# HHS SBIR Contracts Solicitation (PHS-2024-1) – September 2023

**Stephanie Fertig:** Hello, everyone. My name is Stephanie Fertig, and I am the Director of the NIH Small Business Program. I want to welcome you, again, to our HHS SBIR Contract RFP Informational webinar. There's a few housekeeping issues before we get started. The slides, recording and transcript will be made available on our website, seed.nih.gov, in approximately a week. Links and information will be made available in the chat, but if you'd like to ask questions, we really encourage you to utilize the Zoom Q and A feature. There will be time for questions at the end, so please do ask your questions in that Zoom Q and A feature. You'll see that at the bottom of the Zoom window. Now, I have the pleasure of introducing Adam Sorkin. Adam is the Small Business Policy Manager within the Small Business Education and Entrepreneurial Development, or SEED, office here at NIH. Adam Sorkin has over a decade of experience championing small business research and development. He previously supported the Small Business Programs as well as technology transfer activities at the National Institute of Allergy and Infectious Diseases. Prior to joining NIH, Adam led R&D, strategy and fundraising efforts of start-ups developing novel regenerative medicine and anti-infective applications. So, Adam, please take it away.

**Adam Sorkin:** Great. Thanks so much, Stephanie, for that fantastic introduction, and I am very excited to discuss our RFP with you today. As a reminder, we are going to go through a large amount of information very quickly, so I do encourage you to visit our website at seed.nih.gov, which has a wealth of information and resources as well as links to our recent webinars. And we'll post this webinar when it becomes available in a week or so. So, the HHS mission is to enhance the health and well-being of all Americans, and our Small Business Programs supported this mission by helping get great innovations into the hands of the patients, clinicians, caregivers, and researchers who need them.

There are four components of HHS within SBIR program, but today, we are going to focus on the National Institutes of Health, NIH, and the Centers for Disease Control and Prevention, CDC, as the two participants in this solicitation. And speaking specifically to NIH, the NIH mission can

be summarized as turning discoveries into health. Our Small Business Program, in particular, helps NIH accelerate discoveries from bench to bedside. And we do this through Congressionally mandated programs, known collectively as America's Seed Fund, which include the Small Business Innovation Research Program, or SBIR program, and the Small Business Technology Transfer Program, or STTR. HHS has supported ... supports roughly $1.3 billion in small business R&D funding through these programs. It is important to note that the contract mechanism only uses SBIR at HHS. If you would like to propose an STTR project, you would need to use the grant or cooperative mechanisms, and you can find more information on our website about these opportunities.

And so, what are the benefits of NIH funding? Our Small Business Programs are one of the largest sources of early-stage capital for life science in the US, and this is non-dilutive capital. The government takes no equity or debt. We fund small businesses across a spectrum of translational and research and development efforts. Many of these companies are very early stage and new to the program. Unlike other agencies, HHS is generally not the final purchaser of products and services developed through America's Seed Fund. Occasionally, contractors may find opportunities, but by and large, we do not fund Phase III awards directly. That said, our recipients leverage government funding in a number of ways to support new product development, and this includes funding to develop and derisk their technology to attract partners and investors that are needed to take innovation to market. And some are able to get to market directly using our small business funding as well, and many have successfully done so. We do encourage you to review our success stories to get a feel for the types of projects that have successfully leveraged our support programs. So, you'll see here downstream-funding partners and/or launch new products. You can also get a feel for how they have taken advantage of SEED and other NIH resources to do so.

And so, the eligibility for our contract RFP is the same as for our grant programs. As a reminder, eligibility is assessed at time of award. Your business must be organized as a for-profit, US-based business with less than 500 or fewer employees, including affiliates. And please keep in mind that all work must be done within the US, with few exceptions. Generally, the business must be directly or indirectly majority-owned by US citizens, or permanent residents, or

majority-owned by multiple investor organizations. And you can see our website for more detailed guidance on eligibility criteria. And unlike the grant process, we do still request that you provide some demographic information on the proposal cover sheet, notably about whether you are a Women-Owned Small Business or a Socially and Economically Disadvantaged Small Business. And you can read more about this on this slide. Please keep in mind that this is used for reporting purposes only and is very helpful for us. And you can also self-certify by registering your business in the System for Award Management, or sam.gov. And the SBIR program is phased. Phase I projects should demonstrate feasibility, and a Phase II project supports full continued research and development efforts.

One of the hallmarks of the NIH program, in particular, is our flexibility. There are many pathways into the program, whether that is a Phase I proposal, a Fast-Track or a Direct to Phase II project. We also offer a number of opportunities to support commercialization of your Phase II technology and transition into the marketplace. Please keep in mind that most of our following grants opportunities may be available to you even if you receive a Phase I or Phase II contract. The program budget guidelines are listed here, but NIH and CDC also have some flexibility to make larger awards for select topics. Please keep in mind that each contract topic has specific guidelines, so do be sure to read the RFP carefully to understand what flexibilities are available for each topic. And it's also important to understand the work requirements for SBIR, both in Phase I and Phase II. Recipients can outsource up to 33 percent of the effort in Phase I, and this is by total budget, and 50 percent in Phase II. Any deviations must be discussed prior to the application with the awarding components. And information about our currently open funding opportunities is available through this slide. The majority of our applications are actually investigator-initiated projects, received via grants generally through the Omnibus solicitations. We do strongly encourage all applicants and offerers to read the "Program Descriptions and Research Topics" to get a feel for the participating Institute and Centers' priorities. NIH does have some targeted solicitations as well as this contract solicitation but do keep in mind that not all Institutes and Centers participate. It is important to read the RFP carefully and reach out to the appropriate contacts to discuss your proposal. And links to the contract RFP specifically are available on the SEED website. Our SBIR Contract web page

provides information about contract basics, including discussing the difference between grants and contracts. You can also find the RFP and submission information at sam.gov, including the solicitation and all amendments, which will also be listed on our website. And the solicitation itself will open as a large PDF with general information and application instructions, followed by specific topic areas and descriptions for each of the participating Institutes and Centers at both NIH and CDC. This year, we have six participating NIH Institutes and Centers, as well as three participating CDC Centers. Other Institutes and Centers not listed here do not participate in the contract solicitation. If you're interested in proposing a topic to them, you can use one of our grants or cooperative agreement funding opportunities listed on our website. Please keep in mind that each participating Institute or Center has specific contract topics, and you must apply to these specific topics, as described in the solicitation. And be sure to review the required elements of your Phase I, Phase II or Fast-Track proposal, which combines both Phase I and Phase II. This includes both the technical and business proposal requirements. They are listed on this slide and similar for both phases, but there are some distinct differences. Applicants should also note that the Phase I technical proposal includes a Draft Statement of Work this year. This is a new change from previous years. All proposals now require Required Disclosures of Foreign Relationships, and we will get ... provide more detail on that in a few slides. Please remember that all section elements of the technical proposal must be addressed, or the proposal will be removed from competition.

And so, we highlighted the different requirements for the Phase II proposal here, including the Technical Proposal Cover Sheet, which you can find in Appendix D, and the Proposal Summary and Data Record, which you can find in Appendix G. Note that we do require the Required Disclosure again here, as well, which is found in Appendix J. And so, this is a new requirement from the SBIR and STTR Extension Act of 2022. Disclosure is required using the Required Disclosure of Foreign Affiliations or Relationships to Foreign Countries Form, which is linked and can be found on the NIH website. You can find instructions to download and complete this form in Appendix J. It is submitted with the business proposal and required to receive an award, so be sure to include this with your proposal.

As I noted, instructions can be found in Appendix J as well as new requirements for post-award reporting. The associated Due Diligence Program to Assess Security Risks, also required by the SBIR and STTR Extension Act, is discussed in Section 6.2 of the RFP. You can find additional information about these programs and requirements on the SEED web page Foreign Disclosure and Risk Management web page linked on this slide. And it is also very important to notice that SBIR and STTR eligibility criteria have not changed with these new requirements. Disclosing or finding of foreign relationships or affiliations does not necessarily disqualify you from participating in the program, but they do need to be disclosed so we can appropriately assess any security risks that may be proposed by these relationships or ties. Offerers should also be sure to keep the page limits clearly in mind. SBIR Phase I technical proposals should not exceed 50 pages. SBIR Phase II technical proposals should not exceed 150 pages. And a Fast-Track proposal includes a complete Phase I and a complete Phase II proposal, and each phase should not exceed the page limits listed above. Also, very important to note that the Human Subjects and Clinical Trials Information form and its attachments are excluded from these page limits, so they are not included in the above limits.

