HHS SBIR Contract RFP Informational Webinar Transcript
August 12, 2021

Valerie Virta: As Monika says in the chat, thanks everyone for joining us today. I have a few housekeeping items that I want to make everyone aware of. First of all, as the slides are presented by the various speakers during the webinar, people assisting us are going to put some links in the chat so that you don't have to worry about rushing to write down the link that you see on the screen. You can cut and paste them from the chat.

To that end, we welcome questions. We will have a dedicated question and answer session at the end of our talks. And so, we ask that you put your questions in the Q&A box. Please don't put them in the chat. Please put them in the Q&A box. That way, if we are able to type an answer, we will do that. Otherwise, we might save them to answer to the end.

Okay. So, the speakers we are going to have today, we are going to have Stephanie Fertig, the HHS Small Business Program Lead. She will talk about the SBIR program at NIH and for HHS. And then we have our speakers that represent the small business programs for NIH as well as one from CDC. So, from NCATS we will have Lili Portilla, who is the director of the office of strategic alliances. Then, we will have Reema Railkar from NCI. She is a program manager at the NCI SBIR Development Center.

After Reema, we will have Todd Haim from NIA where he is the chief of the office of small business research. After Todd, we'll have Natalia Kruchinin at NIAID where she's the SBIR and STTR program coordinator and team lead at the office of research training and special programs in office of Extramural Activity. Finally, we will end with Sean David Griffiths from CDC where he is the small business innovation research program manager at the Office of Science, Office of Technology and Innovation.

After Sean we will have a Q&A session where we will try to answer as many questions as possible. Please make your questions, sort of, on the general side. For very specific questions, we encourage you to contact us with a follow-up email. Otherwise, we will do the best we can to answer everybody's questions during the seminar. And what I will do is, I will pass the question off to the best person to answer at that time. I will introduce our contract staff who is joining us to be able to answer those contract questions during the Q&A session. Thanks again for joining us. I will turn the reins over to Stephanie.

Small business Education and Entrepreneurial Development (SEED)

Stephanie Fertig: Thank you so much, Valerie. Thank you, everyone, for joining us today. So, as was noted, I am going to provide a brief overview of the SBIR programs at HHS and NIH and CDC. But really then pass it over to the specific program staff and contract officers to provide a brief overview of the specific topics, as well as answer some of those specific questions that you may have. We are going to go through a lot of information, today. If you want more specifics about eligibility, or specific policies, you can find all of those on our website. It is a wealth of information. Not just about the general programs as a whole, but also the specifics around the grant process, as well.

We did have a recent virtual conference. And if you are interested in the grant process, I would encourage you to visit the conference materials for more detailed information about grant submission, review, and tips for successful submission there. In addition, we did have a specific session focused on the omnibus solicitation, that general solicitation. And it was recently released, as well. That will be posted shortly. It is not posted yet, but that recording and information around that will be posted shortly as well.

But this will specifically focus on the contract mechanisms. So, there are four operating divisions within HHS that have a small business program. Today, we are going to focus on NIH and CDC as those are the two participants in the contract solicitation. At NIH, this is our mission. It can be summarized as turning discoveries into health. And we really help, our small business program helps get innovation into the hands of the patients, clinicians, caregivers, and researchers that need them.

The small business programs are part of the $1.2 billion that we have Congressionally mandated to support small businesses. And it's important to note, there is the SBIR, Small Business Innovation Research, and STTR, Small Business Technology Transfer programs. Is important to note that the contract mechanism only utilizes the SBIR program at HHS. So, if you would like to do an STTR, and that is the best fit for your project, you would need to look at the grant, or cooperative agreement mechanisms. You cannot use the contract mechanism to do a STTR.

Now, why small business programs? They are the largest source of early-stage capital in the United States. It’s not a loan. It’s non- dilutive. We won't take a portion of your company. But it's important to note for NIH and HHS as a whole, the vast majority of the time, with only a few exceptions, NIH is not the final customer. You are not making a product for us to purchase. You are making a product to solve a problem that is out there. Again, for those patients, clinicians, caregivers, researchers.

Many awardees are in that early stage, as you can see, here. And they utilize their funding to de-risk their innovation and their product to track investors and partners that will help support them and bring their innovation to market. And we do have successful companies that have done that. And we have a new small business success stories webpage where you can see the wide range of disease areas and modalities that we support through our SBIR and STTR program using grants and contracts. Everything from the National Cancer Institute, to Minority Health and Health Disparities. We have companies that have successfully leveraged this funding to get those partnering investment and bring something to market. So, you can take a quick look at those success stories, there.

So, what is the eligibility criteria? Well, for grants and contracts, eligibility criteria is the same. You can see it here. We have further information, as I said, on our website. Including, a detailed document provided by the Small Business Administration on eligibility. The important thing to note, and I think the one I want to highlight here, is the work done in the United States. With only a few exceptions, work should be done in the United States. Any exception should be discussed with the contract officers prior to submission. It is important to note that the bar for foreign work is higher than a standard NIH grant in these small business programs. And so, it is very important to discuss any work you wish to do outside the United States in advance of submission.

Those who might be new to the small business programs may not realize it is a phased program. There is Phase I - feasibility, and Phase II – full research and development. These are not related to clinical trials phases. It's an unfortunate similarity in the nomenclature. Unlike some agencies, we do provide, NIH has the ability to utilize things like a Fast-Track which combines the Phase I and Phase II into one proposal. Or the Direct to Phase II.

Equally important to note, is that not all Institutes and Centers utilize the Fast-Track or Direct to Phase II for their topic area. For example, CDC does not utilize the Fast-Track or Direct to Phase II. In addition, some topics will specifically note if they allow for Phase I, Fast-Track, or Direct to Phase II. You need to read the topics carefully.

Also important is to look at the allowable budgets noted under the specific topic areas. Again, each specific topic may or may not allow Fast-Tracks or may or may not allow for a specific budget amount. It is important to read them carefully for the topic that you are looking at. SBIRs have some specific policies around what is allowable with regards to work, who can do the work, and what partnering is allowed. You can see that there are guidelines associated with outsourcing. And the primary employment of the principal investigator does need to be with small business.

Again, any deviations must be discussed with the contract officer. We get a lot of questions after the fact that it's very important to discuss that information with us, ahead of time. Again, to emphasize, there are no STTR contracts. It is important if you are interested in pursuing a STTR, you need to go and look at the grant or cooperative agreement.

Unlike the grant process, we are still requesting that you identify, as either a woman-owned or socially economic business, if this is applicable to you, in the proposal. This is for our reporting purposes only. It is extremely helpful for us, extremely helpful for us to know that information. So, we really do encourage you to make sure that you do self-identify and you also self-identify in the System for Awards Management (SAM) when you register or update your registration.

Now, there's a number of funding opportunities that the small business programs utilize to get those different projects in the door. The contract solicitation is the one we are focusing on today. That's why it is bigger and up on the top, here. But it is really important to note that only some Institutes and Centers participate in our contract solicitation. And it is a part of a broader suite of funding opportunities at HHS.

We do have other targeted solicitations in the grant realm. And we have the general omnibus solicitation. If you're looking at the contract solicitation, and unfortunately your project doesn't fit under one of the specific topics you're going to hear about today, that's okay. We do have an investigator initiated grant omnibus solicitation. That would allow you—if you fall within our mission area—to come in and request funding there.

So, I am going to do this in a couple of times, but I really want to emphasize the receipt date and the time on the receipt date. It is very important you note that it’s October 28th, 5:00 p.m. Eastern Daylight Time. You can get information; you can get that specific RFP in a couple of different ways. It is linked on our website. You can see it here at sbir.nih.gov/funding. It is also on SAM.gov. For those

who have been doing contracting for a while, please keep in mind that FedBizOpps did make the transition to SAM.gov. You will be going to SAM.gov for that information.

When you pull up that RFP, this is the first page you're going to see here. And the solicitation is going to be a fairly large document with general information in the front. And then specific topic areas as we go further down. It is really important to read the RFP. There is a wealth of information there. Particularly, if it is your first time doing a contract proposal. Extremely important to do that ahead of time. You will see the different specific topic areas for each of the different awarding components. This year, we have four participating Institutes and Centers and five participating CDC centers. The other Institutes and Centers within HHS that are not listed here do not participate in the contract solicitation.

So, let's talk about a couple pieces of advice. First, please read the RFP several times. It's a wealth of information. There's a lot of stuff packed in there. Really important that you read it thoroughly and look at it very, very carefully. Second, please submit your proposal a day early. Every year, we do get individuals who are unfortunately very upset because the submit button does disappear at 5:00 p.m. The system will not permit files to be submitted once that exact deadline hits. To the second. In fact, sometimes, even if you hit the button a few minutes before the deadline, the file upload won't be instantaneous. So, you might have a late proposal.

