

HHS SBIR Contract RFP Informational Webinar PHS 2016-1

August 13, 2015

>>Betty Royster:

>> Hi, everyone. Thank you so much for joining the HHS SBIR Contract RFP Informational webinar. My name is Betty Royster and I will be your moderator today.

If time permits, we will have a question and answer session at the end of the webinar. So please submit the questions in the questions box in your webinar console. We are only planning to answer general questions about the contract and electronic submission. We will not be answering questions specifically about contract topics. So any sort of specific or technical contract question you have, please send that to the contracting officer who will compile these questions and post a Q and A amendment to the HHS SBIR contract proposal.

And also, these slides and a recording will be available after the webinar. And we will be posting that on our website, which is sbir.nih.gov. And Dr. Matthew Portnoy will begin the presentation, and he is the HHS SBIR and STTR program coordinator. So with that, take it away, Matt!

>> Matthew Portnoy:

Thank you very much, Betty.

Welcome, everyone, to the HHS SBIR Contract RFP Informational webinar for our recently issued contract solicitation PHS 2016 1. My name is Matt Portnoy and I am your host for today. I am the NIH SBIR/STTR Program Coordinator.

Today we will cover these topics on the agenda about the contract solicitation and you will hear from myself and the contract and technical staff at the NIH and CDC Institutes and Centers. We'll begin with a short overview of the SBIR program with details about the contract RFP or request for proposals. We'll discuss differences from this and the HHS SBIR grant program. We'll discuss the deadlines for submitting your questions and where we'll be posting the answers. And the deadlines for receipt of your proposals.

We'll be discussing the new electronic proposal submission process we have put in place this year with the system called eCPS. And finally, we'll be having the Institutes and CDC present an overview of their contract topics.

Please note that two of our Institutes on the solicitation, NIAAA, National Institute for Alcohol Abuse and Alcoholism, and NIDA, National Institute on Drug Abuse, will not have any slides today. They do have topics listed in the solicitation, which you will find in Section 12, and you can feel free to contact the contracting officer for those and any of the other topics that you wish to ask questions for.

So in overview, the SBIR/STTR program is a trans government program whereby 11 Federal agencies set aside a portion of their budget to support Small Business Innovation Research and Small Business Technology Transfer research grants and contracts. HHS is the second largest agency in the SBIR program and in Fiscal Year '13 nearly \$700 million went to this program.

Within HHS there are five components that have an SBIR program, two of which are on the contract RFP. You can see that NIH for the current Fiscal Year has an SBIR budget of \$691 million, and the CDC, Centers for Disease Control and Prevention, have an SBIR budget of \$7 million.

The other components of HHS, ACL, FDA and ACF have programs but are not on this contract solicitation. You can apply to those agencies through our Omnibus grant solicitation.

Very briefly, the SBIR program is a three phase program whereby Phase I is a short feasibility study of six month to one year in length for around \$150,000 in total costs. Phase II is a full R&D effort for over two years, typically for one million dollars. NIH has a second Phase II, called Phase IIB, which continues the Phase II work. That is not subject to the contract RFP.

And Phase III is the commercialization stage whereby the work is continued without SBIR/STTR funds. Please keep in mind that NIH and CDC are generally not going to be the customer of your technology at the end of the day and so you want to consider partnering and your exit strategy early from the program and where you might receive your next infusion of funds to continue the commercialization work.

All information about the HHS SBIR program can be found at our website, sbir.nih.gov. Here you will find information about the programs, our funding opportunities, how to apply, our peer review process, policy and other resources available to you. In addition to the contract solicitation that I'll talk about shortly, all solicitations can be found readily on this website under the funding page.

As I alluded to earlier, this webinar is about our contract solicitation. We do, as you probably know, have a large grant program, approximately 90 to 95% of the HHS SBIR budget is in the form of grants. And our Omnibus grant solicitations at the top of the page, PA 15 269 and PA 15 270, are open and available for grant submissions. The next available due date is September 5th, which I'll remind folks interested in grants is a Saturday, and Monday the 7th is Labor Day, so the due date is actual September 8th for grant submissions. We'll be talking shortly about the different between grants and solicitations. But this is between NIH and CDC. We released that solicitation on July 24th and I'll reiterate this several times has a close date of October 16.

If you wish to stay in touch on the solicitations we issue, whether it be SBIR contracts or grants or any NIH solicitation, whether it's for small businesses or not, please subscribe to the weekly NIH Guide for grants and contracts email shown here

(<http://grants.nih.gov/grants/guide/index.html?CFID=6570236&CFTOKEN=d65480c4a4ae01d-BE20A935-5056-9439-7E81C8451A60C4D5>).

The HHS SBIR contract RFP and materials can be found in three places. First you can find it on the main NIH SBIR website at sbir.nih.gov/funding#phased1 (<https://sbir.nih.gov/funding#phased1>) or just slash funding. It's at the bottom and you can see here a link to the PDF of the RFP and a Word document of the RFP.

If you click the button at the bottom that says contract proposal forms, that will take you to this page, (<http://grants.nih.gov/grants/forms.htm#contracts>) which is on the more general NIH grants page. Again, on the left you can see a reposting of the PDF and Word document of the actual RFP, and on the right are the contract appendix forms that you are required to submit with your submission. Phase I has three appendices, ABC, and at the bottom there are three appendices. There are six appendices for Phase II and Fast Track proposals. With links to the PDF and Word document.

The links to these are also at the back of the solicitation in the appendix section.

The third place you can find the RFP is in the Federal wide contract portal FedBizOpps. The URL is at the top. It's obviously too complicated to read, but this is linked to on our website and through the policy notice we issued for it. Here you will find a link to the full RFP as well.

This is the first cover page of the RFP, and what it looks like for PHS 2016 1. If you see something different, you may have opened the wrong file and please go back and try again. And if you have trouble finding the solicitation also, please email us and we will help you out.

The solicitation is laid out as follows in 12 sections. I'll be referring to these sections throughout the rest of the talk to find key information for you. Of particular note is Section 10 where all of the contacts for the contracting officers are, and Section 12, which is a full detailed listing of all the topics available for submission.

Of course, all the sections are important.

The number one piece of advice that I and we at NIH and CDC can give you is to please read the entire RFP several times. This will give you the full background of the program, what you need to do and the topic definitions and how you submit. And this really will help you quite a long way.

