

HHS SBIR PHS 2020-1 Contract Solicitation Webinar
August 7, 2019, 1PM-3PM

Good afternoon, everyone and welcome to the 2019 contract solicitation webinar. My name is Patricia Swayne, I am the communication specialist and the NIH SBIR STTR office located in Bethesda, Maryland. Today we will have a number of NIH and HHS SBIR staff that will be presenting their contracts solicitations to you. I will go down the list of who will be participating today. In no particular order, we will have Barbara Stewart from the CDC, Elizabeth Powell, George Kennedy, Julio Lopez from CDC, Cathy Young, Lily Portia,

Mike Pecsilis, Mike Peck, Monique Pond, Tiffany Chadwick and Wolfgang Lightner. Everyone will introduce themselves and which NIH Institute or HHS Center they are from. Our presenter today will be Robert Vincent who is the program manager on the office of small business education and entrepreneur development. Rob will run the majority of the overall contract solicitation review and each Institute for centers individual topics will be discussed by the program officers I just named. You are able to access the handout using the console of the go to webinar droll panel under handout. If you have any questions, you can submit the questions using the question tab in the control console. We will answer questions at the end and some during. So without further ado, I want to introduce Robert Vincent. If you're having any trouble hearing us, please also alert us in the questions tab, thank you.

All right, hello everyone. My name is Robert Vincent, the program manager here at NIH. Again, I would like to thank you all for joining us this afternoon. We would also like to thank our program officers and program managers who will be covering their topics. I also want to thank Doctor Matthew Portno for the opportunity to run this particular contract webinar. So without further ado, let's get started. You should be able to see on your screens are slides, our slide deck for this afternoon. The next slide is our agenda. I am briefly going to talk about the overall SBIR program and the contract RST, then some descriptions, or differences between the grant program and the contract program, also the deadlines for questions and answers for the proposal and also talk about, or introduce our speaker Mike Capps is a list who will be covering the eCPS

electronic proposal submission, then we will go into the review of the topic from each of the institutes listed below and CDC.

Okay, we are trying to make sure you all can hear me. I certainly can speak louder if necessary, but I don't think that's the problem. Okay, give us just a second.

Okay, alright. All right, very briefly, because we've got a lot of material to cover, I just want to talk about the overall I'll SBIR STTR program and the agencies that provide small business funding. You can see on this pie chart, on the pie chart we have listed here all of the agencies that provide federal funding, or small business funding. At the very top is the Department of Defense and then we are next, or the second-largest funding agency. This particular slide is important,

because it highlights the fact that most agencies in the light blue provide contracting funding only and in the green our agencies are provide grant funding. Our agency is in a unique position, or HHS is in a unique position in the fact that we do both grants and contracts. This is why it kind of puts this agency in the lead, as far as having resources and flexibility to fund small business awardees, or grantees, awardees, excuse me. The various components of health and human services, NIH is the largest funder where we have a billion-dollar budget, little more than a billion-dollar budget in STTR funding it's \$141 million. But the CDC, administration for community living and the FDA all have STTR budgets. There are smaller budgets, and only NIH has STTR funding. The CDC will be discussing their programs shortly later on in this presentation. The SBIR programs are in three phases. I'm sure most of you are quite aware of this. Phase 1 is a feasibility study, which funding raises ranges from \$150,000 for six months or up to a year timeframe. For phase 2, you can see it's \$1 million for a two year timeframe. Then we also have phase 2 funding, which is the competitive renewal. But the third phase of the SBIR program professionalization phase, NIH or Health and Human Services, we do not provide funding for this particular phase. Now we will do everything in our power. We have several programs that will assist you in receiving, or obtaining commercialization, but we don't provide commercialization funding like Department of Defense or NASA because they will be the end-user. They are trying to get information, products and devices out of the war fighters and space program. The, probably the most important slide will be this slide here, which is our website. Everything we are going to talk about today will be on this website with the link down at the bottom. If nothing else that you get out of this presentation today, please remember our link at the bottom, sbir.nih.gov. All right solicitation due dates. We have four solution dates and dates for grants. You can see NHLBI 273 and PA-19-271 that includes clinical trial. If you do not have a clinical trial to participate or your application did not have a clinical trial, you would submit or use forms PA-19-272 and PA-19-270. So another thing that makes our agency unique is that we have three submission dates. Down at the very bottom of the next submission date, or did it come September 5. We also have, coming up after that, January 6 and April 6 of 2020. Again, this provides the agency with a lot of flexibility as far as providing funding and having resources for individuals who are interested in submitting applications to the agency. All right, the contract solicitation is open until October 23 at 5 PM Eastern standard Time. And for SBIR this will only be NIH and the CDC. Again, this is only SBIR. The solicitation can be found, the notice can be found here at this link. The funding, again I can't stress that enough, but please make sure applications, or contract applications are in. Proposals are in by October 23 at 5 PM okay. All right, this is one of the, there are several avenues, several ways you can pull up contract solicitation with RST. This is one from the NIH funding link which can be found here. The next way, or most common way is probably going to be through