If there are technical issues or user errors that come up in that last half hour, it can be difficult to impossible to get those worked out due to Help Desk volume. So, really important. Please, please, please submit a day early. That's the worst calls we have to take, for those where unfortunately someone submitted just slightly late and there is nothing we can do.

All right. So, let's talk about what is in the submission. Again, contract proposals are a little different than grant submissions. You can see the different components from the technical proposal and business proposal, here. All section elements of the tactical proposal must be addressed, or the proposal will be removed from competition. So, again, read that RFP very carefully and make sure you're addressing and have all those different points. For Phase II submissions, you can see I highlighted those differences between the Phase I and Phase II. Again, all sections for Phase II need to be addressed, or it will be removed from competition.

There are page limits. There are no exclusions to these page limits. Pages in excess of the page limits will be removed from the proposal and will not be considered or evaluated. Now, it is very important to note that human subjects and clinical trials information and attachments are excluded from these page limits. It's important that you do provide all of that information. They are not counted towards those page limits. If you're doing human subjects or vertebrate animal research I encourage you to take a look at those sections that are relevant to human subjects and for vertebrate animals. Very important to make sure you follow those instructions.

It's also important to note that the NIH definition of a clinical trial is different from the FDA or other more colloquial definitions of a clinical trial. In fact, I really encourage you—if you're doing human subjects research—please check out the clinical trials website and our policies on clinical trials. Very important that you read that carefully. The NIH definition of a clinical trial may be broader than you

think. In fact, it is not related to risk or number of participants. We often get a lot of confusion and questions about, hey, this is a low risk, how can it be a clinical trial? Risk is not part of the definition. I really encourage you to take a look at the clinical trials definition. Use the decision tool and determine if you have a clinical trial.

The SBIR contract proposals must be submitted electronically. They are submitted through the electronic Contract Proposal Submission (eCPS) website. Not through Grants.gov. This is another big point that we have, here. Not through Grants.gov. You need to go through the electronic Contract Proposal Submission website. It apparently has an updated interface. I say apparently, I have not used it. Apparently, it does require a little bit to get used to if you haven't used it for that first time. Again, very important to make sure that you familiarize yourself with that submission website before, you know, in advance. Always important to do things in advance.

Okay. One of the big differences between grants and contracts is whom you can talk to, when. Unlike grants, where we really do encourage you to talk with us and encourage you to contact the program officers, you know, right up until the day you submit, you can contact a program officer in the grant world. In the contract world, it's a little bit different. Your only contact is with the contracting officer. Those contracting officers are listed in Section 10. This is a big question we often get. I am going to, it's worth repeating. The contract officer is listed in Section 10. Questions must be submitted in writing by email to the contract officer. The deadline for questions is September 3rd. Close of business. Why is that? Well, because there will be a Q&A amendment that is issued in early to mid-September on SAM.gov and on the NIH SBIR website.

You will see that contract, the original contract solicitation, and then you will see an amendment associated with the questions and answers. What does this mean? Yes, your question and your answer will be posted to the public. So, the good news is, you will get access to everybody's questions and answers. So, really, everyone will be on a level playing field. Any additional questions will be answered at the discretion of the contract officer. It's extremely important that you get those questions in well in advance of that September 3rd deadline so you can make sure that you get a response to your question. Again, that’s to the contract officer, who is listed in Section 10.

Another big question we get is about disbursement of funds. This is a big difference, again, from the grant process. Unlike a grant, we do not disburse funds at the time of award for you to draw down on. That's a big difference between a grant in a contract. In a contract, you submit an invoice after completion of activities or submission of a report. Individual Institutes and Centers can set up a payment schedule a little bit differently. But it is important, we are mentioning this, because companies need to have enough resources to start work first and get those interim payments. Again, it's a little bit different, really, a lot different than the grant process. It's important for you to understand that going into getting and looking at the contract process.

But I am going to segue here and spend a couple minutes talking about something beyond funding. I am part of our new SEED office, Small business Education and Entrepreneurial Development. The SEED office, we really appreciated that many of the companies that were coming to us were being run by innovators where this was the first time at doing a company. They may be brand-new at this. We really wanted to support the entire community and support our companies beyond the funding.

If you read through the article, you're going to see that there are several different resources and different things that are noted. Things like I-Corps. Contractors are available to utilize things like the Commercialization Readiness Pilot Program when they get to their Phase II.

There are also regulatory and business development consultants partnering and investor opportunities that are available for contracts as well. It is important to be aware of some of those opportunities when you see them. When you see them, take advantage of them. In particular, those consultants are available through the SEED office for our awardees, our recipients. That includes contracts and we do have partnering and investing opportunities that do come up where we do, really, again, try to facilitate those connections between the recipients of our SBIR funds and those partners and investors that are going to really take things to the market.

So, with that, I would encourage you to connect with our office. Hoping this will certainly not be the only time that we connect with you. And so, there is a number of ways to get in touch with us. You can see them all here. And with that, I am going to pass this on to Lili Portilla and some of my other colleagues at the NIH and CDC who are going to talk about those specific topic areas and their specific programs at their Institutes and Centers. So, Lili?

National Center for Advancing Translational Sciences (NCATS)

Lili Portilla: Hi Stephanie, thanks very much. Good afternoon, everyone. Can we go to the next slide? Yeah, hi. I am Lili Portilla, I'm the director of strategic alliances at NCATS and I just wanted to briefly tell you about one of our topics we have this year in the solicitation. It's around building some technology and validation of remote measures that can be used in clinical trials for individuals with rare diseases. Rare diseases is a big focus for NCATS and we are looking for technologies that can validate digital health technologies for data capture. And that can be used to assess individuals with rare diseases in remote settings in such a way that it is suitable for sensitive and specific for use in clinical trials. And that being that many of our rare disease patients can't easily access hospitals. Or have the inability to get into a hospital or clinical research organization in order to participate in a clinical trial.

So, if there was a way to do that remotely, we believe that it would really assist this particular population of patients. And we want these technologies to be reliable, secure, and easy-to-use and monitor. And the solicitation has much more specificity around it that we would be happy to answer through our contracting officer, in terms of any questions that may come up. But we are looking for, it will be a, we aren't involving any Fast-Tracks for this particular contract solicitation. It will be Phase I that can last anywhere up to nine months. 325 thousand would be the total cost that we would expect. For Phase II, which would be a separate review for companies that participate in the Phase I. And they can request up to two million for two years. I will say, if you are interested in requesting TABA funding, that that money can be above these caps that we have established, here, of 325 and two million. Any questions, happy to answer them. Thanks for your attention. We look forward to getting some applications or solicitations.

National Cancer Institute (NCI)

Reema Railkar: Hi, Stephanie. Can you hear me? Perfect. Thank you. My name is Reema Railkar. I am a program manager at NCI SBIR Development Center. Next slide, please. NCI has a separate office, NCI SBIR Development Center under the NCI Office of the Director to maintain SBIR-related activities. The ones on the left are some of the core activities at SBIR that includes managing funding opportunities, providing guidance and assistance to our applicants and awardees. Next slide, please. So, we do have set-aside funds for the R&D contracts. Out of our about 180 million dollars budget, about 12 to 20 percent of the budget is set aside every year for funding of the R&D contracts.

Next slide, please. So, finding the contract topics every year is not just NCI SBIR-focused activity. It is a trans-NCI process where program directors from different branches and offices of NCI, including even NCI Director Dr. Sharpless, submit their ideas. This year, we have FDA's Centers for Devices and Radiological Health (CDRH) that contributed to the two contract topic ideas. I will come to them in a few slides.

Next slide, please. These concept ideas, once submitted, go through various levels of review. Including, at the program level, at the scientific leaders level, Moonshot committee and finally, at the Board of Scientific Advisors for NCI. AT every level these ideas are scrutinized for their scientific merit, the need for NCI portfolio, need of the community, and finally, and most importantly, potential of commercialization.

Next slide, please. This has led to 16 contract topics that you will see for the fiscal year of 2022. And you can read about these contract topics here. Please read, as Stephanie said earlier, please read the document carefully and read the contract topics of your interest carefully, as well. For the questions, regarding NCI contract topics, please contact NCI's Office of Acquisitions at ncioasbir@mail.nih.gov.

Next slide please. AS I said earlier, NCI has 16 contract topics for the fiscal year of 2022. I urge you to read them carefully to understand the goals and deliverables of each of the topics. Here, we have provided the links for each of the topics. The budget for NCI topics for Phase I is maximum of $400,000 for the period of up to 12 months. 12 months. This is slightly different from all of our previous years when this used to be, the period used to be up to nine months. This year, it is going to be, for Phase I, $400,000 of the period of up to 12 months. For Phase II, it is a maximum of $2 million up to the period of two years.