And now I'm going to go through various portions of the RFP that are of note. We won't have time in this webinar to go through the full RFP page by page, of course, but these are the highlights that are of most importance to highlight for you.

Section 2.6 highlights the parts of NIH and CDC that are participating in this contract solicitation. Please note, unlike the Omnibus grant solicitation where all the NIH Institutes participate and many CDC Centers and Institutes do, a small number of Institutes and a portion of CDC participates in the contract participation. And it changes from year to year, so it's important that you read the current solicitation.

This year in NIH we have the National Cancer Institute, National Center for Advancing Transitional Sciences, National Heart, Lung and Blood Institute, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, and the National Institute on Drug Abuse for NIH.

Within the CDC we have the Center for Global Health, the National Center for Emerging Zoonotic and Infectious Diseases, the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, and the National Center for Immunization and Respiratory Diseases.

Within the solicitation you will find links to each of these parts of the agency and their missions.

We will accept several types of SBIR proposals under the solicitation. This is summarized in a table in section 1 of the solicitation and reiterated within each topic listed in Section 12. A short synopsis of table 1 is shown here. We will accept three types of proposals. The vast majority of topics, but not all, will accept a Phase I proposal whereby you just submit a Phase I.

A smaller number of topics will also accept a Fast Track proposal whereby you submit a complete Phase I proposal and a complete Phase II proposal.

And finally, a certain number of topics will accept a Direct Phase II proposal, which does not include a Phase I proposal.

And this table lists the topic and what types of proposals are accepted per topic. And as you can see in this table, some topics accept more than one type of proposal.

If you have questions on this, certainly contact the contracting officer listed in Section 10.

Briefly I'm going to go over what constitutes a complete Phase I and II completion, but there's more detail in the proposal. In Phase I this can be found in Section 8.3 of the proposal. All complete submissions consist of two parts, the technical proposal in its own single PDF, and the business proposal, in its own single PDF.

The technical proposal includes the proposal cover sheet Appendix A, a table of contents which you will generate, the abstract of the research plan, Appendix B, and the content of the technical element. The content of the technical element is the meat of your proposal and will include all of the aspects of what is required to tell us about your research and the product, etc. And there are full instructions within the RFP on what constitutes technical element.

The business proposal is essentially the budget. It includes the pricing proposal, which is Appendix C, but also includes other various forms we require, such as the SBIR application Venture Capital Operating Company Certification, if your company is majority owned by a venture capital company, if applicable to you. And for all others, the item 4, the proof of registration in the SBA company registry. This is the half page sheet you get from the sbir.gov website.

And these two essential parts constitute a Phase I submission.

A Phase II submission can be found in Section 8.4 for a full description. It includes again a technical proposal in the single PDF and a business proposal in its own PDF.

The technical proposal includes the cover sheet, Appendix D. Note it's a different cover sheet for the Phase I and Phase II. A table of contents you generate. The abstract, which is the same Appendix B. Content of the technical element, which again is the meat of the proposal and will take up the most amount of space. Draft statement of work, Appendix E, and the summary of related activities, Appendix F.

Also in Phase II a business proposal is required and constitutes the same part as it in a Phase I proposal. The Appendix C, the VCOC form if applicable and the proof of registry in the SBA company registry.

If your project is working with either human subjects or vertebrate animal work, this slide is highlighting the sections of the RFP that are relevant to you. And of course you should read the whole RFP, but if you're working with human subjects, vertebrate animal work, Section 3 with provide definitions for these. Section 4.9, 4.10 and 4.11 will have a description of what constitutes research in these areas, and Section 8.9, 8.10, 8.11 and 8.12 contain detailed instructions of what you are to include in your proposal in these areas if you are doing work in those areas. So definitely pay attention to all of these, but especially Section 8 for instructions.

Page limits for the proposals are found in Section 7.3. Phase I technical proposal, meaning all of item 1 in that PDF, shall not exceed 50 pages in total for all parts.

Phase II item 1 shall not exceed 150 pages. This does not include the business proposal or your budget. If you're familiar with grants, you will note this is very different. The grant page limits are much smaller,

but that is just for the research strategy. This is specific for the contracts and also note we don't dictate what size your technical element needs to be for description of the work, but in total you need to fit your Phase I within 50 pages and Phase II within 150.

Excuse me.

A Fast Track, if you're submitting one, is a complete Phase I plus a complete Phase II proposal submitted separately and we will show you how to do that. Therefore it's 50 plus 150 in their own PDFs, each with their own separate budget pricing proposal.

And section 7.3 describes all of this, single sided, single spaced for the entire proposal and it's all inclusive, including all the pages, cover sheet, tables, CVs, resumes, references, all of your graphics, appendices included, et cetera. And there is no exclusion on the page limits to the technical proposal. Any proposal that comes in in excess, the additional pages will be clipped off the proposal and will not be considered.

That concludes the overview section. And now I'm going to briefly discuss the differences between what we just discussed and SBIR grants. And if you are familiar with the grant program, most of everything you just saw probably seemed very different.

And so on the left are contracts and on the right are grants. Contracts are an acquisition mechanism for agencies. Grants are an assistance mechanism. In SBIR contracts, NIH and CDC are acquiring the R&D from your company. And that's not to be confused with acquiring the technology or buying the product. We are acquiring the R&D.

A grant assistance mechanism. Contracts follows the Federal acquisition regulations or FAR and the SBIR policy directive, and SBIR grants follow the SBIR grants policy and the SBIR policy directive.

Contracts are not investigator initiated. And grants are. If you apply to our grants Omnibus as you know you can apply for any topic that we have listed in our topics document or anything that fits within the mission of NIH.

For this contract RFP you must respond exactly to one of the topics or more that we have listed and meet the criteria expressly.

As such, contract SBIR topics tend to have narrow, very well defined topics with deliverables listed to deliver to the government.

Grants can have broad or narrow topics depending, but they're typically not going to be deliverables.

The lingo is different between contracts and grants. In contracts, the solicitation is called an RFP, request for proposals. In grants it's called a program announcement, PA, PAR or RFA request for applications.

In contracts you are the offeror. In grants you are the applicant. If you get an award, you are a contractor under contracts, and a grantee under grants.

And finally, you submit to us a proposal in a contract and you submit an application to us under grants.

Contacting the agency is very different in contracting and grants. Under this contract solicitation, your only contact allowed is with the contracting officer listed in Section 10. You cannot contact the Program Officer about the contract solicitation. If you do they will direct you to speak to the Contracting Officer.

