HHS SBIR Contracts Solicitation (PHS-2023-1) Webinar Transcript

Stephanie Fertig: Hello, everyone, Welcome to the Contract Webinar for 2022. We're going to wait for a couple of minutes before we get started to let everyone join. So, we're going to give just a minute or so here. I see the participant numbers are beginning to click up, and so we're just going to give one more minute before we get started. But we're happy to see everyone here, and they're here to join us today.

A couple of quick housekeeping issues before we begin. We're going to be putting links and information into the Chat. We will make that available after the webinar is complete on our website, in addition to a transcript and a recording, and the slide deck. The slides will be made available.

If you have questions -- and we do encourage questions -- please put your questions in the Q and A section. While certainly individuals can put information in the Chat, it's extremely helpful if you can put those questions in the Q and A, so we can make sure that we can get to your question, and are able to address it.

All right. With that, I want to again welcome you all today to our informational webinar. My name is Stephanie Fertig, and I'm the HHS Small Business Program Lead. And today I'm going to provide a brief overview of the NIH and HHS Small Business Programs, as well as introduce the Contract Solicitation. In addition, we have a number of individuals from the participating Institutes and Centers here to talk about their specific topics and address any questions that you might have.

So, with that, let's get started.

We're going to go through a bunch of information today, but we've got a wealth of information on our SBIR-STTR website. This is where the information about the webinar will be posted, under the Events. If you will get Past Events, you'll see Recordings, Transcripts, Slide Decks from our previous events, as well as upcoming events. But we also have information about the program as a whole, information about other grants and contracts, so I encourage you to check it out.

Now we're going to focus today on contracts. However, we did have a recent webinar focused on grants. And I encourage you to visit that Past Events page for more detailed information about grant submission, review, and tips for a successful submission. So again, we're going to focus today on contracts; that's where we're hoping the questions are focused. But if you have questions about grants, you want a webinar focused on grants, that is the place to go.

Now, the Department of Health and Human Services has four SBIR programs, the National Institutes of Health and CDC, which you're going to hear about today, FDA and ACL do have SBIR programs, but they do not participate in this Contract Solicitation. So again, it's just NIH and CDC.

Now the NIH mission can really be summarized as turning discoveries into health. And the small business programs really help get those great innovations that are out there throughout the country, into the hands of the patients, clinicians, caregivers and researchers that need them.

The small business programs at NIH have two separate programs; the Small Business Innovation Research, or SBIR program, and Small Business Technology Transfer, or STTR programs. It's important to note that the contract mechanisms only use SBIR -- so if you would like to do an STTR, you're going to need to use the grant or cooperative agreement mechanisms. And it's also important to note that the CDC only has the SBIR program, they do not participate in the STTR program.

The NIH Small Business programs are one of the earliest -- one of the largest sources for early stage capital for life sciences in the United States. We spend $1.2 billion a year on these programs. Now this is a great set of programs, and really, as you can see from the chart today, we are in that space, that early proof of concept and research and development support space for companies. This is non-diluted funding; you don't take a portion of your company, this is not a loan. NIH is generally not the main final purchaser for any of the technologies that you're developing. We're not going to be your main customer. In most of our technologies, we're not going to be the customer at all. People generally use the SBIR programs at NIH and CDC to help them do the research and development necessary to de-risk their innovation, so that they can get them into the hands of the partners and innovators that are needed to take that innovation to market. Again, we tend not to be the final purchaser of your product, even for our contract topics.

If you want to see the different technologies and kinds of innovations we support, I encourage you to take a look at our small business success stories. We support everything from minority health and health disparities to cancer. We have a number of companies that have successfully leveraged funding to get to partnering and investment, and that includes in the contract program, although the vast majority of our funding does go towards grants, and we do have a number of successful contracts as well.

The eligibility criteria for both contracts and grants are the same, and I put them here. You can also find it on the website. In short, it has to be a for-profit U.S. business, the work must be done in the United States, with very, very few exceptions. It has to be small, and it has to have individual ownership. And the individual ownership is generally where we get a lot of questions around eligibility. But all of this eligibility, as noted, is determined at the time of award.

Now one difference between grants and contracts is that you do designate on the contract if you're a woman-owned small business, or a socially and economically disadvantaged small business. So, you can see the two definitions here; you can self-certify in the system for awards management, you do designate it in SAM, and also there is a checkbox on the -- when you submit your contract. Unlike -- we still request that you provide this information as part of your proposal, unlike the grant process, but it's really important to note, this is for reporting

purposes only. This is really for us to do reporting, and is extremely helpful for us. So again, we do encourage you to, if you do meet one of these designations, please identify.

Now the small business programs are phased programs. These phases are not related to clinical trials phases, this is an unfortunate similarity in the nomenclature. Phase I is a feasibility study, Phase II is full research and development. As you can see here, there are a number of ways to get to that Phase II full research and development. And we have different applications, depending upon the project and the company needs, and for the Contract Solicitation, you'll see that specific topics will allow for specific kinds of projects, either Phase I or a Fast Track, or a Direct to Phase II. So, it'll show what is allowable for each of those topics. Regardless -- and you'll see this mentioned in the Contract Solicitation, there are, for your information, there are a number of additional projects at NIH, both a Phase IIB and the CRP, but it's important to note that not all institutions and Centers participate in those programs. We get a number of questions around budget guidelines; you'll see in the topics there is specific information around budget guidelines. But I should note that in general, the NIH and the CDC has a waiver from the Small Business Administration to exceed the SBA budget guidelines that you see here, and that's for specific topics. And you can find those on our webpage. But it's important to note, Phase I, the three different options -- and I think this is extremely important to note -- for the Contract Solicitation, you have Phase I and Phase II, you have someone who submits the Phase I, and you have someone who can then, after that Phase I has been completed, submit a Phase II. You have a Fast Track, where you submit the Phase I and the Phase II, complete Phase I, complete Phase II at the same time. And then you have the Direct to Phase II, which allows a company who's already done the work of a Phase I to submit directly to the Phase II, using that prior work as justification for that Direct to Phase II.

I am putting in the SBIR versus STTR and the critical differences, because I really want to point out what the work requirements are here and the principal investigator requirements that you see. And again, it's important to note that there is no STTR contracts; that's not an option. Even if an SBIR does have a partner, it's important to note that the award is always made to the small business, and the partner is a subcontractor.

There's a number of open funding opportunities. You can find more information on our website. I've starred the SBIR Contract Solicitation because that's the one we're talking about today. But it's important to note that the majority of our applications are investigator-initiated, and come in through those general Omnibus Solicitations. So, if you look at the Contract Solicitation and you don't find a topic that matches what your project is doing, that's okay. We have a number of other program announcements that can help support you and your work. Look at the general Omnibus Solicitations -- again, those are those investigator-initiated solicitations, but you can always go to the specific grant targeted solicitations. It's important to read the solicitations very carefully. Not all targeted solicitations have all Institutes, so not everyone participates, and that's definitely true of the Contract Solicitation. You can find the Contract Solicitation on our website, and that includes the information about how to submit, as

well as the contract itself. And it includes additional information. We have expanded our webpage to include basic information about the contract process and some of the differences between grants and contracts. So, I do encourage you to check that out.

You can also find information about this request for proposals in SAM.gov.

Now when the Solicitation opens, it will open as a large PDF with general information, and then those specific topic areas. The potential awarding components for the Solicitation are listed here. We have six participating NIH Institutes and Centers and two CDC Centers that are participating in the Contract Solicitation this year. The Institutes and Centers that are not listed do not participate. Each Institute and Center has those specific contract topics, and you must come in through one of those specific topics.

I put the Phase I submission components here, and then we'll click to the Phase II submission. A big caution -- all section elements of the technical proposal must be addressed, or the proposal will be removed from competition, so as you see, a little bit different from what the grant application looks like. And here I've highlighted some of the slightly different components for the Phase II submission.

Okay, so we do get a number of questions around page limits. There is, for the Phase I, it shall not exceed 50 pages, Phase II, it's 150. One big difference between contracts and grants is that is the Fast Track proposal. So, a Fast Track for a contract -- you're going to submit a complete Phase I and a complete Phase II. It's a little bit different from the grants, where you put the Phase I and Phase II together into one proposal, and submit it as one. So, it is a different process. It's also important to note that human subjects and clinical trials information forms and its attachments are excluded from those page limits; we want to make sure that you put all adequate information in there, and don't have to worry about page limits. So, you can see kind of the page limits, it's very important to note and abide by those page limits.

There are separate sections for human subjects and vertebrate animals. It's important to know if you're doing human subjects, if you're doing vertebrate animal research, and if you're doing a clinical trial.

It's extremely important to note that the NIH has a very specific definition of a clinical trial that is broader than the FDA definition. I put the clinical trial definition up here, but really, it's when one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. You'll note risk and number of human subjects does not play into this definition. It's extremely important to know whether or not you're doing a clinical trial before you submit; and this is true of grants and contracts. If you're not sure, we do have a decision tool online, and I encourage you to utilize that to determine if you're doing a clinical trial.