For the next few slides, I'm going to be the topic names for each of the topics and a little bit about the scope. Again, before I go into this, again, I urge you to read the topics carefully, because Fast-Tracks and Direct to Phase II's are allowed for only certain topics. Please pay attention to those.

Next slide, please. Topic 430. Development of Senotherapeutic Agents for Cancer Treatment. The goal here is to support preclinical development of senotherapeutics as anticancer agents.

Next slide, please. Topic 431. Cancer Treatment Technologies for Low-resource Settings. The goal of this topic is to support low-resource settings appropriate for technologies for cancer treatment. The

product addressing cancer of the cervix, colon/rectum, esophagus, and oral cavity are particularly encouraged for this solicitation.

Next slide, please. This is a reissue from last year, topic 432, Synthetic Biology Gene Circuits for Cancer Therapy. The goal is development of gene circuit therapies for cancer by engineering wither the immune cells or the cancer cells or both.

Next slide, please. Next one is Developing Unbiased Medical Technologies to Reduce Disparities in Cancer Outcomes. The activities that fall within the scope of this solicitation include development of unbiased technologies to replace existing bias in technologies that contribute to disparities in cancer control outcomes. In this topic there was some erroneous language that was included in the topic and we are taking measures to remove this language from our website. And the update regarding this will be posted in an upcoming amendment that is supposed to be published in September. So, just be aware of that.

Next slide, please. Next topic is 434. Ultra-fast Dose Rate (FLASH) or Flash Radiation Detectors and Safety Systems. The goal is to advance the development and application of devices to allow FLASH or ultra-fast dose rate radiation therapy to be properly evaluated and, ultimately, translated into the clinic.

Next slide, please. Topic 435, Devices to Treat Secondary Lymphedema Following Cancer Treatment. The goal of this contract topic is to support the development of technologies that prevent, reduce, or eliminate, lymphedema following the removal of all radiation of lymph nodes due to cancer in the upper part of the body such as neck, chest, et cetera.

Next slide, please. Topic 436, New Technologies to Analyze Extra-chromosomal DNA in Cancer. The goal of this contract topic is to stimulate development of new and advanced analytical approaches that can support research into mechanisms giving rise to extra-chromosomal DNA formation and organization, and the role of this extra-chromosomal DNA in cancer.

Next slide, please. Topic 437, this is another issue from last year. 3D Special Omics for Molecular and Cellular Tumor Atlas Construction. The goal here is to advance the development and dissemination of imaging workflows. Typical of a mixed level measurement in thick tissue resections or whole biopsy cores.

Next slide, please. That is another reissue. Topic 438, Understanding Cancer Tumor Genomic Results: Technology Applications for Community Providers. The goal here is to develop tools and technologies for the oncologist to understand the NGS results of their patients.

Next slide, please. The next topic is topic 439, Advanced Sample Processing Platforms for Downstream Single-cell Multi-omic Analysis. The goal here is development of technologies to improve single-cell multi-omic preanalytical microfluidic platforms that integrate the steps of preanalytical workflows such as sample processing, single-cell isolation, technologies for solid tumor dissociation and tracking of cancer cells. So, basically everything to help the single-cell multi-omics.

Next slide, please. The next topic is 440, Cancer Prevention and Diagnosis Technologies for Low-resource Settings. The goal here is to develop, adapt, apply, and validate existing or emerging technologies into low-resource setting-appropriate technologies. This is for cancer prevention, early detection, and diagnosis. For cervical cancer, this solicitation has a particular focus on developing rapid HPV diagnostics at the point-of-need suitable situation. For example, a portable loop-mediated isothermal amplification or LAMP-based assays.

Next slide, please. The next one is topic 441, At Home Screening for Hepatitis C Virus. The goal is to develop and validate rapid, sample-to-answer, point-of-care tests for hepatitis C virus. Either for exposure or active infection.

Next slide, please. Topic 442, Quantitative Biomarkers as Medical Device Development Tools for Cancer or MDDT tools for cancer. This is the topic NCI developed in collaboration with FDA. The goal of this contract topic is to stimulate participation of small businesses in FDA's MDDT program to develop quantitative biomarker tests. Activities included in this topic are, development and optimization of biomarker-based assays that meet the criteria defined by FDA's MDDT program.

Next slide, please. This is topic 443, Development of Computer-aided Diagnostic Tools for Upper and Lower Gastrointestinal Tract Cancer Prevention. The goal is to advance the development and application of AI-based algorithms to improve the visual, human-based determination of precancerous lesions examined through visual inspection of upper and lower endoscopies.

Next slide, please. This is topic 444, Evaluation Datasets as Medical Device Development Tools or MDDT Tools for Testing Cancer Technologies. This is our second topic developed in collaboration with FDA. The goal here is to stimulate participation of small businesses in FDA’s MDDT program to develop the utility of qualified datasets as MDDTs to assess the medical devices subject to regulation by CDRH.

Next topic, please. This is our last topic, the 445, and it’s another reissue from last year. Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-based Therapies. The goal here is to stimulate the development of advanced manufacturing technologies that substantially improve speed and cost of producing autologous cell-based therapies.

Next slide, please. So, the contract topics that were developed in collaboration with FDA’s CDRH that is the contract topic number of 442 and 444. They are a little bit different compared to all our other contract topics. So, we have a specific outreach event targeted towards these contract topics on August 24th. And if you are interested in applying for either of these two topics, please do not miss this outreach event. We will have program directors from NCI SBIR, experts from FDA as well as contracting experts from NCI's Office of Acquisitions. They will be there to answer your questions about these two topics. Apart from that, there are other webinars that are happening that are related to contracts. So, I have put them, put the links here. And that is all I have. Stephanie, I will stop here.

Stephanie Fertig: Great. Thank you. Next, we have Todd.

National Institute on Aging (NIA)

Todd Haim: Hello, all. Thank you very much for attending. Next slide. So, we are going to present three topics from the National Institute on Aging. For all topics, of course, we accept Phase I proposals through the contract solicitation. For the first topic, Topic 004, we also accept Fast-Tracks and Direct-to-Phase II. For Topic 005, it is just Phase I proposals that we accept. And for Topic 006, it is Phase I and Fast-Tracks. In all cases we list the Phase II budgets and milestones for informational and strategic planning purposes.

Next slide. So, the first topic is focused on Improving CNS Gene Delivery Systems for Alzheimer's Disease and Alzheimer's Disease-related Dementia Therapy Development. Recognizing that many of the Alzheimer's disease targets, especially many of the novel targets, are in fact undruggable or very hard to penetrate. Also, recognizing the potential promise of gene therapy, but also the challenge for gene therapy, in terms of drug delivery, brain penetration, immunogenicity, cell targeting. So, we really wanted to put these two things together and have a contract topic that encourages innovators to use the technologies to improve gene delivery systems in ways that overcome current challenges and really open up the amount of targets that we can try to address for Alzheimer's disease.

Many of you may know, that Alzheimer's disease is one where we really have trouble having, you know, great clinical data and coming up with new and effective therapeutics. There was one recently approved by the FDA. But we definitely need more to add to the toolbox. And, you know, gene therapy may be a part of that. So, in Phase I, we ask for, you know, in vivo testing. So, animal studies and we list some of the primary requirements there.

Next slide. So, the second topic, and I will say the next two topics are really focused on mechanistic-based studies. The first one, this one is Geroscience-based Chronic Wound Treatment Product Development. Understanding the need and the prevalence of chronic wounds in the aging population and thus the need for wound-healing therapies that actually incorporate everything we now know about aging biology. So, actually taking those aging biological pathways and processes and using them to really optimize wound-healing therapies for the aging population. And that's what we're looking for in this topic.

As I said, this is for Phase Is. In the Phase I, we ask for prototype development testing. You know, just initial, kind of, listing of a regulatory strategy. We don't expect any, you know, human studies or anything like that in the Phase I. And even in the Phase II, focus on, you know, moving towards human studies. But not clinical studies, just yet. Again, the Phase II is not available at this time. Just for informational purposes.

Next slide. So, the final topic that we are going to present is The Development of Mechanism-based Adult Stem Cell Treatments to Combat Aging Pathologies. So, recognizing some of the recent and exciting data that has come out, in terms of blood and specifically blood stem cells that can be used, you know, as a potential treatment modality to combat aging pathologies. But a lot more research and work is needed. And for the development of these therapies, it is going to be critical that they are developed in that mechanism-based way where they actually take advantage of it and harness aging biology to result in the regeneration and rejuvenation of aging tissues. So, in the Phase I, we

ask for physiological, molecular, and cell characterization of that mechanism of action for the therapeutic that is being developed.

For the Preclinical studies contribute to conducting, you know, to ultimately later on conducting the clinical trial. And the development of methods and standards for the product. And the Phase II deliverables are listed there, as well. I think that's the last slide. I believe. Right? So, myself, the contractor officer, Karen Mahon, and three of our program officers will be here joining the Q&A.