And this is because under the FAR you must have fair and open competition.

Under grants you can contact the Program Officer at any time for anything.

Additionally different systems are involved. This year we have a new electronic contracts submission system which I think and hope you will find very easy and intuitive to use call eCPS. Our contract submissions used to be on paper. With grants we have lingo you're familiar with, the SF424, grants.gov eRA Commons.

What types of things do you need to use on the contract? Do you need to register in the SBIR company registry at the SBA? Yes, you do. All offerers must provide this in their proposal.

Do you have to submit a venture capital certification? Yes, if applicable to your company.

Do you need a DUNS number? Yes, you have to have your business formed in order to apply.

Do you need to be registered in SAM, the assistance award management? Yes, but in contracts at time of award. In grants it needs to be at time of submission.

Do you need to register in grants.gov to submit a contract proposal? No. Do you need to register in eRA Commons to submit a contracts proposal? No, however if you have an eRA Commons account you can use this to register and submit in the eCPS system which you will see in a moment. And finally, do you have to use the Electronic Contract Proposal Submission system, eCPS? Yes. This is a system that's been around for a few years, but it's new to HHS SBIR. This is required to submit all proposals under the contract solicitation.

Now we'll discuss deadlines. I want to remind everyone that your only contact with this contract solicitation is with the contracting officer listed in Section 10. There are email and/or phone numbers listed for all the awarding components. You must submit your questions in writing, email, to the contracting officer. The deadline for receipt of questions to the contracting officer is next week, August 21st, 2015, close of business.

We will collectively compile all of your questions and compile answers and issue in a few weeks, early to mid September, at least a month before the deadline, a question and answer amendment to the solicitation that will be posted both in FedBizOpps and on the NIH SBIR website.

So what this means, and you may not be accustomed to, is yes, your questions and the answers that are provided will be posted for all to see to the public to ensure fair and open competition.

Questions of a very technical nature about a specific topic and about your technology may not be able to be answered due to this. But general questions will all be posted for all to see.

After this deadline, additional questions you submit to the contracting officer may be answered at their discretion. They will certainly direct you to the amendment and they may answer at their discretion.

And the big one, the deadline for receipt of all proposals is Friday October 16th, 2015, 5:00 p.m. Eastern Daylight Time. And we'll go in more detail when we discuss the submission system in a little bit.

Electronic submission must be complete by this time, not started. So you will definitely want to have the confirmation time stamp on your submissions by 5:00 p.m. The system will shut down after that and you will not be able to submit.

And I remind you again that we will accept no paper submissions. We will not accept Fed Ex or mail submissions, they will be rejected without review.

Now we will go to discuss the new electronic proposal submission process we have with the eCPS system.

And I know I am reiterating this over and over, but it's important, it's a big change for HHS contract submission. Electronic submission is now required of all proposals. Paper proposals will not be accepted.

Section 7.4 of the solicitation entitled submission, modifications, revision and withdrawal of proposals contains the website and detailed instructions on how to submit your proposal to the NIH and CDC. The website for eCPS is listed here. It is also listed in the solicitation in Section 7.4.

I will now turn the webinar over to Mike Kapsilis on the eCPS team to do a live demo of the eCPS process for registration, submission and revision of electronic proposals.

At this time please don't click on this link and go to the website. You will be able to do that afterwards. We will do a live demo. So Betty, please turn it over to Mike.

>> Michael Kapsilis:

Thank you, Betty. This is Mike Kapsilis and I will give you an overview of the electronic proposal submission system. Again as Matt said, this is for submission of contract proposals, not grant applications.

If you need information on grant applications, you would click on the SBIR website.

This is the landing page for the eCPS and as you can see, there are three main sections to it. The first being the registration section. And I'll show you how to go ahead and log in. I want to stress now that it's important to register as soon as possible. As a matter of fact, maybe after the webinar today we highly recommend you go in and register. It's a very quick process. If you already have an eRA Commons account, you could log in with your eRA Commons. If you need to initiate a new registration, you would do it through NIH EXT, and that's through clicking here. And it's a very brief registration document to initiate a new account.

We turn them over as quickly as possible. We do definitely within three days. We highly recommend you do not wait within the three days of closing because we cannot guarantee the registration will be accepted.

So that's why we highly recommend you go in and register now as soon as possible.

On the right hand side you'll see some frequently asked questions. If you click on any of these it will take you to more details and you can also access the FAQ's at the top of the website.

Towards the bottom of the eCPS site you're going to see the listing of all topics for this particular solicitation. If you click on the solicitation, it will take you to the solicitation in FedBizOpps.

As you scroll down, you'll see every topic by topic title and the points of contact and the awarding component for each topic. This is very important when you go to upload to make sure that you upload your proposals against the proposal against the correct topic. I have not yet logged in. I'm going to go ahead and log in and show you what it looks like after you log in, after you initiate an account request and get your log in and after you log in.

So these are as you can see all topics for the SBIR solicitation.

I'm going to go ahead and log in now.

Once you log in, it takes you to a screen that shows all active topics under the solicitation, and the one change you'll see now is you have a submit button on the right hand side. I have initiated some test submissions, and if I'm scrolling down to some topics that I already submitted on, I'm going to go ahead and submit a Fast Track proposal, Phase I and Phase II, against topic 37. As you can see, because I have already submitted some test proposals, I have several options here, and I'll show you more details regarding those options in a moment.

So if I submit against topic 37, I'll hit the submit button. It's a good idea to verify one more time that you're submitting against the right topic here, and you will see the topic title.

This is where you enter a proposal name and this is the proposal name that you enter in eCPS. And you'll see in your solicitation there is naming conventions, and we also have the naming conventions in the FAQ. I will show you after the online demo, I'll show you three slides that also discuss the naming conventions for the proposal names.

So what we do ask for is that you enter the phase and in this case we're going to do a Fast Track proposal. The concept is the name if you were just doing a Phase I or the one topic that allows for a Phase II, you would just not enter Fast Track here.

So for a Fast Track Phase I we name it this way. You name the phase, Fast Track, the name of your company, the awarding component and the topic number.

Then down below you're given options here. You upload a technical and business proposal. You have the option to upload an Excel spreadsheet of your costs. If you do, that must be identical to the costs that you have entered in your business proposal. It is an option though, so you do not need to enter that Excel spreadsheet.