FedBizOpps and the link is at the top of the page. And then you can find this PHS 2020-one that was the program solicitation is itself. At the very top of this document is stresses the fact 5 PM on October 23 Eastern standard, Eastern daylight Time. In this document you

will find everything you will need to know as far as submitting the contract proposal. Again, another very important piece of the dice is that you need to read the entire document. All right, the overview of the

RST is listed here. It includes an introduction all the way down to dependency. Dependencies are extremely helpful, because they will go into very detailed explanation as to what can and cannot be included. The other items on this list here are also very important, obviously. But please do not take any of them for granted. Please read them in its entirety. Again, please read the documents. All right, the awarding components for NIH, we have NCATS, NHLBI, the Cancer Institute, we also have heart lung and blood Institute. From the CDC the components are listed there were actually providing funding on this contract page. All right, the types of proposals allowed for each of the awarding components, they will go into and talk whether or not you can have phase 1, fast track, or a directive phase 2 award. They will go into each topic. This is a very important you look at the topic and realize hey for phase 1, or NIH- NCI-408 I can have a word one that an application allows. Or the fast track you can have DSS allowed also, but they do not allow it on NCI-408 and directive phase 2. And it goes into the title of each of the proposals. This is an excellent way to see what Institute, or what agency is actually providing the funding on various topics that we have listed. Again, I want to recognize, or emphasize, that the programs, or the contact of solicitation is for SBIR only and we also have a phase 2, directive phase 2 is now part of this proposal and applications can be submitted under that particular mechanism. All right, I wanted to introduce Monique Pond, the program officer for the Cancer Institute and she will talk briefly about the I-Corps program available at NIH.

Good afternoon, everyone, I am Monique Pond. Kristi -- receives the I-Corps NIH program. This program is an eight week entrepreneurial training program or we focus on educating resources researchers, how to translate their technologies from the lab to the marketplace. The program is designed to provide market teams with training as well as mentoring and help to accelerate development of other technologies that are already receiving so from SBIR and STTR funds. There is an opportunity for offers to indicate interest in a potential future cohort of I-Corps NIH. Of all the awarding components participate. So be sure to check this list of solicitation for your particular topic. But all five NIH components Robert mentioned are participating this year. If you are responding to a topic from under the president components, you can indicate your interest by submitting a separate appendix she for what we call the contract pricing proposal. This will include a separate budget that you can request up to a maximum of 50 5K to cover the expense by I-Corps. As part of the 50 5K, I'm sorry you must include attending 2K for the court registration and fees and the remainder of the money you can use for travel expenses to cover time for teams participating, etc. We estimate that this program takes about 20 hours per week for the duration of the course. So this slide highlights the I-Corps at NIH format. The curriculum was first adopted by NSF, then we further tailored and focused it for the needs of life-sciences and biotech companies. The format includes 839 83 day kickoff event, followed by six weeks of online classes and culminating

in a two day lessons learned in person event. Attendance at the events is required for all the teams excepted into I-34. Teams excepted into I-34 will work with instructors and one of three tracks. We have a therapeutics track, diagnostic tools, and e-health track and lastly a medical devices track. If you have additional questions feel free to cut our web sight, SBIR.cancer.gov/ichor. We have a lot of frequently asked questions, answers already up there, as well as some interviews and short videos we have done with companies that participate in the past that you might want to look into checking out. I will hand it back to Robert.

Thank you very much, Monique. Our next slide is going to talk a little bit about, the next two slides were talk a little bit about how, what is necessary to complete phase 1, the mission. The very first item is technical element proposal. The most important, I want to the most important, but the actual meat of the proposal will come under a content of the technical element. Because that's going to be, I will say the most important, but certainly a very technical aspect of the post. The next proposal is the business proposal, which essentially encompasses the budget and/or a phase 2 submission. Yeah, the only difference, or only items that are added under the phase 2 submission of the draft, the statement of work and also the proposal of summary and data record and appendix. Estill also has the content

and technical element with the business proposal included. All right, this particular next aspect of it is whether or not you will have human subjects or vertebrate animals involved. This is new as of last year. We included the single institutional review board. These are items that are now part of the proposal. We also were included in the proposal. You will see where there are instructions for human subjects and for the animals. This is important, even if you do not have new requirements, I'm sorry and they're just like submissions that include human subjects, you still need to complete the form, which is included in this particular proposal. We also have human subjects in clinical trials information form that's included. And again, this form must be included in every proposal. Again, even if you do not have human subject participating, you still must include the form. This just covers the definition of a clinical trial. Next slide. And it's important that you realize even if you don't think it will include studies it probably will be included in the clinical trial. If you answered yes to all of these questions, then it is considered a clinical trial and documents must be completed. This goes more into the clinical trial changes over the last few years. This one is important, please read this. Happy about it if you have any questions speak out to us, or contact us here in the office with the director. This is what I was talking about the clinical trial form and human subjects. If you do not have them check now coming box, but this form must be included in your proposal. Something that is quite unique course takes people by surprise in your technical proposal with applications, or page limits cannot exceed 50 patients pages. Grant proposals are six and 12 patients pages. For this award you cannot exceed 150 pages, that includes everything that goes into that proposal and more information is provided there. All right, again I want to stress are emphasized that if you have quest, please jot them down and we will cover them at the end of the proposal. We have a lot of information and a lot of individuals