Each proposal should be single-sided, single-spaced pages, and these page limits are all-inclusive. It includes all pages, cover sheets, tables, so on and so forth. There are no exclusions to the page limits. Any pages in excess of the page limitations will be removed from proposal and will not be considered or evaluated. Specific information and requirements about ... including human subjects or vertebrate animals in your proposal is ... considerations are detailed in Sections 3 and 5. Be sure to review them closely and address all of the requirements listed here, as appropriate. And in particular, if you are considering a clinical trial for your proposal, please keep in mind that not all ICs support clinical trials through either the SBIR Program or the solicitation, so be sure to read each topic thoroughly. And also keep in mind that the definition of a clinical trial may be broader than you think. The website linked here, at grants.nih.gov, provides a very helpful decision tool that can help walk you through determining whether or not your human studies' research is ... would indeed be considered a clinical trial by NIH, and we do encourage you to use that to help make that determination.

And our number-one piece of advice: It's very important to read the entire RFP several times. Make sure you're addressing all of the requirements appropriately and have not missed any critical information that will jeopardize reviewer consideration of your proposal. It is also very important to make sure you register and submit early. An active sam.gov registration and SBA Company Registry are required to submit to this program, and please note that sam.gov uses login.gov's two-factor authentication system and will be the same account used for eRA and grants.gov as well. And our number-two piece of advice is to be sure and submit your proposal a day early. Every year, we have frustrated applicants because the submittance button will go away promptly at 5 p.m. The system will not permit files to be submitted once the deadline hits. Even if you hit the button a few minutes before the deadline because file upload is not instantaneous, you might be likely to have a late proposal, which we will not accept. Sometimes there are technical issues or user errors that could come up in the last half an hour that are very hard to get worked out, and because of the volume the help desk may be working with at that time can often be high, you may not be able to get technical support in time.

So, we recommend supporting a day early, but you should absolutely be sure not to be submitting within the last hour before the deadline. And all offerers should note that the deadline for questions is September 29th, 2023, at close of business, so that is the end of this week. It is coming up very quickly. As a reminder, your only contact should be with the Contracting Officer point of contact that is listed in Section 10 for each Institute and Center's topics. All questions must be submitted in writing about the specific topics to the Contracting Officer point of contact, and these questions will be addressed in a Q and A amendment to be issued in mid-September at sam.gov and on the SEED website. And the answers to your questions ... Your questions and the answers to the questions will be posted to the public as part of this amendment. Any additional questions will be answered at the discretion of the Contracting Officers. We do get a number of questions about payment and how this differs from our grant awards. Unlike a grant, we do not disburse the contract funds at the time of award. Contractors have to submit an invoice after completion of the activities that are detailed with the submission of their required reports. Each Institute and Center may set up a payment

schedule a little bit differently, but the company needs to be able to have enough resources to start work fast and get interim payments as they progress.

And lastly, as we start wrap-up the initial portion of our presentation, I wanted to highlight a few of the resources available to recipients through SEED and through NIH. We do want our companies to exceed and support them through the availability of Technical and Business Assistance, or TABA, resources, and funds. TABA can be requested either through funding that is built into your award to source your own experts and providers. To do this, follow instructions in Section 8 of the RFP. Additionally, we have some post-award programs that may be made available to our contractors, including the Phase I TABA Needs Assessment program and the Phase II TABA Consulting Services. And lastly, we also offer a variety of other innovator support. This includes regulatory and business development consultants, entrepreneurial support programs and the opportunity to participate in investment and partnering opportunities. Our SBIR recipients have access to excellent expertise to help plan and solve for commercialization-related challenges through our consultations. Our company showcase program provides the opportunities to attend partnering and investment events throughout the year. A number of them are listed here on the slide. And they also have access to transformational trading programs, like I-Corps, that facilitate product development, customer discovery and general entrepreneurial engagement. And I will note anybody interested in participating in the I-Corps program at NIH, in particular, through the contracting program, should read the instructions in the solicitation to make sure they're including the appropriate content in their business proposal. You can find SEED's contact information here. We do encourage you to reach out with any general questions you have about the program or to discuss your potential submission plans or for help accessing program officers at our participating Institutes and Centers.

And with that, I will invite our first Institute and Center's speaker from the National Center for Advancing Translational Sciences to discuss their topic. Mayra, please move forward when you're ready.

**Mayra Alvarez Lopez:** Thank you, Adam. Hi, everyone. I hope everyone is doing well. I want to thank my colleagues at the SEED office for a great overview and introduction to our program. A

little bit about NCATS before I begin and introduction to our topic. Our focus at NCATS is to advance the science of translation, which is the process of turning observations into interventions to improve health. At NCATS, we work with researchers, the public and other stakeholder groups to design new approaches and technologies that will ultimately deliver more treatments to more people more quickly. I'd like to introduce Topic 24.

A little background on the topic, please note that for Phase I we are requesting ... Our budget is 325K. We are not accepting Fast-Tracks. We are not accepting Phase II proposals, and we anticipate awards ... between two or three awards to be issued. Topic 24 is the Small Manufacturing Systems to Produce Research-Grade Pharmaceutical Intermediates. We seek to leverage trends in automation in synthetic chemistry to shift the way that common intermediates in medical chemistry are currently acquired in the laboratory. The innovative platform must incorporate creative solutions to address current limitations and reagent delivery systems, reagent formulations and data interpretation through versatile, reconfigurable systems that utilize step changes in the workflows based on the type of chemistries involved. This project also supports innovation for the acceleration of molecules into the drug discovery pipeline using these newly developed tools, in lieu of traditional, synthetic chemistry efforts.

The project goals: To develop an integrated technology platform through a compact device capable of manufacturing key pharmaceutical intermediates on demand. Specifically, this project seeks to develop a compact device for synthetic chemists that allow for an on-demand manufacturing of pharmaceutical intermediates that can be utilized in medical chemistry campaigns to rapidly prepare diverse analogs for biological testing; utilize current automation technology in synthetic chemistry in the development of device capable of performing a broad range of chemical methodologies in the preparation of key synthetic intermediates on demand, which may be further amenable to reconfiguration, standardization and rapid scale-up; develop a platform for chemical synthesis that is adaptable to real-time data acquisitions, monitoring and interpretation; and provide additional support to develop pharmaceutical intermediates for laboratory use and non-GMP preclinical candidates for animal testing. Please look into the Phase I deliverables if you have any questions, and we ... As Adam has mentioned, please reach

out to our Contracting Officer listed in the solicitation if you have any questions and you're interested in our topic. Thank you.

**Adam Sorkin:** Great. Thank you so much, Mayra. And next, we will move on to the National Cancer Institute. Dr. Sarra Djemil will discuss their topics. Sarra, whenever you're ready.

**Sarra Djemil:** Thank you so much, Adam. I really appreciate you and the great team working on this. This year, the NCI has 11 contract topics. I urge you ... Next slide, please. These are the 11 topics that NCI has. I urge you to read them carefully to understand the goals and deliverables for each topic. Within the slides, there will be links to each topic, but you can also see the topics in the full solicitation or on the NCI SBIR website. The budget for the NCI topics for Phase I is a maximum for $400,000 for a period of up to 12 months. For Phase II, it's a maximum of $2 million for up to 2 years. For the next few slides, I will read the topic and the goal of each topic. Again, please read them carefully. Fast-tracks and Direct to Phase II are allowed only for certain topics. Please read them carefully. Sorry about that. Please read them carefully and ensure that you are fully aware of whether the Fast-Track or Direct to Phase II is allowed. Only some of these deliverables ... These are only some of the deliverables that we have. Again, you'll find the full-scale of activities and deliverables on the website.

Topic 455: Point-of-Care Detection of Prostate-Specific Antigen. The goal of this topic is to develop ... the development of a home PSA test at an appropriate price point. This contract topic supports technologies designed for ease of use at home and using a finger stick to obtain a blood sample. Next topic, please.

Topic 456: Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control. The goal of this topic is to advance the development of new alternatives for HPV testing to the market that are both in a form factor and at a price point that will enable self-testing programs to be established globally. Next slide, please.

Topic 457: Technologies for Detecting Tumor-Derived Cell Clusters. The goal of this topic is to support the development of in vitro technologies that can enumerate and identify cell types in tumor-derived cell clusters, with or without enrichment, to better understand the biology and role of different cells in cancer metastasis. Next slide, please.