So I'm going to go ahead and enter my technical proposal and the business proposal. As you can see here. And in the solicitation it also asks that you label these accordingly, so you have the naming convention in the eCPS header here and then you also have the naming conventions that we asked for on the actual document level.

Here's my technical and here's my business proposal. And again, you have the option to upload the Excel document.

I would hit submit here. So once you hit submit you're going to see a message here. This is verification that the upload was successful.

You can also, and I'll show you in a minute, you can access verification that the upload was successful through my submission history.

Now, because we've uploaded these, we are given the option to update. If you want to change any of these documents up until the closing date and time, you can change these. You can upload a new technical and new business document. It will completely overwrite the old one, it will replace it. You're given this option of course up until the closing date and time.

We now have the option to submit our Phase II Fast Track proposal. We can do it several places. One place we can do it is here. If you back out into my submission history, you're also going to see submit a new alternate proposal. And I'll show you that in a minute, but I'm going to submit it from here.

There's a message that comes up that says are you sure you want to submit a new/alternate proposal, in this case a Phase II Fast Track. This is in case you accidentally hit this and accidentally want to revise your current proposal. If you in fact want to revise your current proposal, you would cancel out of this and hit update proposal. I'm sorry, hit replace file, revise accordingly and then hit update proposal. Because we want to do a Phase II Fast Track, we would hit submit new alternate, click okay and where it takes us back to the same type of window.

And in this case, we're going to submit a Phase II Fast Track.

Again, you put Fast Track, you put your company name. The awarding component and the topic number.

And you would select your technical and business proposals.

And hit submit and you'll have the message regarding the receipt of the proposals.

When you're now back, here's a history log of your actions taken. When you now back out into the previous view, this is the table view with all of the topics. When you scroll down, you will see the one that we had just submitted to topic 37 and, again, you're given the option to revise and to submit a new alternate proposal. In this case, you have finished your Phase II for Fast Track. If you need to revise again, you can go in through here. When you hit revise submission, you're going to get a listing of all of the submissions. In my case, there's a long list because I've submitted some tests here. But when you go down to topic 37, again, you're given the option to revise. So Phase I has the technical and the business, and Phase II has the technical and the business proposal. If you hit revise, it takes you back to that screen that you have seen, and you can revise, or you can replace either the technical and business proposals accordingly.

That is it for the submission of contracts using the eCPS.

One more thing that I would like to add, if you submit a proposal against the wrong topic, accidentally, go ahead and submit against the correct topic and then notify the point of contact, the contracting officer with the wrong topic and they will take care of it. You cannot do this inside the system. You cannot delete a proposal submission against the wrong topic. The priority then is to submit, like I said, against the correct topic and then notify the point of contact for the incorrect topic.

Thank you. Matt, this completes the eCPS section.

>> Matthew Portnoy:

Thank you, Mike. Please keep up the screen up for a minute, Betty. Betty, can you please go back to Mike? Send it back to Mike for one second.

I want to draw your attention to two things, in bright yellow is the countdown clock. It is identical for each of the topics, it is the same deadline for each of the topics. This counts down to 5:00 pm on October 16th.

After 5:00 pm, on October 16th, the submit button will not be available to you. Then if you click one more time, Mike, right there, then on this screen, also, there's a countdown clock, and at the bottom there is a submit proposal and that will not be active. Your proposals must be submitted and you must get the confirmation screen by or before 5:00 pm for any and all of your proposed submissions, especially if you are submitting more than one. As you can see, it's pretty simple to submit. It's basically a title, two documents and hit submit.

Section 7 also describes the late policy. This is very, very different than the grant late policy. This is essentially a zero tolerance late policy, as it is for all contract submissions by and large to the federal government. Your submissions must be complete by 5:00 p.m. We will not accept late submissions for any reason. If, however, the eCPS system itself goes down, then, of course, we will make an accommodation for the length of time that eCPS is down.

But absent the eCPS system going down, there is no late submission after the deadline.

So, please, please, please submit before the deadline for any and all of your proposal submissions.

>> Michael Kapsilis:

Thank you, Matt. I wanted to add, so your submission must, like you said, your submission must be complete, you must get that verification, the congratulations message. You can't have the window open if the time passes, if that time passes, it will not allow you to hit submit.

>> Matthew Portnoy:

And you are able to print the confirmation screen, the congratulations screen for your records, also. All right.

>> Michael Kapsilis:

Also, you cannot see the proposals once you submit them. You can only see the receipt. You can see the fact that you submitted proposals and you can see the document name. But you cannot see the actual proposals. So if you do have a change and you have an updated proposal, you would go in and you would hit update and you would replace it with your new proposal.

>> Matthew Portnoy:

All right. Great. Thank you very much. Mike. All right, Betty, I'll take back control now. All right. So that was the live demo. Now Mike is going to continue to discuss the proposal name and format in more detail.

>> Michael Kapsilis:

Thank you, Matt. So this is basically just going through what we have just gone through on the online system. The proposal name here is the proposal name in the eCPS field. Not on the document file level. So this is the proposal name that we request, that you put the phase, if it's a Fast Track you would then

put Fast Track, you put your company name, you put the NIH or CDC awarding component and then the topic. Just like we did in the online system. Next slide, please.

This is on the actual file level. So when you save your business and technical proposals to your local drive, this is what we recommend, this is what we request that you name them. So you would have your name, NIH or CDC awarding component, topics being proposed under and, of course, the type of proposal that it would be the extension of the actual application. So you would have your company, your topic, technical, your company, your topic, business proposal. And Excel, if you had the spreadsheet.

Next slide.

So this is kind of a visual of what we did for Fast Track. You would enter your Phase I Fast Track name, in eCPS, you would upload your technical and business proposals for your Phase I, you would hit submit, you would hit alternate proposal, you would then unname your Phase II Fast Track, upload technical and business for Phase II and hit submit.

>> Matthew Portnoy:

Great, thank you, Mike. And if you are submitting a Phase I only, of course, you just do steps 1 and 2. And you remove Fast Track from the title. If you are submitting a direct Phase II, you just do the last two steps, steps 4 and 5 and omit the Fast Track language.

And so it should be hopefully relatively simple and intuitive for you to use. And we're glad that we're able to offer it to you finally.