who need to speak in common with materials. I would like to hold them until the very end. But I do want you to address them, but actually jot them down at something. The slides can be found on the handout. If you look on the control panel you will see the slides found with HHS [Indiscernible - low volume]. Again if you have trouble with that, you can contact us and we will be more than happy to provide the slides to you. All right, I wanted to talk now about the differences between the SBIR program and the grant and contract proposal. She can see it listed here, contracts with an acquisition method and a grant is an assistant mechanism. With contracts, things like is a very well defined topic for grants, it is broad and very, but you can also have broad or narrow topics. The contract opposition will be very narrow. With contracts, only with contracts to the contracting officer, you can have contact with. You may only have contact with the contracting officer. For grants you conduct the program officer at any time. You have a small window of time you can speak with the contracting officer. Contracts are submitted on the EC TS system and we will talk about that shortly. I am glad they are submitted on the SF 424, grants.gov and EL .com and separate the application. Some other differences with a contractor, all the offer is capture, register and SBIR company registry. You can also have [Indiscernible - low volume] grants.gov is not applicable and the E.R.A. common system is not applicable either.

All contract applications, or proposals are now submitted using the eclipse system. Next slide. Now as far as questions and answers, as I mentioned, we will talk about those shortly after all of the presentations have finished. One of the things I wanted to highlight is that the deadline for submitting questions is August 27 at the close of business. You can also, you must speak with the contracting officer okay. The only person in writing an email that you may contact us for as questions concerning your proposal. And these proposals will also be made available to the others who are submitting the contract proposal. All right again October 23, you will hear the several more times throughout the presentation. At 5 PM electronic submissions only, no paper submissions. All right, now I want to turn the program over, or turn the discussion over. Before we get to Mike, again, required for all proposals, or electronic submissions required for electronic proposals. No longer paper submissions and the eCPS system that Mike Solis will discuss in the next two slides, he will go more into depth about the system and answer questions toward the end about the system also. Mike, are you online?

Yes I am, thank you Rob.

No, thank you.

I'm sorry, can you quickly go back to the previous slide? Right there, thank you. That's, so that's the URL I was going to take you to, the eCPS landing page when you click on there. The landing page has various resources for how to upload. It has frequently asked questions and you will see a lot more resources the menu will see in the upcoming slides. I wanted to kind of give everybody that overview that you will have that also to check. When you click on that URL it's an Internet site and it will take you and you will have various resources there to

help you out. Next slide, please . Thank you. So when you click on that URL, one of the sections you will see is the login section under want to submit a proposal. You are given the option to login , if you have already registered, or to create a new account . You will see that there were says register a eCPS account. If you do not yet have an account and you click there , yes , thank you, it will take you to this registration screen. Very simple, you put in your information here , then you click continue . Once you do that, it will register your email address and then also send you a pin . What you will do is use that pin to go back and use the pin to unlock the site well it will allow you to submit your proposal. Now, once you have registered and you go back and come see you have already registered your account and you go back in at a later time, at a later date. You don't need to go through the registration process. I'm sorry, if you could go back one screen again and you click eCPS login , once you are already registered you put in an email address that you have already registered. Then it will send you again a one-time pin. So what you do every time you go when is use your email address, along with that one-time pin it provides and it will unlock the door to allow you to get in and I will show you a little bit more details, coming up. That pin, as its stated, I'm sorry next slide again. Has it dates here that is good for eight hours. Once the eight hours hit, it will expire, but you can always request another pin . The nice thing about this is is it does not require you to keep the password you may forget. It's a secure way reregister an email address and every time you want to access it you go in and ask to sit through that one-time pin you get. Next screen, please. Once you go in and you login using your email address and Penny were provided, at the bottom section of the web you will see open solicitations. You can view it during the various ways. One of the ways you have seen here is under the search by agency last product you can check the toggle box for SBIR's and STTR's , then you will get the filtered list of the topics for the solicitation. So you would find your topic from the list that you would like to propose I guess. On the left-hand side you will see the link to the solicitation, which will then take you back to FedBizOpps. On the right-hand side , for your topic you're interested in, you will see the submit button. So when you hit the submit button , you will see what we will see on the next slide. Next slide, please. So as a sample here, we have clicked on the NCATS topic 19 -019. I highly recommend once you hit submit on the previous screen you also check the information at the very top here and verify guess you are submitting, or about to submit your proposal in this case on topic 19. You can verify the title as well. Your login for information will be on the right-hand side up there, your information will be there once you login. And under the proposal name, you will provide and in the upcoming screens I will show you how we like the proposal name of structure to be. That is where you provide your proposal name and then you have your various documents that you upload. The first of which being is your technical proposal . And again on the filling screens we will show you the name you can use for that, your subjects document, your business proposal and then your Excel spreadsheet.

