

## AMENDMENT TWO (2)

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### OFFICE OF ACQUISITIONS

National Institute of Allergy and Infectious Diseases (NIAID)  
5601 Fishers Lane, Room 3D35, MSC 9821  
Rockville, MD 20852

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### **PURPOSE OF SOLICITATION AMENDMENT**

The purpose of this amendment is to:

- Provide updated Contracting Officer points of contact for CDC awarding components;
- Revise the Phase II Budget associated with NIAID Topic 074: Development of POC Assays to Quantify anti-Tuberculosis Antibiotics in Blood;
- and Respond to questions submitted by offerors.

**The hour and date specified for receipt of Offers remains unchanged.**

Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full effect.

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**A recording of the pre-proposal conference and associated materials have been posted here:**

<https://sbir.nih.gov/engage/news>

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**The CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) Contracting Officer points of contact, identified in Section 10 of the solicitation, are revised as follows:**

| <b>Original Point of Contact</b>   | <b>Revised Point of Contact</b>  |
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| <b>CENTER FOR GLOBAL HEALTH (CGH)</b><br><br>Theresa Routh-Murphy<br>Contracting Officer<br>Centers for Disease Control and Prevention<br>Office of Financial Resources<br>Phone: (770) 488-2713<br>Fax: (770) 488-2778<br>Email: <a href="mailto:TRouthMurphy@cdc.gov">TRouthMurphy@cdc.gov</a> | <b>CENTER FOR GLOBAL HEALTH (CGH)</b><br><br><b><u>Candice Simmons</u></b><br>Contracting Specialist<br>Centers for Disease Control and Prevention<br>Office of Financial Resources<br>Phone: 770-488-1432<br>Fax: (770) 488-2778<br>Email: <a href="mailto:ie3@cdc.gov">ie3@cdc.gov</a> |

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| <p><b>NATIONAL CENTER FOR CHRONIC DISEASE AND PUBLIC HEALTH PROMOTION (NCCDPHP)</b></p> <p>Julio Lopez, Contracting Officer<br/>Centers for Disease Control and Prevention Office of Financial Resources<br/>Phone: (770) 488-2892<br/>Fax: (770) 488-2044<br/>E-mail: <a href="mailto:JLopez3@cdc.gov">JLopez3@cdc.gov</a></p>      |  |
| <p><b>NATIONAL CENTER FOR EMERGING ZOOONOTIC AND INFECTIOUS DISEASES (NCEZID)</b></p> <p>Priscilla Turner, Contracting Officer<br/>Centers for Disease Control and Prevention Office of Financial Resources<br/>Phone: (770) 488-2821<br/>Fax: (770) 488-2024<br/>E-mail: <a href="mailto:PBTurner@cdc.gov">PBTurner@cdc.gov</a></p> |  |
| <p><b>NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)</b></p> <p>Vallerie Redd<br/>Contracting Officer<br/>Centers for Disease Control and Prevention Office of Financial Resources<br/>Phone: (770) 488-2845<br/>Fax: (770) 488-2847<br/>E-mail: <a href="mailto:GFJ3@cdc.gov">GFJ3@cdc.gov</a></p>                                 | <p><b>NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)</b></p> <p><b><u>Timothy Williams</u></b><br/>Contracting Specialist<br/>Centers for Disease Control and Prevention Office of Financial Resources<br/>Phone: 770-488-2791<br/>Fax: (770) 488-2847<br/>E-mail: <a href="mailto:TPW8@cdc.gov">TPW8@cdc.gov</a></p>         |
| <p><b>OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR)</b></p> <p>Christine Godfrey<br/>Contracting Officer<br/>Centers for Disease Control and Prevention Office of Financial Resources<br/>Phone: (770) 488-2519<br/>Fax: (770) 488-2024<br/>E-mail: <a href="mailto:CNP9@cdc.gov">CNP9@cdc.gov</a></p>                   | <p><b>OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR)</b></p> <p><b><u>Michael Crow</u></b><br/>Contracting Specialist<br/>Centers for Disease Control and Prevention Office of Financial Resources<br/>Phone: (770) 488-3208<br/>Fax: (770) 488-2024<br/>E-mail: <a href="mailto:WYV2@cdc.gov">WYV2@cdc.gov</a></p> |

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**Section 12 Component Instructions and Technical Topic Descriptions**

**National Institute of Allergy and Infectious Diseases (NIAID)**

**Topic 074: Development of POC Assays to Quantify anti-Tuberculosis Antibiotics in Blood**, Phase II Budget description is revised as follows:

Fast-Track proposals will be accepted

Number of anticipated awards: 1-2

Budget (total costs, per award): Phase I: up to \$300,000/year for up to 1 year; **Phase II: up to \$1,500,000 for up to 3 years**

PROPOSALS THAT EXCEED THE BUDGET OR PROJECT DURATION LISTED ABOVE MAY NOT BE FUNDED.

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## **RESPONSES TO QUESTIONS RECEIVED:**

### **General Questions**

**Question 1: How frequently does NIH announce this contract opportunity? When is the next contract announcement?**

*Answer 1: The NIH and the CDC issue one consolidated SBIR contract solicitation per year, generally sometime between June and August of each year. Solicitation PHS-2019-1 is this year's consolidated SBIR contract solicitation – it was issued on July 18, 2018, and contracts will be awarded from this solicitation in fiscal year 2019. These annual solicitations are for initial SBIR awards, and each awarding component independently manages the solicitation process for transitioning awardees from Phase I to potential Phase II.*

**Question 2: Will the next solicitation have the same Topics as this announcement?**

*Answer 2: No, Topics change from year to year. Occasionally, some Topics of great continuing interest will be repeated, although they may have revisions to the specifications. There is no guarantee that any Topic will be offered again.*

*Topics for each year are not released until a preliminary notice is issued, at least 15 days prior to the full solicitation being made available, on <https://www.fbo.gov/> and on <https://sbir.nih.gov/funding>.*

**Question 3: What is the difference between a contract and a grant?**

*Answer 3: Please refer to <https://sbir.nih.gov/apply> for general information on this topic. For this contract solicitation, it is important that you adhere to all the requirements set forth in the solicitation document PHS-2019-1 and its amendments, which provide all the information necessary to submit a successful contract proposal.*

### **Section 4.2 Offeror Eligibility and Performance Requirements**

**Question 1: Are the 2/3<sup>rd</sup> and 1/2 effort awardee effort requirements calculated on an annual basis?**

*Answer 1: The requirements that for Phase I, a minimum of two-thirds of the research or analytical effort must be performed by the awardee; and for Phase II, a minimum of one-half of the research or analytical effort must be performed by the awardee, are based on total contract performance period.*