Number one important piece of advice--read the entire request for proposal, or RFP, several times. Read it carefully. I know it's long, but it's extremely important that you follow the instructions.

Contract proposals are submitted electronically through the electronic Contract Proposal Submission website. There are required registrations, you have to register through SAM, and you do have to register through SBIR.gov. And it's important to note that SAM does require two-factor authentication.

Second most important piece of advice: submit early. Please submit at least a day early. Every year we do, unfortunately, have people who get very angry because the Submit button went away promptly at 5:00 p.m. The system will not permit files to be submitted once the exact deadline hits, to the second. In fact, if you hit the button within a few minutes before the deadline, and because the file is not instantaneous, you may be late. So please, please do not wait until the last minute. You may be seen as late, if you do. There are sometimes technical errors or issues that come up in the last half hour that are extremely hard to work out because of the volume, and Help Desk support is stretched thin, or may not be able to get to you fast enough. And so, it's extremely important that you submit a day in advance if you can. Definitely do not wait until the last hour.

Please remember that unlike -- and this is an important difference between grants and contracts -- unlike grants, your only contact is with the Contracting Officer listed in Section 10. Please go to Section 10 --those Contract Officers are all listed. Those are the individuals who can answer your questions. Questions must be submitted in writing by email to that Contracting Officer. The deadline for questions is September 14th, close of business. The Q and A amendment will be issued in mid-September, on both SAM.gov and the SEED websites. Yes, your questions are going to be made public, as well as your answers -- that that makes sure that it's fair, everyone has the same information for both the questions and the answers. Additional questions get answered at the discretion of the Contracting Officer, so please do try to have all your questions in before the deadline, and then go back and look at that amendment to see what answer are, because that's going to be, again, another wealth of information for you as you're putting together your proposal.

Disbursement of funds -- we do get a number of questions around disbursement of funds, because this is different. Unlike grants, funds are not disbursed at the time of award. Invoices are submitted after completion of activities or submission of reports, and each funding Institute or Center may set up payment schedules a little bit differently. So, I think the bottom line here is really important to note -- the company needs to have enough resources to begin work and receive interim payments as work progresses. So, this is a little bit different from the grant process, and that's why it's important for us to bring up.

Now I want to transition and talk a little bit about the things in addition to money, because as many of you know, the SBIR and STTR programs, there's some money, but there's also resources that have become available to you. At NIH, we have two centralized Technical and Business Assistance programs, in addition to the option to ask for Technical and Business Assistance in your contractor grant. Now Technical and Business Assistance is a specific program within the SBIR programs. You can ask for Technical and Business Assistance through

your grant or contract. Specifically, if you've got your own vendor, you can ask for funding and indicate as part of your contract proposal that you're going to do Technical and Business Assistance funding, and you're going to use this specific vendor for this specific activity. However, at NIH, you also have another option, and that's use of our centralized Technical and Business Assistance programs. Both the TABA Needs Assessment, which is for Phase I, and provides an unbiased assessment of the areas that are critical for success in the marketplace, and then Phase II is Consulting Services where we provide a limited number of awardees, services in the four specific areas you see listed. You can either get TABA funding, or you can get access to these centralized services -- you can't do both. In addition, CDC does not participate in those centralized services. And if you want more information, we're happy to answer questions here. But also, you can go to our website and get additional information.

In addition to the Technical and Business Assistance programs, we do have Innovator Support that is also open to those who receive contracts. That's regulatory and business development consultants, because we do recognize a number of our entrepreneurs are fairly new to the whole business process. This may be your first business -- that's okay, we have a number of entrepreneurial support programs, and we also have partnering and investment opportunities. We do provide support for our recipients to go to different events and meet with investors or partners, and again, to help make that transition to the marketplace.

So, with that, I'm going to stop this part of the presentation, encourage you to get connected with us. And we're on a number of social media platforms, as well as we do have a listserv where we provide updates. But I want to start transitioning to the specific Institutes and Centers, who are going to provide a little bit of background on their topics this year.

So first, we have NCATS. Mayra Alvarez Lopez is going to kick us off. So, Mayra?

Mayra Alvarez Lopez: Hi. Thank you, Stephanie, I appreciate the introduction. A little bit about NCATS -- at the National Center for Advancing Translational Sciences, we tackle ongoing challenges in research so that new treatments can reach people faster. We focus on what is common across diseases, and develop solutions that reduce [INAUDIBLE] or bypass bottlenecks in the translational process. Our vision is more treatments for all people more quickly.

I would like to introduce Topic 23, Development of Automated Cell Culture Flask Cleaning Instrument. Our current budget for Phase I is $325,000 for nine months, and for Phase II, $2,000,000 for two years. We suggest that proposals adhere to the above budget amounts and project periods. Proposals with budgets exceeding the above amounts and projects periods may not be funded. We anticipate to fund one to two awards, and we want to make sure that it's noted that Fast Track proposals will not be accepted. In summary, Topic 23 deals with -- well, the purpose of Topic 23 is to treat a cell culture flask not as a disposable product meant to act as a vessel for one batch of cells to grow for harvest used in one experiment, but instead, to potentially be a resource that can be used multiple times. The final product will be an instrument or set of instruments that could be integrated as a component of a high throughput cell culture system in an automated fashion, capable of cleaning flasks, regardless of the size.

The long-term goal of this project is to bring this instrument or process to market to meet the needs of those researchers using high quantities of flasks. For cell-based high throughput screening, including complex 3D models and stem cell differentiation.

Please, though, if you have any questions regarding our Topic 23, please contact our Contract Officer listed in the Solicitation. Thank you.

Stephanie Fertig: Great. Thank you so much. So next, we're going to be hearing from NCI -- here, I've got to -- there we go. Going forward took me a minute, sorry about that. So, we're going to hear from NCI next. So Sarra Djemil and Ming Zhao will be taking it away next.

Sarra Djemil: Thank you so much, Stephanie. Good afternoon or good morning, depending on where you are, and thank you for joining us. I'm Sarra Djemil, and I'm a Program Manager at the NCI SBIR Development Center. My colleague, Ming, will join later during the Q and A session.

NCI has nine contract topics for FY '23. I urge you to read them carefully to understand the goals and the deliverables for each topic. The budget for NCI topics for Phase I is a maximum of $400,000 for a period of up to 12 months. For Phase II, it's a maximum of $2,000,000 for up to two years. For the next slides, I will read the topic name and the goal. Please note that Fast Tracks and Direct to Phase II awards are allowed only for certain topics. So again, please read the topic carefully. Next slide, please.

Topic 446, Development of Senotherapeutic Agents for Cancer Treatment -- the goal of this topic is to support pre-clinical development of senotherapeutics as anti-cancer agents. Next slide, please.

Topic 447, Non-Invasive Device Technology Research and Development for Chemotherapy-induced Peripheral Neuropathy Management -- the goal of this topic is to advance the development of innovative, non-invasive device technologies to provide effective mitigation of CIPN in a non-invasive, cost-effective, accessible manner in the home-care setting. Next side, please.

Topic 448, Wearable Devices for Dosimetry of Radiopharmaceutical Therapy -- the goal of this topic is to develop wearable technologies to allow radiopharmaceutical therapy dose to be continuously measured, providing rich, time-based data for RPT agents that can be correlated with a patient's anatomy. Next slide, please.

Topic 449, Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment -- please note that Topic 448 and 449 both deal with wearables -- please don't confuse the two, and read them carefully. The goal of Topic 449 is to improve the availability of new and-or better remote monitoring tools for patients and their clinical care teams during sensitive periods of treatment, with a view to improved health-related quality of life and reduced costs associated with further hospital visits. The primary goal of this topic is the development of a complete remote monitoring capability that includes software and-or analytics capable of supporting decision making and patient care. Next slide, please.

Topic 450, Technology Platforms for Circulating Tumor-macrophage Hybrid Cells -- the goal of this topic is to support the development of platforms to isolate, enrich, enumerate and identify the circulating tumor-macrophage hybrid cells in the blood from cancer patients, or animal models of cancer. This contract topic aims to enable thorough understanding of the biology of circulating tumor-macrophage hybrid cells in metastasis, and provide the novel means to remotely monitor cancer progression and metastasis. Next slide, please.

Topic 451, Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control -- the goal of this topic is to advance the development of new alternatives for HPV testing to the market that are both in a form factor as well as price point that will enable cell-testing programs to be established globally. Next slide, please.

Topic 452, Translation of Novel Cancer-Imaging Agents and Technologies to Mediate Successful Image-Guided Cancer Interventions -- the goal of this topic is to support the translation of novel, activatable agents and-or techniques for sensitive cancer detection in human subjects. Ideally, this would translate existing pre-clinical success with activatable, diagnostic probes to clinical tools that can detect small tumor clusters that are approximately one cubic millimeter in volume via imaging. Next slide, please.

