HHS-SBIR-Contract-RFP-Pre-Proposal-Conference-Webinar-PHS-2025-1-Transcript

September 23, 2024

STEPHANIE FERTIG: Good afternoon, everyone. My name is Stephanie Fertig, I'm the Director of the Small Business Programs within the NIH SEED Office, that's the Small Business Education and Entrepreneurial Development Office here within NIH. We are going to be recording this webinar; in addition, we will be making the slides and the recording available about a week from today. So, approximately a week from today, we'll send that information out. It will also be available on our website, seed.nih.gov, where you can also find information about some of our other programs, as well as other events that we have scheduled throughout the year. We are going to have time for questions and answers. Please, do ask questions in the Q&A at the bottom. We will be including additional information in the chat but for questions, we really want you to ask those questions using that Q&A feature at the bottom, Zoom's Q&A feature at the bottom. And with that, I really want to introduce Adam Sorkin, who is our Small Business Policy Manager here within SEED. And he's going to present about the 2024 contract solicitation. So please, Adam, take it away.

ADAM SORKIN: Great. Thanks so much, Stephanie, for that introduction. And I am very excited to be here with you all today to talk about our contract solicitation. And we are going to go through a large amount of information very quickly today. I do encourage all of you to visit our website seed.nih.gov, which has a wealth of information and resources about our programs. And you can learn about most of the things that we're going to be discussing here today. And so, the Department of Health and Human Services, known as HHS' mission, is to enhance the health and well-being of all Americans. And our

small business programs support this mission by helping get the great innovations that our companies are developing into the hands of patients, clinicians, caregivers, and the researchers who need them. And as you may be aware, there are five components within HHS that have an SBIR program.

Today, we're going to focus primarily on NIH and CDC, who are the two participants within HHS that participate in this contract solicitation. I'm going to provide an overview of these programs at HHS broadly and the NIH program, and you'll hear more from CDC a bit later in this presentation.

And so narrowing in, the NIH's mission can be summarized as turning discoveries into health. And our small business programs, in particular, help accelerate discoveries from bench to bedside. And when we take a look at these programs, these are two collectively, congressionally mandated programs known as America's SEED Fund, including the Small Business Innovation Research Program, or SBIR program, and the Small Business Technology Transfer Program, or STTR. HHS supported roughly $1.4 billion in small business R&D funding last year through these programs. It is important to note that the contract mechanism only uses SBIR at HHS. If you would like to propose an STTR project, you'd need to use the grant or cooperative agreement mechanisms. And you can find more information about this on our website, and I'll point you to a little bit more information later on in my presentation as well about how to get engaged with those programs.

And so what are the benefits of NIH small business funding? Our small business programs represent one of the largest sources of early-stage capital for life sciences in the US, and this is all non-diluted capital. The government takes no equity, no debt. We fund small businesses across a spectrum of translational and R&D efforts. And in fact, many of our recipients are early-stage and very new to the program, so we're very used to working with new startups and helping them get engaged and manage their awards properly. Unlike other agencies you may have worked within the SBIR program, HHS typically is not usually the final purchaser of products and services developed through these programs. Occasionally, contractors may find opportunities, but by and large, we rarely do fund Phase III awards. That said, our recipients leverage government funding in a number of ways to support new product development, pardon me, including developing and de-risking their technologies to the point where

they can attract the partners, investors needed to take innovation to market. And many of them have done this successfully. NIH supports innovations targeting a wide range of disease areas, from cancer to minority health and health disparities, and we really do encourage you to review our success stories on our website to get a feel for the types of projects that have successfully leveraged our programs. You can really see how they have taken advantage of SEED and other NIH resources to secure downstream partners and resources and or launch new products directly.

And so, speaking to the programs directly, who can participate? So generally, this program is open to US-based small businesses, eligibility will be self-certified by contractor at time of award but generally, the company must be directly or indirectly majority owned by US citizens or permanent residents, or in some cases, majority owned by multiple investor organizations. You can visit our website for more detailed guidance and there's, of course, detailed guidance within the solicitation as well. We do very much encourage the participation of women-owned and socially and economically disadvantaged small businesses. Unlike the grants process, you'll note that we do still request that you provide some demographic information on the proposal cover sheet, as defined on this slide. Please, do keep in mind that this is used for reporting purposes only and is extremely helpful for us.

And so, as you may be aware, these programs are phased. Phase I should demonstrate feasibility, and Phase II tends to support expanded or more full research and development. A hallmark of NIH's programs in particular is their flexibility. There are many pathways into the program, whether that's a traditional Phase I proposal, a Fast-Track combined Phase I and Phase II proposal, or a Direct to Phase II project. And you'll note in the contract solicitation that many topics provide these options. We do also offer multiple opportunities to support commercialization of your Phase II projects and transition to the marketplace, such as our Phase IIB competing renewals and CRP projects. Do keep in mind that you may have follow-on grant opportunities available to you, even if you receive a Phase I or Phase II contract. I do list the program budget guidelines here, but NIH and CDC also have flexibility to make larger awards for select topics. And you'll note in the solicitation that each contract topic has specific budget guidelines. So be sure to read the solicitation carefully to understand what flexibilities are available for each topic, in terms of both applying and the budget limits.

And I'm not going to go into length at the differences between the two programs today, but it is important to understand the work requirements for SBIR in Phase I and Phase II. Recipients can outsource up to 33% of the effort in Phase I, and up to 50% of the overall effort, and generally the overall budget in Phase II. Any deviations from these work requirements must be discussed prior to application with your contracting officer points of contact. And as I mentioned, you can find more information about all of our open funding opportunities for our small business programs on our website. Information about our current open funding opportunities is linked on this slide. The majority of our applications are investigator-initiated projects via grants, particularly through the omnibus solicitations. These are listed at the top of the slide, and we do strongly encourage all applicants and offers to read the program descriptions and research topics in our omnibus solicitations to get a better feel for the missions and the research priority of all participating institutes, centers, and operating divisions within HHS that participate in the omnibus.

NIH does have targeted solicitations including this contract solicitation as well. But do keep in mind that not all institutes and centers, and certainly not all of the operating divisions, centers, institutes, and offices participate. So, it is very important to read each carefully and reach out to the appropriate contacts listed in each solicitation. And links to the contract solicitation can be found on our SEED website. The SBIR contract webpage provides information about contract basics including the differences between contracts and grants, what to expect. Generally, we will post any amendments to the contracts here as well. But do be sure to review the sam.gov pages that we link out for the most current information. And you can always view the full solicitation at sam.gov. And you will be able to download the solicitation and open it as a large PDF with a couple of hundred pages, I think. It will have general information about the programs, application instructions, followed by the specific topic areas that you will hear about later in the solicitation and this presentation.

And you will be hearing specifically today from the six participating NIH institutes and centers, as well as the three participating CDC centers listed on this slide. Other institutes and centers, as I mentioned, if they're not listed here, do not participate in the contract solicitation. Each participating institute or

center, you will note, has very specific contract topics. And for the contract solicitation, you must apply specifically for the topics as described. And so, you will want to be sure to review the required elements of a Phase I or Phase II proposal as appropriate, including both the technical proposal and the business proposal. Applicants should note that the Phase I technical proposal does include a draft statement of work. This is a new element that was just added last year, so it may be new if you have previously applied for contracts, but not recently. All proposals now do require disclosure of foreign relationships, and more on that in a few slides. Please, note that all section elements of the technical proposal must be addressed, or the proposal will be removed from the competition. So just be sure that you have a very good understanding of what a complete proposal looks like and ensure that all sections are addressed.

Phase II proposals have similar requirements. I have highlighted the additional Phase II requirements here, notably including the technical proposal cover sheet described in (Appendix D) as well as the proposal summary and data record included and described in (Appendix G). And all instructions can be found in the solicitation PDF. And so, I did want to discuss briefly the Foreign Disclosure and Risk Management requirements. And this is not associated with purchasing supplies or the foreign work requirements, although you do want to make sure you are familiar with the requirements for the SBIR program if you are considering including foreign involvement of some kind.

But disclosure is required using the Disclosure of Foreign Affiliations or Relationships to Foreign Countries form, and it is required that you submit this form with the business proposal as part of your application. If you have submitted an SBIR grant, this is a little bit different. We don't ask for that until later on in the award process, but contractors should be providing this form with their proposal.