Stephanie Fertig: Great. Thank you so much, Todd. Now we are going to hear from Natalia.

National Institute on Allergy and Infectious Diseases (NIAID)

Natalia Kruchinin: Okay. Hello everyone. Thank you so much for joining the webinar. My name is Natalia Kruchinin. I am a small business program coordinator for the National Institute on Allergy and Infectious Diseases. And next slide. Okay. Thank you. NIAID, the second largest Institute within NIH with SBIR STTR budget for the fiscal year 2021 of $181 million. Most of this money goes to support SBIR STTR grants, SBIR contracts, and cooperative agreements. We published, this year, for fiscal year 2022, we published 12 topics. Usually, we actually have more topics. But you can imagine, with COVID, we supported a huge amount of obligations with grants. We have 12 topics again for fiscal year '22.

Next slide, please. Please, a review of the summary of HHS components anticipated number of awards for NIAID is page 59. We anticipate, for these twelve topics, between 19 and 41 awards. And for these awards, the anticipated scientific and technical merit review in approximately March 2022. Anticipated award date, August 2022. Please, review the summary table, page second and third, to confirm if Fast-Track or Direct-to-Phase II proposals will be acceptable for each topic. And I just put example, our topics on page 103-118, you can look for budget information. And below is an example again. Keep in mind, for each topics, numbers can be different. Like, this example, Fast-Track proposals will be accepted. Direct-to-Phase II will not be accepted. Number of anticipated awards and budget. Again, as I said, for each topic, information can be different. Please read carefully.

Next slide, please. From our extramural divisions, Division of AIDS, Division of Allergy, Immunology, and Transplantation, and the Division of Microbiology and Infectious Diseases, Most of the budget of these divisions goes to support to SBIR contracts and SBIR grants and cooperative agreements.

Division of AIDS, the mission of this division is to help ensure to end the HIV epidemics by increasing basic knowledge of their pathogenesis and transmission of HIV virus. The Division of AIDS published three topics for 2022. Topic 101, Novel Platforms for Delivery and/or Expression of HIV Env. Immunogens for HIV Vaccines. Topic 102, Genetically Engineered Mice for Pre-clinical Evaluation of HIV Vaccine Candidates. Topic 103, Development of Diagnostics to Differentiate HIV Infection from Vaccine Induced Seropositivity.

Next slide, please. The Division of Allergy, Immunology and Transplantation published four topics. The mission of this division is to understand the immune system, how it functions in maintaining health and its role in numerous diseases. Topic 104, Adjuvant Discovery for Vaccines and for

Autoimmune and Allergic Diseases. Topic 105, Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases. Topic 106, Production of Adjuvants Mimics. Topic 107, Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models.

The Division of Microbiology and Infectious Diseases, this is the largest extramural division within NIAID. They have more than 300 targets. The mission of this division is to support research to better understand, treat, and ultimately prevent infectious diseases. Except, HIV. They published; this division published three topics. Topic 108, Development of Rapid Point-of-Care Diagnostics for Treponema Pallidum, Topic 109, Development of Monoclonal Antibody-mediated Interventions to Combat Malaria, and Topic 110, Point-of-Care Diagnostics for Antimicrobial Resistant Enteric Bacterial and Parasitic Pathogens.

Next slide, please. We have two topics from the Office of Data Science and Emerging Technologies. This is something new. This office, mission of the office is to coordinate the NIAID data science portfolio science portfolio and leads the planning and execution of trans-NIAID data science research program. Topic 111, Data Science Tools for Infectious and Immune-mediated Disease Research. Topic 112, Digital Tools Against Misinformation about Infectious Disease Treatments and Vaccines.

Next slide, please. Please, keep in mind, because of government acquisition regulations, all questions regarding a NIAID topic included in this solicitation needs to go in writing. Contact the NIAID contracting officer Charles Jackson. I put on the slide his phone number, his email address. Again, all questions, even if only just to me or my team, we will point you to Charles Jackson. Next slide, please. If you would like to learn more about the SBIR NIAID program, I put my email address. Please feel to visit our website, and there's a link to the NIAID small business program team. Thank you so much.

Stephanie Fertig: Thank you. And now we are going to move on to the CDC. Everyone you have heard from previously is part of NIH. Now I would like to let Sean take over for CDC and talk a little bit about their topics.

Centers for Disease Control and Prevention (CDC)

Sean David Griffiths: Thank you, Stephanie. Thank you everyone. Thank you for everybody that has presented so far. Thank you everyone for joining the webinar this afternoon. And it may be morning for those on the West Coast. I am going to talk a little bit about CDC, about our CDC program. And about our topics for this RFP 2022-1. As Stephanie has shared and many others have already talked about, please read the contract solicitation thoroughly. There will be future amendments. Please read those amendments, as well. And they will be question and answers, and potentially, changes to the solicitations. So, please read those. And as Stephanie had mentioned, there will be a receipt date that is October 28th of 2021. That's at 5:00 p.m. eastern time. Please apply early. Want to underscore, please apply early.

If you have any questions about today's webinar, particularly during the question and answer period, or prior to the receipt date, as Natalia just mentioned, we have a director of our Office of Acquisition Services, Deputy Director Julio Lopez, who is on the line, as well as Dale DeFilipps. Please contact our

Office of Financial Resources, Office of Acquisition Services, (OFR/OAS). And in the solicitation you'll have a list of particular contracting officers, or specialists, and please contact them specifically. Reference the responsible contracting officer or specialist, the solicitation, which is PHS 2022-1. The contracting topic number and your specific questions related to the solicitation.

Next slide, please. I'm going to talk about CDC's mission. CDC's mission is working 24/7 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 disease and supports communities and citizens who 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 dangerous threats and responds when these arise.

Next slide, please. I'm going to take a second to talk about the strategic framework that CDC has. I have a few notes here. Our strategic framework consists of five core capabilities that enable our agency' three strategic priorities, all united behind one mission, to protect America's safety, health, and security.

Our work is underscored by the agency's pledge to the American people. Our five core capabilities is world-class data and analytics, state-of-the-art laboratory capacity, an elite public health expertise, responding to outbreaks at their source, global capacity and domestic preparedness, and then, our three strategic priorities: securing global health and America's preparedness, eliminating disease, and ending epidemics.

Next slide, please. The CDC's SBIR program is one in which we have a smaller program than the NIH program. Yet, we have a complicated and diverse program, in the sense that it expands all of our CDC, the majority of our CDC centers, and our one Institute, NIOSH, the National Institute for Occupational Safety and Health. We fund between 15 to 20 or more Phase Is in our contracting program, $243,500, and up to two to six Phase IIs per year up to $1 million each.

We do participate in the HHS omnibus grant solicitations which were just published. P.A.-21-259 and 260. And obviously, we participate in the contract solicitation. CDC also participates in the I-Corps™ at NIH program. And in the solicitation, the National Center for Emerging Zoonotic and Infectious Diseases is one of the Centers in the I-Corps™ at NIH program.

CDC does not participate in STTR, partly because the set-aside formulary is so small, it wouldn't be beneficial for CDC to be able to do that. So, we opted out of that program. We don't participate in Fast-Track, Direct-to-Phase II, Phase II B, or CRP at this time.

Next slide. Now, I'm going to run through our particular topics that are in this solicitation. So, from our National Center on Birth Defects and Developmental Disabilities, the NCBDDD, topic number 020, which would refer when you ask the particular questions to our contracting team, Open-Source and User-Friendly Record Linkage/De-Duplication Tool. From our National Center for Chronic Disease Prevention and Health Promotion, NCCDPHP, topic number 044, Algorithmic Database Food Product

Tool to Align Food Service with Guidelines. From our National Center for Emerging Zoonotic and Infectious Diseases, NCEZID, which is participating in I-Corps™, topic number 028, Develop Rapid, Portable, Point-of-Care C. auris Diagnostic, and topic 029, Product to Inactivate and Stabilize Wastewater Samples for Shipping and Transport.

Next slide, please. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, NCHHSTP, topic number 052, Electronic Health Record to Identify Persons with HIV Not in Care and topic 053, Simultaneous Detection of Molecular and Serological Markers Via Next-Generation Sequencing. And from our National Center for Immunization and Respiratory Disease (NCIRD), topic number 035, Nanoparticle-based Multi-Antigen Influenza Vaccine that Induces both Antibody and Cell-Mediated Immune Responses.

As Stephanie had mentioned earlier, this is a contract solicitation. CDC does also participate in the grant omnibus solicitation. In that grant omnibus solicitation, we also have what we have determine, or call, topics. But we also accept investigator-initiated proposals. So, if you determine that the topics here do not fit your research, please call the IC leads or call the SBIR program team. And we can talk to you. If you're leaning toward a cooperative agreement, or leaning toward a grant, we can then, you know, point you in the direction that might align you with the best mechanism for an SBIR at CDC. Next slide, please. And this is our contact information. CDC works 24/7, protecting America's safety, health, and security. Thank you very much.