Topic 453, Digital Tools to Integrate Cancer Prevention Within Primary Care -- the goal of this topic is to develop a digital platform that provides primary care physicians with validated cancer risk-assessment tools, cancer prevention guidelines and clinical recommendations based on a patient's risk factors to discuss with their patients. Next slice, please.

And finally, Topic 454, Software to Evaluate Artificial Intelligence-Machine Learning Medical Devices in Oncology Settings -- the goal of this topic is to stimulate the participation of small businesses in the FDA's medical device development tool, MDDT program to develop software tools for evaluating and monitoring AI-ML devices in oncology settings. A medical device tool can be a method, material or measurement used to assess the safety, effectiveness or performance of a medical device. To learn more about this topic and other NCI topics, please read the Solicitation carefully, and thank you. Steph, you're on mute.

Stephanie Fertig: Excellent. Thank you very much. So next, we're going to have NIA, Armineh Ghazarian is going to talk about their topics.

Armineh Ghazarian: Thank you, Stephanie. Next slide, please. So, this fiscal year, NIA has three contract topics, all of which are going to allow for Fast Tracks and Direct to Phase IIs. This is just a summary at a glance slide, so now I'm going to get into more detail on each topic. Next slide, please.

So, our first topic focuses on the development of an inexpensive high throughput assay to detect CHIP mutations for research purposes, which could eventually be translated into a diagnostic or a prognostic assay for use in healthcare settings for patient management. And this topic stems from the interest in examining the role of clonal hematopoiesis in the context of age-related diseases, but currently there is no low-cost scalable assay for analysis. I've listed

some of the Phase I and some of the Phase II deliverables. I would recommend that you go through the Solicitation and read them carefully. The budget for this topic for a Phase I is $300,000, and for a Phase II, up to $2,000,000. Next slide, please.

Our second topic focuses on the development of 3D human microphysiological systems that accurately mimic the AD or ADRD micro-environments, including factors that recapitulate both the vast complexity of the human brain while emulating the heterogeneity of the disease for use in AD or ADRD drug development. Again, I've listed a couple of the Phase I and Phase II deliverables. The budget for Phase I for this topic specifically, since it is ADs a little bit higher at $500,000, and for Phase II, up to $2,500,000. Next slide, please.

Our third and final topic is to develop an AI-based tool for Behavioral and Social Science-specific literature visualization and hypothesis discovery that can be marketed to Behavioral Science investigators and research institutions that consume scientific research with a particular emphasis on AD and ADRD. Again, since this is AD-specific, the budget for Phase I is $500,000, and for Phase II, up to $2,500,000. And if there are any questions regarding any of these three topics specifically, I would urge you to contact our Contract Officer listed in the Solicitation. Thank you.

Stephanie Fertig: Great. Thank you so much. So next we have NIAID, Natalia Kruchinin will be taking over and talking about those topics.

Natalia Kruchinin: Okay, thank you, Stephanie. Hello, everyone. Thank you so much for joining our SBIR webinar. My name, Natalia Kruchinin. I am at NIAID, the National Institute of Allergy and Infectious Diseases, SBIR-STTR Program Coordinator. Next slide, please, yes.

Within 27 Institutes, NIAID is the second largest Institute in the group of NIH Institutes and budget for 2022, SBIR-STTR budget is almost $188 million. And this money goes to support grants, contracts -- almost all the amount goes to support grants, contracts and contract agreements. Next slide, please.

Very quickly about the structure of our Institute -- we have four extramural divisions, Division of Extramural Activities, it's Division for policies, grant management, contracts acquisitional, and small business program is under this division. We also have three extramural divisions, Division of AIDS, Division of Allergy, Immunology and Transplantation, Division of Microbiology and Infectious Diseases. Again, most of the budget for these program divisions goes to support grants, contracts and contract agreements. We also have Division of Clinical Research, the Division of Intramural Research and Vaccine Research Center. Next slide, please.

For this Contract Solicitation, fiscal year '23, NIAID have 11 contract topics, and you can check SBIR Solicitation document at Page 95 through 109. Next slide, please.

I highly recommend you to check this page. It's a page regarding the summary of the components anticipated number of awards, and anticipated now and approximately time of the awards, scientific and technical merit review, and anticipated award date. You can look on this page, Page 19 -- I'm sorry, this number 19 to 38. Check Page 2, Summary Table regarding which

mechanism is allowed; Fast Track or Direct to Phase II, or maybe this mechanism is not allowed for each topic. Also, I put on this slide example how it looks on each contract topic. At the beginning, you will see this paragraph which mechanism is allowed, and you will see number of anticipated awards for specific contract topic. And you will see also budget with this specific contract topic. Keep in mind the budget limitations can be different. On this example, NIAID will pay $300,000 up to one year, and for Phase II, $2,000,000 for two years. Okay, next slide, please.

From Division of AIDS, for this Solicitation, we have three contract topics. You can check on Page 95-99. Topic 113 -- Development of a Simian Immunodeficiency Virus and Simian Human Immunodeficiency Virus database. Topic 114 -- Point-of-Care HIV Viral Load, drug resistance and adherence assays. Topic 115 -- Development of diagnostics to differentiate HIV infection from vaccine-induced seropositivity. Next slide, please.

From the Division of Allergy, Immunology and Transplantation, we also have three contract topics, and on Page 99 to 103. Topic 116 -- Adjuvant discovery for vaccines for infectious and immune-mediated diseases. Topic 117 -- Adjuvant development for vaccines for infectious and immune-mediated diseases. And Topic 118 -- Re-agents for immunologic analysis of non-mammalian and underrepresented mammalian models. Next slide, please.

And for Division of Microbiology and Infectious Diseases, we also have three topics, Page 104-106. Topic 119 -- Adaptation of CRISPR-based in vitro diagnostics for rapid detection of select eukaryotic pathogens. Topic 120 -- Modular sample preparation for in-field viral discovery. And Topic 121 -- Artificial intelligence to improve clinical microscopy for diagnosis of infectious diseases. And on the next slide, please.

And we also have two topics from the Office of Data Science and Emerging Technologies, on Page 107 to 109. Topic 122 -- Advanced and immersive visualization tools for infectious and immune-mediated disease research. Topic 123 -- Data science tools for infectious and immune-mediated disease research. Next slide, please.

Again, keep in mind, because of government acquisition office regulations, all technical questions regarding NIAID topics included in the Solicitation, please reach out to Charles Jackson, our Contracting Officer, and I put his email and phone number here. Next slide, please.

And if you would like to learn more about SBIR program at NIAID, I put my email address here. You are welcome to visit our website, and also you can share the link, NIAID Small Business Program Team. Thank you so much. Stephanie?

Stephanie Fertig: Thank you. So next we have NHLBI, Julia Berzhanskaya, and Allison Cristman will be taking over and talking about their topics.

Julia Berzhanskaya: Hello. So, my name is Julia Berzhanskaya. I'm Health Scientist Administrator at the Office of Translational Alliances and Coordination, which oversees management of small business program at the NHLBI [INAUDIBLE]. Joining me today is the main contact for SBIR contract topics for this year, Allison Cristman contracting officer. Next slide, please.

This year, NHLBI has two contract topics; 113 and 114. Topic 113 is clinical instrument for parahydrogen-based signal amplification by reversible exchange, SABRE, for hyperpolarizing probes for MRI. And Topic 114 is device to permit continuous self-monitoring of blood oxygen saturation during activities of daily living for individuals at risk for desaturation during physical exertion. This table will present an overview of those topics as [INAUDIBLE] Phase I, Phase II, Fast Track or Direct to Phase II Proposals are accepted. You can see budget payments and number of expected Phase I and Phase II awards in the table. Next slide, please. Thank you.

A bit more detail from Topic 113, which is clinical instrument for parahydrogen-based SABRE for hyperpolarizing probes MRI. This topic addresses full and [INAUDIBLE] needs, [INAUDIBLE] MRI probes, are slow, expensive and use toxic heavy metal, such as iridium as a catalyst. And SABRE using novel fluorinated catalyst could facilitate removal of toxic iridium and provide a safer method of generating hyperpolarized probes. The project goal is to develop a Class II medical device to deliver hyperpolarized MRI probes for medical imaging. Anticipated number of awards is one Phase I and one Phase II. Phase I deliverables -- an instrument to provide hyperpolarized probes for MRI animal imaging based on SABRE using parahydrogen and fluorous catalyst removed by filtration through a column. Phase II deliverables is built on Phase I, and to develop a Class II medical device for clinical delivery of hyperpolarized probes via parahydrogen-based SABRE with documentation for 510(k) submission through the FDA. I wanted to note that RHD text for Topic 113 has a lot of useful detail, please read the full topic, this is just an overview. Next slide, please. Thank you.