Topic 458: Microbiome Tests for Cancer Research, Diagnosis, Prognosis and/or Patient Management. The goal of this topic is to support the development of innovative tests for early cancer detection and diagnosis, prognosis and/or treatment assignment to be used in research. These advances could lead to the development of microbiome-based CLIA tests, which are laboratory-developed tests, and FDA-approved diagnostic or companion diagnostic tests. Next slide, please.

Topic 459: Automated Software for Point-of-Care Testing to Identify Cancer-Associated Malnutrition. The goal of this particular topic is to facilitate commercial development of novel, automated, point-of-care nutrition screeners that combine first-line questionnaires with automated segmentation from diagnostic imaging, such as but not excluded to repurposed CT images, to detect malnutrition risk early and repeatedly during cancer care and in cancer populations with higher prevalence of malnutrition.

Topic 460: Evaluation of Datasets as Medical Device ... Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies. The goal of this topic is to stimulate the participation of small businesses in the FDA's Medical Device Development Tool, MDDT, program to develop datasets that can be used to assess medical devices in oncology settings. If you're not familiar with the MDDT program, we've provided a link for the MDDT program within the solicitation. Familiarize yourself with this program and then fully read the topic to see whether your tool fits within what they're looking for. Next slide, please.

Topic 461: UItra-Fast Dose Rate (FLASH) Radiation Detectors and Safety Systems for Cancer Treatment. This is a reissued topic, so I highly recommend that you look carefully at this topic because there has been a chance in scope. The goal for this topic is to advance the development of devices for evaluating FLASH radiation therapy and translating it into the clinic. The contract topic focuses on ultra-fast radiation dose detector and safety-related beam delivery components.

Topic 462: Organ-on-Chip for Preclinical and Translational Radiobiological Studies. The goal of this topic is to support the development and validation of organ-on-chip devices for research and preclinical applications in studies with radiation and drug radiation combinations.

Topic 463: Translation of Novel Cancer-specific Imaging Agents and Techniques to Mediate Successful Image-guided Cancer Interventions. The goal of this topic is to support the translation of novel agents and/or techniques for sensitive cancer detection in human subjects. Next slide, please.

Topic 464: Cloud-Based Multimodal Data Analysis Software for the Cancer Research Data Commons. The goal of this topic is to advance the evolution of cloud-based multimodal informatics tools to integrate with the CRDC for broader use community engagement. Next slide.

Topic 465, which is the last topic from the NCI in this year's Solicitation, is Cancer Prevention and Treatment Clinical Trial Tools for Recruitment and Retention of Diverse Populations. The goal of this topic is to support the development of a digital platform that provides primary care professionals with validated cancer risk assessment tools, cancer prevention guidelines and clinical recommendations based on a patient's risk factors to discuss with their patients. Next slide, please.

So those were the topics by NCI for FY2024. As a brief reminder, please remember to read the Program Solicitation carefully for each and every topic that you're interested in. A few reminders that have been mentioned before, submit both sbir.gov and sam.gov registration in time because the proof is required. And finally, questions about NCI SBIR contract topics should be directed to Ms. Cherie Wells, and her email is enclosed here. Thank you and good luck.

**Adam Sorkin:** Great, thank you so much, Sarra. Next, we will hear from the National Institute on Aging from Armineh Ghazarian. Armineh?

**Armineh Ghazarian:** Thanks, Adam.

**Adam Sorkin:** Mm-hmm.

**Armineh Ghazarian:** So, at the National Institute on Aging, our research focus is on Alzheimer's disease and the related dementias as well as aging longevity. So, this year we have one topic entitled Technology to Facilitate Characterization of the Exposome in Under-Resourced Populations for AD and ADRD Studies. The budgets noted on the screen are actually incorrect.

For Phase Is, we award $500,000 over a span of 12 months, and for Phase IIs, we award up to 2.5 million for 2 years. We will be accepting Fast Tracks and Direct to Phase IIs with appropriate justification. This topic's focus, in a very broad sense, is to characterize the exposome to be applied in AD-related studies. So, characterizing the exposome requires collection of both environmental and biological samples. However, hard-to-reach populations who are the ones who often carry the highest burden of age-related diseases are often precluded from participating in epidemiological studies because of the difficulties in collecting these samples. The idea is, by lowering the barriers to these data collection efforts, NIA will be better able to study the etiology of complex diseases such as AD and ADRD in more representative populations. So, with this topic, the goal is to facilitate the development and adoption of technologies that enable the remote of self-collection of measures to characterize the exposome in hard-to-reach populations for AD studies.

Phase I will focus on identifying and developing these technologies. A couple of deliverables include but aren't limited to addressing gaps in current technologies for a sample collection and preservation, demonstrating performance in sample preservation and analysis using traditional methods, demonstrating usability performance in terms of participant self-collection across a wide range of participants and demonstrating the ability to follow subjects over varied timescales. Phase II will focus on validating and scaling the technology. A couple of deliverables would be to adopt a user-centric design transitioning from prototype to that encourages long-term retention in longitudinal studies, a scaled distribution, achieving performance targets at larger scales compared to the gold-standard and scaled manufacturing to drive down costs per unit. And that's it for NIA.

**Adam Sorkin:** Great, thank you very much, Armineh. And next we'll hear from Dr. Natalia Kruchinin from the National Institute of Allergy and Infectious Diseases. Natalia?

**Natalia Kruchinin:** Yes, thank you. Oh, yes, sure. Thank you, Adam. Hello, everyone. I appreciate the opportunity to talk today about NIAID SBIR contract topics. What I would like to mention, that NIAID is the second largest institute within NIH community of institutes with a budget, SBIR/STTR budget, of 195 million, and also, I would like to say that mission of NIAID is to conduct and support basic and applied research to better understand, treat and ultimately

prevent infection, immunologic and allergic diseases. A little bit about the structure of our institute, we obviously have an Office of the Director. We also have four extramural divisions: Division of AIDS; Division of Allergy, Immunology, Transplantation; Division of Microbiology Infectious Diseases; and we have Division of Extramural Activities. I would like to mention that most of the budget of these top three divisions goes to support grants, contracts, and cooperative agreements. Within Division of Extramural Activities, we have policy, grant management, acquisition, or the Small Business Program under this division. We also have Division of Clinical Research, Division of Intramural Research and Vaccine Research Center. I also would like to mention if you would like to read more on each slide, you can see links under each division. You can definitely look and check. Also, I put the link for areas of high priority of interest for the institute and for the Small Business Program.

This Solicitation contains opportunities to submit a proposal under a variety of different topics. For NIAID, for this Solicitation, we have 13 topics and, on this slide, the summary of these 13 contract topics. I would like to mention that please check pages five and six of the Solicitation because you will see the summary table regarding which grant mechanism is allowed because some of the topics allowed only Phase I proposals to be submitted, some of the topics allowed Direct to Phase II, and some of the topics allowed Fast Track proposals. Just to remind you, Fast Track, this is a proposal which include both Phase I and Phase II proposals in one package. Also, I will recommend you to check on these pages, these NIAID pages 103 and 123. I just put example where you can see which grant mechanism ... contract mechanism is allowed ... will be accepted. Also, you will see the budget numbers because for each topic, it can be a different budget dollar amount. And also, there is a table on page 70, I believe, where you will see a number of anticipated awards for NIAID and anticipated time of the awards. Scientific and Technical Merit Review March 2024, anticipated award date August 2024.

For Division of AIDS, we have four contract topics: Development of Next-Generation Devices and Materials-based Platform ... I'm sorry, just one second ... Platform for the Administration of HIV Broadly Neutralized Antibodies; Topic 125: Development of Long-acting Treatment for HCV Cure; Topic 126: Rapid Diagnostic Analysis for Self-monitoring of Acute or Rebound HIV-1

Infection; Topic 127: Multiplexed Patient Administered Diagnostic for Hepatitis B, Hepatitis C, and HIV.

For Division of Allergy, Immunology, and Transplantation, we have three topics: Topic 129: Adjuvant Development for Vaccines for Infection and Immune-mediated Diseases; Topic 129: Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models; Topic 130: Adjuvant Discovery and Down-selection for Vaccines Against Infection and Immune-mediate Diseases.

And Division of Microbiology and Infectious Diseases, we have four contract topics: Development of Bacteriophage for Treatment of Mycobacterial Infection; Topic 132: Novel Diagnostic Biomarker Discovery and Validation for Malaria and Select Neglected Tropical Diseases; Topic 133: Development of a Serological Test for Herpes; and Topic 134: Alternative to Benzathine Penicillin for Treatment of Syphilis.