So moving on ... we will now go to each of the Institutes that have topics, with the exception of NIAAA and NIDA, and the CDC and for them to give a brief overview of their topics, and then we'll use the remaining time for any questions and answers. A reminder, if you are interested in NIAAA or NIDA topics, they have them and they are listed in the solicitation in Section 12 and you'll be able to find everything that you need there, as well as all of the Institutes will have a full detailed description of all of the topics.

And now, I'm going to turn it over to Patti Weber and Johnny Franca-Koh from the NCI to discuss the NCI topics.

>> Patti Weber:

Thank you, Matt, this shows you a clinic link to NCBI specific activities, [Reading link]. Next slide.

So - NCI specific activities. This table, you've already seen some of what Matt showed you, but this basically defines the differences again between grants and contracts. So the scope is defined by the NIH. Now at NCI, we have specific review at the NCI. So we strive to get about 50% of the reviewers from the business community. And as Matt mentioned, the program staff's involvement, once a contract is awarded, is very high. Next slide, please.

So again this just summarizes the opportunity that we have, this receipt date of October 16th. Again, you can find the full RFP at the link shown here. And more about NCI specific topic areas at our link: SBIR.cancer.gov. The next slide we have 14 contract topics this year, covering a variety of areas.

I'm going to show the first, up to topic 348, then I'm going to turn it over to Johnny to go through the rest with you.

So this first topic is 341, it's the development of metabolomics data integration methods and software. This is a topic where Fast Track will be accepted, no Direct to Phase IIs. It's 225k for nine months, 1.5 million for two years. The important key points are for the Phase I deliverables you are going to develop database formats that support the import and export of individual datasets from various metabolomics technologies and laboratory platforms. You are going to provide wire frames and work flows for the graphical user interfaces and we expect for you to have a functional prototype at the end of Phase I. You can see the full deliverables for Phase II at our website. I will make a note here, NCI can provide a dataset of blood samples that were run on three metabolomic platforms for you to evaluate your system. This is topic 342, validation of mobile technologies for clinical assessment, monitoring and intervention. This is a Direct to Phase II topic. Phase I proposals will not be accepted and Fast Track proposals will not be accepted.

The total award amount for a Phase II, this is in error here, there's no Phase I, but it's 1.5 million for the two year Direct to Phase II. So this topic is not intended to support the development of new technology. We expect that you will have a working prototype at a minimum of your functional technology and that you may have some additional work to develop the tool, the Beta version that will then be validated in this Phase II project. I will note that NCI will be checking the application for responsiveness to the Direct to Phase II requirements and that no SBIR, no prior SBIR or STTR funds can be used for the Phase I equivalent work. If that is determined, the proposal will be rejected and will not be reviewed. Next slide.

So this is topic 343. An electronic platform for cognitive assessment and in cancer patients.

In this case, we will accept Fast Track proposals and Phase Is, no Direct to Phase IIs. So this is to develop a software tool to detect subtle cognitive changes associated with cancer patients and with patients undergoing cancer treatment.

And, again, for Phase I, we expect at the end of the nine month period you will have developed a functional prototype system. Again you can review the full Phase I and Phase II in the quick link to NCI's website.

Next slide. Topic 344. Technologies for differential isolation for exosomes and oncosomes. There is a mistake here in the budget, we will accept Phase Is at \$300,000 for nine months and Phase II at 2 million for two years, not 3 million, that's an error. Again, Fast Track proposals for this topic will not be accepted and Direct to Phase II proposals will not be accepted. We expect for this topic that you develop a technology that can differentiate differential isolation of tissue specific exosomes from oncosomes and that you develop a technology that will deal with these distinct preparations in the way that they are in sufficient quality for downstream analysis. Again, you can read the full description of the Phase I and Phase II deliverables in the RFP. Next slide.

This is topic 345. Predictive biomarkers of adverse reactions to radiation treatment.

In this case, we are allowing Phase I and Fast Track. Direct to Phase IIs will not be accepted. The numbers are correct. 300,000 for 12 months, 2 million for Phase II. We will allow you to go up to 12 months for that period. Basically the goal here is to validate the simple cost effective biomarkers that

really will differentiate patients in terms of their radiation sensitivity. And this is to help with treatment planning prior to radiation therapy.

Again, I'm going to direct you to the RFP so that you can review carefully the Phase I and the Phase II activities and deliverables. Next slide, please.

This is topic 346, molecularly targeted radiation therapy for cancer treatment. Again, we will allow Phase I and Fast Tracks. This is the correct budget number, 300,000 for Phase I for nine months and 2 million for Phase II for two years.

The Fast Track will be accepted, Direct to Phase IIs will not be accepted. The goal here is to develop and commercialize a targeted radiation therapy technique that could shorten the treatment cycles and reduce the toxicity to normal tissues. At the end of Phase I, we expect you to have done proof of concept, small animal studies to really demonstrate that you get an improved therapeutic efficacy. And I'm going to direct you on to the RFP to see the full requirements for the activities of Phase I and Phase II. Actually, at this point I'm going to turn it over to Jonathan to move on to the next topic. Oh, I'm sorry, I do have one more. Type 347, this is entitled signal amplification to enable attomolar quantitation in slide based or ELISA biomarker immunoassays.

These budget numbers are correct. 225,000 for a Phase I for six months and 1.5 million for two years for a Phase II. We will accept Fast Track proposals, Direct to Phase II proposals will not be accepted.

So basically the goal here is to incorporate signal amplification methods into a quantitative ELISA or slide based IFA immunochemistry assays low abundance but high value cancer biomarkers. I'm going to again direct you to the RFP to look at the detail. Be careful looking for the Phase I activities and deliverables for both Phase I and Phase II if you choose to submit a Fast Track. So at this point, next slide, I'm going to turn it over to Jonathan.

>>Jonathan Franca-Koh:

Hi, thanks. So topic 348 is for developing a technology that enables identification and capture of enriched tumor zones from free citizen solid tumor biopsies that allow for at least 50% enrichment of tumor cells. So the budget for Phase I is 300,000 over nine months and Phase II, two million over two years. Fast Track proposals and Phase I will be accepted. No Direct to Phase II. The key deliverables are to develop the method to identify and capture viable tumor cells from at least two solid tumor types, while maintaining the frozen state of the specimen. Offeror should be able to demonstrate that at least one labile protein marker is observed and tested. Again, refer to the RFP for further details.