So, the Topic 114 is device to permit continuous self-monitoring of blood oxygen saturation during activities of daily living, ADLs, for individuals at risk for desaturation. And Unmet really is an MD approach wearable device to continuously monitor blood oxygen levels during sleep and activities of daily living. Anticipated number of awards potentially of the two Phase I and one Phase II. Phase I deliverables is to develop an initial prototype of the device and test it in a small group of patients while they're performing common physical activities of daily living, and during exercise of varying type and difficulty. Phase II deliverables -- to conduct focal group studies for usability and durability to optimize the user interface and data output of the prototype, corresponding clinical trials in collaboration with the NHLBI Division of Intramural Research and the approval or clearance as appropriate of the device. Again, I would encourage you to read the specific text of the RHD. Yeah, we can go to next slide, thanks.

Here are our contacts -- all NHLBI contract SBIR Omnibus proposal-related questions should be directed to Allison Cristman, here is her information. [INAUDIBLE] General SBIR-related questions, so for example, what's appropriate grant or contract, or anything talked about our program, this is the email box, NHLBI- underscore-sbir@mail.nih.gov. Please put "Contract Topics" in the subject line so we can quickly distinguish your inquiry from our main inquiries [INAUDIBLE]. Thank you very much for your attention.

Stephanie Fertig: Great, thank you. So, the last NIH Institute we're having present today is NIDA, so Tam Nguyen and Tracy Cain will be presenting for NIDA.

Tam Nguyen: Hi, everyone. I'm Tam Nguyen. I'm joined by my colleague, Tracy Cain, and we're going to present for the National Institute on Drug Abuse. Next slide, please.

Our topic is called Cause of Death Elucidated, or what we call CODE. And on the top you see the funding levels, Fast Tracks are permitted, Direct to Phase II are permitted, number of anticipated awards are three to four. Our budget for Phase I is $400,000 up to 12 months, and the budget for Phase II is $2,000,000 up to two years.

So, the problem is, 20 percent of drug overdose records do not specify the drug involved, and this severely hinders our ability to accurately monitor the drug crisis, as well as to effectively respond. So, we're looking for solutions, and for this initiative we're looking for research and development of new, portable and affordable post-mortem toxicology screening devices for rapid, accurate and accessible testing. We're open to different technology platforms, and the overall goal is to improve the identification of drugs involved in overdose deaths. On the right we see the different tasks that may be involved in the different phases. For Phase I, the task to develop product platform methods and software with the goal of developing a proof-of-concept prototype. For Phase II, task may be to determine performance characteristics, validation testing, design for scale-up manufacturing, ultimately to finalize prototype.

If you have any questions, feel free to contact us. I appreciate your time. Thank you.

Stephanie Fertig: Wonderful. Now we're going to transition to the CDC. The CDC has several Centers that are participating in the Contract Solicitation this year, and Sean Griffiths will be presenting on behalf of CDC.

Sean Griffiths: Thank you, Stephanie. And I appreciate that. Good afternoon, everyone. My name is Sean Griffiths, and I'm the SBIR Program Manager for the Centers for Disease Control and Prevention. Over the next several minutes, I'll be providing a brief overview of CDC and our SBIR program, as well as our topics included in this year's Contract Solicitation. Next slide, please.

The mission of CDC is to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, or are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights diseases and supports communities and citizens to do the same. CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise. Next slide, please.

The Centers for Disease Control Prevention is an operational division within the Department of Health and Human Services. This organizational chart indicates the 10 different CDC Centers and the National Institute of Occupational Safety and Health, or NIOSH, that participates in the CDC SBIR program. The CDC Office of Science is the responsible entity in the overall

management of the agency's SBIR program. This is a little bit complex, but I'll explain in just a moment. Next slide, please.

The 2022 to 2027 CDC strategic plan advances science and health equity, and affirms the agency's commitment to one unified vision; equitable protection of health safety and security. The plan continues to leverage five core capabilities of the agency, reflecting our commitment to equity and diversity, and lifting up where we have invested through the COVID-19 pandemic. 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. There is a strategic comparative to modernize CDC so that it consistently delivers public health information and guidance to the Americans in real-time, a mission recognized by talented people who work here and by public health experts around the globe. Next slide, please.

This slide is CDC's fast facts slide. I'm going to move through this one quickly. I'll start at the top left and go counterclockwise. I'll restate that there are 10 different CDC Centers in NIOSH that participate in CDC's SBIR program. CDC's FY fiscal budget for '22 ranges -- well, I'll just resay that. CDC's FY fiscal budget ranges between $10 and $13 million. There are typically between 20 and 40 topics, areas of interest across all mechanisms, depending upon the fiscal year. CDC will accept what we call "investigator-initiated grant proposals" for emerging public health issues. CDC does support Technical And Business Assistance, or what we call TABA, as part of the award for both Phase I and Phase II, and CDC also has two Centers or Institutes that participate in what we call I-Corps NIH NCEZID for this contract, and NIOSH for the grant Omnibus Solicitation. Next slide, please.

As I briefly stated on the last slide, our fiscal budget for '22 is approximately $13,000,000. Phase I contracts are awarded up to $243,500, as Stephanie talked about earlier. We match the SBA limits typically for a six-month project period. Phase I grants are awarded up to $275,800 typically for six-month project periods. I'm going to back up -- Phase I contracts are awarded at $243,500 for a six-month project period, specifically because of our interest to keep them under 250, and that's a CDC-specific requirement. Phase II contracts and grants are awarded up to $1,800,000 for a two-year project period. CDC participates in both SBIR HHS Omnibus Grant Solicitation, PA 22 176 and 177, and the HHS SBIR Contract Solicitation, which we're talking about today. CDC does also participate, as I just said, in the I-Corps at NIH, and as Stephanie stated earlier, CDC does not participate in the Small Business Technology Transfer program. We also do not participate in Fast Track, Direct to Phase II, Phase IIB, or the CRP program. Next slide, please.

I'm going to talk just for a moment about the two topics, CDC Topics 030 and 054. The National Center for Emerging Zoonotic Infectious Disease, or NCEZID Topic number 030, developing an over-the-counter diagnostic test for Valley Fever, and the National Center for HIV, viral hepatitis, STD and TB prevention, or NCHHSTP, Topic number 054, school illness-related absenteeism and learning modality surveillance. Next slide, please.

CDC uses the NIH electronic contract submission, or ECPS website for Contract Proposal Submission. ECPS is a component of the government's integrated, secure system for electronic submission, capture and tracking of contract proposals. The ECPS website will be the only way to submit proposals under the Solicitation, as stated earlier in the webinar. In this slide, you can see the two CDC topics, the CDC Contract Specialist responsible for those topics, or essentially your POC's at the agency, and the closing date of 11-4-2022. Next slide, please.

As stated previously in this webinar, please read the Solicitation and any future amendments to the Solicitation carefully. We also encourage you to apply early. If you have any questions after today's webinar, specifically during the open Question and Answer period, please contact the CDC Office of Financial Resources, Office of Acquisition Services, points of contacts as stated in previous slides listed in the Solicitation. When you contact CDC, be sure to reference the responsible Contracting Officer or Specialist, the Solicitation, which is this PHS 2023-1, and the CDC topic number along with your specific inquiry question. Next slide, please.

We want to thank you for your interest in the NIH and CDC SBIR programs. If you have specific questions or general questions about the SBIR program in CDC, feel free, or please email us at sbir@cdc.gov, and we'd be happy to get back to you. Back to you, Stephanie.

Stephanie Fertig: Thank you. So again, I just want to remind everyone that that deadline is -- it's a hard deadline, it's extremely important that your electronic submissions must be complete. We're not doing paper submissions, and we really do encourage you to submit early.

So, here's the good news -- we've got plenty of time to address some of the great questions that I've been seeing in Q and A. Please do submit your questions in the Q and A section. If you look on Zoom, under Q and A, please submit your questions there. It does make it easier for us to address those questions and keep track of questions.

I did see one question about investigator-initiated projects. So again, it's important to remember that for Contracts, you must submit under one of those specific topics that was talked about today. The topics are extremely important. You must submit under one of those topics. We do have investigator-initiated options for both grants and in the either SBIR or STTR programs, and that is through the Omnibus, the general Omnibus Solicitation for grants. We do have those program announcements specifically for the grant program, but again, for contracts, you do need to come in through those specific topics.

We've had a couple of questions come in, and so I'm going to start with these specific questions, because we've had a number of individuals ask different variations on these themes. So, one of the first questions I want to start with, since I talked about grants and contracts is, what are the difference between grants and contracts? I know -- I'm going to stop sharing my screen, we're going to get some of the different panelists up here, so give me one second. Great. So, I'm going to ask -- we have both program staff, as well as the Contract Officers available today to hopefully answer some of those great questions that you have.

So, with that, the difference between grants and contracts -- and I'm going to invite any one of our panelists to jump in and talk about some of those differences, since we may have people who are maybe more familiar with the grants process than with the contracts process. So, Natalia, I see you're on.