**Question 2: If a proposed subcontract, such as a CMO for drug-scale up, does not do any 'research', does this work still count as part of the one-third effort that we are allowed to have completed by someone other than the applicant small company?**

**Also, if the applicant small company is doing software development, would this be included in the calculation of the applicant small company's own 'research or analytical effort' in regards to Section 4.2 performance requirements?**

*Answer 2: For this solicitation, we have stated that we will be measuring the 'two-thirds effort' requirement for a Phase I (and the 'one-half effort' requirement for a Phase II) by using the total contract dollars allocated in the budget. All dollars spent toward a subaward of any type will be counted towards the proportion of effort completed by someone other than the SBIR awardee itself. The Government will review the Appendix C budget and total all dollars that will be allocated to the small business applicant's own effort versus all dollars that will be allocated to subcontractor and/or consultant effort, regardless of the nature of that effort.*

**Question 3: Does the number of employees of a subcontractor count against the 500 employee limit for "Small Business Concern" if the Subcontractor IS NOT an Affiliate?**

*Answer 3: No, as long as the collaborating organization (performing a subaward) does not meet the definition of "Affiliate" (as established by federal regulation here: [http://www.ecfr.gov/cgi-bin/text-idx?SID=b02d16dbfcddf646e5c0728d5e632a61&mc=true&node=se13.1.121\\_1103&rgn=div8](http://www.ecfr.gov/cgi-bin/text-idx?SID=b02d16dbfcddf646e5c0728d5e632a61&mc=true&node=se13.1.121_1103&rgn=div8)), the subaward's business size does not have any relevance.*

**Question 4: Can a foreign entity be involved together with a US company?**

*Answer 4: The research or R&D project must be performed in its entirety in the United States. Whenever possible, work outside the United States which is necessary for the completion of the project should be supported by funding other than the SBIR contract. In those rare instances where the study design requires use of a foreign site (e.g., to conduct testing of specific patient populations), the investigator must provide compelling scientific justification in the application for the need and use of a foreign site. Similarly, in those rare instances where it may be necessary to purchase materials from other countries, investigators must thoroughly justify the request. NIH will consider these instances on a case-by-case basis. If requesting a deviation, please clearly state this in your business/pricing proposal AND your technical proposal, along with the scientific justification, to ensure that all parties review the request appropriately. You must receive a written authorization for this deviation at the time of your contract award to be in compliance with SBIR requirements.*

**Question 5: Does the Principal Investigator on the offer need to be a medical researcher? Does the Principal Investigator need to have a Ph.D. or M.D.?**

*Answer 5: The Principal Investigator, and other significant team members, must demonstrate the training and experience necessary to carry out and lead the specific technical approach proposed. Technical personnel proposed will be evaluated for sufficiency to perform the technical approach proposed, and there is not a requirement for any one particular type of background or degree.*

#### **Section 4.14 Prior, Current, or Pending Support of Similar Proposals or Awards**

**Question 1: Can one company apply for two awards?**

*Answer 1: A company may submit only one SBIR/STTR application or proposal to a Department of Health and Human Services (HHS) component for each unique research project. Therefore, a company may submit more than one application/proposal for consideration as long as they are each for separate and distinct projects.*

*You may not submit an application/proposal for a project that is “essentially equivalent” to a project already submitted for consideration for any SBIR funding opportunity within the Department of Health and Human Services. See Section 4.14 of the solicitation document, as well as the definition of “Essentially Equivalent Work” in Section 3.1 of the solicitation document.*

**Question 2: If two contracts are awarded, can clinical studies overlap, as long as requirements of both contracts are met?**

*Answer 2: Two contracts or grants may not be awarded if the work would be essentially equivalent, as discussed above and in the solicitation document. If there is a component of work that could be leveraged for two different, successful research proposals, this should be communicated with Government staff during the pre-award negotiation phase for any affected proposal, so that the Government may incorporate safeguards into the award documents to avoid situations where services rendered could be charged under more than one award.*

**Question 3: If two contracts are awarded, are two PI's needed?**

*Answer 3: The PI on any SBIR proposal/application must be more than 50% employed by the small business applicant company; however, there is not necessarily a minimum percent effort that must be contributed by the PI on each project. During the evaluation process, technical reviewers will review whether the PI commitment to the individual project is found sufficient to successfully complete the work proposed. There is no rule prohibiting a PI 100% employed by the small business from applying 50% effort to one proposed, discrete project, and 50% effort to a separate project – however, each technical review panel will have the opportunity to evaluate whether the proposed effort is sufficient on each individual project, and weaknesses noted in technical evaluation will have an impact on the competitiveness of a proposal.*

*Note, as well: OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.*

## **Section 4.16 State Assistance and Technical Assistance**

**Question 1: We are preparing an SBIR fast track proposal to the current solicitation. Is the Technical Assistance amount of \$5,000 applicable to each year of the project? So, for a fast track, would there be \$5,000 for Phase I and \$10,000 (\$5K each year) for Phase II?**

*Answer 1: The Technical Assistance of up to \$5,000 can be allocated once for each Phase of the SBIR program. Therefore, if you are doing a Fast Track submission, you could include up to \$5,000 for Technical Assistance both in the Phase I budget (via the Appendix C included in the Phase I proposal) and the Phase II budget (via the Appendix C included in the Phase II proposal).*

## **Section 4.17 Payment**

**Question 1: What schedule is in place for distributing monies? What are the Disbursement terms - are they upfront, installments, or reimbursement?**

*Answer 1: For general information on how payments are processed for federal contracting, review Section 4.17 of the solicitation document.*

*Individual contracting officers may use their discretion in setting up appropriate payment schedules. If you are notified that your proposal is being considered for award, you may begin discussing the potential payment schedule with the specific contracting officer point of contact named in that notification.*

## **Section 5 Contract Requirements**

**Question 1: Who owns the intellectual property/technology/capabilities/source code developed under SBIR contracts?**

*Answer 1: Review Sections 5.11, 5.12, and 5.13 of the solicitation document in regards to Copyrights, Technical Data Rights, and Patent Rights. In general, the small business concern normally retains rights and ownership, while the Government is granted a royalty-free license.*

*The Government does typically require the delivery of source code and object code developed, modified, and/or enhanced under a Government contract; however, it will not be used in a way inconsistent with the rights discussed above.*