And we also have two topics on the Office of Data Science and Emerging Technologies: Topic 135: Software or Web Service to Automate Metadata Enrichment and Standardization for Data on Infection and Immune-mediated Diseases; Topic 136: Software or Web Service to Represent Existing Scientific Data and Knowledge into a Knowledge Graph Format. And you heard this commented a few times today, but because of government and acquisition regulations and policies, we cannot answer questions. If you have questions related to these topics or, in case of NIAID, please reach out to Jonathan Bryan, and I have his phone number, email address here. Again, all technical questions related to topics, please reach out to a contracting officer. If you would like to learn more about the SBIR grant program at NIAID, please contact me. I put my email address. Visit our website and connect with NIAID Small Business Program Team. Thank you so much.

**Adam Sorkin:** Great, thanks very much, Natalia. Next, we'll hear from our colleagues at the National Heart, Lung, and Blood Institute. Julia, when you're ready please.

**Julia Berzhanskaya:** Thank you. So, my name is Julia Berzhanskaya. I am Ad, Innovation and Commercialization Office, and I will be talking about NHLBI contract topic today, and for the contact, please contact Lynn Furtaw. Her contact information is listed on the last page. So, the

objective or strategic priority of National Heart, Lung, and Blood Institute is providing leadership in research, training and product development for heart, lung, blood and sleep diseases and conditions. Our topic this year, Topic 115, is Clinical Instrument for Para-hydrogen-based Signal Amplification by Reversible Exchange, or SABRE, and we accept Phase I applications to the value of 350K and Phase II applications up to 3 million. This topic is designed to address an unmet clinical need where carbon-13 MRI allows for imaging of metabolic activity in vivo, but current methods of hyperpolarizing carbon are slow, expensive and use toxic heavy metal as a catalyst. Therefore, signal amplification by SABRE using novel fluorinated catalyst facilitates removal of toxic chemicals and provides a safer method of generating hyperpolarized probes. Overall project goal is to develop a medical device to deliver hyperpolarized MRI probes for medical imaging. As I mentioned, they accept Phase I, Phase II, Fast Track and Direct to Phase II proposals are accepted. The expected deliverables for Phase I is an instrument to provide hyperpolarized probes for MRI animal imaging, and Phase II expected deliverable, a medical device for clinical delivery of hyperpolarized probes including interaction with the documentation of ... for 510(k) submission is expected as one of the deliverables. Please read carefully a more detailed description of the topic, and if you have any questions, please contact Lynn Furtaw in Office of Acquisitions. If you feel that your proposed project does not fit exactly to this topic, I would be happy to discuss other small business grant opportunities. Thank you very much.

**Adam Sorkin:** Great, thank you, Julia. And next, we will hear from Dr. Vasudev Rao from the National Institute of Mental Health. Vasu, please.

**Vasudev Rao:** Yeah, thank you, Adam. So, this is the first time NIMH is participating, and I just want to make sure that folks understand it's only Division of AIDS Research at NIMH that is participating in this year's Contract Solicitation. Hi, everyone. My name is Vasudev Rao, and I am in charge of the SBIR portfolio in Division of AIDS Research at NIMH. We will be highlighting two different Contract Solicitation opportunities today. For these Solicitations, we are accepting Phase I applications with a budget of 300,000 for 12 months and Phase II application with a budget of 2 million for 24 months. Since this is the first time we are participating, I just wanted to give a bit of background. So, what you wanted to ...today, over a million people in the US live

with HIV, and around 13 percent of them are unaware of their status. New infections continue to occur, and these new infections disproportionately affect marginalized populations, so this epidemic is far from over. Antiretroviral therapy is a powerful tool that can suppress the virus, allowing individuals to lead healthier lives and preventing the spread of HIV. The way to monitor disease progression and treatment efficacy in these people with HIV is through HIV viral load assays and by entering that the patients are adhering to ART medications.

So, the two Solicitations, the first Solicitation is about HIV viral load monitoring as well as adherence assays. Here are some of the key parameters to be considered while developing the viral load assays. As a home test or in the use of ... It has to be a test as a home test or used in local clinics or pharmacies to detect HIV from a finger stick or other biospecimens. Acutely infected PrEP users with low viral load, ART treated with loss of viral suppression need to be detected. The minimum sensitivity for these viral load assays is less than 500 RNA copies per mL, but the optimal sensitivity is around 50 RNA copies per mL. These tests should have a short diagnostic time to result, 20 minutes to 1 hour, and, of course, they need to be cost effective. As part of the same Solicitation, we are also seeking another thing about pharmacological adherence monitoring for antiretroviral therapy. So, the key parameters for this ART drug adherence assays is they have to be rapid point-of-care methods that measure long-term adherence to antiretrovirals. They need to be able to measure drug levels in various biological matrices, for example, urine, hair, or dried blood spots, so you can focus on any of these or all of these. They need to be able to monitor PrEP adherence, ART adherence to trigger adherence interventions, drug levels of long-acting ART or PrEP formulations or monitor blood donations for PrEP and ART drug levels as an indicator of HIV exposure or infection. Again, more details about this first Contract Solicitation can be found in the PDF shared earlier, and these are on page 126 and 127.

The second Contract Solicitation request from NIMH is focused on Development of novel In-vitro and In-vivo Models to support NeuroHIV Research. Despite excellent biologic control by antiretroviral therapy, CNS disease, also known as NeuroHIV, including neurologic, neurocognitive, and mental health problems are observed in a significant proportion of people with HIV. Considerable gaps exist in the understanding of pathogenesis of CNS disease

associated with HIV, so there's a need for developing novel modern systems that will help better understand the immune CNS pathogenesis in the context of HIV and antiretroviral therapy. So, our second Solicitation is to develop novel models for NeuroHIV research. These include organoid models incorporating human immune cells amenable to HIV infection and neuronal cells with measurable neuro-modulatory outcomes. These also include humanized small animal models with systemic and CNS immune cells amenable to HIV infection that can be used to understand mechanisms of neuroimmune dysfunction in the context of long-term infection of HIV as will comprehend the role of CNS viral reservoirs. Also included is developing blood brain barrier models using organoid-based framework with human immune cells, neuronal cells, and vascular components to help comprehend the pathways leading to adverse CNS outcomes in the context of HIV and ART. Last but not least, it is to develop in-vitro and in-vivo models to test the impact of HIV-associated immune dysfunction on synaptic transmission and plasticity. Again, once again, more details can be found in the Contract Solicitation. For this, it's page 127 and 128. Thank you.

**Adam Sorkin:** Great, thanks so much, Vasu. And that concludes the NIH topics included in the current Contract Solicitation. Next, we will hear from Sean Griffiths, the Small Business Innovation Research Program Manager at the Centers for Disease Control and Prevention who will discuss their program and their topics. Sean ...

**Sean Griffiths:** Thank you, Adam.

**Adam Sorkin:** All yours.

**Sean Griffiths:** Yep, thank you, Adam, appreciate it. Good afternoon, folks. My name is Sean Griffiths. I'm the SBIR Program Manager for the Centers for Disease Control and Prevention. For the next several minutes, I'm going to be speaking to you about the CDC, our SBIR program and specifically about this 2024 Contract Solicitation. Next slide, please. The mission of the CDC is to protect America from health, safety, and security threats both foreign and in the US. Whether diseases start at home or abroad, are chronic or acute, curable, or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. To accomplish our mission, CDC conducts critical science and provides health information that

protects our nation against expensive and dangerous health threats and responds when these arise. Next slide, please. The CDC Strategic Plan advances Science and Health Equity and affirms our agency's vision equitably, protecting health, safety, and security. The plan leverages five core capabilities of the agency, a diverse public health workforce, world-class data and analytics, state-of-the-art laboratories, rapid response to outbreak at their source and a strong global capacity and domestic preparedness. Our work is underscored by the agency's pledge to the American people and dedication to use timely data and science to drive and communicate customer-centered high impact public health action. There is a strategic imperative to modernize CDC so that it consistently delivers public health information and guidance to Americans in real time, a mission recognized by the talented people who work here and by public health experts around the globe.