Natalia Kruchinin: Sure, I can start, thank you, Stephanie. Okay. It's basically grants are award of financial assistance, yes? Contracts mechanism acquire a property or service. And quite simple, quite simple actually, grants have no deliverables -- pardon me, today I don't know what's going on with me. Anyway, but it was grants usually, once a year we will ask for a progress report. But you can see from Stephanie's presentation from Solicitation that with contracts, it's specifically topics what we're looking for. You need to have deliverables. And I also want to mention, it may be a little bit my personal opinion, because I believe it was a question about why to apply to contracts and not to grants -- I feel that success rate when you're applying to contracts, it's higher versus when you're applying to grants. About 80, 85 percent of SBIR-STTR applicants are using Omnibus Solicitation, you can imagine the amount of people. And with contracts, because it's specific what Institute is looking for, less applicants, people who submit in proposals -- sorry, Stephanie, it might be a long speech, but anyway --

Stephanie Fertig: No, I think that's great. And I would encourage any other of our panelists want to talk about the difference between grants and contracts -- again, I know at NIH, the vast majority of our portfolio, it uses the grant mechanism. Only less than 10 percent of our portfolio is contracts. So, I imagine many of our regular companies may not be used to the contract process. So great to hear, if anyone else wants to jump in.

George Kennedy: Thank you, Stephanie. This is George Kennedy in the Acquisitions Office. While it's an in over-simplified answer, because there are many differences between the two mechanisms that really go into the whole logistical process that we follow, for the award document itself, I think it's important to understand that a contract represents a legally binding agreement between the two parties, your organization and the government. And what I like to express as some of the distinguishing factors are that the contract is going to be very specific in setting forth what the performance requirements are in your statement of work, and detailing a deliverable schedule that not only identifies the deliverables, but also the dates that are expected for performance. So that legally binding agreement that sets for the expectations for what work is being performed and what's being delivered to the government.

There's a relationship, I think, with that concept and some of the questions, a theme of the questions I am seeing come in that speak to who the ultimate purchaser of your technology is. And within the contract document, what you'll see are deliverables that are identified. And because the SBIR program is really set forth to support research that has a high commercialization potential, the deliverables that are identified within contract awards are typically in the form of reports, progress reports, so that the government official can firmly assess the progress and the promise of any product that's being developed under an SBIR contract.

I hope that helps to clarify, but Stephanie, please fill in with anything in the context of the overall SBIR program that I may have left out.

Stephanie Fertig: No, I think that's extremely helpful, and I was going to let some of the other Program Officers jump in and discuss that as well. I mean, the only other thing I would add, actually, before I open up to any of the other contract staff or Program Officers to talk, I would note that there was a question that was specifically talking about, well, what about the CDC and FDA? Wouldn't they potentially be the purchasers, as they use this as a procurement mechanism? So, it's, again, important to note that the FDA does not participate in this Solicitation, so I think that's extremely important to note. The FDA does not participate. I don't know, Sean, if you want to jump in to specifically address the CDC as a use -- and the CDC's, whether or not it would procure any SBIR-STTR technologies.

Sean Griffiths: Yeah, thanks, Stephanie. So that's not something we've typically done in the past. There may be one circumstance where that may have occurred, but that was a very unique situation. So, to answer the question, that's not a typical scenario for the agency. Over.

Stephanie Fertig: Great, thank you, Sean. So again, I do think for those who are more familiar with the contracting process maybe at other agencies, we are, again, each different SBIR agency does utilize their program a little bit differently, and that includes HHS.

Ming Zhao: Thanks, Stephanie. I would like -- sorry, I would like to add a few words here. I'm from NCI, this is Ming Zhao from NCI. So, for a question related to NCI, again, as Stephanie pointed out in her presentation, you're not allowed to discuss your contract-related questions directly with your Program Officers. You have to contact a specific contract office here. So, the contact for NCI is Cherie Wells, so you need to contact her. So, the contact information is listed in the Solicitation if you have any specific questions. And then you're welcome to contact her, and then once your question is answered, then we're going to pose your question and answer in the public so everybody can get access to those answers. So be careful when you ask questions, because if you ask questions in writing, you want to make sure you don't post any proprietary information in the public.

Stephanie Fertig: That's a really important point. And I do -- I think it's important to emphasize that this is a big difference between grants and contracts, is this public posting of both the questions and the answers. So be very careful when you ask that question that you don't have sensitive information in there. So that's an extremely important reminder, thank you very much for bringing this up.

Tracy Cain: Stephanie, if I could chime in for one moment. My name is Tracy, I'm the Contracting Officer for NIH -- NIDA's requirements into this program. And just something I thought it might be good to note regarding the previous question about whether or not any of the agencies ever procure the devices developed under SBIR, is that one of the major advantages that an SBIR contract does offer a vendor is the potential for what are called Phase III SBIR awards. And while it is true that NIH generally does not really engage in very many SBIR

Phase III awards, the vendor is right to sell the product to any government agency as a sole-source procurement under an SBIR Phase III award for, I believe, 10 years after completion under a Phase II, is one of the major advantages or incentives that a vendor might experience through developing using an SBIR. So, NIH is generally using these awards to try to create in the marketplace devices that we would like to be available for purchase, whether or not our agency expects that we have a specific need for them. But the entire federal government, if they might have any need for a device that's developed under a Phase II SBIR contract would be able to purchase it on a sole-source basis from you for a significant period after its development under these contract mechanisms. So that's just something to be aware of.

Stephanie Fertig: That is an extremely important point. And actually, one of the benefits of the small business programs overall -- and this is true across the federal government -- is that is one of the significant benefits of the SBIR program.

So, we do have a number of questions in the Q and A, and I do thank everyone for continuing to post those questions there. So, we have a number of questions. One of the ones that I did want to talk about that recently came up is, there was a note that -- look, it looks like there's two options, there's contracts or grants. I would throw in also cooperative agreements -- that is an option as well. But it appears that there are these two options -- are some of the opportunities described offered as both a grant or a contract? Basically, there's a question of, well, if it's a topic in the contract, does that automatically mean there's a program announcement, or an opportunity as a grant? So, I don't know if some of the Program Officers want to discuss that. If not, I can, but I'm hoping someone else jumps in. I mean, I will say that the general Omnibus Solicitation is an investigator-initiated solicitation that is open for those projects that fall within the mission areas of the NIH, CDC and FDA, so that is always -- that is an open solicitation that is our investigator- initiated solicitation. But I don't know, I see both Sean and Ming are both pinned to and visible right now, either of you are welcome to take it, or anyone else.

Ming Zhao: Yeah, I think that's a -- this is Ming again from NCI. I could say a few words here. So, for us, I don't believe we have any specific grants program announcement for the contract topics we have. In previous years, we did have contracts and also program announcement at the same time, because we want to stimulate certain areas. But again, for this year, I don't believe so.

Natalia Kruchinin: Sean, I want to mention, very quickly -- Natalia -- okay, Stephanie, I want just to mention that we talk about Stephanie's presentation for a whole hour, contracts topics are so specific. This is what Institute is looking for. And Omnibus Solicitation, the mission of Omnibus Solicitation is so broad, with 24 Institutes within NIH participating in the small business program Everything which, at the end, improve human health can go into Omnibus. Keep this in mind. And therefore, I'm talking about NIAID, for example -- I'm sure in your plans, you would consider applying -- or you had decided between contracts or grants -- just check the areas of High Priority. I have it on my slides for our Institute; you can just click on the link and check each division areas of High Priority -- I'm talking about grants. But contracts topics are so

specific. It can be overlapping NIAID; I'm talking about our Institute between topic area and grants, the Omnibus Solicitation. Okay?

Ming Zhao: So, a few more words. Thanks, Natalia, to bring that out. So, you're welcome to apply for Omnibus Solicitation if you think your technology even fits with a contract, and you want to go with a grant approach -- so that's fine. But please remind yourself, you can't submit two identical proposals to both grants and contracts at the same time. And also, you can't submit two identical proposals to any federal agency at the same time. So, you have to just go with the one program announcement in this case.

Natalia Kruchinin: Stephanie, are we going to mention about good news? No? I just want to add, actually to add that yes, you cannot submit grant proposal and contract proposal at the same time. But just example, if, for example, you have a Phase I awarded contract, and unfortunately -- I hope not -- but Phase II was not awarded, you actually have an option to submit to grant Omnibus Solicitation as Phase II. Again, if you have Phase I Contract Solicitation, you can submit to Omnibus Grant Solicitation Phase II.

Stephanie Fertig: Now -- oh, sorry, Sean, go ahead.

Sean Griffiths: Yeah, I was just going to add, because I'm looking at the question that came in on that, on the Chat, where they were asking, it seems there are only two options, grant or contract, to apply for a given opportunity. So, we have specific funding opportunities -- and Stephanie, maybe you can elaborate a little bit -- because CDC is looking at unique, specific funding opportunities that home in on a unique topic area of interest, and research area of interest. It is a grant or request for applications. So, it still is in the grant, it leans in on the grants, it's not a contract. It leans in on the grants. But I'll stop there and let Stephanie talk more about that.