## **Section 6 Method of Evaluation**

**Question 1: Can your proposal be technically acceptable and not awarded and if so, does that happen?**

*Answer 1: This occurs frequently, as there are often more proposals deemed technically acceptable than there are funds available. Therefore, the Government will consider all of the evaluation factors for award stated in Section 6 of the solicitation document to make funding decisions that are deemed to be in the best interest of the Government.*

## **Section 7.3 Limitation on the Length of the Technical Proposal (Item 1)**

**Question 1: Are links acceptable in the proposal?**

*Answer 1: Technical proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information. Augmentation of the page limit through use of hyperlinks, etc. is not permissible.*

## **Section 7.4 Submission, Modifications, Revision, and Withdrawal of Proposals**

**Question 1: Should registration in eCPS be done by a business leader or the research principal investigator?**

*Answer 1: There is no requirement about which company personnel should register or submit within eCPS.*

## **Section 8 Proposal Preparation and Instructions**

**Question 1: Could you clarify the requirement for a Business Proposal. Is this a proposal for commercialization of the product?**

*Answer 1: It is important to distinguish between the Commercialization component of the Technical Proposal and the Business Proposal. A Phase I Technical Proposal must address potential commercial applications of the product being proposed, as set forth in Section 8.8(A)(7). Likewise, a Phase II Technical Proposal must include a more thorough discussion as part of a Commercialization Plan, as set forth in Section 8.8(B)(9).*

## **Section 8.2 Fast Track Proposal Instructions (NIH Only)**

**Question 1: Do we need to include our CVs for both Phase I and II, if we submit a Fast Track submission?**

*Answer 1: As stated in Section 8.2 of the solicitation, a Fast Track submission must include a complete Phase I proposal and a separate, complete Phase II proposal. These proposals will be evaluated and scored separately and independently of each other. Therefore, Senior/Key Personnel and Bibliography of Directly Related Work should be addressed in your Phase I proposal in accordance with Section 8.8(A)(8), and Personnel should be addressed in your Phase II proposal in accordance with Section 8.8(B)(4).*

## **Section 8.10 Research Involving Vertebrate Animals**

**Question 1: Is it allowed to submit the IACUC approval papers after the October 22nd deadline? If so, what is the latest time for submission of IACUC papers?**

*Answer 1: IACUC approval is required prior to the final award document being issued.*

*Please refer to Section 8.10, to ensure you describe your plan/process for complying with NIH vertebrate animal requirements in your proposal, so that it is clear that you understand the requirements, in the event IACUC is not completed at the time of proposal submission.*

## **Section 8.12.8 Plan for Single Institutional Review Board (sIRB)**

**Question 1: Is IRB approval required before a notice of award is received?**

*Answer 1: It is not required that IRB approval be obtained prior to contract award/project start date. IRB approval must be obtained prior to any human subjects research activity beginning, however.*

*Also, please be sure to review the NIH's single IRB policy, to make sure that you plan to be in compliance, as discussed in SBIR solicitation PHS 2019-1.*

## **Section 8.12.15 Inclusion of Women and Minorities in Research Involving Human Subjects and Inclusion of Children in Research Involving Human Subjects**

**Question 1: The link provided in the NOTE referring to the Inclusion Enrollment Report, in accordance with the Office of Management and Budget (OMB) Directive No. 15, no longer works. Is an updated link available?**

*Answer 1: <https://wonder.cdc.gov/wonder/help/populations/bridged-race/directive15.html>*

## Section 12 Component Instructions and Technical Topic Descriptions

### NATIONAL CANCER INSTITUTE (NCI)

#### *National Cancer Institute (NCI), Topic 385: Leveraging Connected Health Technologies to Address and Improve Health Outcomes of Long-Term Cancer Survivors*

**Question 1: Does the solicitation apply only to solutions that are directed at only cancer survivors (post active cancer treatment), or it accepts also solutions built for patients ON treatment which can be extended to patients eventually surviving post treatment?**

*Answer 1: In response to your question, NCI would clarify that this topic is intended to be directed at long-term cancer survivors, not patients on treatment, since the needs are different.*

**Question 2: What is the definition of “long-term” survivor? Or patients who are no longer on active cancer treatment?**

*Answer 2: A long-term survivor is no longer on active treatment for their cancer. They are no longer receiving chemotherapy, radiotherapy or immunotherapy. Long-term breast cancer survivors may still be on Tamoxifen or aromatase inhibitors. Long-term can include months or years after active treatment ends. Most patients exiting active treatment are provided survivorship care plans but survivors that are 2, 5, or 10 years from treatment are likely to be lacking that information.*

**Question 3: I was wondering if a mobile app connecting cancer survivors with patient navigators and allowing for collecting of PROs would meet the definition of “connected health technology” for PHS 2019-1 Topic 385? Or is this RFP is asking specifically for wearables and more automated collection of biometrics data?**

*Answer 3: Topic 385 is not specifically limited to wearables and other automated collection of biometrics data. Topic 385 seeks novel and essential approaches to improve the quality of life for long-term cancer survivors, enhance care quality and effectiveness, provide real-time feedback to cancer survivors, and allow care delivered beyond clinic walls into the home setting, ultimately aiming to improve patient outcomes. NCI is not specifying how it would be accomplished. NCI is seeking to capitalize on a rich portfolio of research in meaningful ways to enhance symptom management, timely patient-centered clinical care, and improve health outcomes for cancer survivors -- particularly those who are managing the late and long-term effects of cancer treatment and transitioning to primary and community-based care.*

**Question 4: Is an app that is a specific application of the components identified in the contract call, such as a specific intervention that includes monitoring of certain symptoms, connectivity with a sensor device, and communication to providers appropriate or are they only seeking broad and comprehensive applications?**

*Answer 4: NCI would advise that it would consider such a project to be within the scope of the Topic. We would further note that a proposal does not need to be all-inclusive in terms of cancer symptoms to be considered appropriate for consideration under this Topic.*

#### *National Cancer Institute (NCI), Topic 386: Novel Approaches for Local Delivery of Chemopreventive Agents*

**Question 1: We would like to propose the use of an agent that does not have FDA approval for chemoprevention; however, there are a few clinical trials and publications that have shown promising results. Would this be considered for award under Topic 386?**

*Answer 1: According to the Topic Description for Topic 386, novel chemoprevention agents that have not been approved by the FDA for prevention will be considered for award. Adequate justification for the appropriateness of an agent for chemoprevention is critical. Offerors should demonstrate significant reduction in cancer incidence in suitable cancer prevention animal models. During the technical evaluation process, the peer review panel will assess the validity of the chemopreventive agent in the form that the investigator is proposing, for the cancer type that the offeror is proposing to address.*