Next slide, topic 349 is for developing reagents and a method for an antibody based proximity assay for highly sensitive and quantitative detection of high value cancer biomarkers from tumor sections. So the key in this contract topic is so that the technology will retain the spatial information present in tumor sections. Proximity based techniques can include things like fret or radio frequency tags and the key deliverables are the offeror needs to develop antibody pairs for at least two high value biomarkers in Phase I and have this assay and the reagents independently verified and tested. Again, refer to this project, this contract topic allows for Phase I budget of 300,000 over six months and Phase II, two million over two years. Phase I and Fast Track are allowed, Direct to Phase II not allowed. Next slide.

Topic 350 for novel chemical probes or biosensors ... preferably living cells or also in vivo animal models. 225,000 over nine months, Phase I 5.5 million for two years. Fast Track accepted along with Phase I, again no Direct to Phase II proposals for this topic. The key deliverables are to develop and characterize redox probe or biosensor and demonstrate in live cells or animal model. Ideally these techniques should involve minimally invasive perturbation of the system. Again, refer to our website for further details and RFP. 225 over nine months, 1.5 million two years for Phase II. Next slide.

Topic 351 is modulating the microbiome to improve efficacy of cancer therapeutics. 300,000 for nine months, Phase II, 2 million for two years. Only Phase I proposals accepted, no Fast Track and no Direct to Phase II. The key goal of this contract is to develop new technologies to modulate the gastrointestinal microbiota in a way that enhances the therapeutic efficacy of an existing or novel therapeutic or reduces a side effect associated with this therapy. The purpose of this topic is not to look for characterization of the microbiome or a standalone therapeutic. They need to define the microbial ... And to develop a targeted intervention strategy that will improve outcomes. At the end of Phase I you should have an in vivo proof of concept model. Again, refer to the RFP for the details. Next topic.

352, for cell and animal based models to advance cancer health disparity research. The Phase I budget for this is 225,000 over nine months, Phase II 1.5 million over two years. Only Phase I proposals will be accepted for this contract topic. No Fast Track, no Direct to Phase II. The goal is to develop models relevant to cancer related health disparities between different racial or ethnic groups. This can be the form of either cancer cell lines or primary cells from different racial or ethnic groups. Patient derived xenograph models or genetically engineered models. Again, refer to the RFP for further details. Next slide.

Topic 353. Cell free nucleic acid based assay development for cancer diagnosis. Phase I budget is 300,000 over six months, Phase II, two million over two years. Phase I and Fast Track proposals will be accepted. Not Direct to Phase II. The goal is to develop a cell free nucleic acid assay for clinical use in the evaluation for cancer diagnostics for determining prognostic indicators and response to therapy. Offeror should have one or a panel of cell free nucleic acid markers that can be assayed from a sample of choice and they should demonstrate high reproducibility and accuracy as well as sensitivity and specificity.

And they need to be able to show that the assay can distinguish these cancer samples from healthy samples. Again, refer to the RFP for further details.

And I believe this is our final topic. Next slide, topic 354, companion diagnostic for cancer immunotherapies, as a budget for Phase I, 225,000 over six to nine months, Phase II 1.5 million over two years. Phase I and Fast Track proposals will be accepted but not Direct to Phase II. The goal is to develop companion diagnostic assays that will determine whether particular immunotherapy regimens will be safe and effective for individual patients. The key deliverables in Phase I to develop working diagnostic assay for specific cancer, immunotherapy regimen, demonstrate reproducibility for use and critically all offerors will need to show that they have established a collaboration or partnership with a diagnostic or pharmaceutical company that is actively engaged in a clinical or research project that can provide the relevant clinical trial specimens.

That ends our presentation.

>> Matthew Portnoy:

All right. Thank you very much Patti and Johnny. There we go, finish up with the

>>Jonathan Franca-Koh:

Sorry. So forgot about that slide. So as Matt mentioned, we unfortunately are not allowed to answer your questions on these topics, so please direct any questions that you have, especially those that are related to the topics we presented and technical nature to Ms. Rosemary Hamill, her email shown here and she will compile the questions for us to then answer and the answers will be posted on the website. Thank you.

>> Matthew Portnoy:

All right, thank you very much, Johnny and Patti. Moving on to the National Center for Advancing Translational Science, NCATS, we have Lili Portilla.

>> Lili Portilla:

Good afternoon, everyone, this is Lili Portilla, I'm the Director of strategic alliances here at NCATS and very happy to talk to you about our two contract topics that we have this year.

Please advance the slide, Matt, for me. Thanks.

So the first topic here is the NCATS topic 013, the development of stem cell based assays for high throughput screening of chemicals of toxicological concern. We anticipate that we would award between two and three of these contracts, Phase I budget is up to 225,000 for up to 12 months. And for the budget for the Phase II is up to 1.5 million for up to two years.

For the Phase I part of this contract, the goal is to develop toxicological related assays in some type of homogenous format. These assays are going to be used to test targets, pathways and cellular phenotypes that are related to any kind of xenobiotic toxicity in human cells or iPS derived cells. For the Phase II, we would expect the goal, the main goal of the contract to be to miniaturize these assays and do a 348 well format or preferably the 1536 which is what we work here at NCATS using the 1536 well plate format. Jeff Schmidt is our point of contact for all contract questions, this is his email in the event that you have any questions. Please advance the slide one more time.

And our last topic is NCATS topic 014 which is the development of the smart plate technology. We expect to award up to two to three awards to be made under this specific topic. For a Phase I it's up to 225 k. For up to nine months. Phase II up to 1.5 million for two years. What I failed to say on the previous topic was that we will not be accepting any Fast Track or Direct to Phase II, same applies for this topic, the smart plate technology topic. For Phase I the key goal here is to develop prototype specifications that transform a regular microtiter plate from being a single use vessel for experiments, to becoming one where you can do real time measurements on data and give data on the samples that are being tested.

And the Phase II goal of overall goal would be to develop a prototype using the specifications that are developed in the Phase I and to evaluate the features. These features that are developed.

So that concludes NCATS' topics and I'll throw it back to Matt.

>> Matthew Portnoy:

Thank you, very much, Lili. Turning it over now to Jennifer Shieh atmosphere the National Heart, Lung and Blood Institute.

>>Jennifer Shieh:

>> Thanks, I'm Jennifer Shieh, the small business coordinator for National Heart, Lung and Blood Institute. And I'll be highlighting a few points about our four contract topics in this contract solicitation. But, of course, please read the solicitation for all of the details.