Stephanie Fertig: So, there are specific grant program announcements -- so there is this general Omnibus Solicitation, but there are also targeted grant funding opportunities for targeted areas. And then there are contract -- there is the Contract Solicitation which has these specific topic areas. I have found in general; the contract topics are very specific. They're maybe even more specific of them.

We did get a question in here also about NOSIs, and the difference between a NOSI, a Notice of Special Interest, that's attached to the general Omnibus Solicitation and the contract topics. And again, a NOSI -- yes, that does indicate a topic, a Notice of Special Interest; it is a topic of special interest. And I encourage you, if that applies to what your project is and that makes sense for you, that is an option. But again, for the contract topics, this is a very specific topic that has been identified by the NIH, and you would be coming in under that specific topic, and we don't allow investigator-initiated contracts. We don't allow something that doesn't come in under one of those specific topics. So, it is a little bit different, it's different ways that NIH can signal interest, and show interest in either a specific topic or a specific area.

George Kennedy: Along with specificity, I see some questions about the review process. And while I can't speak directly to the review process for grants, I do think it's important for people to understand the process we go through for peer reviewing the contract proposals. To Stephanie's point, because the requirements are identified and described specifically under each of these research topics, the way that the review will be conducted is that each awarding component will assemble a panel of peer reviewers, so similar to grants review in the sense that it's peer review. But the expertise that's gathered for those panels is going to be collected based on the needs and requirements of the specific topic. So, proposals submitted under a topic will be reviewed together by a peer review panel that's reviewing against the criteria that's stated in the Solicitation. But the expertise represented by the panel is assembled based on the needs of that specific research topic.

Stephanie Fertig: And most grants are reviewed through the Center for Scientific Review. There are special emphasis panels for grants. But they are -- those special emphasis panels have general research areas that they cover. Your application comes in and is assigned -- for a grant, is assigned an Institute and Center, as well as one of those scientific review groups, again, based on the scientific content. If that -- for some of our program announcements they do have specific scientific review groups, and in that case, they would be assigned to that specific scientific review group for that specific program announcement -- RFA or PAR. So, there are some specific program announcements in the grant space that do have specific study sections. But the vast majority do go to the standard SBIR and STTR study sections through the Center for Scientific Review.

Ming Zhao: So, for NCI, the contract proposals will be reviewed by the study section assembled by NCI, actually, like George point out, and also Stephanie point out. We have separate study sections for contract review. And those contract reviewers with expertise in that particular topic area will be assembled together, and then they're going to review your contract proposals.

Stephanie Fertig: And since I have you and you're up here, there was a follow-up question around your comment about not being able to submit the same proposal to NIH through a grant and the Contract Solicitation. The question was, but can't you submit essentially equivalent work to multiple agencies, like NIH and DOD, as long as you marked so at the time of submission?

Ming Zhao: So, if you have identical proposal -- let's say if you have the same specific aims, and then the question is, no, you can't submit multiple proposals, the same specific aims to different agencies. You have to have different specific aims. Basically, you have to submit different proposals to different agencies or different program announcements.

Stephanie Fertig: Yeah, and I think the important thing to remember is, you're submitting to the NIH here. You're submitting to -- when someone is coming and saying, well look, when you say we can't submit to a grant and a contract at the same time, we're talking about a grant and a contract within this agency. And remember, the agency is HHS. So, each individual Institute or

Center is not their own agency. So, when you're submitting a grant to the NIH, you're actually submitting it to the HHS, to the broader agency -- that's what we're talking about when we're talking about -- you could, technically submit that grant to, say, the DOD or NSF or another agency, as long as you designate it. But what we're talking about, and I think just as a quick clarification, we're talking about within this agency, within NIH. You cannot submit both a grant and a contract and have them being under review at the same time. So important clarification.

There was another clarification, and there were two issues that I think on the grants versus contracts that I think are important to answer. So, the first one was, if someone who had originally planned to submit a proposal to the Omnibus Solicitation got feedback on their aims from a Program Manager, does that mean they can't submit to the Contract Solicitation if they fit under one of those topics?

Ming Zhao: The answer is, if you decide to submit a contract proposal from there, you cannot discuss your contract proposal with, let's say, Program Officers in NCI, and I guess any other agencies here. So, if you discuss your proposal previously for grant purpose, and then you're still allowed to -- in my opinion -- you're still allowed to submit a contract proposal here. Again, you just cannot discuss your contract proposal with any Program Officers here.

Stephanie Fertig: Anyone else want to jump in and add anything to that? Okay.

There was another question around grants versus contracts, and that question was, sometimes there's overlap between contract versus grant. So, what's the recommendation? How does someone decide -- you know, since they can't, do they reach out to the Contracting Officer and discuss their options? What's the best way to get a recommendation on either grant versus contract?

Natalia Kruchinin: Stephanie, can I mention quickly, as we all mentioned several times, because of government regulations, you cannot ask questions regarding contract topics. But you can always reach to Program Officers to discuss your projects and if you're considering applying to grants. What I'm saying that Program Officers -- let me put the camera -- always within NIAID, we always will reply and happy to discuss. We will connect you with subject matter expert, and you can actually discuss these options, like, to see what's the matter for this idea, for this technology. Is it better to consider grants or is it better to consider contracts? I would like, and always when I'm doing presentation, I am asking, when you're reaching out to me, for example, please send a short abstract, nothing confidential, specific aims. It will help you to understand what is the mission of our Institute. If not, we will help you to find a place within NIH. But again, Program Officers -- it's our role. It's our job. We're always happy to help, and we're always encouraging to reach to us. I'm talking about grants, not contracts. If you will send me all about contracts, I will be happy to say no, cannot talk. Contract an Officer. Anyway, thank you.

Stephanie Fertig: And I see Tiffany has her hand raised, or at least you were first.

Tiffany Chadwick: Hi. I work in the contract office for the National Cancer Institute. So, what I would say you should do, if you have any question about whether or not your project squarely

falls within the topic description for a contract in this specific Solicitation, PHS 2023-1, you should send an email to the person listed in the point of contacts for NCA, in that Solicitation. Write out a little description, a brief description of your project, and ask whether it falls within the scope of Topic XXX. We will give you a response. So that's the appropriate way we like to handle it. If it is something that falls very squarely into what the topic is asking for, generally people will find that their odds are better going with a contract, because it usually is a smaller pool of competitors because they are narrowly-tailored topics. But if it's a stretch to get within the topic, then it might not turn out very well for you, and it might be better to go under the grants route. But we would say to email a description to the contract point of contract for us to begin that conversation.

Stephanie Fertig: Great. And I see another hand -- excellent.

Tam Nguyen: Hi. I'm Tam Nguyen, Project Officer at NIDA. So just to answer in general, I'm happy to talk to any offers in terms of about their technology -- not specifically about the SBIR contract. Our office is always interested in the rate of technology, so we can talk about that and how it fits to other funding mechanism besides SBIR contract, to be SBIR grant or STTRs, or general information. Essentially it would be nice just to talk to our officers and kind of see where they are.

Stephanie Fertig: But again, I would remind everyone, if you have a specific question about the contract, it has to go through the Contracting Officer.

Tam Nguyen: Yes.

Stephanie Fertig: And so, I think that's the important thing to remember here, is that this is a little bit different from the grant process, and this is something that, while normally I'm up here telling everyone to contact their Program Officer before submitting a grant, this is a different process, and there are different rules here. So, it's important to reach out to the Contracting Officer prior to submitting.

We did receive a number of questions around Phase III, since we did mention the Phase III. And the two questions I want to pose to the group is, one is specifically for Sean, and there is that whole question about, does CDC have a Phase III-like NIH? So, there was this comment about one of the benefits of the SBIR is that Phase III and the ability to potentially sell the project more broadly federally. So, one question was, does the CDC have a Phase III-like NIH? And then the second question, which is probably a more broad one, is, does the awarding agency help disseminate the resulting technology? But let's start with that CDC question first.

Sean Griffiths: Yeah, thank you, Stephanie. And that's a really important question. So, this last year, CDC had its first SBIR Phase III. And CDC and the U.S. [INAUDIBLE] Service had come together in collaboration in response to COVID-19 and funded what we call SBIR Phase III. So, this was the first for CDC, and we're still in the process of walking through this process, because it is the first. So, to answer the question, yes. We have funded a Phase III, and it is possible. So,

we'll have more information as we work through and begin reporting on this first Phase III at CDC. Hopefully that's helpful.

Stephanie Fertig: I think it's important to note, you're saying words, "the first"?

Sean Griffiths: Yes. It is.

Stephanie Fertig: And so, I want to point out that it's not that it's impossible that we wouldn't do a Phase III, but it is extremely rare. The NIH and CDC, and actually across HHS. So, I just want to point out that in general, we tend not to be the final purchasers. That is generally, we're not going to be doing Phase IIIs. So, I just want to emphasize that again. While that is possible, and certainly there are rare instances where it has occurred, it's not the main -- that should not be your main goal.