**Question 2: We are seeking to develop new therapeutic compounds for chemoprevention but were not sure if that qualifies for the 386 contract topic.**

*Answer 2: New chemoprevention agents are acceptable for NCI SBIR Topic 386, as long as it is focused on local delivery and focused on prevention and not treatment.*

***National Cancer Institute (NCI), Topic 389: Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts' Radiation Therapy Planning for Prostate Cancer***

**Question 1:** We have a question about the following statement in the topic description:

**“Companies must already have a dataset including patients in the 3 risk groups, including radiation data and outcome (at least one year post treatment to assess toxicity) in hand before Phase I starts.”**

**Question: Can an offeror refer to a collaborator's dataset for the purpose of the proposal, and if the funding is granted, can that data be used for the project?**

*Answer 1: NCI is not concerned with who owns the data – it is sufficient if the SBIR offeror has access to an appropriate data set and documents permission from the organization who owns the data to use it for the project being proposed.*

**Question 2:** A question regarding the 3 expert teams required by NCI Topic 389: Could the three experts come from the same medical school, or must they come from the different organizations?

*Answer 2: NCI would not find it objectionable to have the 3 experts come from the same medical school for Phase I of the project.*

***National Cancer Institute (NCI), Topic 390: Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators***

**Question 1:** Would a novel in vitro cell-free DNA quantification method suitable for development into a high throughput clonogenic platform be within the scope of Topic 390?

*Answer 1: This Topic is focused on clonogenic assay that can be done through a robust HTS approach. Hence, an alternate assay is not appropriate for this Topic. You are encouraged to review the SBIR/STTR omnibus grant funding opportunity announcements, which can be viewed at <https://sbir.nih.gov/funding>.*

***National Cancer Institute (NCI), Topic 395: Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia***

**Question 1:** Would a proposal be eligible for award if the proposal did not yet have IP established for a lead agent before submitting the proposal, but the Phase I research would seek to initiatively screen for antibodies?

*Answer 1: A Phase I cachexia project plan that includes identifying leads on a validated target that will be patentable would be eligible for award under Topic 395. It is advised that proposals discuss how the leads will be patentable. Animal efficacy studies do need to be proposed in Phase I, as well.*

***National Cancer Institute (NCI), Topic 396: Imaging for Cancer Immunotherapies***

**Question 1:** Is Topic 396 imaging for preclinical research and/or imaging for the clinic?

*Answer 1: Either preclinical or clinical research & technology development or the combination of both in the areas of imaging for cancer immunotherapy would be within the scope of SBIR Topic 396.*

**Question 2:** Would creation of an MRI compatible version of a technology that can generate a dynamic oxygen supply, be within the scope of Topic 396, in the sense of being able to modify the BOLD tumor baseline and

**achieve higher contrast and more information by going from hypoxic to hyperoxic states? Or, would this be a better fit under the NIH SBIR Omnibus Grant Funding Opportunity Announcement?**

*Answer 2: If the MRI compatible version could be used to identify patients who are likely to respond to cancer immunotherapies, evaluate the efficacy and potential toxicities of the treatment, and/or monitor cancer patients' treatment prognosis, the proposal is responsive to the SBIR contract topic 396. However, if the proposal will only focus the technology development on being able to modify the BOLD tumor baseline and achieving higher contrast and more information by going from hypoxic to hyperoxic states, the application should target the NIH SBIR Omnibus Grant Funding Opportunity Announcement.*

**Question 3: Instead of a new imaging modality to predict response to immunotherapy, would a machine learning algorithm that interprets whether a patient will respond or not based on a scanned pathology tumor slide fall under this contract description?**

*Answer 3: Yes, a proposal to build an imaging-based machine learning algorithm that could interpret whether a patient will respond to cancer immunotherapies or not based on a scanned pathology tumor slide would fit into the scope of SBIR Topic 396.*

### **NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)**

***National Institute on Alcohol Abuse and Alcoholism (NIAAA) – Topic 016: A Wearable Alcohol Biosensor that Quantifies Blood Alcohol Concentration in Real Time***

**Question 1: What does the NIH see as the eventual scope and specific uses of any resulting device?**

*Answer 1: The scope is to measure, record and store blood alcohol levels in real-time. As stated in the contract solicitation, "It is envisioned that wearable alcohol monitors will serve useful purposes in research, clinical, and treatment settings, may play a role in public safety, and will be of interest in the consumer market to individuals interested in tracking personal health parameters".*

**Question 2: Specifically, are any such devices intended to be used in a monitoring facility, such as an institution, or for general public use?**

*Answer 2: We don't intend to limit the use. Offerors should fully justify the intended use of the device proposed. However, the criminal justice market is already adequately covered by several other business concerns and is not NIAAA's intended market. NIAAA's intention that the use of the alcohol biosensors will always be voluntary, whether in treatment, research, or the consumer market.*

**Question 3: Will the devices be allocated and their use supervised, or will it be left to the individual?**

*Answer 3: NIAAA's intention that the use of the alcohol biosensors will always be voluntary. The small business that develops them may sell them to whomever they wish. It is the goal of the SBIR program for the Small Business to take the product to commercialization.*

**Question 4: What is the target user demographic?**

*Answer 4: The device should be appealing to all demographics but the target demographic should be clearly articulated in your proposal. Per the solicitation, "Proposals should identify the intended target audience(s) and provide the rationale for their design decisions regarding both technology and form factor".*

**Question 5: Is the device intended to be discreet, disguised or to be worn openly?**

*Answer 5: As stated in the contract solicitation, "The device should be inconspicuous, low profile, and appealing to the wearer. The design can take the form of jewelry, clothing, or any other format located in contact with the human body". As Offerors, you will determine the form factor, so it is your choice on whether to propose a disguised design or something that people would be willing to wear openly. Since there are so many other*

*measuring devices on the market, an alcohol biosensor could easily blend in. NIAAA's goal is that the device avoid causing stigma.*

**Question 6:** **Apart from alcohol monitoring, does the user receive other motivations or benefits?**

*Answer 6: Additional uses are up to the Offeror.*

**Question 7:** **Is the device output to alert the user, or report to a base station or their handler?**

*Answer 7: This answer depends on the intended use of the biosensor. Proposals supporting either function will be considered.*

