The only thing that in the end counts is the funding Institute listed on your award. The two letters next to the activity code.

>> Stephanie Fertig: That's the primary assignment.

>> Matthew Portnoy: Primary assignment, that's correct.

Are AIDS related grant proposals allowed? Yes, they are. They come in on the main deadlines of April January, April and September 5th, but it has to be a Phase II from one of the participating Institutes. But we do accept AIDS applications.

Can the CRP fund activities needed to gain the CE mark enabling export to Europe?

>> Stephanie Fertig: The CRP can cover those activities. That said, keep in mind again that where the work occurs, those rules associated with the SBIR still apply. So foreign work is something that is only permitted if it can't be done in the United States. The other thing is, obviously we like to see things approved, treatments approved here in the United States. Although I recognize that for medical devices, often a CE Mark, going to Europe is the first step. So I would encourage you to talk to your Program Official and discuss the plan and what you are planning to propose. I think that's generally a good piece of advice regardless. But technically, yes. You can have that be part of the overall plan, although, you know, certainly we mentioned the FDA specifically in the program announcement. And I would also like to add that since many people are working to maybe go to Europe first, but then are working on approval in the United States, I would encourage you to start talking to the FDA earlier rather than later, as usually some of the tests that you use to get approval in Europe also are required for FDA approval. So you don't want to have to do those twice.

>> Matthew Portnoy: Great. We had a couple of questions about resubmission. Can you resubmit a CRP application, how many times?

>> Stephanie Fertig: Well, it has the same kind of submission policy as any other NIH grant.

>> Matthew Portnoy: That's correct. So you can submit two times. The first time and the resubmission, which we call the A1. Since CRPs are considered renewals of Phase IIs, it really is two times. Are Gene and Kristin still on?

>> Yep, yep, we're on.

>> I'm here.

>> Matthew Portnoy: We have a couple of review questions. Very important questions, especially for this community. Usually about conflicts of interest. So if industry experts are reviewing, how are conflicts of interest avoided?

>> Well, obviously we try to get the experts that match the expertise required by the application. If we identify an expert that is so close with what the interests of the applicant are, we try to identify one that has all of the appropriate expertise, but is not directly a competitor of the applicant.

>> Matthew Portnoy: Right. And it's the same answer for how do you protect a lot of company related confidential info, how do you avoid conflict of interest. Sometimes reviews are from rival companies. I think you answered that quite well.

>> If there's any concerns about the applicants, they should contact the SRO and discuss it with them. Obviously, it's a fine line that we run to try to identify the very, very best reviewers for any given application without crossing that line into identifying direct competitors of that technology.

>> And if somebody knows of a specific individual who they feel is a direct competitor and they are concerned about them being in conflict, can they put that specific individual or that specific company in the cover letter?

>> They can absolutely do that. They can absolutely do that and it would be advantageous if they gave a heads up. They would probably be contacted by the SRO to specifically outline their concerns for their application. We in review have found that sometimes concerns are overly grave. Often, the reviewer that the applicant thinks is most in conflict may actually be the greatest proponent of their technology since they can appreciate it the best. So it certainly is a fine line to try to identify the reviewer that has the best expertise without crossing over into being a direct competitor.

>> Matthew Portnoy: Great. How does one volunteer to be a reviewer from industry for these applications?

>> The reviewer, potential reviewers are welcome to contact the SROs. Directly.

>> Matthew Portnoy: The SRO contact is listed in Section 7 at the bottom of both of those solicitations, very clearly.

Can a company apply for multiple CRP technical assistance awards, one for FDA, one for manufacturing, one on the CE mark. The answer is no. It's going to be one CRP award per Phase II. Or IIB.

>> That said, if a company has more than one Phase II, and would like to apply for a CRP related to a Phase II on one disease and one disorder and a CRP related to a completely different Phase II, that could be allowable. I would encourage you to again contact program staff, but provided they're two separate Phase IIs

>> Matthew Portnoy: Yes, correct. Two separate awards. Yes.

Is there a budget limit for technical assistance under the 027 which is the technical assistance plus late stage with the remainder available for R&D. So is there a 300 k limit for technical assistance on the larger CRP with the difference going to R&D or late stage development.

>> Stephanie Fertig: We did not make that limit. However, when you're putting your budget together, keep in mind it needs to be well justified. And I think looking carefully at your budget and make sure that what you request is reasonable for the activities proposed.

>> Matthew Portnoy: Okay. Great.

If the Phase IIB ended three years ago or less, are you okay to apply? The answer is yes.

Here's a review question, scientists in industry are not always savvy to the various issues that define the net present value of a product - whether it can be commercialized. How do you determine how well

reviewers understand this? Will you be able to recruit marketing experts or other types of expertise as part of the review panel?

>> We will recruit expertise to cover all aspect of the applications. We will definitely be doing reviewer training and in addition to that, as far as making sure there's a good fit, we will do as much as we can in terms of seeing what those reviewers have produced themselves and match them with the application. But we'll also be reading critiques in advance of the review meeting and ensure that they understand the review criteria and are a good fit to review that application.