You can review (Appendix J) for instructions, as well as the post-award reporting requirements and other compliance activities that may be required. You can review the considerations as part of the due diligence program to assess security risks that will be included as part of the award selection process, how this will all figure in into whether or not your award can be selected for funding. And as with many

other elements, you can find additional information on our website, specifically at the Foreign Disclosure and Risk Management webpage listed on this slide. It does include a lot of very helpful information including an overview of the risk areas that are considered as part of the assessment, as well as a number of very helpful illustrative case studies that have been recently updated. And so, all of our contract proposals must be submitted electronically. The page limits for the proposals are discussed here.

Keep in mind that Phase I proposal has a 50-page limit for technical proposals, 150 for Phase II. And these limits apply to each phase of a Fast-Track proposal as well. Also note that this does not include any human subjects and clinical trials information. These are excluded from the page limits in the technical proposals.

And you can find more information about human subjects and vertebrate animal considerations in Section 3 and Section 5 respectively, be sure to review them closely. And I did want to note that if you are considering a clinical trial, do keep in mind not all ICs support clinical trials through the SBIR program or the solicitation specifically. Do be sure to read through each topic thoroughly to make sure that it will allow clinical trials or if it specifically excludes them. Also, keep in mind that the definition of a clinical trial at NIH may be a little bit more broader than you think. There is a very helpful decision tool at the site listed on this slide that can really help walk through your study and give you a better feeling for whether or not NIH will consider the study that you're proposing to be a clinical trial.

And I did want to reiterate our number one piece of advice, do be sure to read through the RFP several times. It's dense, but there's a lot of very helpful information there including making sure that you have all of the registrations in place to be able to submit your proposal through the Electronic Contract Proposal System or ECPS website. We will require a system for award management registration which can take several weeks or sometimes over a month to complete. And it does need to be renewed yearly. Also, an SBA company registration at sbir.gov is required as well.

If you have specific questions about any of the topics you're going to hear about today, those need to be submitted in writing by email to the contracting officer. Do keep in mind that the deadline for questions is tomorrow, September 24th at the close of business. So, you should only reach out to the

contracting officer listed in Section 10 of this solicitation for each institute or center at CDC. And we will be issuing a Q&A amendment likely in early October at sam.gov, it will also be listed at the SEED contract website. And any questions and answers will be posted to the public as part of this amendment. Once the deadline has passed, further questions may be answered at the discretion of the contracting officer.

We do get a lot of questions about payment for SBIR contracts. Unlike grants, we do not tend to disperse the funds at time of award for contractors to draw down on. Contractors have to submit an invoice after completion of activities or submission of reports. Each IC may set up payment schedules a little bit differently, but the company in most cases does need to be able to have enough resources to start work first and get interim payments as they progress.

And I do want to remind you the deadline for receipt for all proposals is October 18th at 5 P.M. Eastern Daylight Time. We always encourage everybody to submit a day early. Every year we tend to have frustrated applicants because that submit button will go away promptly at 5. The system will not permit files to be submitted once the deadline hits. This is going to be very different than grants. Even if you hit the button shortly before the deadline, sometimes the file upload is not going to be instantaneous, and you may end up with a late proposal. Unfortunately, we simply can't accept it at that point. So please, please, please try and submit early as possible. And as we wrap things up, I did just want to highlight a few of the excellent resources available to recipients through SEED.

We do want our companies to succeed, and we do support them through a lot of programs, such as the technical assistance and technical and business assistance program or TABA. TABA is available either through funding that is built into an award to use your own service provider or vendor or through centralized TABA services that are described here. And as always, you can find details available on the website and specific instructions to request TABA are included in the solicitation as well.

We also offer a variety of excellent innovator support resources, often through our regulatory and business development consultants. SBIR recipients have access through them to access expertise to help plan and solve for commercialization-related challenges.

And recipients often have the opportunities to participate in a number of partner and investment events throughout the year as part of our company showcase program. And lastly, I just wanted to highlight a number of pre- and post-award opportunities for entrepreneurial training and support, particularly the I-Corps at NIH program listed here is available to Phase I applicants. Do keep in mind that offers need to include an option to participate in the I-Corps program as part of their proposal, and that will later be offered the opportunity to apply as during the period of performance of their Phase I award.

And with that, I just wanted to provide the information of how you can connect to SEED online, through social media, via email. Please, find us on LinkedIn, we are very happy to engage with you there. And I do encourage you to sign up for NIH and SEED updates at seed.nih.gov/subscribe to make sure that you have access to all the news and updates related to our program. Thanks so much for your attention, and with that, I am very happy to turn you over to Dr. Balki Balakrishnan, who is the director of the Office of Strategic Alliances at the National Center for Advancing Translational Sciences. Balki, it's all yours.

KRISHNA "BALKI" BALAKRISHNAN: Hey, good afternoon, and thank you very much, Adam. That is a great introduction to how to navigate the SBIR contract world. My name is Balki Balakrishnan, I am the director of the Office of Strategic Alliances at OSA at the National Center for Advancing Translational Sciences. This is the latest institute center established at NIH, it was established in 2011. So, we are fairly new, but we have been proudly supporting the SBIR program right from inception. So, in the next slide, I want to talk a little bit about what our institute really does. The National Center for Advancing Translational Sciences, NCATS, is one of the few institutes which doesn't have the name of an organ or the name of a disease in its name.

So, our main mission is to develop more treatments for all diseases with greater speed and efficiency. So, we look at the problem of translational challenge as a scientific as well as an engineering problem, where we look at the translational pipeline and see that there are hurdles placed along the way which reduce the number of treatments that go from left to right because things fall down across the translational pipeline. So, the inability to better predict the toxicity of new compounds or the efficacy

or not having better predictive models. These are some of the hurdles and bottlenecks that we hope to remove through a systematic approach to drug development.

Next slide, please. So, in terms of the key approaches that NCATS takes, we look at diseases not as single diseases but as groups of diseases. We look at all the groups of diseases and try to understand across a group of diseases what some of the common problems are so that we can then remove those bottlenecks and be able to develop multiple treatments at the same time. We are also looking for ways to develop better predictive models, models that would actually mimic the human condition as best as possible and predict toxicity or predict efficacy. We also look at systematic ways to enhance the setup as well as the conduct of clinical trials, so that the clinical trials have the right kind of representation and the right kind of human conditions represented in this study.

And we also try to leverage real-world data so that real-world data can be used to enhance clinical trial information in order to make treatments available faster. Let me go to the next slide. So NCATS is very happy to support two contract solicitation topics this year, and these are both innovations that will accelerate the development and generation of new treatments and cures.

Next slide, please. The first of the contract topic, topic 25, is the development of a versatile, small-footprint benchtop device that will perform evaporation of solvents. Now we are looking for a benchtop device that can efficiently remove solvents in a parallel fashion because ideally what happens is, in most chemistry labs the removal of solvents is one of the biggest bottlenecks. So, we are looking for methods by which you can do 90% of the evaporation within 10 minutes with full automation capacity. We plan to support one to three awards during the first phase. Right now, we are not anticipating supporting any Phase II unless the Phase Is are successful.

So, the next slide describes this particular concept in a little bit more detail. The idea is to have a batch evaporator that will be doing multiple high-recovery vial solvent evaporations all at once. This will be an exciting opportunity where NCATS itself might purchase some of these devices, but the company that develops this is free to really commercialize it and sell it to other customers.

The one interesting thing about this particular topic is the fact that it supports what is known as ACS, or automated chemistry synthesis. So, in any automated chemistry synthesis lab you want methods which speed things up and also automate the processes. We have a number of patent applications that we have filed on the prototype and the offeror might actually be able to take advantage of that by getting a non-exclusive license to the intellectual property. So that could make the final product a little bit more attractive from a commercial point of view.

Next slide, please. So, the next slide is a completely different topic, it's more biology-related. It is to support the scalable development of three-dimensional liver and brain organoids that are derived from human pluripotent stem cells. We are looking for reproducibility as well as scalability because many of these organoid development processes are extremely time intensive, extremely labor intensive, and they're not that reproducible and very hard to scale. So, we're looking for something that we would be able to provide robust tools for disease modeling and drug development because if these 3D models can be developed at high efficiency and scalability, these can be made available for lots of researchers.