Q&A

Stephanie Fertig: Thank you, Sean. Thank you to all of our speakers today. Again, I want to do an extra reminder about the specific timing, with regards to the deadline. It's very important that you make sure to complete your proposal in advance of that deadline and submit it. There is no paper submissions. You have to do that electronic submission. And it is really important for you to submit early. So, we can't emphasize that enough. That is the most heartbreaking calls that we get. It's so important to do that.

With that, I think we have plenty of time now for questions. And I know we have a number of questions that have popped up in our Q&A box. So, please, if you do have those questions, please put them in the Q&A. With that, I am going to turn it over to Valerie, who is going to be helping us with our Q&A today.

Valerie Virta: Thanks very much, Stephanie. Thanks to all of our speakers for sharing information about the topics. As well as making sure that we have plenty of time for the questions and answers. So, with that, I will attempt to go chronologically, but also try to group questions together if they are related.

Stephanie Fertig: Well, Valerie, we do have those contracting officers on, today.

Valerie Virta: Yes.

Stephanie Fertig: They can answer some of those questions.

Valerie Virta: Yes. I'm sorry. Thank you very much for reminding me. I had planned to include our contracting, contract staff. We have several people from the CDC, today. And so those include Amy Bowers from NCCDPHP, Julio Lopez from OFR, Barbara Stewart from NCHHSTP, Christine Morrison from the same division, and Michelle Mathieson from NCCDPHP. Like I said, there are several staff from CDC who are able to answer questions. From the NIH there is also Charles Jackson from NIAID as well as George Kennedy from NIAID, and Tiffany Chadwick from NCI, as well as Tina Urv from NCATS. Yes. I will go ahead and answer the question, and then I may pass it off, or someone can jump in and say I am ready to answer that question.

Question: One question that we have is whether, how similar applications can be if people decide to apply for the omnibus grant application and the contracts applications. So, somebody wants to know, do they need to pick one to apply to or can they try applying to both and pick if they get the award?

Tiffany Chadwick: Hi, this is Tiffany Chadwick from NCI. I guess I can start on that. If anybody else wants to pick up and address anything I leave out, that would be fine too. So, I would say, the most important thing to note is that you cannot submit them both and figure it out later. There is a law that says, you can only submit, you cannot submit, essentially, equivalent projects at the same time within one agency. So, within any HHS SBIR opportunity—grant contract—you should pick where you think you're going to have the best chance and only submit it once. You cannot do it again until you get back a decision. A final decision on whether or not we are going to fund that.

So, essentially, the equivalent is defined in the contract solicitation. If you want to go look at that, if you have anything that is sort of similar, you should address whether or not it is essentially equivalent. If it is even close, you should address it in your business proposal that you do submit for an SBIR contract, so that we can assess whether we agree with you that it does or does not fall within the definition of, essentially, equivalent. Beyond that, my advice would be, that generally, success rates tend to be higher under the contract opportunities because we are focusing on specific topics with objectives and deliverables that we would like to see. So, because of that, generally, there are fewer proposals submitted.

And the competition is a little bit less in the contracts arena than in the grants. However, we do only offer the contracts once a year. And because the topics are very well defined, if you have a great idea, but it doesn't hit the required deliverables, it is not going to be likely to be successful. So that would be an instance where it would probably be more advantageous to go the grants route. I will stop there and see if anyone else says anything to add.

Valerie: Would anyone else --

Natalia Kruchinin: This is Natalia. I just want to add, again, as already was discussed, you can submit a grant and contract on the same topic. It is not allowed. I want to mention about, for example, if somebody want to go from grant, from contract to grant, if for example, this is allowed. I can give you example. Phase II contract for example. You want to apply to Phase II B grant, it is allowed. Keep in mind, Phase II contracts don't need to be completed prior to application, but it must be completed prior award.

Valerie Virta: Okay. Anyone else want to add anything else to that?

Julio Lopez: Yeah. Good afternoon, this is Julio Lopez. I wanted to add, if a vendor has expertise in several topics, and they plan to propose in multiple topics to make sure they are not proposing the same staff of both. Because of all the sudden they went both topics, then there would have a problem if somebody is full-time. Proposed full-time on both. So, that is just a caveat I wanted to add. Thanks.

Valerie Virta: Thank you for that. Yeah. Even if it is a larger project, if you can make distinct applications to where you are not sending the same application multiple places. As Julio says, with the same people. Then you are okay. All right. So, let's see. So, there is –

Question: The next question is about the solicitation says that for the most part, scientific reviews will happen in February, March, and April. My question is, will these applications be reviewed along with applications sent in during the grant deadline in January? The timeline seems similar and would affect the type of proposals we would plan to put in for each deadline. What they are asking is, are the contract proposals reviewed alongside with grant proposals?

Deepa Narayanan: This is Deepa. I can take that. Grants applications are usually reviewed at the Center for Scientific Review. Contract proposals are usually reviewed within the Institute or Center. They do go to different review panels. I hope that answers that question.

Valerie Virta: Thank you. And I see -- Oh, sorry. I see that Christine is also typing an answer. Does anyone else want to add what Deepa said?

Stephanie Fertig: I was actually, this is Stephanie Fertig, and I was going to actually ask, since the review of contract proposals is a little bit different, I don't know if anybody wants to talk briefly about some of those differences to provide a little bit of color. I think there were a couple of questions about the review of grants versus contracts.

Valerie Virta: There were, Stephanie. I was going to ask those questions, next. There are definitely some general questions about how contracts are reviewed and what the differences are. Whoever can weigh in on that and explain how things work in their IC or operating division, that would be really helpful.

Deepa Narayanan: I can start again, this is Deepa. So, there are differences in the way the grants and contracts are reviewed. Both are peer-reviewed. That's a similarity. Meaning, we try to get peer reviews and we get peer reviews for both. Some of the differences of the review criteria are slightly different for grants and contracts. The review criteria for grants are a significant innovation approach, investigators, and facilities. The review criteria for contracts are called technical factors. And they are present in the proposal. This includes soundness of technical merit, the potential for technical evaluation. The one important difference is that the potential for commercial application is a factor for Phase I, in contrast, it is not a factor. It is not, at least, a quantitative factor for grants. So those are some of the differences. The entire review criteria is present in the solicitation. So, I

suggest that you take a look at that. Another difference is that the contract, these factors are weighted for contracts. They are not really weighted for grants. That's another difference. When contracts are reviewed, there is also this thing called technical acceptability or unacceptability that is considered for contracts, which means, if a contract is being designated as technically unacceptable after initial review, then that's a contract that we cannot fund. So, there are these kind of nuances between the contracts and grants reviews, I spoke about some and I'm sure I am missing some that someone else can talk about.

Natalia Kruchinin: Deepa, this is Natalia - NIAID. Just small comment to add. Actually, participants can read more about review criteria and percentage of points, location to allocate each of these areas section six, page 32. And one more comment I would like to mention, that basically, every topic in this solicitation will have their own review panel, essentially. Thank you.

Valerie Virta: Thanks Natalia and Deepa. What anyone else like to weigh in? Would anyone from CDC like to weigh in?

Christine Morrison: Yeah. Hi, this is Christine Morrison. I would second everything that Deepa said but we do have two separate review processes. Of course, for our SBIR grants, the reviews are actually done at NIH with NIH sections and section panels. Whereas the contracts are done by technical panels that are conducted at CDC with technical experts at CDC.

Deepa Narayanan: And this is a very important point because these reviews which Natalia mentioned. With one, they are done within the ICs, and two, they are done, you generally have a panel set up for each topic. So, if a topic receives 20 proposals, you have a panel for that. If a topic receives two proposals, there is an entire panel set up for reviewing those two proposals. It might just be that you get a little bit more in-depth review, sometimes with a contract proposal because it depends on the number of proposals that you get.

Question: And one more follow-up question to that. Does the applicant company get a summary statement for their contract proposal in the way that they do for a grant proposal?

Tiffany Chadwick: This is Tiffany. I will jump in on that one. So, I do think this is something that is best addressed with each individual office that you are working with. So, in front of whichever topic you apply for, there is going to be an identifier that says, NIH/and the name of one of our ICs. The same thing with CDC. So, if you want to get the most accurate expectation of what is going to happen, you can reach out to the point of contact for that office, that is set forth in section 10 of the solicitation. I will just go ahead and answer, on behalf of NCI, we generally do have a practice where you don't automatically get to access any summary statement in the system. But we do have a contracting officer who we have decided as, just a matter of course, will go ahead and provide a summary to all the unacceptable proposals back to the companies so they can learn from their comments. So that is something that we do handout without having to have a request. But I would say, you do, you make sure that you reach out to your office because not all offices might offer that, unless you do ask for it.