Once you have uploaded those, you have named them Professor Lee, you have uploaded, you will then hit admit. So you you up each section , name your proposal and select your technical and your other forms. You

queue them up and then you hit submit proposal and then you will get a validation, verification screen telling you that if proposal has been submitted. If you could please go to the next screen, thank you. So that first field that was on the previous screen, the proposal name field, not the one particular tooth a document, but the proposal name field, this is the format you should follow in naming your proposal. So in this example at the very bottom you will see your agency name, the awarding component and then the topic number. Topic and on the previous screen we had 019, he would name it accordingly. When? That's at the very top. Can you please go back one more screen? Thank you right there. So that would be at the proposal name field, right there thank you very much. So moving along to the individual document names, if you can go to the next screen and then the next screen after, thank you right there. The first document you upload your technical proposal for example, this is how we would like the technical proposal made. For example, XYZ company name and then awarding component, topic, the topic number and then technical.pdf. The same for your human subjects sheets one, company, awarding component, topic number, human subjects PDF, same for your business and your Excel spreadsheet, just to be consistent. To have your naming at the very top that you will and then you have the naming of the individual document. So of course the Shabbat morning topic the awarding and that I number but next slide, please. For those who are submitting a phase 1 and phase is a phase to fast-track proposal, for phase 1 you would follow the instructions like we have gone through. You would add phase 1 beginning on the upper level, on the

eCPS proposal name you would add phase 1 to the beginning, that would be the only difference. Here is on the next couple of steps. Once you upload, you queue up your associated documents, your technical, your business, your human subjects form, your Excel spreadsheet. That would be but a number two here. You would queue them up and hit submit. Once you hit submit, next to that same topic, instead of just seeing the submit button that we initially saw, you will see a new button that says alternate, or new proposal next to the submit button. You click, thank you, you could the alternate new proposal, submit new/alternate proposal and you go through the same process. Once you click that it takes you back to the upload window, which we sought. The only difference now being he would name it and title it phase 2. Then you would proceed with uploading the associate phase 2 technical business human in Excel spreadsheet form documents. So you those up, hit submit and once you do that, you'll get your other unification of receipt form and notice. In addition to that notice you will get a pop-up screen and an email sent to your registered email address verifying if the was sick upload was successful. Is the 840 CPS portion. Thank you and I turned back to Rob, thank you.

Thank you very much, Mike. Now we are going to go into the overview of the topics with program officers from the five Institute here at NIH and also representatives from the CDC. First, our presenter from NCATS, the national Center for advancing translational sciences is Lily Portia and Lily I will turn it over to you.

Thanks Rob, I'm hoping you guys can hear me and him great, awesome. I'm going to talk about our contract topic 019. Alternatives to commercially available cell culture insert membranes and manufacturing techniques. This is a topic that we expect to make 1 to 3 awards. Please note we are not expecting fast-track proposals, nor direct to phase 2 proposals under this particular topic. The general goal of this contract topic is to identify

new biodegradable membranes that can be used in cell culture into place and this is really relevant to high in vitro drug screening. And we want to be able to develop some technology via the contract that we would be able to have these microtiter plates act as a vessel where you can basically do individual reactions between the biological model in the sample that would be in these well plates. Clearly there is more information on this topic in the contract proposal, but here we put a few of the expected deliverables we would want to see under a phase 1 proposal and depending on, we also give some ideas of what we would like to see for expected deliverables for a phase 2. If you have any questions about this topic, please contact our contracting officer Jeff Schmidt listed here in his email. As Rob said, please do not refer your questions to me or other staff members at NCATS, we will not be able to answer your question. They need to go through our contracting officer. And with that I will turn it back to Rob.

Thank you very much, Lily. All right, we would like to have Tiffany Chadwick from the National Cancer Institute talk about their program.

Hi Rob, this is Monique Pond, I believe I will talk about the products with NCI.

My bad, I'm sorry.

No problem, no problem. If you could just go back one slide, please. Yeah, so hi, everybody I am Monique from NCI. If you have questions on the topics am about to discuss, please contact our contracting officer Tiffany Chadwick at the email. We have 16 topics this year and allowed for information on our website, and CIR.cancer.gov on the contract topics and deliverables. Here I've included a little bit of background on contract finding through NCI. Contract topics are developing in key areas in NCI interests, but also strong potential for commercialization's. In terms of budget, it really varies year to year what projects come in. At NCI we do not have a set amount for contracts. I am showing here some information from the past six years just to show contract funding has ranged anywhere from about 15% up to about 35 percent of the total NCI SBIR budget. Next slide, please. So here I have listed are 16 topics for this year with the NCI topic number as well as the title. Fast-track proposals will be accepted for all NCI topics this year and direct to phase 2 topic proposals will not be proposal accepted. Next slide, please. I just want to mention, I'm showing the maximum budget for each topic on the next several slides. I won't go through each of them, but be sure to check many of the contract topics that fall over and under the NCI topic weavers. When developing your