In this case, again, we are looking to support one to three awards of Phase I. Next slide, please. So basically, what happens is when you take iPS cells, which is on the right side of the cartoon, you can either make 2D cells or 3D organoids. And what we find is that if you take human cells and develop them into three-dimensional organoids, they become much, much better disease model predictors, as well as they are much better models for testing the in vitro efficacy of both toxicity and efficacy. And what we believe is that the 3D organoids, we start with liver and brain to begin with, but if this particular project is successful, it can really make the therapeutic development process much more faster. So, I will stop there and proceed to have the next IC present. Thank you. I think the next IC is NCI.

MELISSA LI: Yes, thanks, Balki. Hi, everyone, my name is Melissa Li. I'm a program director with the National Cancer Institute SBIR Development Center. I am excited today to share our 13 topics. NCI is a prolific user of the contract mechanism, and we cover the entire spectrum of cancer technologies, diagnosis, to prevention, to treatment. And so as reflected by our topics, we have a wide variety of technology areas and indications that we're interested in. So, this is just a summary table of our topics,

Phase I, Fast-Track, Direct to Phase II. And I'm going to quickly go through each one. 13 topics is a lot to get through, so I'll try to keep it brief. I also wanted to mention, as Adam had said before, we have a budget waiver. So, at NCI, we allow budgets up to $400,000 over 12 months for Phase I, and for Phase II, up to $2.25 million over two years.

So, our first topic here is novel delivery systems for RNA-based cancer vaccines. And the goal is to support the development of new delivery systems with enhanced properties to accelerate the development of RNA-based cancer vaccines. And for each of these topics, I'll have a few of the Phase I activities and deliverables listed so you can get an idea. But of course, to echo what Adam said, please read the solicitation very carefully. You'll see the remaining Phase I and Phase II activities and deliverables in that PDF.

Our next topic is the development of cancer immunoprevention agents. So, this is to advance the development of novel, safe, and efficacious immuno-preventive vaccines or immunomodulatory drugs for cancer prevention, specifically well-identified high-risk cohorts. And so here we have some examples of high-risk populations including smokers, Barrett's esophagus, etc. Our third topic is synthetic microbes for immuno-oncology therapies. This is excluding oncolytic viruses and looking to develop safe and effective synthetic microbial-based immuno-oncology therapies for clinical use. So, this could be used as a single-agent therapy or as a combination therapy as an adjuvant to existing immuno-oncology treatments.

Next, we have the development of novel therapeutics for HPV-related precancer. This topic is to develop effective HPV therapeutics that can treat chronic HPV infections and or cause regression of precancers by preventing HPV-related cancers from developing at relevant organ sites, such as cervical or pharyngeal. Topic 470 is precision nutrition interventions to reduce cancer-related symptoms. This is to develop nutritional products for patients experiencing nutrition impact systems to help clinical care teams maintain a patient's nutritional status, maintain their quality of life, and bolster patient's tolerance during cancer treatment. Next, we have drug-loaded carrier particles for improved oral delivery for colon cancer prevention. This topic is to develop oral preventative agents for, again, high-risk patients with IBD, like colitis and Crohn's disease and to prevent colon cancer.

Projects under this topic should extend the formulation development and testing of carrier particles in suitable in vivo animal models for oral delivery of cancer prevention agents to the colon. Topic 472 is the antibody-drug conjugates as radiopharmaceutical theranostics for cancer. This is to improve efficacy of ADCs by labeling them with radionuclides, and for a new theranostic treatment strategy that includes diagnostic image-based patient selection, followed by two-arms therapy, both chemical and radiation-based.

Next, we have point-of-care technologies for GI cancer prevention and early detection. This topic is to advance the development of an affordable and scalable point-of-care test to effectively screen for precancerous conditions and early cancers in the GI tract. Then we have the development of digital biomarkers and endpoints for clinical cancer care. This is to facilitate the commercial development of digital biomarkers and or endpoints that would help clinical care teams improve patient care, for example, remote monitoring of a patient's response to a treatment. Digital biomarkers will utilize data from digital health technologies. This could be anything like heart rate, oxygen saturation, sleep data, and demonstrate clinical utility for patients.

Our next topic is on digital twin software for optimization of cancer radiation therapy. This topic is going to support the development of digital twin software that can inform radiation therapy and patient care by using multi-scale data, molecular, cellular, organ, to family history for treatment optimization purposes. Our next topic is wearable technologies to facilitate remote monitoring of cancer patients following treatment. This is to facilitate the commercial development of wearable sensors that can provide remote patient monitoring and assist clinical care teams in identifying cancer treatment- related toxicities early on.

Finally, we have the topic 478, this is advanced biomaterials to improve cancer modeling for research. This is to advance the development of versatile and accessible biomaterial-based tools for cancer researchers. These biomaterials should be able to change or adapt in response to tumor initiation, progression, or metastasis.

And with that, I just wanted to point everyone out again to some helpful links. The contract solicitation, the NCI, SBIR website also lists each of the topics in a single page. And then, of course,

check out NIHSEED for updates on this solicitation, and if you have any questions, this contact is listed in the solicitation as well to email Tanya Renwick in our Office of Acquisitions. And with that, I will turn it over.

ADAM SORKIN: Thanks so much, Melissa. And now we'll hear from Dr. Rajesh Kumar at the National Institute on Aging.

RAJESH KUMAR: Hello, everyone. My name is Rajesh Kumar, I'm the program officer in the Office of Small Business Research at the National Institute on Aging. Next slide, please. So, we have three contract topics for this year. So please note, that these topics differ in the phases of the grants that you can apply to, as well as in the amount of funding. I will talk about these topics in more detail in the next slides. Next, please. So, on the first topic, topic number 11, this is about developing digital technologies as tools to screen and monitor Alzheimer's disease and related dementias. So, as we know, on Alzheimer's disease and related dementias, there are gaps related to screening, early detection, enrollment in clinical trials, and monitoring.

So, devices such as mobile phones or monitoring and sensing devices that analyze gaze, speech, eye movements, hearing, etc., for example, can provide simple, cost-effective tests that can fill the above-described gaps. So, this topic supports development of tools for the evaluation of these medical devices. So, by the FDA, through their medical device development tool program, or MDDT program, you can learn about this MDDT program and the recently approved MDDT topics on the FDA's website.

Next slide, please. So, this topic will accept only Fast-Track applications so in Phase I of the proposal, the applicants will prepare an MDDT proposal demonstrating the suitability of the tool. The other deliverables of Phase I will be to submit a complete qualification plan to the FDA's MDDT program. In Phase II, the offerors will submit a full MDDT package that includes all the data collected as per the FDA's accepted MDDT proposal in Phase I. Next slide, please. So, this topic number 12 is on modeling aging through micro physiological systems. The majority of aging research has been conducted using static cell cultures and animal models that only partially recapitulate aging in humans. So micro physiological systems, or MPS, could provide more translationally relevant and cost-effective models to 2D cell cultures and animal models.

So, this SBIR contract solicitation invites offers to create self-contained systems that maintain 3D tissue constructs to allow for human-relevant modeling of molecular and cellular aging processes and or drug discovery for zero protectants and treatment for aging-related diseases.

Next slide, please. A couple of Phase I deliverables include developing an MPS that recapitulates human molecular and or physiological aging phenotypes, and developing a sensor for data acquisition, and real-time detection and analysis for longitudinal measurements. A couple of Phase II deliverables include benchmark performance of the MPS against applicable in vivo animal models or non-human aging research or intervention studies, conducting pre-market and user testing, and to initiate the process for FDA qualification.

Next slide, please. So, our third topic is-- this topic's long-term goal is to yield a deployable social robot to add the caregiving process in persons with dementia. Okay, so currently available assistive technologies have many limitations such as causing cognitive overload and are limited to specific domains or tasks or dependencies such as device literacy. So, the goal here is to not only yield a social robot but a robot that is meaningfully advanced over the capabilities of what is currently available. So, this topic will accept fast-track and Direct to Phase II applications.

Next slide, please. So, these Phase I deliverables include demonstrating iterative development with stakeholder feedback, demonstrating a functional architectural framework that leverages multi-modal and gen-AI, evidence of adapting existing monolithic system architecture to a modular architecture, and demonstrating real-world and AI-generated training data and environments. The Phase II deliverables include demonstrating evidence of enhanced functionalities and deployability in preliminary real-world testing, rigorous real-world testing in a caregiving situation, and evidence of architectural flexibility. And that's it for NIA. Thank you.

ADAM SORKIN: Great. Thanks so much, Rajesh. Now, we'll hear from Megan Ryan at the National Institute on Alcohol Abuse and Alcoholism.