**Question 8:** **Is the device intended to be worn during sleep?**

*Answer 8: To be broadly marketable for all uses, we would prefer a device that could be worn during sleep but intent of use dictates the necessity and should be fully addressed in your proposal.*

**Question 9:** **Can we explore three different approaches under one SBIR? This is with respect to measuring three different alcohol vectors.**

*Answer 9: NIAAA will not limit the approach taken by the Offeror as long as it fits within the budgetary guidelines expressed in the RFP.*

**Question 10:** **Is the device intended to be worn for long periods, say, greater than 8 hours?**

*Answer 10: In general, the device should be constructed for long term wear. For example, if intended use is for research treatment programs, we would prefer 24 hour wear for weeks or months at a time.*

**Question 11:** **Would it be reasonable for a user to have two devices, one being worn, while one is on charge?**

*Answer 11: Yes – as long as the two devices are synced and provide a continuous data stream.*

**Question 12:** **How often should the device wake up and sample?**

*Answer 12: The sampling frequency is dependent upon the technology proposed. As a guideline, the devices currently in use in the justice setting sample every 30 minutes, but NIAAA would prefer real time monitoring, that would be more frequent than that for our purposes.*

**Question 13:** **Is the output result an alarm (threshold exceeded) or an alcohol (say, BAC) value?**

*Answer 13: The output is primarily the BAC value. This value might (or might not) then be used to set off an alarm, in treatment settings, for example. For research settings, no alarm would be necessary. Ideally, the alarm could be activated for either or completely deactivated.*

**Question 14:** **What level of accuracy is acceptable?**

*Answer 14: We'd like to be able to discriminate intake (consumption) at the 1 standard drink level. The standard (SCRAM) has been 85% accuracy level. The solicitation states that the achievable levels have not yet been demonstrated, so your proposal should state your intended limit of detection, say 0.02% BAC, 0.06%, or whatever is achievable.*

### ***National Institute on Alcohol Abuse and Alcoholism (NIAAA) – Topic 017: Data Science Tools for Alcohol Research***

**Question 1:** **For the "Data Science Tools for Alcohol Research" topic of PHS 2019-1, four Phase 1 activities and deliverables are listed. Are you seeking proposals that address all four of these deliverables, or would a proposal that focuses on a single one be appropriate?**

- Answer 1:* The deliverables that are listed are possible deliverables. NIAAA looks forward to receiving proposals that can cover any or all of those possible deliverables.
- Question 2:** The proposal mentions electronic health records (EHRs) as one of the data types in which NIAAA has supported studies; what EHR record sets, if any, are available via NIH or NIAAA either publicly or specifically through this contract?
- Answer 2:* There are several existing research networks that would be possible partnership opportunities with researchers who have access to electronic health records and an interest in addiction/prediction/treatment outcomes. A few examples are:
- (NIH-funded) Health Care Systems Research Collaboratory, <https://commonfund.nih.gov/hcscollaboratory>
  - (NIH-funded) Clinical and Translational Science Awards (CTSA) Program, <https://ncats.nih.gov/ctsa/about/hubs>
  - Health Care Systems Research Network, <http://www.hcsrn.org/en/>
- Question 3:** Is there any value in extraction of information from study texts?
- Answer 3:* Possibly, the value is dependent upon the type of tool.
- Question 4:** Are there specific questions you want answered with regard to integrative analysis deliverable and software applications deliverable? Are there ongoing NIAAA studies or grants that these tools could or should support that could be identified in term of targets for analysis algorithms and tools?
- Answer 4:* NIAAA is interested in analysis approaches and tools that can integrate data (i.e. genetic, social, economic, EHR, treatment approaches) to predict the development of alcohol use disorder, or the effectiveness of interventions the reduce or delay the onset or progression of alcohol use disorder, or guide effective treatment and management strategies for alcohol use disorder, including recovery and relapse.
- Question 5:** Is building an integrated /aggregated database within scope of 'software applications'? Or interfaces on top of existing databases only?
- Answer 5:* All funded NIAAA studies can be found in the public database, NIH RePORTER, <https://projectreporter.nih.gov/reporter.cfm>. Multiple studies of brief interventions of binge drinking in college students are an example of multiple datasets.
- Question 6:** Does a tool for AUDIT-C / use-assessment fall within the 'improving data collection' category?
- Answer 6:* Yes
- Question 7:** This topic is very broad in range, can you clarify the goals NIAAA has for outcomes of this project?
- Answer 7:* NIAAA is interested in analytical approaches and tools that can integrate data (i.e. genetic, social, economic, EHR, treatment approaches) to predict the development of alcohol use disorder, or the effectiveness of interventions the reduce or delay the onset or progression of alcohol use disorder, or guide effective treatment and management strategies for alcohol use disorder, including recovery and relapse. One possible example is a tool that assists researchers in developing a risk algorithm for alcohol use disorder when researchers combine multiple existing data sets. The tool could parse out age, sex, quantity/frequency/binge alcohol use, consequences and other risk factors.
- Question 8:** Will NIAAA be able to provide programmatic (API or other) access to NIH public databases or will this information need to be aggregated in another way?
- Answer 8:* Open or controlled access to public databases is dependent upon the data access committees for each database or data archive. Requests for access should be submitted to the committees. Potential archives that contain NIAAAA data are the database of Genotypes and Phenotype, dbGaP, <https://www.ncbi.nlm.nih.gov/gap>, Collaborative Studies on Genetics of Alcoholism (COGA), <https://niaaagenetics.org/>, National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC-III), and the NIMH Data Archive, NDA, <https://data-archive.nimh.nih.gov/>. As per notice, NOT-AA-18-010,

<https://grants.nih.gov/grants/guide/notice-files/NOT-AA-18-010.html>, NIAAA expects investigators and their institutions to submitting grant-related human subjects data to a NIAAA-sponsored data repository, for all applications submitted after January 25, 2019.

## **NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)**

### ***National Institute of Allergy and Infectious Diseases (NIAID), Topic 067: Methods Improving HIV Protein Expression: Cell Substrate and Protein Purification***

**Question 1:** Is CHO the only cell substrate accepted for the improvement of HIV Env protein expression for this topic? Is it acceptable to submit the improvement of the antigen expression in a cell line such as BHK-21?

*Answer 1:* Other cell substrates are acceptable for generating HIV Env protein as long they comply with the FDA Regulations and Guidance. Specifically, BHK-21 (baby hamster kidney cells), like any cell substrate for GMP manufacturing, must be demonstrated to have been free of viral contamination (e.g., Adventitious viruses, endogenous viruses. etc) and controlled exposure to animal derived products as per FDA Guidance for Industry Q5.