Next slide, please. Last year, CDC launched an effort to refine and modernize its structures, systems and processes around developing and deploying our science and programs. The goal was to learn how to pivot our longstanding practices and adapt to pandemics and other public health emergencies, then to apply those lessons across the organization. This review identified several important areas which CDC is committed to and actively working toward improving. On the right side of the slide, you will see the CDC Moving Forward Core Areas of Improvement, as well as the cdc.gov link for this information. Next slide, please. The Centers for Disease Control and Prevention is an operational division within the Department of Health and Human Services. This organizational chart includes the 12 different CDC centers, institutes and offices that participate in the CDC SBIR program. The CDC Office of the Science is responsible for the overall management of the agency's SBIR program. Next slide. The FY'23 budget across all CDC centers, institutes and offices was approximately $16 million in FY'23. Phase I contract budgets are 243,500 for a 6-month project period. Phase I grant budgets start at 295,924 for a 6-month project period. Phase II contracts and grant budgets are 1.9 million for a 2-year project period. CDC participates in both SBIR grant Omnibus Grant Solicitations, PA-23-230 and 231, and the Contract Solicitation we're talking about today. CDC also participates in PA-21-345, the Administrative Supplements to Promote Diversity in Research and Development. We have three CDC ICs, the National Center for Environmental Health, the National Center for Injury

Prevention and Control and our National Institute for Occupational Safety and Health that participate in this administrative supplement. CDC does not participate in the Small Business Technology Transfer, or STTR, program at this time. CDC also does not participate in Fast Track, Direct to Phase II, Phase II B or the Commercialization Readiness Pilot Program. Next slide, please. CDC does not currently participate in the overall NIH TABA program. If you are a CDC offeror and wish to utilize your own technical assistance provider, you are required to include those costs ... or these costs in your budget and provide a detailed budget justification. You may request up to $6,500 for the Phase I project and up to $50,000 per Phase II across all years for assistance. Offerors currently must submit their intent to use these TABA functions or these TABA options when applying for Phase I funds.

In regard to other technical assistance, CDC does participate in the I-Corps at NIH program. Two CDC ICs are currently participating in I-Corps at NIH, NCEZID and our National Institute of Occupational Safety and Health. The National Center for Emerging and Zoonotic and Infectious Diseases, or NCEZID, does have a topic in this Solicitation. Next slide, please. CDC uses the NIH electronic Contract Proposal Submission, or eCPS, website for contract submission. The eCPS is a component of the government's integrated secure system for the electronic submission capture and tracking of contract proposals. The eCPS website will be the only way to submit CDC SBIR proposals under this Solicitation. In this slide you can see the eCPS snapshot of the first four CDC topics, the contracting official responsible for those topics which are your POCs at the agency and the closing date of 11/14/2023. Topics 031 NCEZID, the National Center for Emerging and Zoonotic and Infectious Diseases, Development of SHERLOCK Assay for Detection of High Threat Orthopoxvirus. Topic 055, NCHHSTP, National Center for HIV, Viral Hepatitis, STD and TB Prevention, Software Solutions: Bridging the Gap Between Public Health and Pharmacies. Topic 056, NCHHSTP, Electronic Health Records, EHR, Algorithm to Identify Persons with HIV Not in Care, and Topic 057, NCHHSTP, Device for Point-of-Care Nucleic Acid Purification Detection of HCV.

Next slide, please. I'll say it again, or I'll state again. CDC only accepts proposals via the NIH eCPS, electronic Contract Proposal, secured system. In this slide, you can see the next two CDC topics, the contracting official responsible for those topics and the closing date, again, of

11/14/2023. Topic 036, NCIRD, or the National Center for Immunization and Respiratory Diseases: Improved Diagnostic Assays for Measles, Mumps, Rubella and Varicella. And then Topic 037, or 037, NCIRD, Rapid Diagnostic Tests for Measles, Mumps, Rubella and Varicella. Next slide, please. As stated previously in this webinar, please read the contract solicitation and any future amendments to the solicitation carefully. Adam stated this previously, and I'll restate it again. Please read any future amendments to the solicitation carefully. We also encourage you to apply early. If you have questions after today's webinar or specifically during the open question and answer period, please contact the CDC contracting officials listed in the solicitation. When contacting CDC, please reference the solicitation PHS 2024-1, the responsible contracting officer or specialist, the CDC topic number, along with your specific questions. Remember that the question-and-answer period ends Friday, September 29, 2023, which is this Friday. Next slide, please. Thanks again for your interest in the CDC, our SBIR Program. Thanks again to NIH and our team at SEED for sponsoring this webinar, and my colleagues across the NIH ICs that are also participating in this program and our CDC colleagues across the CDC who are also supporting me and our colleagues across CDC. We continue to work 24/7 protecting America's safety, health, and security. For any general questions about our program, please contact us at sbir@cdc.gov. Back to you, Adam and Stephanie and team.

**Adam Sorkin:** Great. Thanks so much, Sean. Just as a final reminder, the deadline for all proposals is Friday, November 14th, at 5 p.m. Eastern Time. Submission must be completed at that point. And with that, I will hand things back to Stephanie Fertig to moderate the Q and A session.

**Stephanie Fertig:** Excellent. Thanks so much, Adam, and thanks to all of our speakers today. So, this is an opportunity. We've been getting a number of questions in the Q and A. Please do put your questions in the Q and A. We are going to work to address as many of those as we possibly can, and I may be bundling some of those because there are some themes that we're beginning to see within the questions. So, one of the questions that I did see, and it was answered in a couple of different ways, was, "How is the SBIR grant different from the SBIR contract?" And so, I will state we have information about the grant mechanism on our website, seed.nih.gov, but can you all really talk about what's the difference between an SBIR grant and an SBIR contract?

**Adam Sorkin:** Sure. I think we'd be happy to, and there is some great information about this on both our website and linked out to the general NIH grants website, as well. But grant is an assistance mechanism to support research for the public good, namely in service of HHS' public health mission. A contract, on the other hand, is a legally binding agreement to acquire goods and services for the direct use or benefit of the government. So, whereas for a grant, generally, you receive assistance for your research and with fairly limited government oversight, and the expectations are is that you will report on the outcomes of your research when it's complete. For a contract, on the other hand, you will have specifically defined deliverables in the contract agreement that you will be expected to provide according to a specific delivery schedule and, generally, more involvement from the government with both your contracting officer and contracting officer's representative.

**Stephanie Fertig:** Great. And as was pointed out several times during the presentation, but I do want to reiterate, contracts, there are specific topics for contracts. If you have a project that may not fit within one of these topics, that's okay. We do have the General Omnibus Grant Solicitations. We do have other ways for you to seek SBIR or STTR funds to support your company and the project that you're doing, so I would encourage you to go to our website. Again, the contract topics are really specific topics, and you do have to come in under one of those contract topics. Now, one question that we did receive was around, "Can a PI or company submit two proposals to this solicitation? Can you submit two proposals to the ... within the contract solicitation? Also, what about per topic?" So can you talk about the idea of multiple proposals.

**Adam Sorkin:** Yes. I believe we certainly welcome proposals from an offerer to more than one topic. Callie, can you address whether or not we can accept multiple proposals on the same topic from one offerer?

**Callie Prassinos:** Sure, absolutely. So, my name is Callie Prassinos. I'm from the Office of Acquisitions at NIAID, and yes, we can accept proposals ... two proposals from one company under each topic, as long as they are different, and objectives are different and that they are distinct projects. And in doing that, understand that they have to be two proposals. They're separate. They need to be submitted separately in eCPS, as well, and that they are going to be

evaluated separately as well. So, if there is a company or a PI that has two different projects, make sure that that is identified and that they are submitted separately.

**Adam Sorkin:** Great. Thanks so much, Callie.

**Stephanie Fertig:** Great. There were a number of questions around the different elements of a proposal, as we're talking about proposal submissions. So, one of the questions we got: "Can you further specify what content should be placed in the technical objectives, the detailed approach, the methodologies, et cetera?" And we might not want to go into all that detail there, but where can individuals find that specific information, and I will also want to put there as a similar question about, what about proposal formatting guidance, number of pages per section? Where can people find the guidance on some of these issues? Callie, I don't know if you want to jump in on that. You're welcome to do so.

**Callie Prassinos:** Sure, absolutely. So, in the solicitation, there is lots of sections that point to this. In Section 7, there is proposal formatting and what to include and how to include it, what goes in each section, what to include in your technical proposal, what to include in your business proposal, because the technical proposal does have that page limit. So, you want to make sure that you go and look to make sure that what's included in each proposal. And then in Section 8, there's also preparation and instructions, exactly what technical needs to go in each section to be evaluated, and yeah. And I would definitely look at each topic because each topic is going to have specific things that topic is going to look for, intent letters, numerous things that that topic is going to be evaluated for, so really look at that topic and that description and what needs to be included as well.