MEGAN RYAN: Thank you so much, Adam. So, I'm Megan Ryan, I'm the SBIR/STTR program director for the National Institute on Alcohol Abuse and Alcoholism. We have three topics.

Next slide. I'm going to go through here. But first, I wanted to touch on the mission and research focus for the NIAAA. So, our mission is to generate and disseminate fundamental knowledge about the effects of alcohol on health and well-being and apply that knowledge to improve diagnosis, prevention, and treatment of alcohol-related problems including alcohol use disorder across the lifespan. Alcohol use disorder is a chronic disease that's characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences.

A few stats to show the impact of alcohol consumption in the US and globally. In 2023, 28.1 million American adults aged 18 and older had AUD in the past year. 178,000 deaths in the US alone were attributable to alcohol use, making it one of the leading preventable causes of death in the US. It's a $249 billion problem in the US alone, and globally 2.4 million deaths were attributable to alcohol consumption as of 2019.

Next slide. So, let's jump into our solicitation topics. The first topic, 020, is alcohol-activated locking systems for firearms and firearm storage units. So here, we're seeking development of an alcohol-activated locking system, either for firearms and or firearm storage units. The ideal solution would enhance firearm safety and prevent alcohol-related firearm injuries and fatalities by enabling reliable detection of blood alcohol levels, ease of use with minimal training required to use the technology, and affordability and durability. We are allowing Direct to Phase II proposals, Fast-Track proposals.

We are not allowing Phase I proposals. We anticipate one to two awards. Phase I in the Fast-Track, we're allowing for $400,000 for up to 12 months. Phase II is $2 million for up to two years. Next slide. Topic 021, data science tools for accelerating alcohol research. Here, we're seeking the development of data science tools to collect, clean, harmonize, integrate, and analyze existing data sets to predict alcohol use-associated conditions, evaluate interventions, and guide treatment strategies. The solution should leverage advanced techniques like machine learning, deep learning, neural networks, and large language models. Solutions may include generation and implementation of new algorithms for use with existing data sets, software tools for data processing, analysis, and visualization, and computation models predicting outcomes of alcohol use.

For this topic, we are allowing Phase I proposals only. We anticipate one to two awards, and the budget for Phase I is $250,000 up to 6 to 12 months.

Next slide. Lastly, topic 022, a non-invasive wearable alcohol sensor. Here, we're seeking support for the development of a non-sweat-based, e.g., infrared or the like, discrete non-invasive wearable alcohol biosensor capable of real-time blood alcohol concentration measurement and recording to enhance the accuracy and reliability of alcohol consumption monitoring in clinical research and treatment settings by enabling passive continuous detection, accurate real-time or near real-time measurement, and secured data storage and wireless transmission.

We are allowing Direct to Phase II proposals, Fast-Track proposals. We are not allowing Phase Is for this topic. We anticipate one to three awards. Phase I budgets $500,000 for up to one year, and Phase II $2,045,816 for up to two years. I think that was it for us. Next, we have NIAID.

ADAM SORKIN: Great. Thanks so much. Next, I will introduce Dr. Natalia Kruchinin of the National Institute of Allergy and Infectious Diseases.

NATALIA KRUCHININ: Thank you, Adam. Hello, again, Natalia Kruchinin, I am NIAID's Small Business Program Coordinator, and my role is to oversee all activities related to small business. And I just want to mention that National Institute of Allergy and Infectious Diseases is the second largest institute within NIH. Our SBIR/STTR budget for fiscal year '24, $193.8 million, which is quite a big amount of money. On this slide, I put some information about our institute. We have four extramural divisions, Division of AIDS, Division of Allergy Immunology Transplantation, Division of Microbiology Infectious Diseases, and Division of Extramural Activities. The first three divisions, extramural divisions, most of the budget of these divisions goes to support SBIR or STTR grants and cooperative agreements, and also SBIR contracts. And Division of Extramural Activities, Oversees Policy, Grant Management, Acquisition Office, Review.

Small Business Program is under Division of Extramural Activities. We also have Division of Clinical Research, Division of Intramural Research, and Vaccine Research Center. For 2025, in the SBIR contract solicitation, we have 11 topics. And you can take a look, pages, it's a big solicitation.

I put quite a bit pages numbers on my slides just to help you take a look. Page 120, 136, 11 NIAID topics. Also, I would like to point that on page 73, you can see the timeframe, anticipated time of the award because we're getting this question quite a bit. Scientific and Technical Merit Review, approximately March 2025. Anticipated award date, August of 2000, oh, I'm sorry, '26, 2026. And we, NIAID, anticipating between 21, 41 awards. On page 67, you will see summary table regarding which topic will allow Fast-Track or Direct to Phase II.

And then also, I want to bring to your attention about budget because each topic may have slightly different budget numbers. You will see at the top of the topic example below, something like this, which mechanism is accepted, which is not, and what's the Phase I dollar amount, and yes.

Okay, next slide. Let's talk Division of AIDS. We have three topics from Division of AIDS, page 120, 124. topics 137, new drug classes with novel mechanism of action for HIV, hepatitis B, and tuberculosis. Topic 138, devices, and materials-based platform for the delivery of broadly neutralized antibodies. Topic 139, rapid diagnostic assays for self-monitoring of acute or rebound HIV-1 infection. For the Division of Allergy, Immunology, Transplantation, we also have three topics. You can read on page 124, 130, topic 140, adjuvant discovery and down selection for vaccine against infection and immune-mediated diseases.

Topic 141, reagent for immunological analysis of non-mammalian and underrepresented mammalian models. Topic 142, adjuvant development for vaccine and for autoimmune and allergic diseases. And for Division of Microbiology Infectious Diseases, we have four topics. You can check page 134, topic 143, development of diagnostic for mycoplasma genitalium infection. Topic 144, development of medical intervention for treating non-tuberculosis mycobacterial infections. Topic 145, diagnostic to detect host immunity in valley fever or histoplasmosis. Topic 146, discovery and development of oral small molecular direct-acting antiviral targeting viruses of pandemic potential.

And finally, we also have Office of Data Science and Emerging Technologies, the so-called ODSET. They have one topic, you can read about the topic on page 134, page 136. Topic 147, software or web services to access quality and reproducibility of data and information about therapeutics and vaccine. I just would like to remind you that because of government and acquisition regulations policies, we

cannot answer questions related to NIAID topic, including solicitation. The only person with whom you can communicate, it's Jonathan Bryan, NIAID contracting officer, Office of Acquisition. And I put his phone number and his email address on this slide. But if you have questions or you want to learn more about SBIR program at NIAID, feel free to reach out to me. You can visit our website. I have a wonderful SBIR team of five people. And again, if you have questions related to policy or you would like to be connected with subject matter expert, we can help here. And I think this is the last slide. Yes. Thank you so much.

ADAM SORKIN: Great. Thanks very much, Natalia. Next, we will hear from Dr. Vasudev Rao at the National Institute on Mental Health.

VASUDEV RAO: Thank you, Adam. Good afternoon, everyone. We will be highlighting two different contract solicitations for division of AIDS research at NIMH. The first one is focused on ART adherence assays and the second one on development of novel in vitro and in vivo models to support neuro-HIV research. Today, over a million people in the US live with HIV, and around 13% of them are completely unaware of their status. New infections continue to occur, disproportionately affecting marginalized communities.

The epidemic is far from over. Next slide, please. Antiretroviral therapy is a very powerful tool that can suppress the virus, allowing individuals infected with HIV lead healthier lives and also prevents the spread of HIV. Next slide, please. Disease prognosis in people with HIV is heavily dependent on ART adherence, and it is important to ensure adherence to medications. And thus, we are soliciting applications for development of assays for pharmacological adherence monitoring of ART or antiretroviral therapy. Some of the key parameters for developing ART adherence assays are listed here. They need to be rapid point-of-care or pharmacy-based assays that can measure long-term adherence to antiretrovirals.

They need to be able to measure drug levels in various biological matrices, for example, urine, hair, dried blood parts, etc. In addition, they should also be able to monitor PrEP adherence, ART adherence to trigger adherence interventions in case there is ATI or long-term ART, drug levels of long-acting ART. There are several new long-acting ART formulations and PrEP formulations, so they should be able to

monitor long-acting ART adherence as well as monitor blood donations for PrEP and ART drug levels as a risk indicator of HIV exposure.