### ***National Institute of Allergy and Infectious Diseases (NIAID), Topic 073: Mobile Health Point-of-Care Diagnostics***

**Question 1:** I would like to ask if the diagnostic POCT tool can be a standalone analyzer that is integrated with a smartphone application that receives and explains results, and other features of the sort? Or do all of the projects under this solicitation have to have a smartphone capable of POCT analysis?

That is, can analysis be done through a remote analyzer which is its own system, that is then accompanied with a smartphone application to contain features such as that mentioned above or if the analysis had to be integrated with the application.

*Answer 1:* Our response is that the integrated smartphone should be capable of analysis. Therefore, under this solicitation, the POC diagnostic itself should not be a standalone analyzer.

**Question 2:** The solicitation topic lists tuberculosis, malaria, distinguish between influenza and respiratory pathogens, river blindness, bacterial and viral pneumonia, as particularly interested areas. Do we need to develop software to diagnose all these diseases, or we can address only one disease (such as malaria)?

*Answer 2:* You can address/select one disease to submit in your proposal.

### ***National Institute of Allergy and Infectious Diseases (NIAID), Topic 074: Development of POC Assays to Quantify anti-Tuberculosis Antibiotics in Blood***

**Question 1:** Topic 074 states the Budget of Phase I: up to \$300,000/year for up to 1 year; Phase II: up to \$1,500,000/year for up to 3 years. Please clarify if this means for Topic 074 the budget would be \$4,500,000 for 3 years?

*Answer 1:* For Topic 074, the budget is changed to read: Phase I: up to \$300,000 for up to 1 year. Phase II: up to \$1,500,000 for up to 3 years.

### ***National Institute of Allergy and Infectious Diseases (NIAID), Topic 075: POC Diagnostic for Gonorrhea and Determination of Antimicrobial Susceptibility***

**Question 1:** Are you looking for molecular-only techniques in this solicitation, or willing to consider alternative techniques (e.g. optical methods using aptamers as capture mechanism?)

Answer 1: NIAID is not limiting the techniques employed by the Offeror to molecular techniques.

**Question 2: Development of rapid (<1 hour) POC diagnostic: is 1 hour the time limit for antibiotic susceptibility testing as well as determination of pathogen?**

Answer 2: The goal is for the final product to identify *N. gonorrhoeae* and determine antibiotic susceptibility in <1 hour.

**Question 3: Would renting lab space and paying for supplies count toward the 67% of work we are to perform?**

Answer 3: Yes.

## **NATIONAL INSTITUTE OF DRUG ABUSE (NIDA)**

***National Institute of Drug Abuse (NIDA), Topic 165: DEA-Compliant Drug Detection and Deactivation Technology to Deter Opioid Theft in Hospitals for Next Generation Controlled Substance Diversion Prevention Program (CSDPP)***

**Question 1: For the purposes of this contract, in meeting the commercialization requirement, we are working with skilled nursing facilities and/or assisted living facilities where an estimated 50% of patients consume controlled substances. Would these facilities qualify as a “hospital”?**

Answer 1: Yes. Any medical facility that handles opioids and is required to meet DEA requirements for documentation of disposal would qualify as a hospital for this topic.

***National Institute of Drug Abuse (NIDA), Topic 166: Leveraging Health IT Solutions to Combat Opioid Misuse***

**Question 1: On Page 52, there is a note as follows: For all proposals, complete the Inclusion Enrollment Report, and use ethnic and racial categories, in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: [http://www.whitehouse.gov/omb/fedreg\\_notice\\_15](http://www.whitehouse.gov/omb/fedreg_notice_15) .**

**This link no longer works. Please provide the link to the latest version or the version of the OMB Directive No. 15 that we are required to use.**

Answer 1: <https://wonder.cdc.gov/wonder/help/populations/bridged-race/directive15.html>

**Question 2: In what way, if any, will the U. S. Department of Health and Human Services, The National Institutes of Health and the Centers for Disease Control and Prevention assist in marketing commercially the product developed by the contractor?**

Answer 2: The government will not assist in the marketing of your technology. You are expected to do those activities yourself or acquire those services.

**Question 3: The topic mentions multiple data sources that may be available for use in Phase I. We are interested in using a specific data source but have only been able to find detailed data through a commercial source. As an offeror on this Topic, would it be possible to access the detailed data free of charge?**

Answer 3: For proposal purposes, please assume that you will need to use the commercial source. Without having your technical proposal we cannot determine the scale of the data set needed and cannot commit to being able to provide the data set free of charge. The cost of the data from the commercial source can be included in your pricing proposal as a direct cost.

## CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

### CENTER FOR GLOBAL HEALTH (CGH)

#### *Center for Global Health (CGH), Topic 010: Multiplex Detection of Recent and Prior Exposure to Pathogens*

**Question 1:** As I scanned through the list of topics in the solicitation, I thought we can apply for the item CDC/CGH 010: Multiplex detection of recent and prior exposure to pathogens. However, I noticed the description on this item seems to focus on antigen detection, not detection of pathogen DNA. I wonder if I could submit a proposal focusing on development of multiplex assays for pathogen DNA detection?

*Answer 1:* The purpose to develop this specific approach is to support the public health surveillance and response program in resource constraint settings through direct detection of multiple pathogens and associated different antibody or immune responses in single assay without requiring to perform additional steps such as nucleic acid extraction and amplification (e.g. Detection of Arbovirus NS1 Antigen, IgG, IgM in single assay).

#### *Center for Global Health (CGH), Topic 011: Preservation of Supply Quality During Unmanned Aerial Vehicle (UAV) Transport*

**Question 1:** Is there a specific drone or drone size that the CGH is considering for this task? If not, is there a cargo carrying capacity you desire, like up to 2 lbs? Drones that can carry more cargo are also more expensive. For instance, an \$18,000 drone can carry 20 lbs but a \$100 drone can barely carry 1 oz (0.0625 lbs) if its camera is removed. More expensive drones can also fly for longer time and a greater distance. If given a box weight range, we can provide a couple of box options.

*Answer 1:* The primary goal of project is to engineer a “lightweight transport box” prototype which is suitable for the transport of perishable materials (with particular interest in clinical specimens, vaccines, reagents etc.). Although no specific carrying capacity of transport box is specified, a reasonable “maximum” cargo capacity for realistic field transportation of such materials in public health settings should be proposed in the prototype development and testing (e.g. X number of blood specimens or vaccine vials).