**Stephanie Fertig:** Great, and I do know that we have a new section this time that was highlighted by Adam, a new component which is the draft statement of work. Can you talk a little bit about that since that is a new ... kind of a new requirement? So, I'm sure people are very interested to get a quick summary on that as well.

**Callie Prassinos:** Absolutely. And so, the statement of work, we would like to be submitted with the original proposal to get the ball rolling. There is the draft template that ... in the appendix to follow, and really, we want the offerers to submit what they want to do, how they want to do it

and really just take a stab at outlining everything that's in that template and to follow what the technical objectives are in each topic and outline what activities will be conducted in that statement of work to complete that topic.

**Stephanie Fertig:** Great. So, we are getting a number of questions around review and the differences between in contracts review and a grant review, as well as how are contracts reviewed? Is it all one big review panel, or is it really separate reviews? Can we talk a little bit about the contracts review process?

**Callie Prassinos:** Sure. So, contract review is a bit different than grant review. Each agency is going to take the proposals, and they are going to put together a panel of peer reviewers to evaluate each topic. So, each topic is going to have its own peer review panel, and on that panel is going to be people from the community, their peers, to evaluate. And they're going to evaluate based on the technical evaluations that are found in the solicitation and each valuation factor. So, it is a peer review panel, but it's going to be each agency for each topic is going to do their own peer evaluation.

**Stephanie Fertig:** Great. One of the questions that I'm getting, so what from the perspective of feedback do ... As many of us know, SBIR and STTR grants, you do get a summary statement. What about contracts? Is it similar?

**Callie Prassinos:** I'm not sure. I will have to check on that one.

**Stephanie Fertig:** One of our analysts ... One of our other panelists certainly can jump in. Otherwise ...

**Natalia Kruchinin**: This is Natalia. I can comment, but I ... you guys are experts. But I believe that there is a debriefing, yes, and if somebody is not successful, they can submit a written request for debriefing within 3 calendar days of being notified that its proposal was not selected for the award. And I believe it's going to be conversation. That's all that I know.

**Callie Prassinos:** Yes. Thank you, Natalia. You are correct. There will be a debriefing. If an offerer gets an unsuccessful notice, they can request debriefing, and we will submit, and the

contracting officer will submit information of why they were not selected in the process. Thank you, Natalia.

**Stephanie Fertig**: Great, and that does come ... We did get several questions about individuals who were not successful in receiving a ... Either they put in a proposal for a contracts previously and were not successful, or they put in a proposal ... they put in a grant application and were not successful. Can they take project ... Obviously incorporating any feedback that they did receive, can they take that and submit here?

**Callie Prassinos:** Yes, absolutely. That's why we provide the feedback, is to improve on those proposals so that they can be resubmitted and hopefully for success in the future.

**Stephanie Fertig:** Great. So, one of the other questions that we did receive, and I'm going to be switching gears a little bit here, is around ... So, a couple of budgetary questions. So, one of the questions that we received was around the 7-percent fee. Is the 7-percent fee, which is part of the grant application ... You can ask for a 7-percent fee. That's the 7-percent profit. Can you do that here in the contract solicitation?

**Callie Prassinos:** So yes, you can request fee, but each contracting officer will do their own analysis on whether the fee is reasonable or not on that particular topic and activities. So, propose the fee, and we will do our analysis to determine whether that's reasonable, if the 7 percent is reasonable or not.

**Stephanie Fertig:** There was also a question around the I-Corps program and how to incorporate or put I-Corps as part of the contract mechanism. So again, through grants there's a specific way to do that, but what about contracts? How is I-Corps handled? And the I-Corps program ... And I don't know if, Adam, if you want to jump in and talk about a little bit about the I-Corps program, just to explain that briefly, and then we can talk about how it's applied through contract.

**Adam Sorkin:** Sure. So the I-Corps program, or the I-Corps NIH program, is an 8-week intensive entrepreneurial trading program that allows small business companies to engage in a, over the course of that period, a intense data-driven customer discovery process where they can really hone in and understanding who their customers are and what their specific product needs are

and get a lot of information that can really help them pivot as needed into Phase II and focus on product development that is addressing a real comprehensive market need. The I-Corps program is available to participants ... or to our SBIR Phase I contractors, but they do need to include a specific appendix ... I believe it's Appendix C ... in the pricing proposal, and specific instructions on how to include that are, I believe, included in Section 2.5 of the RFP. So, you can read that, get specific information about how to do that, but do make sure that that is included in your proposal. And then you will get the opportunity to apply to one of the cohorts downstream when they become available during your performance period.

**Stephanie Fertig:** Great. So, I think this really highlights the importance of reading the solicitation very, very carefully. It is a wealth of information and instruction as you're putting together your proposals, so very important to read that carefully and all the different pieces and instructions that are part of that. There was a question around multiple PIs. So, one of the questions was around eligibility. Are both of the PIs ... Do both of the PIs need to meet that 50 percent requirement to be eligible, or can it be only one, and can the other one not meet that 50 percent employment requirement? So, for SBIRs, the PI really does need to be employed by the small business ... What about multiple PIs?

**Callie Prassinos:** So at least one of them does need to be 50 percent employed by the small business.

**Stephanie Fertig:** Great. And I do want to point out that we did briefly talk about this idea of if you were unsuccessful previously in getting either a contract or a grant, you can certainly turn around here with that information, whatever feedback you've received, and submit a proposal. But the opposite is also true. So, say you are unsuccessful in the contract process, and I don't ... We obviously would love people to submit a solid proposal, but if you go through this process, and you're not successful, that's okay. Again, you can still submit a grant application, and that's part of the reason why we're having the program officers ... different program officers here speak as well. You've heard many of them say, "Hey, if you're interested in the broader program, come contact us." So, it's important to know that while for the contract solicitation, the specific contract points of contact are your points of contact for this solicitation. The broader program, if you're interested in grants, if you're interested in funding opportunities, we

do have program officers that can speak with you. There aren't the same limitations around contacting questions with grants as there are with contracts, so they are fundamentally different mechanisms. Really important difference between the two we haven't highlighted, by the way, is who you can talk to when. Grants are a little bit more flexible on that front, so very important to remember that. All right. So, another question that came up is around foreign work, and specifically, the questions was around collecting samples in other countries, but I'm going to broaden that a little bit and talk ... encourage ... Callie or Adam, encourage you guys to talk a little bit about foreign work and how foreign work is handled within the contract solicitation.

**Callie Prassinos:** Sorry. My mute wouldn't come off. I don't know how to start. Foreign work is allowed under certain topics. We would have to get ... It would have to be disclosed in the proposal all the details about the foreign relationship. There are additional foreign disclosures that are happening this year as well, and I don't know if Adam wants to kind of talk about that.

**Adam Sorkin:** Sure. So yeah, in addition to detailing ... Well, just to, I guess, take a step back, the SBIR program requires that all work be performed within the United States. However, we do have provisions to make exceptions on that case-by-case basis. If some work can't be performed within the US, for example if you need to access patient populations or specific specimens or materials that might not be available domestically, in those cases we can consider specific exceptions. New this year is the requirement to disclose any relationships or affiliations with foreign countries. So as part of your proposal, in the business proposal, as described in Appendix J of the solicitation, you'll find instructions for downloading and completing this form and attaching it to your proposal, in which case you'll need to disclose any foreign ... It'll walk you through a series of questions disclosing any foreign ties or affiliations, covered individuals in the project, so this is the PI, other senior personnel ... key personnel, what have you, may have in foreign countries. If you are working ... including a foreign component in your project, obviously very important to disclose that, but you'll want to disclose any other ties as well.

**Stephanie Fertig:** And that's a really important point, is that there is that new disclosure form, that it's important that you do disclose. That is separate from the eligibility criteria. That is separate from foreign work. It really is a broader disclosure. So, one of the questions that we

have received was around, "How does it work with regards to Phase I versus Fast-Track versus Direct to Phase II? If a topic only lists a Phase I, does that mean you can't submit a Fast-Track or Direct to Phase II? How do you pick if there are options?" So, can you talk a little bit about that as well?