Next slide, please. The second solicitation request that I'm going to discuss today is focused on development of novel in vitro and in vivo models to support neuro-HIV research. Next slide, please. Despite excellent biological control by ART once folks are adherent, CNS disease, termed as neuro-HIV, including neurologic, neurocognitive, and mental health problems are observed in a significantly greater proportion of people with HIV compared to the general populace. Considerable gaps exist in our understanding of the pathogenesis of CNS disease associated with HIV.

There's a need for novel model systems that will help us better understand the immune central nervous system the pathogenesis access in the context of HIV and adrenal antiretroviral therapy. Next slide, please. This solicitation is for developing novel models for neuro-HIV research. These possible topics include organoid models incorporating human immune cells amenable to HIV infection alongside neuronal cells with measurable neuromodulatory outcomes. QNI small animal models with systemic and CNS immune cells amenable to HIV infection that can be used to understand mechanisms such as neuroimmune dysfunction, especially in the context of long-term HIV infection and chronicity.

Development of blood-brain barrier systems using organoid-based frameworks with human immune cells, neuronal cells, and vascular components to help better comprehend the pathways leading to adverse CNS outcomes. And development of in vitro and in vivo models to test the impact of HIV-associated immune dysfunction on synaptic transmission and plasticity. Next slide, please. Thank you. Next is Diana.

ADAM SORKIN: Thanks so much, Vasudev. Next up, we will hear from our colleagues at the Centers for Disease Control and Prevention. I will hand things off to Diana Bartlett at CDC. Thanks, Diana.

DIANA BARTLETT: Hi, everyone. I'm Diana Bartlett, I work in the SBIR program for the Centers for Disease Control and Prevention. I'm going to speak to you about the CDC in general, or SBIR program, and then talk about the nine contract topics that we have. Next slide, please. So, the Centers for Disease Control and Prevention, CDC, is part of the US Department of Health and Human Services.

We are a separate federal agency from the National Institutes of Health. So just to repeat again, we are not a center of the National Institutes of Health, we are a separate federal agency. The mission of the CDC is to protect America from health, safety, and security threats, both foreign and domestic. And to accomplish our mission, CDC conducts critical public health science and provides health information that protects our nation against dangerous health threats and responds when these arise.

Next slide, please. So, the CDC's strategic plan advances science and health equity and affirms the agency's vision, equitably protecting health, safety, and security. There are five main core capabilities of the agency that we, or the plan leverages diverse public health workforce, world-class data and analytics, state-of-the-art laboratories, rapid response to outbreaks at their source, and strong global capacity and domestic preparedness.

Our work is underscored by the agency's pledge to the American people and dedication to use timely data and science to drive and communicate customer-centered, high-impact public health action. Next slide, please. So, for those who may not know, this is our organizational chart, it includes our agency's centers, institutes, and offices. The centers at the bottom of the chart, along with our Office of Readiness and Response, all participate in the CDC/SBIR program. And the CDC's Office of Science, where I'm based, is responsible for the overall management of the agency's SBIR program.

Next slide, please. So, the CDC participates in both the SBIR/HHS omnibus grant solicitations, as well as the contract solicitation. And all of our nine topics that we'll be discussing today have a Phase I contract budget of $243,500 and a Phase II contract budget of $2,045,816 for a two-year project period. Our overall set aside for fiscal year '24, to give you a sense, is about $10 million. Three of our centers also participate in the SBIR administrative supplement to promote diversity in research and development. These centers are the National Center for Environmental Health, National Center for Injury Prevention and Control, which has topics for this particular contract solicitation, as well as our National Institute for Occupational Safety and Health.

It's also important to note that CDC does not participate in the Small Business Technology Transfer, STTR program for contracts or grants. And we also don't participate in Fast-Track, Direct to Phase II, Phase IIB, or the Commercialization Readiness Pilot, CRP program.

Next slide, please. CDC does not currently participate in the NIH technical and business assistant program, which Adam mentioned on slide 29 of this webinar today. However, if you apply for SBIR funds and wish to utilize your own technical assistance provider, you are required to include these costs in your budget and provide a detailed budget justification. You may request up to $6,500 for Phase I and up to $50,000 per Phase II project across all years for assistance.

Offerors currently must submit their intent to use this TABA option when applying for Phase I funds. CDC also participates or does participate in the NIH technical and business assistance, TABA needs assessment program. This program provides a third-party unbiased assessment report of a Phase I project's progress in technical and business areas that are critical to success in the competitive healthcare marketplace. There is no cost for this report, and the time commitment for participation is minimal, so we encourage you to participate. CDC also participates in the I-Corps at NIH program. And of the CDC offices and centers participating in this contract solicitation, only the National Center for Emerging and Zoonotic Infectious Diseases, or NCEZID, participates in I-Corps.

Next slide, please. So now I'll start talking about our nine contract topics. Six of them are described here, and they're from our National Center for Emerging Zoonotic and Infectious Diseases. And the contract officer listed is Michael Crow, and his contact information is on page 76 of the solicitation. Let's see here. So, our topics include topic 32, oh, this is a snapshot of what it looks like in the NIH's electronic contract proposal submission system website. So, topic 32 is canine vaccines to prevent tick bites. Topic 33 is a rapid affordable point-of-care carbapenem-resistant acinetobacter colonization screening diagnostic.

Topic 34 is improved diagnostic assays for foodborne and waterborne bacterial pathogens. Topic 35 is improved diagnostic assays for parasitic diseases. Topic 36 is developing an over-the-counter diagnostic for valley fever. Topic 37 is enhancing the CDC autocidal gravid ovitrap to control dengue vectors.

And the next slide, please. These are two topics from our National Center for Immunization and Respiratory Diseases. Again, the contract specialist, contract officer is Michael Crow, who you can follow up with questions. Topic 38 is development of a molecular panel to detect febrile rash illnesses.

Topic 39 is synthetic immunoglobulin M antibody controls for measles, mumps, and rubella assays. And the next slide is our last topic, it's from our National Center for Injury Prevention and Control. Again, the contract specialist is Michael Crow for you to direct questions to. And it's topic one, and it's data science solutions to characterize polysubstance use behavior from online sources. Next slide, please. And just some last reminders, as stated previously in the webinar, please read in the contract solicitation any future amendments to the solicitation carefully. We also encourage you to apply early, if you have questions after today's webinar or specifically during this open question-and-answer period, questions are due tomorrow, as Adam mentioned.

Please, contact Michael Crow or again, page 76 of the solicitation. And when you do contact CDC, please reference the solicitation number, the CDC topic number, along with your specific questions. Next slide, please. And this is our last slide. Thank you for your interest in CDC and our SBIR program. And if you have any general inquiries about our program, you can send us an email at sbir@cdc.gov. And we appreciate your time. Back to you, Adam.

ADAM SORKIN: Wonderful. Thanks so much, all of you, for walking through your programs and your topics. Lastly, just a final reminder that the deadline for all proposals is October 18th, 5 P.M. EDT. And please, please, please submit as early as possible. With that, I will hand things over back to Stephanie to moderate the Q&A discussion.

STEPHANIE FERTIG: Great. Thank you so much, Adam. And thanks to all of our speakers. And again, I would just really like to reiterate that deadline and really request that you at least submit a day early if possible. It is always heartbreaking when individuals work so hard to submit that proposal. And if they submit it a little bit late, we're unable to accept it. So that's a hard part of our job. We hate saying no, but we have to. And so, we really want to make sure that that great proposal can get to us. So, with that, I'm going to launch into some questions. And the first question that I really like, actually, I think this is for Adam to answer. We did get a number of questions specifically around the difference between an SBIR grant and an SBIR contract. So, can you talk a little bit about the differences between grants and contracts?

ADAM SORKIN: Absolutely. And I did know those questions as well. Whether it is a contract, grants, or even cooperative agreement, these are all SBIR, Small Business Innovation Research awards. However, the difference between these two programs is a grant provides you funding assistance to complete your research project as described in your grant proposal. We are assisting you to complete your research and development program. A contract, however, you are entering into a formal agreement with the government to specifically provide the deliverables that each institute and center has identified in their topics. So, the nuts and bolts are going to be a little bit different. As I mentioned, there are some differences in how you can access funding. But a contract is going to be that specific formal agreement to complete the deliverables for the specific topics identified in this solicitation.

STEPHANIE FERTIG: And there was a follow-up question here about how the contract topics are really different from the targeted topics that one might see in a grant solicitation.