budget, be sure to check with the maximum budget allowed for that particular topic is. Okay, I'm sorry. Topic 397, manufacturing innovation for the production of cell-based cancer immunotherapy is. The goal of this topic is to develop new technologies, devices, or processes that will improve product manufacturing. Authors are expected to demonstrate the utility of the innovations for at least one cell-based cancer immunotherapy and we are anticipating make anywhere from 2 to 4 awards. , Please. NCI topic 398, development of analytic agents for cancer treatment. The goal of this topic is to support the preclinical development of agents and they can be used in a neoadjuvant setting or possibly combined with other cancer therapies. Offers should demonstrate the optimization of the cells and also include potential efficacy benefits and demonstrate those potential benefits and relevant animal models. And we are making 3 to 4 awards for this topic. Next slide. NCI topic 399 , combinatorial treatment utilizing radiation to locally activate systematically delivered therapeutics . For this topic we encourage proposals that either address new treatment strategies for include design or evaluation of innovative therapeutic agents. We also encourage the proposal to develop new drug formulations , for example nano formulations and we anticipate anywhere from 2 to 4 awards.

Next slide. Topic 400, sensing tools to measure biological response to radiotherapy . The goal here is to create either in vivo or in vitro sensor tools to help define radiation dose and specifically include biological response. Ideally proposals will include sensors that can allow for noninvasive , dynamic, as well as real-time data collection, for example CT, MRI and the nano-based sensors are also encouraged under this topic . And we anticipate making anywhere from 3 to 5 awards. NCI topics for quantitative biomimetic phantoms for cancer imaging. The goal of this topic is to stimulate diagnostic imaging or treatment of cancer and offers should divine imaging modalities, such as MRIs , etc. and they should also include the tissue type of organs that the Phantom will Minnick mimic and propose feasibility studies should include, using the developed Phantom, and demonstrate not only its quantitative capabilities, but also the message for calibration with the tool. And we anticipate 3 to 5 awards for this topic. Next slide.

Topic 402, artificial intelligence aided imaging for cancer prevention, diagnosis and monitoring. So in this topic we are interested in proposals that develop artificial intelligence, or AI-aided imaging software and the software can either be used as a stand-alone tool, or as a tool for assisting decision-making in a clinical setting down the road. And we encourage proposals for these developed systems to be proud based, hopefully and we anticipate 3 to 5 awards. Next topic . Topic 403 spatial sequencing technologies with single cell resolution for cancer research. So the goal of this topic is to develop research tools that can seek DNI or RNA and rash, frozen or six cells without using spatial contact. So potential offers for the project immigrate imaging without bodies with all Mex measurements. If so you are working on a project where you are proposing all Mex measurements, other than sequencing , you should respond to the next topic I am going to talk about. Topic 404. Then this topic, I'm sorry, let me go back one slide Massari. In this topic is specific to sequencing technologies. And we anticipate making 3 to 5 awards for this topic. Next slide, please. Okay so topic 404, subcellular Mike asked if he and all Mex and cancer cell biology. The goal of this topic is to stimulate innovation in an

area of cellular imaging modalities and project activities will include a demonstration of feasibility when combining these imaging modalities with other assessments such as genomic or cardiac analyses. And we anticipate 3 to 5 awards for this topic.. Topics 405 , enter tumor sensing technologies for tumor Pharma carpet hoping the proponents for this topic must include in vivo measurements. Looking at specific intratumoral markers of anti-cancer activity , when the therapeutic agent is delivered and offers should propose multiple experiments and demonstrate future capability of supporting clinical decision-making. We anticipate 2 to 3 awards for this topic. Topic 406 , software for patient navigation to the cancer care continuum . This topic is to support development of new software tools for patient navigation and projects submitted under this topic can be tools that are aimed there at approving tasks either for patient or for patient navigators , they are both covered under this topic. And we anticipate making 2 to 4 awards. Okay, topic 407, cloud-based software for the cancer research data, and. For this topic we are interested in proposals that develop solutions for cloud-based informatics that will integrate with the CRTC. Officers should develop a prototype and conduct a small alley feasibility study as part of this project as well. And we anticipate 3 to 5 awards. Topic 408 , tools and technologies for visualizing multiscale data. We aim to promote development of tools or technologies that will ultimately improve data sharing , I'm sorry, improve data analysis by making visualizations of multiscale data possible. So in the project first approval, offers should propose at least three different types or scales of data , examples of different types are listed here , genomic, molecular, cellular, issue an individual, patient or population and again proposed using at least three of these and incorporated into the tool. And we state today's rewards. Next slide. Topic 409 , software for automated analysis of images for improved cancer health. This topic proposal should include software development for automated imaging analysis and we included some examples here such as automated assessment of data watching speeds, or automated in-home monitoring of patient compliancy with the medications or pass physical therapy regimens and offers should develop a dysfunctional prototype as well as conduct a small feasibility study. Dissipate 3 to 5 awards. And topic 410 , cancer clinical trials recruitment and retention tools for practice of engagement. Proposals for this topic can include developing tools that are either clinic pacing or patient basing tools. All tools proposed though should address clinical trial recruitment and retention issue, or possibly both. And be easily adaptable for a variety of local trial design down the road. Dissipate 3 to 4 awards. Slide. Topic 411, the identification software tools for cancer imaging research. The proposal for this topic should include software tools that can protective health information , patient data sets and images. For example, images produced by whole flight imagers . They should be able to retain the data they remove for down application and be able to recognize multiple file formats and be adaptable. And we anticipate 3 to 5 awards for this topic. And this is the last NCI topic for this year , 412 software enabling data integration from wearable sensors for cancer pages. And the goal of this topic is to support development and tools that apply to cancer research applications involving wearable technologies . One of the activities for this topic is the development of a functional