Natalia Kruchinin: This is Natalia, again. I just want to echo, the best way to reach out, again, to a contractor officer from an awarding company, in case of NIAID, is Charles Jackson. I just want to point that you will have an optional debriefing. If you will note that your proposal is not successful, you can write a request for a debriefing within three calendar days of being notified that your proposal was not selected.

Amy Bowers: This is Amy Bowers with Chronic. And I just wanted to say, our contracting officer is Jerry Outley. If you need any feedback or contact follow-up, you would contact Jerry.

Todd Haim: For NIA – questions should go to contracting officer Karen Mahon. I am putting her information in the chat, as well.

Valerie Virta: Thanks a lot. Does anyone else want to add anything else? Okay. Thank you. Let's see.

Question: So, we have some questions about Phase I and Phase II applications. One asks, would a Phase I and a Phase II be completed under the same contract?

Tiffany Chadwick: This is Tiffany again with the NCI Office of Acquisitions. So, I would say, if you are successful in getting a Fast-Track award, that typically does mean that you would get Phase I and Phase II in one contract if everything goes as planned. We would give you a contract that would have a base requirement for Phase I and then near the end of Phase I, we would make a decision, internally about whether we thought it was progressing as expected. If so, we would exercise a contractual option that would put into effect, sort of, all of the preestablished statement of work tasks and deliverables schedules and payment schedules. All of that is negotiated for both Phase I and Phase II, upfront. We would exercise that option to make the Phase II effective.

Other than that, and most proposals are not Fast-Tracks. In the majority of cases, what is going to happen is you only get a contract for Phase I and it only addresses Phase I. And then once you have completed that contract, your individual contracting office will reach out to you to ask for a proposal that can be considered for moving on to Phase II. And then it would go through this whole process again. You would get in your Phase II proposal by the deadline established. The Phase II proposal would go through the peer review process. We would make the award decision about whether or not to move forward with it. If it was successful, we would issue a new contract that now only has the Phase II information in it. I hope that addresses the question, but if there were other aspects you are unsure about, you can ask that again.

Valerie Virta: Okay. Thank you. And I see that Christine Morrison is also typing an answer there. Our question has disappeared for me. But we did answer it. Unless anyone else wants to add anything, I will move over to the next question.

Question: The next question is, again, about Phase I and Phase II. It said, we submitted a Direct-to-Phase II application, but it was not accepted. They are thinking to submit a Phase I application, instead. They would like to know if this would count as a resubmission.

Valerie Virta: Does anyone want to take that one? I know it's a little bit tricky. It actually is asking about several different topics.

Tiffany Chadwick: Right. I will just weigh in quickly again, Tiffany with the NCI. I am in the Office of Acquisitions. Resubmission is a grants term. I'm going to, first of all, reiterate that this webinar, we are talking about a contract opportunity. Grants and contracts processes are very different and separate at the NIH. If this is an NIH question, I would say, resubmission, however that works in the grants world, is not going to be applicable to the contract solicitation. With that, you know, I can't really comment on what normally it is. What we have talked about, before, essentially, equivalent proposals can't be submitted at the same time until you have gotten a final decision. So, in this scenario, it does say that application failed. So, you got a final decision. At least, at that point, you could look at resubmitting in some fashion. I'm not sure about whether moving from Phase II to Phase I would make a lot of sense. In the contract world, if you submit under this proposal, you have to look at what those Phase I technical objectives, milestones, and expected deliverables are, and see if that is something you haven't done already. We are not going to be looking at paperwork that has already been done. So, if that is something that you still need to do for your project, if it is within the scope of a topic, and that's work that hasn't already been done, then you can submit that proposal. Maybe with that, I will see if anybody has any thoughts.

Natalia Kruchinin: This is Natalia, NIAID. I completely agree. Again, resubmission is not determined for contracts plus every year the contract topics can be different for each awarding company. You know, you need to keep this in mind. I think, for somebody who, if somebody's contract is not successful, maybe you can consider applying for grants. In this case, feel free to reach a program coordinator for Institutes and discuss and talk about your project and your specific aims.

Charles Jackson: Yes. This is Charles Jackson. From what I am hearing, it sounds like they should request feedback in a debriefing for their Phase II. If that same topic comes back as a Direct-to-Phase II next year they should have comments -- So, I don't understand why would they go back to a Phase I. I don't even know if it was a Phase I award, initially. And then they went to a Phase II. Or if it was Direct-to-Phase II. If it is a Direct-to-Phase II, I don't see a need to go back to Phase I.

Stephanie Fertig: This is Stephanie. I think I want to weigh in here. This sounds like somebody that might be looking at the contract mechanism for the first time and may be more familiar with the grant process. So, you know, in the grant, again, for the contract solicitation, the question of resubmission is not really on the table. As a program officer, this is more of a general kind of comment, there have been times where people have gotten feedback from either their grant, or having gotten feedback about their contract proposal, and realized that, actually, a Phase I makes more sense. This does occasionally happen. Again, as we noted, for a contract solicitation, which is what we are talking about today, you don't have a resubmission. You will take a look at the contract topics and make a determination as to whether or not you fit into those. Depending on whether those topics allow Direct-to-Phase II, Phase Is or Fast-Tracks, and determine what makes the most sense for you. Hopefully, that helped answer your question.

George Kennedy: Stephanie, this is George Kennedy. I would also like to add, this is a good example of when there is a question that a potential offeror has that is specific to a topic. We have said it a

few times, but this is a good example of the best source of information will be that contracting officer identified in section 10 of the solicitation for that topic.

Valerie Virta: Okay. Thanks very much. The next question has been touched on a little bit, but I want to go ahead and give everyone a chance to address it.

Question: The question is, what's the success rate comparison between grants and contracts under SBIR?

Natalia Kruchinin: I can start. Natalia, NIAID. And then I hope Charles Jackson, our contracting officer will add. For grants in case of NIAID: Phase I between 17 and 20%. Phase II around 40% for grants again. For Direct-to-Phase II approximately, maybe, the level of Phase I; 17%. Just keep in mind, there can be variation from year-to-year. What is contracts? I just recently, actually, looked at the numbers. They look at numbers total amounts the amount submitted and total awarded. Total maybe percentage around 40%. Maybe Charles can add if you have additional information. We are talking about NIAID.

Charles Jackson: Natalia, I don't have that at my fingertips, right at the moment.

Natalia Kruchinin: It's okay. Approximately, again, somebody mentioned keep in mind, with contract, success rate is higher. It is understandable. We are getting less proposals because, again, what is the biggest difference between grants and contracts? Keep in mind, for grants, basically, it is very simple. Grants have no deliverables. Yes? Basically, with contracts, IC will tell you what needs to be done. It is very specific. It is very targeted. With grants, you will write your specific aims. It is your idea and therefore again, less applicants toward contracts so success rate is higher. Again, year-to-year, like for NIAID, this year because of COVID, it is crazier. But again, year-to-year it can be different.

Valeri Virta: Okay. Thank you. Does anyone else want to add to that?

Stephanie Fertig: I'm going to add something, briefly. It's just to emphasize, I think it’s difficult to talk about success rates because grants and contracts are so different, as was indicated. The contract is very limited in the number of topic areas. And even the number of Institutes and Centers that participate. I want to emphasize, we make a lot fewer contracts throughout the year. And we get a lot fewer proposals to the contract mechanisms. In general, the number of contracts, the percentage of contracts across the total funds that are provided to the SBIR and STTR programs, you look across everything, contracts makes up about 8% of the different, you know, the funding that we give to different recipients. So, it's important to note that contracts are a small portion of what we do. They are an important portion of what we do, but it is often difficult to compare contracts specifically with grants because of their targeted focus. And so, I would say, if you fall under one of the contracts areas, if what you are doing falls under one of those targeted topics, I would encourage you to apply for contracts. We’re going out with those contracts and saying, look, this is what we need. Hopefully, that will help with, you know, help answer that, as well.

Todd Haim: Yeah. And to add to that, completely agree. To add what Stephanie said, you know, many years experience guiding companies on applications. You know, I will say, it wouldn't make sense to, you know, fit a square peg into a round hole. So, to Stephanie's point, if what you are doing really fits what a contract topic is asking for, and there is that set aside, then yes, the contract proposal is probably your best bet. But if your technology and what you are trying to do really is not a real match to the contract topic, then trying to, you know, jerry rig it and make it to address the contract topic I have found often does not work. And you would have been better off considering, you know, a grant through the omnibus as an example. So, just consider that.

Charles Jackson: This is Charles Jackson. I went back to some of my data. Some historical facts on the success rate going back to 2016. These are all Phase I's. 39% there. 2017 was 35%. 2018 was 46%. So, it varies. That's all I have at this time, though.