ADAM SORKIN: I'm sorry, can you repeat the question?

STEPHANIE FERTIG: So, what are the differences between, say, these contracts topics, and if somebody's more used to submitting to a specific notice of funding opportunity in a grant, you often see some general topic areas in a specific notice of funding opportunity. How are these contracts different? How should they be thinking about it a little bit different?

ADAM SORKIN: So, with a grant notice of funding opportunity, in many cases, the majority of cases at NIH, these are really going to be open topic areas that broadly address the mission spaces of all of the institutes and centers. In this contract proposal, you're going to see very specific, tightly defined topics with very clear goals that each of these participating institutes, centers, and offices have identified that clearly address a specific need identified by the funding agency.

So, these are not investigator-initiated projects, you're really going to want to make sure that your project specifically addresses the need and the deliverables identified in that topic.

STEPHANIE FERTIG: Now, we did get a number of questions around STTR, and I just want to emphasize again, we're not going to be touching on STTR today because we don't have an STTR contract solicitation. So, if you're interested in STTR, I do encourage you to go to our website, seed.nih.gov.

You can look at the open funding opportunities that includes open opportunities for STTRs utilizing the granting mechanism. And so, really take a look there for our STTRs, we do have a set of omnibus solicitations specifically focused for STTR. So again, that's where you would find opportunities for an STTR. That said, there was a question here specifically if you could have an individual on the contract solicitation who may be a co-PI or somebody who is involved, how can academics be involved in a contract solicitation? Can they be co-PIs like a multi-PI, can they be subcontracts? So how can academic institutions be involved even though this is an SBIR and the STTR isn't available?

ADAM SORKIN: Sure. So as with all SBIR awards, there is a requirement that the principal investigator is primarily employed by the applying small business concern. This means that the majority, greater than 50% of the time they spend on work is as an employee of the small business. It does preclude full-time employment at any other institutes or organizations. That said, small businesses can certainly subcontract out to academic centers, include academic faculty as co-investigators or other key personnel on the project. That's absolutely fine.

STEPHANIE FERTIG: Great. So, we had a number of questions specifically around foreign involvement. We had a question around eligibility associated with, say, a Canadian company, whether or not some of the work could be done outside the United States. So, can you talk a little bit about foreign involvement and what's allowable within the SBIR program and specifically, the contract solicitation?

ADAM SORKIN: Absolutely. I'll speak generally about the SBIR program and then let Kelly chime in if she cares to about the contract specifically. But the SBIR program by statute requires that all work on the project be performed within the United States. In rare cases, we can make exceptions if a specific resource is not available within the country. In some cases, perhaps there's a material or patient population that just simply cannot be accessed domestically. But generally speaking, you do want to make sure that that work does get performed in the United States if it can in any way it can be.

Yes. Thank you, Adam. I think that is correct. And anything that does come up after the contract award, you would work out with your contracting officer to figure out how you would get those resources after the award.

STEPHANIE FERTIG: So, we do have a question around what we will fund through the solicitation as well as through the SBIR/STTR program. So, the question was, do you only fund therapeutics? This individual is working on an AI idea. So, can you talk a little bit about what can and cannot be funded through the SBIR program?

ADAM SORKIN: Absolutely. We fund R&D for the development of products and services across the biomedical space. They can be therapeutics, diagnostics, software tools, AI applications are absolutely of interest to a number of our institutes and centers. That said, for this specific solicitation, the specific deliverables and end goals of the research and development projects are going to be very tightly defined for each specific topic. So, if you are unsure of whether or not the end product has to be a specific kind of product or service, always a great idea to reach out directly to the point of contact for the institute or center who has included that topic in the solicitation.

STEPHANIE FERTIG: And there was another question here about, are the contract topics designed to fill a gap of the agency's current ongoing projects or are they completely independent projects? And I think the answer is, these topics are set by the different components, so it really does depend. I don't know if you want to go into a little bit more detail.

ADAM SORKIN: Absolutely. It very much depends on the goals and the priorities of the specific institutes and centers. In some cases, they are high priorities that they want to highlight, in some cases, they are needs that they don't feel are being met elsewhere. It really just depends on the goals of that institute and centers and how they individually approach the contract program.

STEPHANIE FERTIG: And I'd encourage everyone here to really read through those topics and see if you have a solution and can come in under that topic. I mean, that's really what we want you to do, is read through those topics and see, do you have a solution to the problem that is being talked about in one of those topics? Okay. Let me see. I'm just checking to make sure I'm paying attention here. So, another question that is here is a question specifically, if according to the forms, how does someone designate whether or not they're a woman-owned business or indicated as a socially or economically disadvantaged business?

ADAM SORKIN: Thanks, Stephanie. And I did note this question because I saw specifically, a reference to Forms H. So, this is one of the technical differences between the contract proposal and a grant application. So, if you see something related to Forms H, that's going to be a grant application element. And this is one way in which the contract proposal differs. Unlike the grant proposals in which we no longer ask you for any demographic information, as I mentioned earlier in the presentation, the cover sheet does include a question asking for whether or not you are a woman-owned small business or a socially and economically disadvantaged business. So, do you want to indicate that directly on the cover sheet?

STEPHANIE FERTIG: Since we're talking about forms and how to apply, what registrations are required? There was a question around registrations, these registrations are so important. So what registrations are required for somebody to submit their proposal?

CALLIE PRASSINOS: Do you want me to take that one, Adam?

ADAM SORKIN: By all means.

CALLIE PRASSINOS: So definitely reference the eligibilities and the requirements for proposal submission in the solicitation. You need to be registered as a small business company at the SBA, you also have to have a SAMS account as well.

STEPHANIE FERTIG: But you do not have to have an active SBIR or STTR, you do not have to have previously been awarded an SBIR or STTR. In fact, we really do encourage individuals who are new to the program to really, again, take a look at those topics and see if that's something that you're working on fits within the topics that you heard about today. So, we want to make sure that we emphasize that really want to support brand new companies to come into the program. So, can one of you explain a little bit more about what a draft statement of work is about and what somebody is expected to put in there?

CALLIE PRASSINOS: Absolutely. I could take this one. So, at the end of the solicitation, (Appendix E) is the draft statement of work that we've provided as a template. And really what you want to include is the base points of what your proposal is going to be about, what you want to accomplish, what

technical approach you want to make, how you want to get to the end of it. It's going to be the road map for the year that you're participating in this contract award. Following Section 8 really has the sections that you want to put into it, into your statement of work, and briefly describing what aims you want to make throughout the year that you'll be performing as a SBIR contractor. And if there's any questions, you can have you can work that out through your contracting officer. If they have any questions about your statement of work, they will come and they will ask, and it can be tweaked, and it will be a working document until it's awarded at the time of award.

STEPHANIE FERTIG: Great. So, there's been a number of questions around the budget since we're talking about, again, forms. I figure we'll hit some of these questions associated with the budget and submission and how to submit. So actually, I'm going to start with a more general one because we did talk about Phase Is, and Phase IIs, and Fast-Tracks, and Direct to Phase IIs. So, can you talk a little bit about what needs to be submitted if somebody's doing a Fast-Track? And I'm pointing this one out in particular because it is different from how it's done in the grant program. So, can you talk a little bit about the differences, if somebody wants to do a Fast-Track, how is that different from a standard Phase I versus how is that different from a Direct to Phase II?

CALLIE PRASSINOS: Absolutely. So, a Fast-Track is different because you're going to need to submit two proposals, a proposal for Phase I and a separate proposal for Phase II. And they'll be evaluated separately as well. But at the time, if they are deemed acceptable and in need of the awarding component, then they will be awarded together with Phase I being awarded at the beginning, and Phase II will be an option to be exercised after Phase I is completed. That doesn't guarantee it will be exercised, it just means that there is not an additional proposal that needs to be submitted and the awarding component can just exercise the option so that Phase II can start immediately after Phase I is done.

STEPHANIE FERTIG: And then for those that are standard Phase I, and I would encourage everyone to take a look at those topics because they indicate whether or not they're for Phase Is, Fast-Tracks, Direct-to-Phase IIs, there is that information in each of those topics. But if somebody is coming in for a topic where there's only allowed for Phase I, how would that Phase II transition look, how is that different, what does that look like for these contracts?