If you have any questions regarding the NHLBI contract topics, please contact John Taylor, the NHLBI contracting officer. If you want to learn about grants funding opportunities or other resources available to innovators working on heart, lung, blood or sleep technologies, you can visit our website, sign up for the listserv and follow us on Twitter @NHLBI_SBIR.

The goal of NHLBI topic 94 is to develop a transcatheter cavopulmonary bypass endograft. To manage the treatment of children with congenital heart disease. Eventually getting to the point of investigational device exemption for first in human testing in the United States. Phase I Fast Track and Direct to Phase II proposals will be accepted. The NHLBI division of intramural research offers, but does not require ... as well as to participate in the development of the clinical protocol and perform the clinical trial at no expense to the awardee. Next slide, please.

The goal of NHLBI topic 95 is to develop an active MRI transeptal needle and accessories getting to the first in human testing in the United States. Phase I Fast Track and Direct to Phase II proposals will be accepted. Again here the NIH division of intramural research offers but does not require the small business to work with contractors to provide feedback about design in all stages of development and will test the final deliverable device in vivo in swine. Next slide.

The goal of NHLBI topic 96 is to develop an absorbable scaffold stent for neonatal aortic coarctation for first testing in the United States. Phase I, Fast Track and Direct to Phase II proposal will all be accepted. Again here the NHLBI division of intramural research offers but does not require the small business to perform the clinical trial ... work with contractors on performing in vivo proof of principal experiments in swine as well as to participate in the development of clinical protocol at no expense for the awardee.

Finally topic 97 is to develop novel minimally invasive methods for early detection and monitoring of cardiac injury due to cancer induced cardiotoxicity. Phase I, Fast Track and Phase II will all be accepted. Please read the full solicitation for more details and contact John Taylor, the contracting officer for NHLBI if you have any questions. Thank you.

>> Matthew Portnoy:

Thank you very much, Jennifer. And now I will turn it over to Chelsea at the NIAID to discuss their contract topics.

>> Chelsea Lane:

Thank you, Matt. My name is Chelsea Lane, one of the SBIR coordinators for the National Institute for Allergy and Infectious Diseases. NIAID has 7 SBIR contract topics in the 2016 program solicitation and as with everybody else, I encourage you to refer to the solicitation for more details. Next slide, please.

The first topic, topic 33 focuses on precision genome engineering for HIV eradication. The objective of this topic is to design improved nucleases for disruption of integrated HIV pro virus and/or essential cellular proteins, so HIV replication is no longer supported.

Next slide, type 34 focuses on high-throughput assay platform for quantifying latent HIV reservoirs. The objective is to develop innovative approaches to quantify latent, replication-competent HIV that are more efficient than a viral outgrowth assay (Q-VOA). Next slide, please.

Type 35 focuses on a method for the detection of minority populations of drug resistant H.I.V. The objective of this topic is to develop inexpensive methods to detect important minor variant mutations causing resistance to each of the antiretroviral drugs. These must be detected in all HIV subtypes. Methods that detect a set of relevant point mutations and methods that collect full sequences are both acceptable. Next slide, please.

Topic 36 focuses on simple, inexpensive device to purify DNA from sputum for tuberculosis testing. The objective is to develop a simple, inexpensive device to purify DNA from sputum for use in molecular TB diagnostic and drug resistance testing. The purified DNA sample should be compatible with different technologies, thus removing the sample processing step from the development of the tests.

Next slide, please. Type 37, focuses on telemonitoring for infectious diseases, and the development of a remote system for assessing patient parameters and specimen analysis. The objective of this topic is to develop a device that can ... [Reading slide]. Next slide, please.

Topic 38, focuses on innovative oral formulations for anti infective drugs. The objective of this topic ... [Reading Slide] Next slide, please.

This is our last and final topic, topic 39. Which focuses on the development of vaccines against pathogens with small market potential. The objective of this topic ... [Reading Slide]. Next slide, please.

Again, if you have any questions, we encourage you to contact our contracting officer, Charles H. Jackson, Jr., from the Office of Acquisitions at NIAID. With that, I will turn it back over to Matthew Portnoy.

>> Matthew Portnoy:

Thank you, very much, Chelsea. And last but certainly not least, I will turn it over to Sean Griffiths at the Centers for Disease Control to present a brief overview of CDC and their topics. Sean?

>> Sean Griffiths:

Thank you, Matt, as previous my stated by my colleagues, as well as Dr. Portnoy, please, for those who have questions about the topics that CDC included in this solicitation, see Section 10 where we have listings for our contracting officers for each of our Institutes or Centers have that submitted topics in this solicitation. Next slide.

CDC's SBIR program is managed out of our Office of the Associate Director for Science. The program works with our Center's Institutes and Offices to make determinations as how best our SBIR funds can be used to support high impact SBIR projects, which would overall benefit public health and the agency's specific mission and priorities. Again, as Dr. Portnoy shared early in his presentation, CDC participates in the overall HHS NIH Omnibus grant and contract solicitation. We do want to stress that CDC does not

participate in the STTR program at this time. But we have opted into the majority VC ownership authority as of FY '15. And so that's listed in the solicitation and if you have questions or concerns about that, please look for that in the solicitation. As Dr. Portnoy also mentioned, our budget at this point is \$7 million approximately for FY '15. Next slide.

The uniqueness of CDC's SBIR program, as well as CDC's mission around public health and emergency response, which is not only domestic but international. Our awards are approximately 25 Phase I's up to 150k. We do have a cap of \$150,000 for our Phase I's and approximately five to six Phase II's per year, again capped at one million each. We have broken a little bit down as far as our grants versus contracts in FY '13, we had about 58% grants and 42% contracts and in FY '14, 25% grants and 75% contracts.

We want to take a moment and talk just a bit about CDC strategic priorities and our key winnable battles to give a frame or a look into what we are requesting folks to align their proposals or applications to. CDC's strategy priorities are specific in that we have one, two, three, four, five, strategic priorities around strengthening, surveillance, epidemiology, and laboratory services. Improving the ability to support our state, tribal local and territorial public health. Improving global health impact as well as increasing the policy impact and better preventing illness, injury, disability and death. Along with that comes what we call winnable battles. To keep pace with what we call emerging public health challenges, we have initiated this effort to achieve what we call measurable impact to quickly target a few specific areas. These areas are CDC's winnable battles: tobacco, reducing tobacco use; what we call health care associated infections, reduction of that; teen pregnancy, reduction of teen pregnancy; and associated mortality and morbidity issues associated with nutrition, physical activity, obesity and food safety; motor vehicle injuries and crashes associated with those; and then the issue around HIV and mortality associated with HIV infection and AIDS. Those are CDC's winnable battles. Next slide, please.