**Callie Prassinos:** Yes. So, if a topic only is requesting for a Phase I at that time, that's what we will be looking for at the time of the proposal, is a Phase I proposal, but that doesn't mean that a Phase II won't be a future opportunity once the Phase I is completed. Then each program will have the opportunity to invite Phase II proposals down the road when they deem that it's time for that Phase II proposal to be evaluated. There are proposals that have Fast-Tracks that are listed there, and that means that they can ... that an offerer can send in a proposal for a Phase I and a Phase II. The Phase I proposal will be evaluated separate from the Phase II proposal, but they will be awarded together. But the Phase II will not be funded at the time of the award of the Phase I. So, Phase I will be awarded and then after Phase I is done, then if an agency decides to move forward with Phase II, then the option is what we put ... It ends in an option would be awarded at that time, without the need to evaluate that Phase II again. It would just be part of that contract. And then there are Direct to Phase II, which means there is no need to have a Phase I proposal. Then you can submit just a Phase II proposal for that topic.

**Adam Sorkin:** And, Callie, I believe ... Correct me if I'm wrong, but that is one of the ways our contract and ... This is one of the ways in which our contract and grant programs differ, is that you can be awarded ... you can submit a Fast-Track application and only be awarded the Phase I component of the award. Is that correct?

**Callie Prassinos**: You can be ... Correct. You can be awarded just the Phase I contract. If you submit both, and program feels like the Phase II proposal needs more time or needs more Phase I activities to make that proposal better, then you could get awarded just the Phase I, and then the invitations for Phase II down the line when Phase I is completed will happen at that time.

**Stephanie Fertig:** I think ... I just want to highlight one of the things that you indicated around submission of the Phase II after an offerer has successfully completed their Phase I. You talked a

little bit about if ... how that Phase II process works, because it is very different from the grant process. So, I don't know if you want to maybe highlight that again because I did see a question or two come across on that specific topic.

**Callie Prassinos:** Sure, absolutely. And I think this will differ a little bit between each agency, but after the Phase I is completed, there will be an invitation for a Phase II proposal within each topic after that Phase I is completed and will give the opportunities for those contractors that have that Phase II ... that Phase I contract to submit a Phase I proposal ... or Phase II proposal, excuse me.

**Stephanie Fertig:** And just to highlight a significant difference between the grant process and the contracts, in the Fast-Track, you're submitting basically two full proposals versus, in the grant process, it's Phase I and Phase II is combined into one proposal. So, it is a little bit different. Just do ... There are some significant differences between the grant and the contract process, but what about the Direct to Phase IIs? There is a question here about asking for guidance on when do you choose to go Direct to Phase II versus Fast-Track versus Phase I? If you have the option, and you have any of those three, what do you do?

**Callie Prassinos**: I think the best recommendation I can give is, if you have enough data to make that Phase II proposal successful is when you would want to submit that Direct to Phase II.

**Adam Sorkin:** And I'll just add that many of the contract topics make clear what the expectations are for ... and deliverables will be for Phase I and Phase II. So, you should have a relatively clear idea of whether you would be able to satisfy the Phase I, Phase II or, in case of Fast-Track, both sets of deliverables.

**Stephanie Fertig:** Right, and I ... there are two questions here about how quickly the Phase II is funded, and is this is a very ... How quickly between the Phase I and Phase II, and if there's another application and review process? And I think that's where we were coming to, is there is a ... It's kind of a separate request or process.

**Callie Prassinos**: Yes, and it will vary each topic how quickly that process goes along. So, it is going to be a separate proposal for Phase II after the Phase I is completed, and then there will

be a separate evaluation on those proposals as well, with the whole process to award on that Phase II proposal, after Phase I is completed.

**Stephanie Fertig:** Now, there are some questions here around how advanced the technology needs to be if it's being proposed, and there's a discussion at NSF, which does grants, really is looking for earlier proposals. There was a question about, "Hey, can we do a contract on an already-patented technology? What are you really looking for?" And my guess is the answer is going to be somewhat, "Look at the topic." The topic is going to be really an important driver, but I don't know if you'd like to add anything there.

**Callie Prassinos:** I think any specific questions about the technical topics, please submit to your contracting officers by Friday, and then we will get the program staff to answer those specific questions and post them with the amendment in mid-October.

**Stephanie Fertig:** And I am seeing a number of questions about specific topics here in the Q and A, and what we're going to potentially do, and we can circle back, but I would encourage you to please submit your questions about those specific topics. That's going to be very, very important. Submit them to the contracting officer, and we can make sure that you're able to get those questions addressed. There was a question in the Q and A about the NIMH contact person. We can make sure to provide that. That's one of the questions, so hopefully, Callie or Adam or someone can provide that information so that they'll be able to ask their question of the NIMH topics as well.

**Callie Prassinos:** And I think that you can submit that to me, and I can ... If we don't get that information to you by Friday, please submit that question to me, and my information is in the solicitation. And I will get it to the appropriate person in time.

**Stephanie Fertig:** Great. Thank you so much. I just want to make sure that people know where to go, particularly since we are trying to encourage individuals to make sure to contact the contract officer there. All right. One of the other questions that we received is around the number of awards for the solicitation. So, it's interesting. In the contract solicitation, it talks about the ... It does provide some information, and so someone indicated, "Well, wait a minute.

Does NCI fund only three to five awards for all of their solicitations?" And you can probably put any Institute or Center there, so is there ... How is that handled?

**Callie Prassinos:** I'll probably ask Adam, too, to kind of help me with this question, but it's an estimate on the need and the budgetary restrictions that we have. Correct, Adam?

**Adam Sorkin:** Yeah, effectively. Each Institute and Center approaches this a little bit differently, but yeah, they take a look at what their anticipated budget is for the year and how many projects they expect to ... essentially, Callie covered it ... what they expect to be able to fund there. Things vary. They're not locked into those estimates.

**Callie Prassinos:** Right.

**Adam Sorkin:** But this is their best assessment at time of developing the topic.

**Stephanie Fertig:** "If someone has received a Phase I from one group, could they apply to another agency for Phase II?" And I think in contracts, that's a little bit different. That Phase I to Phase II conversion, again, is very different from the grant process, and I can speak for grants. When you're submitting your Phase II after a successful Phase I, it usually automatically gets assigned to the Institute or Center that funded the Phase I, unless there is a significant shift in the focus of the research. So sometimes, individuals ... And again, this is for grants, and the process of the grant will have a pivot and will end up coming in ... may come in for a Phase II that gets assigned to another Institute or Center. But again, contracts in that Phase II process, very different, unless you'd like to add anything, but I think that's the key here, is that that Phase II submission is a different process than with the grants.

**Callie Prassinos:** Yes, that is correct.

**Stephanie Fertig:** Now, I know you were trying to answer this one, and you got pulled into the Q and A here, but what about letters of support? Are they required? If so, how many, from whom?

**Callie Prassinos:** Yeah, so letters of support is one of the things that will be topic specific as well. You want to look at each topic, and they will list what is needed, but rule of thumb, letters

from subcontractors, consultants, is usually a requirement. Any outsourced activities, any third parties, a letter of support or intent is usually a requirement.

**Stephanie Fertig:** And I did see something also about a letter of intent and asking, "Well, wait a minute. Do we need to support a letter of intent before submission? What would we need to provide prior to submitting the proposal?"

**Callie Prassinos:** So, a letter to intent to propose is not a requirement. It's a recommendation to provide that letter of intent to help the offices know, the agencies know who is coming in for these, but it's not a requirement.

**Stephanie Fertig:** And I think we did address this question about the Single Scientific Review Board that is going to review all of the potential proposals. And if that's not the case, it's not going to be everything in the solicitation, but I do think that's something that is Institute by Institute with regards to the specific topics that they have, correct?

**Callie Prassinos:** Correct. Each agency is going to put together their own evaluation, topic specific. So even in the agency, they will have different review for each topic.

**Stephanie Fertig**: Right, and just to clarify when we're talking about agency here, because sometimes agency versus Institute and Center, do keep in mind HHS is an agency. So, when we're talking about submitting to an agency and duplicate of topics and that ... HHS is the agency. We do have different operating divisions within HHS. We have, in this case, CDC and NIH, and then within CDC and NIH, we have different Institutes and Centers. It can be a little bit complicated. Sometimes we will use agency more broadly, so I just want to make sure that that's clear and really encourage if you're not sure ... "Hey, I've got a proposal. I've got something under review. Can I submit?" That is a great question to ask if you're not sure. So, I know there are provisions around submitting duplicative applications to an agency, so just, that's why I pointed that out. Question around resubmission. So, in the grant program, you can resubmit. Resubmission is kind of part of the process. What about contracts?

**Callie Prassinos:** So, I'm assuming that the question means after you have provided a proposal already, and you're in the process of ... You haven't gotten an unsuccessful letter yet. The

contracting officer should ... might open up for negotiations and have questions, and then at the time proposals could be revised and resubmitted at that time.