prototype, as well as providing provided [Indiscernible - low volume] we anticipate making 2 to 3 awards for this topic. Again, if you have questions on any of these topics, please feel free to contact Tiffany Chadwick. With that I will turn it back over to Rob.

Thank you very much, Monique. I guess we can all see where the money is. Our next topics for heart, lung and blood Institute will be presented by Mike Peck .

Good morning, everybody, just briefly if you want to learn about the [Indiscernible - low volume] program the contact information is listed there. And a correction made a lot of heart and but do not contact Robert Letterman, contact Kristi Cooper who is listed in the funding contract information there., We have two topics this year. First is topic 109, transcatheter tray leaflet for repairs is. We will accept fast tracks as well as phase 2 proposals. We anticipate making two awards with the phase 1 and phase 2 amounts listed here for a total cost and the duration . The goal of this project is to develop a catheter system to achieve nonsurgical tricuspid repair. More information is provided both here and in the announcement. And for both of these, I should just know that the intramural laboratory contracting author is interested in testing and working with the contractor to test and validate. The second one is topic 110, MRI myocardial biopsy system. Fast tracks will be accepted and phase 2 will be accepted. They're just making two awards and the focus of this is to develop a myocardial biopsy catheter chart to extract [Indiscernible - low volume] tissue. The project should generate an early feasibility study for clinical evaluation at the NIH or other medical centers and anticipated at this point to continue on after the contracts completes and possibly a phase 2 bridge toward and ultimately into [Indiscernible - low volume] thank you.

Okay thank you very much, Mike. Are you in a train station or something? [Laughter] no, thank you very much.

Sadly clinical center.

Okay I was wondering man, good gracious. Okay our next topic will be presented by Cathy Young and I believe Elizabeth Powell from our national Institute on alcohol abuse and alcoholism ,

NIAAA. Kathy if you are on the line, it's all yours.

Kathy?

Kathy? Okay, I tell you what we will do. We will skip NIAAA for the moment and go to NIAID with Doctor Wolfgang that nursed or Natalia .

Hi, this is Wolfgang Leitner from the national Institute of diseases and I will be introducing fiscal year 2020 SBIR six from NIAID . So on the falsification NIAID calls for proposals in response to the following 11 topics. I will briefly describe the objective and scope of each of those. I would like to point out that all 11 topics allow fast track

puzzles , but not all of them allow the right to phase 2 proposals. Please make sure to take the specific solicitation before applying. I would also like to remind you that budget caps for phase 2 proposals [Indiscernible - low volume] topics. Next slide, please. So the first four of the 11 topics are related to HIV research . 76 addresses the needs for it to candidates for moving B and T cells, enhancing DNA and broadening responses with low or no reacted in the city and this will be achieved by a selected civil vaccine adjuvant. The program supports early-stage or clinical development of promising HIV antigen adjuvant formulations for preventing HIV vaccine. Next slide, topic 77 calls for a NexGen HIV vaccine based on the co-delivery of HIV immunogens on particles. A variety of HIV immunogens have been described in the objective of this topic and it's to promote strong and long-lived neutralizing antibodies combining immunogens with an effective multivalent and genetic display system or particles. And such platforms may also promote maturation of anti-HIV in the body. The program supports a range of development, evaluation,

validation and manufacturing activities. Next, please. Topic 78, support sequence based assays to quantify replication competent into the reservoir. It prevents her of infected individuals. The proposals omitted in response to this particular call should begin developing and commercializing assays to monitor the size of the location competent into the reservoir and clinical research. Secondary assays being developed for this program should be able to discriminate between active transcribed and latent viruses. Next, please . So the last a related topic on the NIAID lift calls for the discovery for design of small molecules that specifically target HIV RNA . The objective of such drugs is to prevent RNA processing translation in order to stop viral application. Next, please. The next three topics from NIAID are in support of the institutes vaccine adjuvant program. So topic 80 supports novel adjuvant [Indiscernible - low volume] include all immune diseases, allergic diseases, but also transplant rejection . And in addition to screening of compounds of formulation, the program supports the catheterization and early-stage optimization of lead adjuvant candidates from the screening. Next, please. Topic 81 supports the next phase adjuvant research, the development of novel adjuvant, are again vaccines against infectious or immune mediated diseases. All infectious diseases are included except for HIV. The program is designed to accelerate preclinical development and optimization delete adjuvant candidates, or a combination . Together with the vaccine that it's intended to prevent human disease caused by infectious agents, or undesirable immune responses. Novel adjuvant have to be combined with the vaccine. This can either be an extra mental vaccine for licensed vaccine. And under this topic, they cannot be developed as a standalone . Next, please. So a small number of adjuvants with favorable clinical track record have been developed and reported on , but they are generally not available to the widened vaccine research community. Therefore topic 82 supports the development, validation and production of such adjuvants either based on, or very similar to these types of late stage developed adjuvants so they can be provided to the vaccine research community either as commercial products or through licensing agreements. Next, please.