Now I want to -- oh, Sean?

Sean Griffiths: Yeah, Stephanie, if I may, these were exceptional and extraordinary circumstances during the COVID response. And as one is aware, CDC is a public health response agency. And this Phase III came in under COVID funds, and it was a COVID funding situation. So as Stephanie just said, this was our first Phase III, and it was extraordinary and unique. So, I'll leave it at that. Over.

Stephanie Fertig: Great. So, let's talk about that second question about disseminating the resulting technology. Does anyone from some of the different Institutes and Centers that are on want to talk about, do you help to disseminate the resulting technology? How does that work?

Tracy Cain: Stephanie, this is Tracy. Since I caused this can of worms, I wanted to chime in first, just sort of to clarify that, NIDA also does not generally have a significant number of Phase III awards ourselves. I think we've had one also in my tenure here. And we do not publicize results or disseminate results to other agency. But what we would definitely encourage vendors to do is, if you, in the course of your doing business, are responding to requests from other agencies, or see a request for information or sources sought notice for which technology you developed under an SBIR program as a potential solution, we do suggest that notifying the requiring agency in those cases that it is potentially available under an SBIR Phase III, because that's just a term that means a government contract awarded to purchase something that was developed under an SBIR contract. It's not -- rarely is a device solicited as a Phase III, because the agency soliciting it may not know that it's available.

But it is an option that you will then have in your portfolio in terms of how you potentially can market it to federal agencies. And certainly, what we have done is, when we have had SBIR participants who were in the position of trying to sell equipment developed under SBIR contracts to, I think, the Department of Justice for a device of some kind, we were happy to serve as a point of reference to verify that, yes, it was developed in this way, and this is an acceptable mechanism. But there's not -- I don't want to deceive you into thinking that there is

a formal path in place where a result of these are propagated against the government. To the best of my knowledge, there's not one at most NIH agencies for that.

Stephanie Fertig: But I do think it's important to note that we do have a number of Innovator Support opportunities and ways that we support you to help you as you're moving towards the marketplace. So, while we don't help you sell your technology, we do provide -- and that was that expertise and guidance that I was talking about at the end of my presentation, there are different resources and opportunities to again help you as you're moving your technology to the marketplace, or trying to attract investors or partners. So, our recipients do have access to those resources, and they can be very important as you're looking to get your technology out there and into the hands of the individuals that need them. And Vicky was nice enough to put a link to some of those programs in the chat.

We are getting a number of questions about, what are the trade-offs with Phase I and Phase II, you know, and Phase I and Fast Tracks, and Direct to Phase IIs, and also about how the Phase II process works. Hey, I have a Phase I -- how can I get access to a Phase II? What if I have a Phase I grant and now I want to come in for a Phase II contract? So can you all take -- first I would say that the difference between the trade-offs between a Phase I Fast Track and Direct to Phase II -- how the Phase II process works, if you've received a Phase I contract. And then if you have a Phase I grant, can you come in for a Phase II contract?

Tiffany Chadwick: I can start -- Tiffany from NCI. So, the question that I first saw was about trade-offs between doing a Fast Track versus only a Phase I, and then moving to a Phase II. I think of this as, like, a high risk-high reward sort of decision. If you are able to secure a Fast Track award, you can move directly from Phase I right into Phase II with no gap in funding. However, the application process for putting together the proposal for the Fast Track is a lot more intensive. So, you're going to have to spend more time getting a lot more documentation together and explaining much more of your project, all the way through the Phase II stage. I will tell you that we don't award a huge amount of Fast Tracks, so the likelihood that that's going to turn out successful for both the Phase I with the contractual option to move directly into Phase II, it's not a high percentage each year. We do it only for a couple, if even that. But when it does work out, it works out very beautifully, and you don't worry about a gap.

Your alternate scenario is that we might only award a Phase I even if you do put in a Fast Track proposal. We might say we like the Phase I, but the Phase II's got too many unknowns or too many risks, so we're just going to do only a Phase I. If you're doing that, what happens is, at the end of your Phase I, we're going to invite you to submit a proposal for Phase II at that time. Now you have all of your results from your Phase I research. And we're going to assess that through the peer review process again, now that we actually have all of that information, and decide whether or not, again, we're going to move on with the Phase II award for you. So, you go through the entire formal source selection process twice; once at Phase I and again at Phase II. If you are successful with the Fast Track, you only have to do it once. And then it's an internal

NCI decision whether we are convinced that we want to give you the funding for the Phase II. I hope that makes sense. And that's all I'm going to say.

Ming Zhao: So, thanks, Stephanie. To follow on your comments there, so please remember, for Fast Track contract proposal, both Phase I and Phase II are reviewed separately So you've got two separate set of scores here for both Phase I and Phase II. That's why, as Tiffany pointed out, your Phase II could score really poorly and your Phase I score well, and then you can just get a Phase I award. But at the same time, if your Phase I scored poorly and your Phase II scored, like, a perfect score, but you're not going to get any awards, because you don't have Phase I here. So that's the process here.

Again, regarding second question, it's about grants or something -- I was going to make a comment.

Stephanie Fertig: Well, the second question was around, one, how does the whole Phase II process work?

Ming Zhao: Oh, okay.

Stephanie Fertig: So, if you've gotten a Phase I contract, how does, even if it's a standard Phase I, how does it transition into a Phase II? How does that process work?

Ming Zhao: So, yeah. So, if you get a Phase I, and as Tiffany point out, you're going to receive the invitation for Phase II application. I remember the second question now. So, if you have a Phase I grant, can you apply for a Phase II contract? The answer is yes, if that specific topic accepted Direct to Phase II. So, you have to read that Solicitation carefully and make sure that specific topic does accept a Direct to Phase II.

Stephanie Fertig: And this --

Natalia Kruchinin: I'm sorry to interrupt, can I just mention very quickly to add to Ming's point about Fast Track -- it's actually additional point, the difference between your grant and contracts Fast Track mechanism. And maybe it's additional actually advantage [INAUDIBLE], or SBIR contracts, because as Ming mentioned, if you have Fast Track application to be reviewed separately, Phase I, Phase II, and there is a chance that Phase I can be awarded, Phase II not, but you still have a chance, yes? With grants, it will go as one package, Phase I, Phase II together, and it will be viewed as the whole package, and will be one score. If you are not awarded, you're not awarded.

Stephanie Fertig: That's a really, really good point. And I was also going to add, for the Direct to Phase II, in the grant process, we clearly state that we don't care where that data comes from. And so again, I think it's important to read the Contract Solicitation very carefully, and determine whether or not you want to do a Phase I, a Fast Track, or the Direct to Phase II. If it's allowed in the contract topic -- again, each individual topic, and you heard this when people were going through their specific topics -- may or may not allow Fast Tracks or Direct to Phase IIs. So, for some of you, if you're interested in a specific topic, this decision will be made for you.

We're getting a number of questions around Technical and Business Assistance. So, I don't know if one of the Contract Officers wants to discuss how Technical and Business Assistance is awarded, if it's asked for within the contract.

Tiffany Chadwick: Sure. So, I can get on. So, this year, and past years, all that we're looking for is, if you are requesting Technical and Business Assistance, please make it very clear in your Appendix C, your budget, that it is one of those other Direct Costs. So, you'll see a little space on the template in the Budget section where you can note the fill-in-the-blank line item, and you can write "Technical and Business Assistance" and the amount within the certain parameters that are listed in the Solicitation, that will tell you the top level amount that you can request for. Then in the follow-on pages, still Appendix C, there's a couple of pages following on to the front page that have blank spaces where you can just enter a narrative. We would like to know, what are you going to do with that? You can tell us a proposed vendor, proposed activities. And then as we have questions, before we make the award, we will reach out and clarify with you. Thanks.

Stephanie Fertig: So, you would be asking for those Technical and Business Assistance funds as part of the proposal. So, it doesn't happen after, it's part of the proposal. And it gets -- that's all part of that proposal package, gets reviewed as part of that proposal package. So, it occurs at that time. So, there were some questions about where in the process that occurs.

There were also some questions about the centralized Technical and Business Assistance. Again, this is for NIH only -- NIH offers two centralized options. So, if you do not receive Technical and Business Assistance funding, you can come in for these Technical and Business Assistance centralized services, either the Needs Assessment program or the Consulting Services program, depending on if you're either a Phase I or a Phase II. So those specific programs are, if you don't receive TABA funding, you can come in for one of those centralized -- you can request one of those centralized services. And I see Vicky did put a link to those programs in the Chat. So, I don't know if any of the other Program Officers or Contract Officers want to talk a little bit about the TABA program, because I'm sure there are plenty of questions about it.