CALLIE PRASSINOS: Yes. So, when a Phase II is completed and the awarding component has determined that they want to move to Phase II, then they will send out a request for proposal and they will send out an additional request with more information. It will follow this solicitation that the original Phase I was put under, but it will have different dates of when the proposals are due and additional information so that you can submit a Phase II proposal to be evaluated and awarded after the fact. And yes, there could be a gap depending on how the timing goes with that invitation, the evaluation, and the award of Phase II. So, there could be a gap between Phase I funding and Phase II.

STEPHANIE FERTIG: So, if somebody submits a Fast-Track and the Phase II isn't considered adequate when Phase I is funded, how does that work? Are they going to be allowed to then submit a Phase II?

CALLIE PRASSINOS: Yes, absolutely. There are times where Phase I can be awarded and the Phase II proposal has just not made the mark at that time. So, there is the ability to have another opportunity if the awarding component makes the determination that they want to move forward with that Phase II to provide another proposal for that phase to get another evaluation on it. So, there is another bite of the apple after the fact because we understand that sometimes you do need that Phase I data to help that Phase II proposal.

STEPHANIE FERTIG: So, I have to ask because there are a number of questions here about the review process, how it is different between grants and contracts, how that evaluation is different, and how are these proposals are going to be evaluated.

CALLIE PRASSINOS: So, an SBIR proposal will be evaluated by a peer review panel which is a panel of peers, other professionals, and scientific experts in the field that will evaluate the proposals per Section 6 which has the method evaluations, has the criteria that they're evaluated against, and the point structure that's in Section 6. Those peers will provide that evaluation in a meeting, and they come up with a technical evaluation report that is provided, the contracting officer and the technical expert team to help in making the awards if they want to move forward with those SBIR contract awards.

STEPHANIE FERTIG: Now, what happens if someone is interested in more than one topic? They have their great technology, and it could be applied to more than one topic. What should they do in that case, what can they do?

CALLIE PRASSINOS: So separate proposals for under one topic is acceptable, ensuring that they are separate proposals, and they have separate needs and separate aims under the same topic. And or if you find two topics under two different awarding components, two proposals are acceptable for under one company if they want to send two proposals. Just ensure that they are separate proposals, and they need to be provided separate emissions in ECPS as well. So, if you are proposing on two proposals under one topic, they need to be submitted separately under two different submissions. Please, help us out and make them clear that they're separate with different topic names labeled differently as well. That will help us throughout the process, and if you have any questions with submission, please let me know.

STEPHANIE FERTIG: What if somebody wants to submit-- they see a great contracting topic here, that's something they can submit to you, but they we're also thinking about submitting a grant on that topic. They were already planning to submit to maybe the omnibus solicitation or a notice of funding opportunity on that, utilizing that technology and doing something very similar. What should they do? And I don't know, Adam, if you want to take this one because this is grants not contracts question.

ADAM SORKIN: Sure. So, you can only have one proposal under review at HHS on a given topic or for a specific project at a given time. So if you're really unsure of whether or not it would be appropriate to address as a grant, or you might be interested in addressing it as a topic, it's a really great idea to reach out to perhaps the-- if you're leaning toward the contracts, reach out to the point of contact listed in the contracts solicitation, if you're really unsure, each of our institutes and centers has a small business program manager listed on our website, seed.nih.gov that you can reach out to you discuss your goals and project, and they can give you some feedback about what the best path forward might be.

STEPHANIE FERTIG: And that's a great point, and I'd like to emphasize, and I know particularly when we were talking about the difference between say, NIH and CDC, we throw around the word agency a lot, but when we're talking about that question of whether or not you can have something under

review again, we're talking HHS here as the broader larger agency. We did have a number of questions around budget, and I don't want to ignore those, so one question that I see here are the TABA funds on top of the contracting funding limits?

CALLIE PRASSINOS: Yes, absolutely. So, the topics have specific funding limits. Each topic has its own funding limits. The TABA funds are above those funding limits, they will be included in the contract award, but it will be in addition to what those contract limits are.

STEPHANIE FERTIG: And when you're talking about subcontractors what pricing data is required for those subcontractors, what information is required from a subcontractor around budgeting or pricing when you're trying to pull together your proposal?

CALLIE PRASSINOS: So, as a contracting officer, we like as much information as possible. It makes our job easier to determine what's reasonable because that's our job as stewards of congressional funds is determine the funds to be reasonable and realistic. So as much information as possible is greatly appreciated. And we understand that some information is not going to be provided, some information is proprietary to that subcontractor. Provide as much as you can to help us determine what is reasonable, and if a contracting officer needs more information, they'll reach out and ask for it.

STEPHANIE FERTIG: Do you have to have your own resources to do the study and then invoice? And there's some differences between payment for contracts versus payment for grants. So, it sounds like for a contract, there's an invoicing component. So, can we talk a little bit about that difference, and maybe highlight that? And I know Kelly, you can talk about it for contracts. And then Adam if you want to add anything around the differences for grants?

CALLIE PRASSINOS: Yes, absolutely. So, the contract will have a pavement schedule and put into it, and it will determine when payments will be made. And every awarding component will do that differently, but that will be done on an invoice level and invoicing will be submitted to the Office of Financial Management. And it's an electronic-based system now but it will be invoiced and then payment will be submitted electronically as well. So, there will be need, yes, something that needs to be done to get paid.

STEPHANIE FERTIG: Do you need to include a budget justification in the application? It doesn't seem to have space. So where can individuals justify the budget that they're asking for?

CALLIE PRASSINOS: So yes. The Appendix C is the format for pricing proposal. That doesn't mean that you can include quotes or additional pages to justify what you're proposing on that Appendix C pricing proposals template. As I said, we appreciate as much information as possible, pricing breakdowns, explanations of what needs to be proposed. So just include it in your business proposal. So therefore, a business proposal does not have page limits, so you can include that with that. And the business proposal is not submitted to a technical evaluation, only the contracting officer will see that information.

STEPHANIE FERTIG: And then there was a question. So, for pricing, you would appreciate vendor quotes.

CALLIE PRASSINOS: Yes, please.

STEPHANIE FERTIG: And the small business would have to upload everything to the ECPS, or do the subcontractors need to have an account to upload? So, is it really the small business that's uploading the entire proposal?

CALLIE PRASSINOS: Yes. So, when you're submitting a proposal it's underneath the small business offer, and the ECPS will take three attachments, the business proposal, the technical proposal, and the human subject form. It won't take additional information, so the small business offer will need to submit that all at as one proposal at the time.

STEPHANIE FERTIG: Because this is different from a grant, so what resources are available to individuals, are there sample proposals, is there a template anywhere, where can people find the best information on how to prepare this proposal?

CALLIE PRASSINOS: I really push people to read the solicitation, there are templates in the appendix, we try to provide as much information as possible to make it easy to follow. If there are additional questions, reach out to the contracting officers that are listed on page 74 of the solicitation. And we cannot provide templates for proposals because that information is proprietary, but we really hope

that we provided enough templates within the appendix to help.

STEPHANIE FERTIG: Do individuals need preliminary data in hand in order to apply?

CALLIE PRASSINOS: I point everybody to look at the topics and each topic will outline what the requirements are, and it's the offeror's duty to provide a proposal that will meet those requirements to be evaluated, to provide the best proposal to be evaluated for those requirements. And data or no data, just ensure that you have a proposal that meets those requirements.

ADAM SORKIN: And I believe Direct to Phase II proposals will specifically require you to walk through and describe the equivalent Phase I preliminary work as part of that technical proposal.

STEPHANIE FERTIG: So, there have been a couple of questions around intellectual property, so do contracts have intellectual property, either a patent or to work on the starting point, or can someone start work and then file that intellectual property? So, do you have to have that patent filed, or do you have to have that patent in hand before you apply, or can it be either? Also, who owns the intellectual property, how does that intellectual property ownership work?

CALLIE PRASSINOS: Adam, do you want to start with the patent question?

ADAM SORKIN: Sure. I don't believe you specifically need to have the patent in hand relative to the technology you're looking to develop. You do want to have some room to operate and be able to develop your technology and carry that forward to commercialization. But in many cases, our recipients are going to be developing intellectual property, or I would say in most cases, they're going to be developing intellectual property that they will subsequently go on to protect. And we are often very interested in how they're going to do that and provide a number of resources to support that as they go forward. As with all SBIR awards, the awardee does own any intellectual property that they develop during execution of the project. The government does receive certain rights to access that technology in a couple of different ways, but it belongs to you as long as you meet a handful of administrative and reporting requirements.