NIAID supports the use of a wide variety of animal models. Unfortunately and and analogical analyses certain mammalian models are

severely hampered by the lack of suitable reagents. Most notably reliable antibodies that when allow researchers to identify and track immune cells, or to analyze immune function. Therefore, topic 83 supports the development and validation of such reagents. This would be specifically for arthropods, amphibians, nematodes, marine tech nights. In terms of the underrepresented, on the alien models, would be for guinea pigs, ferrets, rats, different pig species, rabbits and marmosets. Next, please. So the next two topics from NIAID support the development of therapeutic . Topic 84 calls for research on antiviral drugs to cure chronic hepatitis B infection. Namely research on candidate drugs with mechanisms of action that are different than those of existing drugs. The executive objective is a functional cure of hepatitis B, which is very difficult to achieve with current therapies. So under this program, such novel drug should be developed further with the intent of commercializing them. The program also supports the parallel identification of additional determinants of treatment and efficacy. Next, please. Topic 85, supports research in the area that recently emerged as a high priority for NIAID , the development of broad spectrum monoclonal antibody therapeutics against human enterovirus's. They can be individual monoclonal in the bodies, or a cocktail of maps that each have narrow specifically, as long as the final product targets different strains of the retroviral family, multiple species or multiple species of enterovirus. Next, please. So the final NIAID topic in the solicitation , topic number 86 calls for the development of rapid diagnostics for select endemic dimorphic fungi based on the timely recognition and treatment of invasive fungal diseases is the key to reducing morbidity and mortality , but also to reduce the inappropriate use of antibiotics . Diagnostics being developed under this topic should be rapid, sensitive, specific, simple, cost-effective and they should be useful for detecting fungal disease in the primary health care setting. And next slide. If you have any questions related to any of the 11 topics from NIAID please make sure not to contact any program staff, but relay the questions to Charles Jackson . Thank you.

Thank you very much, Wolfgang. We are going to go back and Cathy Young is on the phone now, so take it away Kathy.

Okay.

Hello, hello.

Hi, Kathy. Oh Elizabeth, Elizabeth. Elizabeth Powell was on the phone.

Hi, I can take These two so we can move along.

Okay, thank you.

This is from an alcohol biosensor from and I AAA , it is fast-track up to nine months or \$500,000 and also the phase 2 of up to 2 million for two years. The number of anticipated words is 1 to 3. The key thing here is that this is evidence of a functionable, functional marginal alcohol biosensor and we want real times dancing . The next one is the

data science and this one is for data science tools for alcohol research, it is phase 1 only, no fast-track with 1 to 2 anticipated awards. This goal is to develop software applications and algorithms for our

NIAAA funded alcohol researchers. Any new deliverable is possible, but the key thing with this offer is here that they should contact NIAAA funded researchers, which is through the public databases, to discuss the act of will individual needs. Any questions for these topics should go to Jeremy White. Thank you.

Thank you very much, Elizabeth. All right, the CDC topics will be presented by Barbara Stewart and I believe Julio Lopez. So guys on the phone please take over.

Hi, this is Barbara Stewart, I am the Deputy Director of the [Indiscernible - low volume] office or the SBIR research program for the infectious disease centers and I am going to be presenting the six topics we have today for CDC. One thing we want to reiterate at this part in the conference call is please read the solicitation in any future amendment. It is very helpful to the applicants in two different companies that they were the solicitation and are provided all the information and follow all the requirements in that. If you have any questions regarding any of the CDC topic, please refer to the 63 in the solicitation and you will see the different contracting authors for the different topic areas and you will also see for general administrative questions are off science came in with us and mem Kelly available also. Please your questions you have been emailed and also copy our office of science general in our mailbox, which is the tran02@CDC.gov email address. As soon as the office manager's the CBCs SBIR program the office works with the ventures and has a SBIR set-aside to ensure SBIR funds are a quality high impact SBIR projects. CDC participates in both the grants and solicitation. CDC has opted to participate in the majority BC ownership authority. CDC does not participate in the STTR program at this time. Also CDC does not participate in fast-track director phase 2 or phase 2B. Therefore the CDC takes solicitation for phase 1 only. The CDC has set up a approximately \$10 million. We ordered approximately 30 phase ones, usually up to 150 each, then for phase 2 -1 million each. Normally CDC funds up to 150 for six months and for phase 2 award up to 1 million for up to two years. CDC does participate in SBIR's technical assistance program, the niche assessment, commercialization Excel is a greater program and Pond I-Corps. National Center for chronic disease prevention and health motion measurement of opiate withdrawal in newborns. It is phase 1 and the project goal is to create a wearable device that objectively measures a newborns withdrawal symptoms. The activities and deliverables build upon existing technology to create a device that not only captures body temperature, movement, sleep and sound and muscle tone, ensures the device is small enough and safe for anyone work, creates a user-friendly interface to view symptoms and guide diagnosis, treatment and management of opiate withdrawal in newborns.