**Adam Sorkin:** And topics are also reissued occasionally between year to year, so you may have an opportunity to come back and address the said topic in a year or two after the initial ... your initial proposal if unsuccessful.

**Stephanie Fertig:** And you can always think about that and turn it around and look at the grant solicitation as well, but it's important to note that even if a topic comes back, it may change. I think we had an example of that this year that was shared earlier, so that's a great ... Again, really important, that number-one tip, read the solicitation carefully, and in particular, read that topic that you're interested in. That's so important as you're looking. You put all that time, effort, and energy into a proposal, please read the topic very carefully. Read the solicitation very carefully. For subcontracts or even for the broader proposals, so for ... How do the reviewers weigh science versus commercialization? How do they ... How is that handled? And again, I think this is a question of grants versus contracts, but I'd say I'd submit again. My guess is it's going to be a lot about the topic and reading the topic very carefully, as some topics may be a little bit more in the early development versus others.

**Adam Sorkin:** And if you do review the RFP, there are very specific evaluation criteria for both Phase I and Phase II proposals that attach specific weights to both the science and the technical merit of each proposal as well as the potential for commercial applications, so this is discussed pretty thoroughly within the solicitation.

**Callie Prassinos:** Yes. I was trying to look for the commercialization section.

**Adam Sorkin:** I believe ... Yeah.

**Callie Prassinos:** But yes, I would definitely look at the solicitation and each topic and how commercialization is related.

**Stephanie Fertig:** Will the topic-specific ... Since we've really been emphasizing asking questions, "Will topic-specific questions that are sent by Friday be addressed to the submitter

only, or will they be made publicly available?" And I think that's a really important question, so I want to emphasize the answer here.

**Callie Prassinos:** To the best of our ability, we would like to answer all questions to the community at whole in this amendment. So, we will try to post all of the questions reworded to desensitize it for the community so everybody gets the same answers. After that, it will be on the contracting officer preference of how they answer any questions after that.

**Adam Sorkin:** And you will be able to find that amendment both on the SEED website as well as the solicitation page at sam.gov.

**Stephanie Fertig:** That said, if you have a question, don't wait, and think maybe someone else will ask it. We really do want you to ask your question. Make sure that you put that ... you send in those questions. There's a question here about whether or not the questions we're answering will be posted alongside the slides or by email to the seminar participants. Again, we do try to take the information that we're pulling together here and put that as much as possible into the amendments. There will be a transcript of this available so you will have that as well, so we do try to make this Informational as public as possible. There was a question around, "Would letters of support, potential customers, potential investors, et cetera, make the application more competitive versus" ... And there was a question ... It's not just letters, but really that question of potential customers, investors, et cetera, not just individuals like subcontractors or consultants.

**Callie Prassinos:** I'm sorry, Stephanie. Letters for everybody, is that what the question is?

**Stephanie Fertig:** Yeah, so there's kind of different kinds of letters of support, right? Obviously, we are interested in ... There's letters of commitment from subcontractors or consultants, but there was a question about letters of support from either potential customers, investors, et cetera, make an applicant more competitive?

**Callie Prassinos:** I think you need to look at the topics to see and look at the technical evaluation criteria and what will be evaluated in the technical evaluation criteria. That's what we will be evaluating on, and if that will help that evaluation, then go for it. But really, it's the

technical approach and it's the science and the criteria that's listed in the solicitation that will be evaluated.

**Stephanie Fertig:** So, I have another question around foreign entities. So, the question was ... This is kind of a two-part question. "Can a small business have ... Can two small businesses come in, one as a prime and one as a subcontractor?" And the answer there is yes. However, there's an additional question: "Can that subcontractor be a foreign entity if there's adequate justification?"

**Callie Prassinos:** Yes? Adam?

**Adam Sorkin:** Typically, it comes down to that adequate justification when we consider a foreign entity. Is it ... Has it really been clearly justified that the service that they're providing is not available domestically and is critical to a successful completion of the program, and how much of a priority the particular project is for a given Institute or Center's needs?

**Callie Prassinos:** Thank you.

**Stephanie Fertig:** So, there was a question here, and I think this is down to submission, a question about, "How do we find the RFAs for each call? Can you provide a link for the RFAs? There's not live links in the solicitation." So, this might be something ... As people are looking to submit their proposals, how does that work?

**Callie Prassinos:** So, submission of proposals are done in the eCPS system, and it's linked in the solicitation. And I can get you the page. And each proposal would be submitted in that system, and there should be a link under each topic to be provided for each proposal. And make sure that each proposal is submitted. If you have multiple, make sure you submit it separately and that that proposal is all-inclusive of the technical proposal, the business proposal and any other attachments that need to be included.

**Stephanie Fertig:** As we're beginning to wrap up, we've got a couple of ... And again, there's a number of very topic-specific questions. I do encourage you to reach out to the specific contract officers about those topics. We had enough general questions here today to fill up the Q and A time, and so we're ... I'm really going to, again, encourage you, please, please, please,

submit those specific topic questions to the contract officer. They're the best person to address those specific questions. We really do encourage you to do so. We can also provide those questions to them, but really, the best way to make sure you get your question answered, email your contract officer. Best way to go. A question was raised about, "For the Phase II, Phase II is invited for submission, how does that work with review if it's not a topic in the current year?" How does that even ... How does that work? And again, I think people are thinking about it from the grant perspective, which is a little bit different. So how does that work for contracts?

**Callie Prassinos:** That's why it's an invitation. So, the program will put together that invitation when they get proposals, and it will go through the same evaluation panels. They will create the panels for that topic, and it will be reviewed ... peer-reviewed by a panel for that topic.

**Stephanie Fertig:** So last couple here, and I think this is a really important one. "Is there a path to propose a topic not covered by the list of current topics but would clearly serve a critical need?" So, what should someone do if they've got ... they know they've got something that's really serving a critical need out there, but it's not on this list?

**Adam Sorkin:** Well, the easiest way to address that is to submit an investigator-initiated proposal to one of our grant Notices of Funding Opportunities. We have three standard receipt dates for our Omnibus solicitations, which accept proposals on any topic of interest to NIH, CDC, or FDA.

**Stephanie Fertig:** And our next receipt date is January 5th.

**Adam Sorkin:** Mm-hmm.

**Stephanie Fertig:** So, it's right around the corner. It doesn't feel like it, but it really is right around the corner. One question here that we received is, "Do you plan to have an additional time for submission given that the time is short? Is there an expectation that there will be maybe another deadline in the future for this solicitation?"

**Callie Prassinos:** No. Unfortunately, at this time, the receipt date is November 14th at 5 p.m. Eastern Standard Time, so that is the deadline for this solicitation.

**Stephanie Fertig:** But again, if you do miss that deadline, there are other grant opportunities that are available to you. And I'm going to end with one last question that someone provided fantastic information. "Are people available post-webinar for follow-ups?" So, I think we're going to try to emphasize it. I think this is such an important point is, after this webinar, as you're reading the solicitation, as you're reading those topics, who can people go to?

**Callie Prassinos:** Definitely the contracting officers that are listed in the solicitation. I am also available if you would like to reach out to me for anything as well.

**Adam Sorkin:** And if you really don't know where to go or would just prefer to ask general questions about the SBIR program or connect to any of our Institutes and Centers, you can always reach out to us at seedinfo@nih.gov, and we will be happy to have that discussion with you or connect you with the appropriate points of contact, as necessary.

**Stephanie Fertig:** Great. Well, with that, I really do want to thank everyone again, all of our speakers, for coming on and talking a little bit about the different contract topics that they have through this year's solicitation. Thank you, Adam, and Callie, for answering questions about the contract process as well as the solicitation. So, with that, we really do encourage you, please reach out, ask your questions. The slides, transcript and ... The slides and transcript and the different information from this webinar will be made available on our website, seed.nih.gov, under past webinars, so you can go on that homepage. You'll see an events tab. There's going to be past events. You can go there. So again, seed.nih.gov, and we will post that information there as well. And for the contract solicitation, please do try to get your questions in. We want to get those questions by Friday, and those will be released as an addendum to the solicitation, so be looking for that as well. And, Callie, how long does it take after Friday for that to be released?

**Callie Prassinos:** We're hoping to get the amendment released in mid-October, so very quickly.

**Stephanie Fertig:** Great. All right. Thank you, again, to all of our speakers, and thanks to all of you for attending today's webinar.