CALLIE PRASSINOS: And I want to direct you to Section 4.19, it has specific information about contract technical data and reporting on that data. And then also in Section 5, there's data sharing and patent

information as well that can really help with that kind of information.

STEPHANIE FERTIG: There is a question here about the I-CORPs program and that option, and I know we walked through that earlier, but if somebody is interested in doing I-CORPs, is it optional, do they need to include it within their budget, how does that I-CORPs work?

CALLIE PRASSINOS: I-CORPs is optional. You do need to put it in the solicitation, I mean, in your proposal, in Section 2.5, it has a whole breakdown of what is needed, what is provided, what you need to propose to be in the I-CORPs program and the application process including that information in the contract pricing proposal, how much, what not to exceed. So, I would read through that section, and it starts on page 9 of the solicitation.

STEPHANIE FERTIG: And really, I think the importance of reading through the solicitation and following the instructions in the solicitation becomes so important. So, I'd encourage individuals to do that. Now, I do see a number of questions about specific topics and a number of those are around how much preliminary data is expected, hey, I have this topic and I'm not sure if it fits under this topic. Can I talk to somebody? So, when individuals have questions about specific scopes around topic, hey, does what I'm working on fit within this topic? Or specific questions about the topic in general, again, around preliminary data, if clinical trials are allowed, et cetera, what should individuals do? Because we have a number of them, a good number, we're not going to get to all of them today. So how should people handle those questions?

CALLIE PRASSINOS: Submitting the question to the contracting officer that is listed on page 74 of the solicitation is the best action. We will be providing responses as an amendment to the solicitation once the question period ends and we get all of the documentation for today's webinar, we would be posting that amendment with all the responses hopefully, within the next two weeks to provide the responses to all of those questions. We will also pull the questions that are listed in the Q&A and get them to those contracting officers as well as best as we can. But reaching out to those contracting officers and ensuring that they get your specific questions so that we can respond to them in the amendment.

STEPHANIE FERTIG: But it's important to remember that, and this is something that maybe people might miss, if this is their first time doing a contract, we're going to answer those questions in the amendment. That means everyone will have access to that answer, not just you. So, make sure when you're writing that question, you are writing it in such a way that you're comfortable with the fact that it will be open, that question will be provided more broadly in that amendment as well. So again, I know a number of the questions are, hey, are clinical trials allowed for this, or exactly how much money here, or and how much preliminary data? And those questions will be provided as part of the amendment. But just do keep in mind that in the interest of fairness we're going to provide that information to the broader community as well. Closer and closer to the end here. Are there any changes from last year's solicitation that you all want to highlight? Is there anything that as a particular note that you want people, if they maybe did it last year, hey, make sure you pay attention to this section, although you should read the whole thing.

CALLIE PRASSINOS: There wasn't a big change to the contract language or there wasn't any huge policy changes this year from last year. Definitely look at the appendixes, the foreign disclosure document, making sure that's signed when you provide the proposal.

ADAM SORKIN: I would want to point out that the human subjects and clinical trial section was actually updated from the proposal last year. So, it should be much more consistent with the same section that you would complete for a grant as well.

STEPHANIE FERTIG: And does the limit on questions on the topics, are they for the topic owners, for the contract-- how does that timeline for questions work? And this is something that's a little bit different, just as a quick aside, compared to grants because grants really, you can ask questions up until the exact moment that you submit that application. It's a much more I don't want to say open process, but it allows for questions a lot longer in the process. So, for those who are new to contracts, Kelly, do you want to talk a little bit about how the Q&A works for contracts and some of the limitations there?

CALLIE PRASSINOS: Yes, absolutely. Since we are trying to-- and in contracts, we need to be as fair as possible. We give a deadline of when questions needed to be submitted so that we can provide the

responses to the community as an amendment. As Stephanie says, we want to ensure that we're getting all contracting offerors the same information. So that's why we will set off that-- we try to give that question deadline so we can respond to the questions, provide that amendment to the whole community within enough time so that offerors can adjust their proposals and take in consideration that any new or clarifying information that's provided in those questions so everybody has the same information when they submit their proposals.

STEPHANIE FERTIG: I think it, maybe this was lost when we were addressing the questions around university participations, but can a university be a subcontractor?

CALLIE PRASSINOS: Absolutely. Just keep in mind that the small business needs to do two-thirds of the work, they need to provide two-thirds of the work, and we take in consideration that percentages of the cost of the work. But a subcontractor or consultants can definitely do 33% and can be proposed for be doing 33% of the requirements. It does not have to be a small business.

STEPHANIE FERTIG: Are there any exceptions to that?

CALLIE PRASSINOS: There might be some exceptions, but there they're far and few between. A special request, a special approval needs to happen for a small business to do less than two-thirds of the work. So, it's not a regular thing that happens.

STEPHANIE FERTIG: Where can individuals find information on the page limits? We did see a number of questions here on page limits and how that all works. So where was the best place to make sure because we can say a page limit here, but trust me, when you're in the middle of it, that's the moment we're going to be thinking, wait, what was that page limit again? How much space do I have? So, talk a little bit about page limits.

CALLIE PRASSINOS: Absolutely. The technical proposal has a page limit for Phase I, which is 50 pages, that includes and, and I had it here and I'm trying to find it. That includes all resumes and includes all letters that are submitted. The thing that it doesn't include is the human subject form is not included in that page count. But if we do get a proposal that is above that page count, we will only take the first 50 pages and that will go for a review. So just keep that in mind.

STEPHANIE FERTIG: And so really, it's important to, again, read the solicitation. And I would always say this is true across the board for grants and contracts, read the solicitation, read the requirements for a grant, read that notice of funding opportunity, read the requirements of the solicitation here for this contract, read those topic areas carefully. It has all that information about the different budget components, page limits, the information for the topics. That really should be your source to make sure that you are addressing and providing everything that is needed.

CALLIE PRASSINOS: Yes, it's on page 44.

STEPHANIE FERTIG: Excellent. Thank you. So, I know we are coming to the end of our time today, so I'm going to ask is there any parting words that you want to make sure that people hear and are just critical? And I'm going to take the easiest one to start. Please, please, please, submit a day early, please. I can't emphasize that one enough, really that's the thing that is the most heartbreaking. So again, please, submit a day early. So important. So, Adam, Kelly, you can rock, paper, scissors for it if you'd like.

CALLIE PRASSINOS: Just we're very excited for these proposals come in, the innovation that we see is very exciting. So please, just look at the requirements that are under each topic and be clear to how you're going to meet those requirements. Also looking at how they'll be evaluated so you can make them clear so that we can really understand what you are proposing, what you want to do, and how you're going to accomplish these innovative topics. So, thank you, guys.

ADAM SORKIN: All right. And I will make a two-part answer just because our CDC colleagues did just reach out and ask me to follow up with an answer. As part of the presentation. There was a question of whether or not $10 million was for Phase I or Phase II? To clarify, that is CDCs entire SBIR budget for the year. That includes all Phase I and Phase II grants and contracts, so not just the solicitation. They also participate in the SBIR omnibuses. As far as my final words of advice, I think, I will just again, pointing it to if you're really unsure of what to do or how to move forward with your proposal reach out to that SBIR program manager listed for the institute or et cetera, you're interested in approaching. They can really give you some great advice about what the best overall fit for the work you're trying to do and how to take that forward in our programs.

STEPHANIE FERTIG: That's a great point. The small business programs, SBIR/STTR are also known as America's SEED Fund, it is the same thing as a little bit of rebranding on the part of the small business administration. But anytime you have a question throughout the year, and I know this was mentioned by several of the institute colleagues today, anytime you have a question throughout the year about the small business program, we do have small business program managers who are there to help answer those questions about the SBIR/STTR program. Again, specific questions about the topics, specific questions about this specific contract solicitation, do make sure you send emails to those contract topic points of contact.

There is a deadline for those questions as we noted but definitely send those in and we'll be providing answers through an amendment. And we'll also be looking through the questions that were asked today. And with that, I really want to thank all of my speakers and all the speakers today, everybody who participated in the webinar, asked these great questions today. So, thank you so much. Be looking for the posting of the slides as well as the recording and the questions in approximately, definitely the slides of the recording in about a week or so, questions a little bit longer on that amendment. But we are going to be working to make sure that everyone has access to this material and information, and you can utilize that when putting together your great proposals. And with that, again, thanks to everyone, great to see you, and have a wonderful evening.