Christine Morrison: Hi, this is Chris Morrison at CDC. I think the other factor is, we can't predict how many people are going to apply to a particular topic. So, if there is a topic that is particularly popular, the success rate, you know, the denominators are much bigger than the success rate for any individual, it would be less. You know, it has been said before, if you have something that is a perfect fit for a contract topic, you know, you have a very good chance of being able to compete successfully for that.

Valerie Virta: Thank you. Okay. The next question is towards Sean at CDC. And they wanted to ask, let's see --
Question: They are asking about I.T. contracting opportunities at CDC.

Sean Griffiths: This is Sean. What I would encourage folks to do who have a small business interest at CDC is to email our office at SBIR@cdc.gov and we can refer them to the appropriate office at CDC if it is not related, specifically, to this particular contracting mechanism.

Valerie Virta: Okay. Thank you for that.

Question: Our next question is about NCI topic 440. And they wanted to know, what preventative nutrition potentially fit under this topic? So, Reema, what are your thoughts?

Reema Railkar: I think I will defer this question to Deepa, if Deepa is around.

Deepa Narayanan: I did take a look at that question. Right now, it is a little difficult for me to answer that question. I would recommend sending an email to ncisbir@nih.gov to ask the question with exactly what you propose. And somebody will get back to you with a response.

Valerie Virta: Okay. Thank you. Thank you.

Question: And the next question is on topic 442 for NCI. And they want to know about the choices of cancer biomarkers that they would use. Specifically, is the goal or end-product a device for quantitative measuring of cancer biomarkers?

Deepa Narayanan: Yes. The goal of this topic is a device for a biomarker measurement. But what I would like to add, this is a little bit of a complicated topic. And so is the other FDA topic that we have -- both for the development of medical device and develop mental tools. We do have another webinar that is scheduled but I think the link is already in the chat. If not, we will put it there. So, we will have representatives from the FDA attend those webinars and provide additional information about what MDDT Tools-- do and so on. I would encourage anybody who would like to apply to any of those topics to attend that webinar because I understand it's a little bit of a complex situation because we have contracts on the other hand, and you are working with the FDA to do -- To go through their MDDT and take qualification plans. So, I know there are a few additional questions on that topic. So, I answered both of those, I think.

Valerie Virta: Okay. Thank you. Skipping around just a little bit.

Question: We have one about the NIAID topics. For topic 112, can you speak to what kinds of HSR would qualify for a clinical trial? For instance, would memory for or endorsement of misinformation be considered a qualifying outcome?

Natalia Kruchinin: This is Natalia - NIAID. I just want to mention, regarding -- I saw this question. My advice would be to Charles Jackson. He can actually have a discussion with program officer who wrote this topic. Or maybe this question could be submitted -- The answer to this question could be later posted in the amendment to the solicitation. I don't know, Charles, what you think?

Charles Jackson: No, I agree with you, to tell you. Submit that question and we will look into it. And the person that wrote the question should look at what we have identified in the description and goals and everything. And any information to help them guide them through this process. But, yeah, submit the question and I will get it to the person that actually wrote the topic and get more clarity.

Valerie Virta: Okay. Thank you. Thank you for that. I am not clear if this is a different asking of the question that we already asked CDC, so I'm going to ask it again, just to be on the safe side.

Question: It says, in my understanding, CDC is not participating in small business technology. Our company has a new software development we are working on and it is mostly I.T. related. We are a AAA I.T. firm. Is this related to today's discussion?

Sean Griffiths: This is Sean again. It could be based on the sentence whether or not CDC is participating in STTR. But I'm not quite sure. I can make a blanket statement that CDC doesn't participate in the program because we have 10 ICs with approximately four SBIR $12 million program based on our research. Four or 5% would leave us with not enough resources across our centers or institutes to put together enough resources to fund programs we don't participate. What we would ask, is for the attendee to submit that question in an email format to SBIR@cdc.gov. Also, if it is appropriate, we would send it to our of our contracting staff to answer. We will decide what is most appropriate. Thank you.

Valerie Virta: Thank you. Let's see. Sorry, I'm having a little bit of trouble with the little box here. Excuse me. I think one of the questions just disappeared. Pardon me.

Charles Jackson: I apologize. That was Charles Jackson. I was looking at that question, and

Question: they were trying to, they said that they were unable to get a Phase II. It was a fast track. And they didn't qualify for the Phase II under a grant. And they wanted to see if they can come to a contract for the Phase II.

Charles Jackson: It works in reverse it okay? If you provided something under a contract. If it fits under one of our topics, we would be able to look at it. If we said that we have a Direct to phase II, we can address that. If we don't have that, you can't submit a Phase II to us for that. Sorry about the question disappearing.

Valerie Virta: oh no it's okay it's okay i understand. Thank you. Okay so uh i do see that tiffany is typing an answer but it also seems like a question that other people could answer as well so i'll go ahead and throw it out there.

Question: The question is, please explain more about the funding differences between grants and contracts. My understanding is, grants also require some reimbursement forms on a monthly or quarterly basis and so how is that different from what happens with contracts?

Tiffany Chadwick: So, I will go ahead and start since i was typing. Tiffany with the NIC Office of Acquisitions so I think what's just important to note is that in the world of federal contracting, which is different than grants, the baseline that we start with is that you will provide the service and then we, will pay you. However, we know that you know generally doing an entire Phase I project waiting until you've completed it and then asking to be paid is really a hardship on a lot of small businesses. So, what we've done is come up with a payment schedule that gives you some interim steps that you can complete and then request a partial payment in accordance with the schedule. And really I think one of the fundamental differences is that for most of the NIH SBIR contracts (and maybe CDC can chime in if they're different) we issue them on a fixed price basis so it's not really done on a reimbursement basis after we issue the award. And this was kind of strategic because there are a lot of regulations involved with federal contracting and as soon as you say that something is going to be a cost reimbursement basis you're expected to comply with a lot of accounting regulations and oversight on your end and also actually on ours for us to be able to issue you that payment. We have to do a lot more with reviewing each individual invoice than we're able to do in a fixed price so sort of cutting through the bureaucracy and the administrative burden we're doing a lot of fixed price, and we're coming up with payment schedules where we can give you out bits of that once you've submitted some interim deliverables. So, I think that's really what I would have to say and I don't know if anybody else wants to answer…

Speaker: I would have either Julio Lopez or Dale Phillips the contracting officers answer that to be sure that I'm not misspeaking, but we do make fixed price awards. In other words when I approve a funding memo it's for the full amount that was requested so how that gets distributed after I've approved it. Again, I would defer to our contracting officers at CDC.

Stephanie Fertig: I would also encourage the contracting officers to talk a little bit about how long it takes for those invoices to be paid and that whole process, because that's another question I see George typing an answer to you. But I think that might be a good one to answer live as well. So maybe George wants to answer

George Kennedy: Yeah let me unmute here. after I… Depend on the response because there are a few questions that I think are related to that um and what my response that i just sent to the Q&A list is indicating is that it's reinforcing the point that Tiffany was just making. Your contracting officer point of contact is going to be the most direct source of information either for questions related to existing SBIR awards that you may have, or for topic specific questions that you have here. But in contracts the delivery and payment schedules are going to be negotiated on a case-by-case basis. So, the terms the schedule in one award may not be identical to the schedule in another award. But generally speaking, the way that the awards are structured is that there's a payment schedule associated with a number of deliverables. The frequency of those deliverables, which often take the form of progress reports, is going to be part of the negotiation for an award. And in the fixed price environment the payment is made when the identified deliverable, for example, a progress a monthly progress report, is reviewed and accepted by the government. An important point is that, that I would like to make, is that invoicing does take place electronically at NIH invoicing instructions will be included in all awards that are made in terms of submission submission to the office of financial management and the payment terms are included in in the awards themselves. I don't know if someone from CDC would like to add anything regarding invoice submission procedures

Sean Griffiths: This is Sean. My contracting leads had to move to another call, so if um, we need to we can accept the question and they can respond, but they're not here at the moment.

Tiffany Chadwick: Okay, I might just jump into to add to what George said to just say you know it's not instantaneous. You don't get to draw down your funds and submit a statement about what you drew down. So, you submit that invoice, and I would say it takes at least 30 days and when everything's working well before that's going to be dispersed. There's a review and approval process. And then, even after we approve it goes from the contracting office back to our financial management office and then they schedule a disbursement -- so it's not too fast, unfortunately.

Valerie Virta: all right um, uh let's see so um the next question is, um

Question: If our phase one proposal gets rejected, or I suppose this might apply to other phases as well, if our proposal gets rejected is there any mechanism for appeals?

Tiffany Chadwick: And George would you like to take that, or do you want me to?