Ming Zhao: So yeah, so thanks, Stephanie. I would like to add a few words here. So, for NCI, let's say for TABA program -- two things you probably want to pay attention to. One is the budget. So, for Phase I $6500, for Phase II $50,000, for Phase II. And then the budget for TABA could be on the top of, let's say, the total cost, the cap. Let's say Phase I for NCI, the budget cap is $400K. You can request additional on the top of the $400K, additional $6500. And the same thing goes with the Phase II, $50,000 additional dollar amount. And the second part is, in your TABA proposal, if you include that in your contract proposal, please make sure you have specified your vendor in terms of doing all assessment assistance, etcetera. If you don't do that, you say, okay, to be determined, we're going to find one to help us to do something -- and then that's not going to work.

Stephanie Fertig: I think this question, TABA costs and the budget, is something that other Institutes, Centers may want to jump in and talk about.

Sean Griffiths: Stephanie, real quick -- oh, sorry, Natalia.

Natalia Kruchinin: Oh no no no, Sean, I already interrupt you once. Just go.

Sean Griffiths: It's okay. Just really quick, there's a Chat in that 123 and 131 where George Kennedy answered for CDC, so I just wanted to make sure that those that are in this conversation have a chance -- the participants have a chance to read that, because CDC has very specific requirements around TABA funding. Thank you. Natalia?

Natalia Kruchinin: Sorry. Very quickly, just to add what Ming also mentioned, the same for NIAID, it's above award, this TABA cost, above award. This actually question I'm not 100 percent sure. I know for grants, for Phase I TABA, it can be $6500 for the year, like, for each year; like if the project for two years, it can be $6500 for one year. Stephanie, the same for contracts -- I'm not actually sure it's the same for -- because Phase II, it's $50,000 for the whole award, yes? But Phase I, the same, yeah?

Stephanie Fertig: Yes, that's correct. And that's the same across the entire SBIR programs, just that it is consistent at $6500 per year for a Phase I, and up to $50,000 per Phase II project. So that's across all years for the Phase II. And you can request up to these amounts for each Phase in a Fast Track application. Sean was mentioning that comment about CDC, and it's really important to note that CDC -- again, CDC does not participate in those centralized NIH TABA programs. If you are a CDC offer, and you want to utilize your own technical assistance provider, again, you're required to include those in that budget and provide that budget justification. You have to put it in that budget of the proposal. So, make sure that if you are interested, particularly if you're with the CDC and you want to use TABA funding, you need to put that in the proposal.

Sarra Djemil: Tiffany, and I'd like to add that for NCI as well -- the TABA funds must be added to the proposal, because we do not participate in the solicitation where you can request additional funds post-award. But the NCI does support companies who did not request funds at the time of proposal to participate in the TABA Needs Assessment and the TABA Consulting Services that SEED runs. You can ask for either-or, not both.

Stephanie Fertig: Well, so you can ask for -- and the important thing to remember when we're talking about Technical and Business Assistance is that it's per phase --

Sarra Djemil: Right.

Stephanie Fertig: -- not per total project. So, you can ask for -- and this is a fine thing -- so if in your Phase I you took advantage of the centralized Needs Assessment program, if you were to come in later for a Phase II, you could ask for TABA funding as part of that Phase II, and it would be perfectly fine.

Sarra Djemil: Yeah, thank you for clarifying my point.

Stephanie Fertig: Yeah. It's a little complicated. The Technical and Business Assistance program is an extremely complicated one. And it can be confusing.

Sarra Djemil: What I had meant, if you request the funds, you cannot request the Needs Assessment, for example.

Stephanie Fertig: That's right.

Sarra Djemil: But funds in Phase I -- for per phase, you can't ask for Phase I funds and Needs Assessment.

Stephanie Fertig: That's correct, and that's a great point.

So, we did get a question around the -- for our COVID technology. And there was a question that said specifically, we've got COVID-19 technology. Would you advise us, and we want to do this as quickly as possible, should we be doing grants or contracts? And I guess this leads me to a more general question of, which one is faster for companies? And there was a previous question about, wait a minute, there's a smaller company, are you saying for a startup we would need to have money in hand to be able to move forward with a contract? So, let's talk a little bit about this B2 award, and then what happens after that award. And I touched on this in my presentation, but I think it's important to touch on again, because that's a significant difference between grants and contracts. Don't all the Contract Officers jump in at once.

George Kennedy: Stephanie, I'll speak to one portion of that, and it's a question of contract structure and payments. For those of you familiar with government acquisitions, the fixed price contract type, we received a couple of questions about that. And typically, that fixed price arrangement is such that a contractor won't receive that contract price until full performance of the contract has been completed. We recognize that the SBIR program is intended to provide SEED money, in the sense that we're supporting the research for the awardees. And while the fixed price mechanism is what we anticipate Phase I awards to be, that payment structure is typically going to be associated with the defined deliverable schedule.

As I alluded to before, most of these SBIR contract deliverables are going to be progress reports, whether that be on a monthly basis or a quarterly basis, it's going to be specific to the award. But payments will be associated with the delivery of those progress payments. We don't expect that any SBIR awardee would be in a position to where they're performing this work and won't receive a payment for that work until the completion of the contract itself. With that being said, it is a contract, and the ability to perform a contract is part of what's being assessed by the peer review group in the evaluation of your proposal. So, I would say exercise your professional judgment when writing your proposal, because you do want to put your best foot forward in communicating the likelihood of success in your ability to perform the work that you are proposing. Thank you.

Stephanie Fertig: And does anybody want to talk about the speed? Is the time from submission to receiving an award similar to that from a grant for a contract? Is that a similar timeline?

George Kennedy: Oh, thank you, Stephanie. So, while I can't speak to the timeline in SBIR grant awards, the Contract Solicitation does identify, and in the interest of transparency, we try to communicate what the anticipated timeline is for the contract awards. And that information is identified in the Solicitation -- I'm going to look for the section that that's identified. And while they are estimates, we want to be as transparent as we can with the community so that they understand what the process is. So, within the Solicitation, Section 9 contains projected dates for when review and award will take place. Keep in mind that much like the information in Section 12 associated with numbers of awards, dollar amounts are estimates, it is put there to help offer or understand what the process is. Thank you.

Sherrie Randall: Stephanie, this is Sherrie Randall I just want to speak to that, just kind of on the CDC side, just to chip in. A lot of times, it just kind of depends on when our Program Office receives funding, or when they actually -- oh, Start Video, okay. Can you see me -- okay, here I am. So, it just kind of depends on when the decision is made in the sense of who's going to get the award. And then we have to wait for our Program Office to get funding. So sometimes that it depends -- sometimes we're not sure what quarter we're going to get the funding in; for example, I believe this year we didn't get it in until maybe around the summertime. And then it just kind of depends on the process of the award from that, because we still have to go out, get a proposal, do a review, and all of that. So, it just kind of depends. But we definitely try to make things happen before the end of the school year. So, I hope that's helpful.

Stephanie Fertig: Anyone else want to jump in on the time to award? I mean, I have generally seen that it is similar to the -- it can be similar to the grants time to award as well. So that is, I think if people are looking for speed, one versus the other, I'm not sure there's a significant difference there.

So, I know we're coming to the end of the time, and I do want to touch on one last issue that I see raised, and that is around how these topics were selected, and if awards are going to be made. If a topic, and this is a question that was asked, if a topic allows for a Straight to Phase II award, or any other kind of award, what's the likelihood it's been written with a specific Phase I award in mind? And then a related question, are these topics aspirational? If you get good proposals, are you really planning to fund for those specific topics, or are these more concepts and aspirational, and you may or may not, because many of you have mentioned, there were specific numbers and specific numbers of proposals that you would potentially provide funding for. So, are these aspirational? Or is there really money set aside for these? And were these written with a specific offer in mind?

Tiffany: So, this is Tiffany from NCI's contract office. I just wanted to quickly chime in and assure everybody that we did not write these topics for somebody in mind. And I appreciate the question, because it comes up every year. So, if there's anything I want you to take away from this, it is just that because they are more narrowly scoped than a typical grand solicitation, it does not mean that we are thinking about a very specific company or a very specific technology, at least at NCI. These topics are coming out of our program areas and go through a

very rigorous vetting process. It's like a very thorough procedure. And I think sometimes there is just a misconception, because they're different than grants. So, we specifically use contract topics to target areas of interest, and that's why they're narrower, not because of an affiliation or an interest in a specific company. Thank you.

Tam Nguyen: Hi, this is Tam from NIDA -- so from the program side, we just identify the problem and we state the problem and the offers that provide the solution, that we're technology agnostic. If there's a good solution, we'll fund it.

Stephanie Fertig: Yeah, that's great. And I think that's the -- and I'd love to end with that today. We invite -- we are looking for the best solutions to these difficult problems that we've identified. That's what we're interested in. We're interested in you coming to us with those great solutions. And so, with that, I encourage you to come in, read those topics and come to us with your great solution to these really difficult problems.

We will -- as noted, we will be providing the recording, slides and transcripts will be made available on our website in about a week after this event. And you will be receiving an email when those resources are ready. Thank you all again for participating, asking those great questions. And please be looking for that email about the materials being available.

Sarra Djemil: Thank you so much.