>> Matthew Portnoy: Great. So another note here, NCI is not listed, is there an equivalent program for NCI, is it the bridge program? So NCI and many programs are not. If you have a Phase II or Phase IIB, maybe a Bridge or IIB or maybe something else, but if they're not on it, they're not on it. They could choose to be on it if they want to later on.

Are GMP drug manufacturing for Phase I clinical trials allowed. I assume under the larger 027 CRP.

>> This is a question about manufacturing clinical study materials. And that is one of the bullets that is allowed. However, you know, again keep in mind not every Institute will accept clinical trials through the CRP.

>> Matthew Portnoy: So this actually leads very well into the next question: Are you making a distinction between clinical study and clinical trials for those Institutes that do not support clinical trials?

>> Stephanie Fertig: So I would read carefully what each Institute indicated in their description, there's specific descriptions for each Institute in that technical assistance and late stage development CRP. I can speak for NINDS that, yes, my language does make a distinction between a clinical study and a clinical trial. The definition of a clinical trial at NIH concerns an intervention, so there has to be an interventional component. The specific definition of clinical trials, if you have a specific question about whether or not what you're doing is a clinical trial, I would encourage you again to reach out to program staff and ask them is this covered. When you say you don't cover clinical trials, is this what you mean? Is this considered a clinical trial?

I would say if you are doing any kind of human subjects work, if you are doing any kind of either clinical study or clinical trial, I would rather have you reach out to the program officials and ask that question. And make sure that you get a clear answer. Because I have found that if I want to pick one of the most frequently asked questions that I get, it is - is this considered a clinical trial. More often than not people don't know where they stand, whether it's or not and vice versa. So please reach out and talk to us ahead of time.

>> Matthew Portnoy: Sorry about that, I was muted.

>> Can the technical assistance for regulatory submission be used for a program at the FDA?

>> Stephanie Fertig: No. Please go ahead.

>> Matthew Portnoy: I mean, I would say since that's a program at another federal agency, the answer is probably going to be no.

>> Stephanie Fertig: I think the real distinction and a quick way to think about it is, if you are getting money from the NIH, to turn around and give to another federal agency, the answer is going to be no.

>> Matthew Portnoy: A couple one or two review questions. Will the roster of potential reviewers be published 30 days ahead like they are for other panels?

>> Yes, they will.

>> Matthew Portnoy: Great, that's all available on CSR's website and in fact the link is usually available within your eRA Commons account to the review information.

Again, we've got people coming in late. All of the slides, recording, including the recording of this Q&A will be posted shortly, hopefully by the end of the week, if not early next week, we will send an email around to everyone about that.

This is a question for review and it was one that you thought might be asked, Gene. What meeting format will be used for the review of these applications? In person, IAM. You can maybe describe each of those, but then go ahead and answer.

>> Certainly. It certainly depends on the number of applications that are associated with these program announcements and we gauge them toward that. It will likely be, seeing the interest here right now, it would be a larger format and if it is a larger format, we would go to a face to face or probably an IAM (Internet Assisted Meeting) one or the other. The larger format would be face to face.

All of the formats that we use here at CSR for review are deemed to be compatible and comparable with each other. People have their own preferences certainly. IAM is Internet Assisted Review where it's essentially reviewers will meet online and submit their opinions online throughout the meeting. I anticipate with the response so far, that I have seen to this that will probably not be the one that is used.

>> Matthew Portnoy: Will industry reviewers be selected from small business only or from companies larger than small businesses?

>> I think it will depend upon what expertise we need. I think we need to see the applications that come in, and see what experts that we have available to us before making that call. My guess is that we'll try to lean towards small business, people from small businesses. But again expertise will be the priority.

>> Larger businesses in some cases have started off in small businesses. But certainly together with the topics as well as the business aspects of it, we would again identify folks that could span actually from academia to business, small business to possibly large business, as Kristin mentioned, we will get the folks with the expertise required for this.

>> Matthew Portnoy: Great. Thank you. We've got a number of questions on how many applications do you expect, how many awards will you make, things like that. The honest answer is we don't know. That will be essentially up to you, to how many you, the greater you, come in the door. Of course that the submission is limited to Phase II and IIB awardees from the Institutes participating and in the end there's no set amount of awards to be made or not made. It will all be dependent on what comes in; the quality of the project; the commercial potential; the budget and priorities within the Institutes who are participating in the CRP; and their program balance between their science, Phase I, II and CRP. We honestly don't know. It's something that we will keep track of and publish every Fiscal Year as we do for all of our other metrics.

There are other questions, most of them are relatively specific. If there's a project specific question, definitely feel free to refer to the Program Officer. How many review panels are planned? It will probably honestly depend on how many applications come in the door every round.

I think that with that, I would like to thank all of you for participating today.

I have a question of how many folks were on the webinar. We had almost 1,000 registered and I wasn't keeping an eye on it, we hit at least 600 or 700 at our peak, still over 400 hanging out now. I want to thank all of you for attending, thank Stephanie, Gene and Kristin and Betty for helping us run the webinar today. Again, the slides will be posted, the recording and the transcript, which is probably a really easy way to get all of the Q&As. Within a few days we will send an email out to everybody, thank you very much and happy holidays to everyone!

[End of webinar].