George Kennedy: I, I, apologize. I was looking at another question, I'm sorry. So, you go for it

Tiffany Chadwick: All right, so with any federal contracting opportunity, there is a protest process that's in place and I think the solicitation um gives you a point of contact. Let me see…well if not you can just reach out to your contracting office point of contact in section 10. They would be the best

person to contact. So, there you would just have to look at the federal acquisition regulations -- you can find out what your rights are. They're about the same as they would be for any federal contracting opportunity. You do have to state the grounds for why you feel like there was something unfair or that wasn't done in accordance with the solicitation. So, if you're trying to do it purely on a technical merit type of grounds, that's not likely to be successful. You know courts have really said that they give it a lot of - they give a lot of discretion to the agencies when deciding how to judge technical merit. But if you think there is really something fundamentally wrong with the way that the process was handled, then I would say to look at your federal acquisition regulations and see what your protest rights are.

Valerie Virta: Thank you, thank you does anyone else want to add anything to that? Um okay uh so I'll shift gears a little bit to another question.

Question: it says I applied to a topic last year under NIAID, that has been…a very similar one has been issued under NCI this year, so even though our application wasn't uh recommended for award last time could we still apply for the topic if we if we feel like we still fit the topic?

Deepa Narayanan: So, I wasn't aware that there was a topic under NIAID, so I need to look at this**.** But I can still answer the question. So, if there was uh…if you received feedback last time and you can improve your proposal based on that feedback and submit again to NCI you are… you're welcome to do so.

Natalia Kruchinin: This is Natalia – NIAID. Just actually a question -- in this station like this do they need to actually mention? Because they cannot talk about their submission, they can just submit a new proposal to NCI.

Deepa Narayanan: Yes

Natalia Kruchinin: yes that's all

Valerie Virta: Yeah so then it seems like it's in line with some of the other questions. That the contracts process is very different from the grants process and the contracts process is really kind of a one shot and then if but if your very specific topic comes up again another year even with a different agency and you've strengthened your application then then why not try.

Deepa Narayanan: Yah but I'm very curious about this particular topic now, so I need to go and do my research

Natalia: Actually, me too - let me know please!

Stephanie Fertig: Well and and just a quick clarification -- it's not each…so we're all part of the same agency, but you could have a topic come up that's a different component of the agency or something that is similar within this agency. but we are all part of the same agency.

Valerie Virta: Yes yes, I apologize, I didn't mean to misspeak, um but uh yeah. They didn't list exactly what the topic was so that that yeah that wasn't clear in the question. Okay so there's uh there's a few questions left…um oh there have been more questions added.

Question: One question is about um the part about achieving deliverables and the sort of fundamental difference between grants and contracts**.** So one person asks, what happens if we don't achieve the deliverables set aside in the contract in a worst case scenario?

Tiffany Chadwick: Uh a fund**..**oh Deepa do you want to answer that's fine.

Deepa Narayanan: I'll start with that

Tiffany Chadwick: okay go ahead

Deepa Narayanan: so um you know we understand it's R&D and things never go according to plan and we sort of realize that. So um uh so uh if..if for example… if there has been work done towards a particular experiment, and the experiment failed but you already spend the money we're not going to ask for your money back because of that. The problem comes when you have to change your aims --- you were supposed to do something else and then you decided that those are not the right aims and you want to do something else --- in such cases if you you have to reach out to uh to the contracts office and the program officer that is managing your particular contract or the contracting officer's representative and um and submit a process for a change of um uh change in the statement of work. So that that goes through a modification process. If…if that's not done, and you decide to do your own experiments because of whatever valid reasons but it's not being …but it's not received prior permission from uh the institute then you might be asked to provide some of the funds back because it was not under with permission. If you again choose to deviate and go off topic, I mean if the proposal is, for example, if the proposal is for a particular indication -- for example say liver cancer, and you decide and now it doesn't make sense to do liver cancer we are going to go and do um you know brain cancer… then in such cases again you know that's where we may have to uh discuss and maybe terminate the contract. But, but if experiments go wrong we totally understand those things happen

Tiffany Chadwick: Right I would just chime in and say you know even in the federal acquisition regulation, there is a mention for R&D contracts that you're expected to provide your best efforts. So we certainly don't have the expectation that every single task will be successful but we do have an expectation that you will have best efforts in following through with what the agreed to plan was and working with your project officer to adjust your plan as a moves forward.

George Kennedy: and actually I'll dd something to reiterate what tiffany was explaining earlier from a procedural standpoint because I see that there was one or two follow-up questions regarding the process of payment and it is a an
important distinction between grant awards and contract awards. There isn't an account where the funds are provided to an awardee in advance that are then drawn against the process for being paid for the work that you're performing under a contract is done through the submission of an invoice.

And that invoice is what is submitted using the instructions that that will be in in a contract award submitted to the office of financial management. That invoice is then reviewed to ensure that that the deliverable it's associated with has been accepted by the government and then payment is released through electronic funds transfer in response to the submission of that invoice. And that process of submission through review and then payment being released typically happens in about a 30-day period that's all.

Valerie Virta: thank you George um so I see somebody commented uh about the the topic that had been under NIAID last year but is under NCI this year and um it's the HCV uh point of contact molecular test. I just wanted to let you guys know um okay

Question: There's a question for um the uh NIA Topic 6 and they want they're asking would treating knee osteoarthritis fit into that topic as repairing tissue?

Todd Haim: Candace are you available to get that question

Valerie Virta: I'm sorry can you repeat that?

Todd Haim: I was asking Candace if she's available to unmute and take the question.

Candace Kerr: hi Todd, I'm here yes um. Yes, so um that is one of the areas that we're looking into as long as the focus is on a Stem cell-based therapy; whether it's the use of stem cells or biologics that help endogenous NEB cells would be the focus. The importance of our initiative is that the focus is on either aging stem cells or aging models to test out the mechanism.

Valeri Virta: okay thanks very much in which case it sounds like there's another question that might be helpful to ask now um which is…

Question: Do we have less chance of succeeding if it is not this listing topic or not adult stem cells?

Todd Haim: yeah so I mean this you know this kind of goes to what I said before about you know fitting a square peg into a round hole. I mean you know I would look at the topic in detail and if if it's not what we ask for in the topic, then yes you may, you know, that would reduce your chance of being successful um because the reviewers really do read the topic and review based on what the topic asks for. Um if there's questions of you know if what you're doing would fit the topic then that's a perfect question to send to Karen Mahon at the email I provided um uh but yeah that's the general answer to the question.

Valerie Virta: okay thank you yeah and that does seem helpful in terms of um because there's kind of a specific part but there was also the more general part how closely do we need to hue to the topics. And it seems like especially for contracts it's important to ask yourself how well you fit the topic because if you fit well you have a good chance if you don't…you have less of a chance. Okay well uh let's see um, uh there there was another question uh, that was asked a while ago about…

Question: the anticipated number of awards, and uh if they refer to both Phase I and Phase II awards combined or for each category?

Valerie Virta: So uh Deepa had indicated that she'd like to answer the question but it seems like one that other people could weigh in on as well

Deepa Narayanan: So the anticipated number of awards is for um is typically for Phase I because most uh most contract opportunities are for Phase I. But in some cases if there is a Direct to Phase II or a Fast Track it does include that in the typical number of awards. But um the Phase II is generally by invitation and that is not included in in this particular number of awards uh mentioned

Uh I also wanted to say that this is a guesstimate. For most cases it doesn't mean that we have to award that many. If we get great proposals we may even exceed the number of expected awards so, it's just a guesstimate on our part.

Natalia Kruchinin: this is Natalia – NIAID. I completely agree with Deepa. First of all this solicitation is for SBIR contract Phase I, and if Phase I uh proposal will be awarded then uh I believe award component will send invitation to apply to Phase II with instruction how to submit proposal.

Sean Griffiths: and this is Sean from CDC and I'll just reiterate what Natalia and others have just said that we also um it's for Phase I and that we may fund more depending upon resources and availability and I'll leave it at that thank you.

Valerie Virta: Yes thank you so much for your answers um and um**…**oh well another question um uh under the wire here uh and and I see that tiffany is answering it…

Question: Do we talk to the contract officer for an invite to do a fast track?

Tiffany Chadwick: Yes so I was just typing in there to say you you do not need an invite to do the fast track. It's any topic that says fast track allowed. So if you go to the section one introduction there's a nice table in any of those topics that say under the column fast track aloud that say yes, you can submit your fast track. And to do that you're going to go -- in and there's detailed instructions about this in the solicitation so try to follow those -- because you should be submitting one entire submission in eCPS for your Phase I and then an entire separate submission in eCPS for your Phase II.

Valerie Virta: okay thanks very much for that and with that we have answered all of the questions. So I want to thank all of y'all for attending today and for those of for those of you who served as panelists and to help answer questions ; we really appreciate uh your help and thank you very much! And with that I think we can call it day…

[End thank you remarks – close]