So where does CDC's SBIR program intersect with small business concerns, venture capitalists and entrepreneurs? Because CDC supports this ground breaking medical research and real time emergency response activities in order to keep the United States safe, healthy and secure, as well as globally; CDC promotes and funds research and development that will support our mission and strategy priorities. Our role is not only local, state and federal, but also on a global level, as one can see in the news, as our work in west Africa continues, the SBIR program is a way for innovators and entrepreneurs to contribute to making not only the U.S., but the world, a healthier, safer place.

And so our topics are oriented towards both our mission and our strategic priorities and these winnable battles. Next slide, please.

We have seven specific topics listed in this solicitation. The first topic is related to our global health center, the Center for Global Health, diagnostic tools to support the elimination and control of neglected tropical diseases. One to two anticipated awards. The Phase I up to 150,000 for six months, the specific project goal is to have a prototype field compatible test that can address the following issues currently faced by national NTD programs. [Reading Slide]. Next topic, please.

This is out of our National Center for Emerging Zoonotic and Infectious Diseases. Number of awards up to one, up to 150,000, capped for six months. The project goals are ... [Reading Slide]. Next slide, please.

This type is also from the National Center for Emerging Zoonotic and Infectious Diseases, detecting lower intestinal microbiome and disruption of multi drug resistant organisms, MDRO's. [Reading Slide]. Next slide, please.

This is out of our National Center for HIV/AIDS, Viral Hepatitis, STD and TB prevention. [Reading Slide]. Next topic, please.

This is also out of our National Center for HIV, Viral Hepatitis, STD and TB prevention. [Reading Slide]. Next slide, please.

This is from our National Center for Immunization and Respiratory Diseases, Transcutaneous immunization against rotavirus using a dissolvable microneedle patch. [Reading Slide]. Next topic, please.

Topic 032, Thermostable dry powder live attenuated influenza vaccine for nasal delivery. [Reading Slide]

Those are CDC's topics, thank you very much for your attention. Again, if there are specific questions related to the topics themselves, please contact or look in the solicitation under Section 10, there you will find our contract officials related to the specific centers that have the topic areas and we look forward to working with you. Thank you very much. Back to Matt.

>> Matthew Portnoy:

Thank you very much, Sean. As we wrap up here, I would like to remind everyone, if you have any questions, please send them to the question panel, we'll have time for a few of them. Some of which we've answered along the way and I'll reiterate them. I want to thank all of our speakers today for presenting their material. As a last reminder, the deadline, Friday, October 16th, 5:00 pm eastern time, electronic submission using the eCPS system, no paper submissions. Finally, in general for NIH, if you want to stay in contact with us and find out about what's going on, please sign up for our listserv. Sign up for the weekly email listserv (<https://sbir.nih.gov/engage/listserv>). Sign up for the NIH Guides for Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html?CFID=6640718&CFTOKEN=8b6a2815a49180bb-CA33B661-5056-9439-7EA50C140719DD5B>), and Follow us on Twitter (<https://twitter.com/NIHsbir>) and go to our website (<https://sbir.nih.gov/>).

At this point, I would like to now take some questions. And I would go to the question panel and there's been a bunch of questions about the slides and the presentation. The slides, a recording of this presentation, which includes a recording of the live demo, and a written transcript of the presentation will be posted on the NIH SBIR website, SBIR.nih.gov. Give us a few days to a week, it should be out in plenty of time for you to take a look at it prior to the deadline. So you will be able to grab the slides and the presentation. Most of the questions so far are about that. The listserv is shown on this slide. If you are not sure if you're on it, you can send us an email.

We have a question about eCPS. To access eCPS, who do you log in as? The Signing Official or the PI?

>> First, you cannot get to eCPS from the Commons, the eRA Commons, there's no link to it. But the link to eCPS is in the slide deck and of course within the solicitation.

Who should upload and submit the proposals to the agency? It should be whomever at your company has the authority to do that. That certainly would be the Signing Official, that may be the PI. But the system doesn't validate on the type of Commons account.

Questions about the live demo. There was a question about intellectual property. For contracts, does the company own the intellectual property arising from the work? The answer to that question is yes. Whether it's a contract or a grant, the intellectual property and SBIR data rights are afforded to the company as listed under SBIR policy.

And someone asked if someone submits to the contract solicitation, can they also submit to the Omnibus grant solicitation? And I presume you are asking can they submit essentially the same project and the answer to that question is no. We have language within the contract solicitation saying that you cannot do that. And you essentially cannot submit the same proposal within the agency under two different solicitations.

The question is when and how will the contract review for proposal reviews will available? I would direct you to, I believe it's 5 of the solicitation which describes the review. And section 9 in the solicitation describes the timelines for review and potential awards.

Question asks when it says number of anticipated awards, one to two, what does that really mean? Well, that means that essentially what it says, that first off, under any topic, the NIH, the CDC and the government is under no obligation to make any awards. So if we get proposals and they don't do well under technical review, it may be possible to make zero awards. But what it means that with one to two awards, if there should technically be acceptable proposals, then the agency will make one or two awards, depending on their needs and the quality and the type of proposals. For the same topic, I should say.

Question: What happens in a contract is awarded but the milestones are not reached?

I'm sorry, about these things coming up in the system. That will be up to the Program Officer or the contracting officer as to what happens if your milestones aren't reached.

Can a proposal be submitted by a virtual company with no office or lab space? The answer is yes. However, part of the review process will be the facilities and capabilities of the company to carry out the research, which you'll have to describe within your technical proposal. And so you'll certainly want to, if at the moment if you don't have space, you're going to want to describe the space that you would rent or lease at the time of award. And in contract negotiations, likely provide proof that you have the space.

At this time, I don't see any other questions coming into the system. If you have additional questions, we were not able to get to, please send them in to the contracting officer listed in Section 10. Question, how many proposals a company can submit each cycle? You can submit unique proposals to as many topics as you wish.

And is the review process different for contracts than it is for grant proposals? It is essentially the same, but Section 5 describes the review criteria and process.

And so with that, I would like to thank our speakers, thank everyone who attended the webinar, reminder that the slides and presentation will be posted on the website within a short time. Thank you and have a good day.