**Question 2:** What is meant by “impervious to outside temperature”? Are you looking for an actively cooled box (i.e. a flying refrigerator which will drain the battery and reduce range) or simply an insulated box that will keep contents cool for a short duration (time of flight to destination)?

*Answer 2:* It meant to build an innovative approach to maintain the desired temperature of cargo (specimens, vaccines, reagents) during the time of flight duration under different outside temperatures. The project is desired to promote the best innovative ideas which will maintain the desired temperature of proposed cargo while maintaining maximum carrying capacity and flying distance.

**Question 3:** What is meant by “highly secure”? Are you looking for a flying safe that cannot be opened without a key or code (very heavy), a box that can withstand a 30 ft drop without opening but cannot withstand hammer blows, or would a cloth bag that is water resistant be sufficient? The heavier the box, the less cargo it can hold and the less distance the drone can fly before draining its battery.

*Answer 3:* Transport box security and integrity should be measured against all disruptive conditions (falling, fire, immersion, etc.). It includes a security key or code protected to protect cargo in case of drone crashes. The project won't expect to withstand intentional destruction like hammer blow etc.

**Question 4:** How long would the contents need to be kept at the “adequate ambient temperature”? For hours or just for the flight time (less than 30 minutes)?

*Answer 4:* It depends on the proposed functionality of drone by the applicants. The project desires a product capable to withstand the longest flight time (and distance) while maintaining a reasonable cost for public health programs in resource-constraint settings.

**Question 5: Does the transport box need to be detachable to be left at the delivery location or does it stay with the drone and is opened after landing?**

*Answer 5: As long as the transport box fulfills the required specifications such as temperature control, airtight, light weight, secure etc., it can be either detachable or stay with the drone.*

**Question 6: For the fire disruptive condition, I am assuming this is for a drone that flies through a wildfire briefly and not for sustained exposure. Is this correct? The drone itself cannot endure much heat. Is the box expected to be left at a location and survive if a wildfire burns through that location?**

*Answer 6: The project only expects natural outdoor temperatures in different geographical locations such as hot and humid countries where drone operation is feasible. The project won't require to test in extreme sustained exposure like wildfire or volcano explosions etc.*

**Question 7: What is the size (volume) of the items to be transported? Are we talking about a couple of vials and syringes or bags of blood and jugs of water?**

*Answer 7: The project is flexible to accept proposal with different carrying capacity depending on the payload capacity of drone which can be used for public health programs in resource constrained settings. The applicants can propose as scalable container size (e.g. small, medium, large containers) as proof of concept.*

**Question 8: Would a transport box that can also carry an extra battery for extended range but reduced cargo be attractive?**

*Answer 8: This project will only focus on development of transport box with maximum carrying capacity for specimens, vaccines, test kits etc. in desired conditions as stated in the project goal. The providing extra battery (ies) will be arranged via separate mechanism.*

**Question 9: What is the general Concept of Operations of the intended application? Is the box intended to be deployed while in flight? Or landed and handled by ground personnel? The reason I ask this is because of the of the call out for integrity “against all disruptive conditions (e.g., falling, fire, immersion, etc.)”. And is there a set of baseline metrics to be considered in relation to temperature control, impact rating, immersion depth, etc.?**

*Answer 9: The intended application is to transport patient specimens, vaccines, test kit reagents and enzymes etc. safely and securely using a rotor and hybrid style drone with vertically take-off and landing capacity (VTOL). No baseline metrics was provided to give the applicants with opportunity to invent scalable and feasible proposals. However, the temperature control should fulfill the standard cold chain required for laboratory specimens, vaccines and reagents etc.*

**Question 10: What sort of payload capacities should be expected and over what distance/time of flight should the UAV be able to carry it? This is important in determining whether the transport box will need active or passive temperature control (i.e. using TECs and/or solely relying on good insulation techniques).**

*Answer 10: The Phase I project will mainly focus on the transport box design suitable for commercial drones (not expensive military type drones) with optimal payload and flight distance options for public health use. The innovators may propose different combinations (i.e. trade-off between payload and flight time) while maintaining the temperature stability for >8 hrs to days as described in the solicitation.*

**Question 11: The topic also calls for testing in “a controlled environment, and mimic extreme outdoor temperature and weather conditions while the internal transport box integrity and temperature of its contents is monitored.” Is there a set of standards to be followed in relation to these desired tests?**

*Answer 11: No benchmark is set to maximize receiving proposals with all possible innovative ideas from small businesses. At minimum, current recommended transportation conditions required for clinical specimens, vaccines and reagents should be fulfilled.*

**Question 12: We would like to inquire about your expectations regarding the Phase I goal. The solicitation requires that the drone to be used meet the “current national aviation regulations for weight,” which puts a total limit of 55 pounds on the drone plus cargo as defined by the FAA.**

*Answer 12: Phase 1 goal is only focusing on achieving the innovative designs of drone transport box to transport of clinical specimens, vaccines, lab reagents and enzymes. Successful Phase 1 product may receive opportunity to implement Phase 2 activities which include compliance with FAA regulatory requirements as well as desired payload and flight time to support public health response activities in the field.*

**Question 13: Given the assumed 55lbs gross take-off weight limit, what are your expectations of the weight of the cargo and the range the vehicle must cover? A key trade-off is often driven by the split between battery/energy weight (resulting in more or less range of the vehicle) versus cargo weight (resulting in more or less stuff the vehicle can transport).**

*Answer 13: Our basic assumption is that by successfully designing the transport box with required specifications (temperature control, security etc.) to transport intended shipment in Phase 1, there will be ample opportunities for further development of a scalable transport systems which can be deployed with different types of drones for optimal payloads and flying distances needed in different field deployment conditions.*

**Question 14: If the vehicle is meant to carry tissue or organs, is there an idea which organs these might be?**

*Answer 14: Clinical specimens could be ranging from blood, body fluid specimens for culture and molecular diagnosis to small tissue biopsy specimens obtained from the affected individuals or animals. It won't include whole organs for the shipment.*

**Question 15: Are smaller (highly adaptable - 3D printed - low cost - possibly disposable/expendable) vehicles able to deliver items like insulin or epinephrine also of interest?**

*Answer 15: As far as the proposed product specifications meet the required parameters stated in the solicitation (i.e. airtight, temperature control and secure), we welcome to receive all possible innovative ideas and proposals. Although cost of production is not included in the solicitation, it will be an important consideration for successful commercialization potential criteria during the proposal review process.*