The next topic is with the national Center for environmental health number two. The web-based platform for flooding on her body and health care access. This is also phase 1. The project goal is to launch a

portal or platform providing high-resolution spatial information on baseline flood risk and real-time inundation information. The proposed data platform intended to receive updated data feeds from federal agencies and private partners and protect human health during flooding disasters by facilitating access to health care and emergency care.

Activities and deliverables: collect and synthesis of publicly available baseline flood risk information, creation of a national data set of critical healthcare facilities, merging two data sets into a single pilot based platform that overlays flooding with healthcare facilities, generating potential facilities at risk from flooding. Our next three topics are from the national Center for emerging and zoonotic infectious diseases, topic 21. Assays to detect and quantify E. coli 0157 and water samples. We anticipate wanted to phase 1 awards. Project goals: to develop and assay that can detect and quantify E. coli and water samples. Activities and deliverables, develop and adapt a method to detect if I and quantify E. coli and water samples. Determine the sensitivity and passivity to test against E. coli 0157, other ST EC serotypes and non-STC E. coli. Conduct matrix evaluation understand the assay performance in different water types. Our next topic is topic 22, device development for microbial surface blank, field extraction collection. We anticipate wanted to phase 1 awards. The project goal, to develop an nonsampling device able to efficiently collect microorganisms from a solid surface and extract and concentrate organisms from the device into a vial or tube in the field. Phase 1 activities and expected deliverables, develop prototype sampling illusion and concentration device. Test efficiency of recovery by placing the quantities of Staphylococcus aureus and Acinetobacter the money I sells and clustered areas the for seal sports if anaerobic chamber is not available on the surfaces, then use the device. It will be determined by quantitative microbial cultural and they compare the number of cells and spores based on the surface. Topic number 23 is diagnostic testing platform to assess antibiotic activity for microbial communities with cystic fibrosis pages. The number of anticipated awards is 1 to 2. To do for the development of a standardized diagnostic platform for use in a clinical laboratory to determine the microbial community susceptibility and type program of an infection using primary cystic fibrosis clinical specimens. Phase activities and expected deliverables: establish a laboratory developed in vitro test methodology model that can test clinical sputum specimens for microbial community susceptibles or yield the microbial community and I'll buy over him. Apply the model from deliverable one for an existing set or bank of clinical specimens to track so sputum community composition following one or more in biotics. Proof of concept, compared he the community changes observing and clinical but am specimens during antibiotic treatment. At our last topic is from the national Center for immunization and respiratory diseases, it is a phase I award. The project goal is to develop a test that can rapidly detect viable Legionella bacteria and water samples collected from environmental sources. Phase 1 activities and expected deliverables: demonstrate proof of principle by comparing results with traditional Legionella cultural methods. Determine ranges of sensitivity and passivity for water sample sources tested. Develop a protocol to validate the assay in the field. I read Rick, please contact our contracting officers listed in the solicitations for each contract area, thank you.

Thank you very much, Barbara.

Again, I would like to stress that the closing date , receipt date for all proposals , October 23 5 PM Eastern daylight Time, okay. Again, I want to thank Patty for running the webinar itself and keeping me on track. And again, thinking Matt Portnoy for putting together the slides we used today. And Patty is going to close us out.

Hi, everyone. Just in closing I want to remind you that the slides , the webinar recording and the transcript will be posted on our website in the next two weeks. Please refer all questions in writing so contracting officers located in section 10 of the soul is the solicitation, these questions will be compiled and answered and an amendment which we will announce and also post our website, sbir.nih.gov for the public to view. The questions and answers will be included in the amendment. All questions must be submitted by August 27. In the meantime , we ask that you stay connected with us through our listserv and follow us on Twitter at @NIHsbir. For all of the questions in the console, I will ask you submit those questions if they were not answered in the webinar to sbir.nih.gov. We will do our best to answer those questions. Again, we ask you read the solicitation in its entirety and further topics and funding institutes and centers that you are interested in applying to, please contact the contracting officer, not the SBIR program officer.

Again, if you have any other questions, feel free to contact the SBIR STTR central office team at sbir@od.nih.gov . We thank you for participating with us today. Thank you again to all of our presenters. Thank you Rob for manning this post and we will be in touch with the community soon. Have a good day. Bye-bye.

[Event Concluded].