## **NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)**

### ***NCCDPHP, Topic 041: Community Based Worksite Wellness App Linking Employees to Wellness Resources***

**Question 1: Who will own the app once it is developed? Will this app be integrated into the CDC's workplace health promotion website?**

*Answer 1: The Contractor will own the innovation/product once developed. The developed app is not expected to be integrated into the CDC's workplace health promotion website.*

**Question 2: What data or resources will be provided to develop the app?**

*Answer 2: The funded SBIR awardee will have the contract funds to allocate to the project as outlined in the contract proposal for staffing and other resources. CDC may provide information on known wellness resources if available during the project period.*

**Question 3: After the feasibility study is completed on a selected population in Phase I of the contract, will there be a Phase II to promote the app nationwide? Will we be compensated by participation or will we be a paid as a web app operator?**

*Answer 3: All funded Phase I awards who are able to successfully establish the technical merit, feasibility, and commercial potential of the proposed R&D effort would be eligible to apply for a Phase II to continue the R&D efforts initiated in Phase I.*

**Question 4: What are the expected measurable outcomes or benchmarks for the app?**

*Answer 4: The solicitation outlines the overall goal of the application and outlines the desired capacity of the app for businesses in the Project Goals section. In addition, in the Phase I Activities and Expected Deliverables section, specific requirements for the app are described including details for the interface and the website wireframes with interface requirements within five specific deliverables for Phase I.*

**Question 5: Will we be involved or responsible to evaluate the effectiveness of the app and its impact on the outcomes and success metrics?**

*Answer 5: Typically, evaluation of a product and its impact on outcomes and success metrics are a part of a Phase II application.*

**Question 6: Is there someone to whom we could send an executive summary to receive feedback? With this contract opportunity, we are eager to ensure that our proposal meets the wants and expectations of NCCDPHP and its people, so any possibility of pre-application feedback would be helpful if available.**

*Answer 6: In order to maintain the integrity of the procurement process we are unable to provide feedback on an executive summary nor can we provide any pre-application feedback.*

**Question 7: If phase I is awarded and deliverables are satisfactorily met, is 041 eligible for Phase II funding or does it have to move straight into the commercialization phase?**

*Answer 7: All funded Phase I awards that are able to successfully establish the technical merit, feasibility, and commercial potential of the proposed R&D effort would be eligible to apply for a Phase II to continue the R&D efforts initiated in Phase I.*

**Question 8: Can a multi-entity collaboration/partnership be the “contractee” or does it have to be a sole entity? If it is a sole entity, are all other collaborators considered subcontractors or is the sole entity considered the backbone organization that receives the contract funding but collaborating partners are not necessarily subcontractors?**

*Answer 8: It would depend on how the collaboration/partnership decides to submit its proposal. If the contractor is submitting as a sole entity, the sole entity would be the primary contractor with any collaborators from other organizations would be subcontractors. If the collaboration partnership proposes as a joint venture, said joint venture would need to have a formal agreement and be registered in SAM.gov with its own DUNS number, and financial account.*

*Please refer to Section 4.5 of the solicitation for further information regarding Joint Ventures and Limited Partnerships.*

**Question 9: Regarding the commercialization/ownership of the end product by the contractee, what is the scope of CDC’s use of R&D acquired through development by contractee once commercialized? Does CDC promote use to others who then license through contractee?**

**Can CDC just give R&D and/or licensing to anyone at their discretion without involving the contractee?**

*Answer 9: As described in Section 5.13 of the solicitation, the Government receives a royalty-free license for any invention developed with Government support for its use, reserves the right to require the patent holder to license others in certain limited circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 USC 205, the Government will not make public any information disclosing a Government-supported invention to allow the awardee to pursue a patent. Thus, CDC will seek a royalty-free license to use and modify a commercial end product that will be developed from a funded SBIR, but will not promote or market the contractor product to other who then will license through the contractor. Marketing promotion of any successful product resulting from a SBIR award will be the responsibility of the contractor. CDC does not intend to R&D and/or license to anyone at their discretion without involving the contractor.*

**Question 10: Regarding a joint venture, do the parties involved in the joint venture need to formalize into a new entity that acquires a financial account, DUNS #, etc? Or can one of the parties involved in the joint venture be named the fiduciary agent, using their duns # and account?**

*Answer 10: If the parties submitting a proposal do so as a joint venture, the joint venture needs to be a formal entity with its own financial account, DUNS number, SAM.gov Registration, etc. The resulting joint venture would also need to qualify as a small business concern.*

**Question 11: There appears to be no “gold standard” for measuring muscle tone. Additionally, all of the methods appropriate for infants are highly subjective and rely on a person skilled-in-the-art to make an assessment based on range of motion or resistance to movement. Does the CO or TPOC have suggestions or recommendations for a preferred approach for muscle tone assessment?**

- a. The solicitation mentions the device should be single use. By stating this, do you mean that single use is to use the device for an infant during the full length of their stay in the hospital? To be clear, a different interpretation could be that single use means a device is replaced every 12 hours so that the data is captured for 12 hours without interruption.
- b. What type of device is preferred for readout and evaluation of the data? Is a smart phone or tablet acceptable as a Phase I demonstrator?
- c. What is envisioned for the long term for a readout/evaluation device? A mobile, handheld device, mobile room-based unit similar to an EKG/SpO2 system or a direct-to-the-hospital network approach?
- d. What are the expectations for data transmission frequency from the wearable device to a reader?
- e. What is the expected frequency of data analysis and evaluation? Once every hour? Once every 8 hours? Once every 24 hours?
- f. Are there any preferred wireless communication protocols that should be used in Phase I and subsequently leveraged for commercialization? How far is “far enough” for wireless readout?
- g. Are there any body locations that should be avoided or targeted for attachment of the wearable device to the infant?
- h. Clinical trials are not accepted for Phase I. Is there a suggested approach for demonstration of the developed device?
- i. Does the device need to reject any noises (e.g. adult conversation)?
- j. Does the device need to determine if the newborn is being held or changed or moved?
- k. Newborns are commonly swaddled to prevent flailing. Are there any opportunities for measurement of tremors if the newborn is wrapped up?
- l. Is there any guidance or good references for decoding sensor data into a diagnosis?
- m. Is there any non-subjective medical measurement that can confirm that a newborn is undergoing opioid withdrawal?
- n. Is sterilization required?
- o. What happens if this device diagnoses incorrectly, leading to the “incorrect treatment” referenced in the solicitation?

**p. Out of all 5 of the target stimuli to be sensed per the project goals, is there prioritization for measuring body temperature, movement, and sleep cycles?**

*Answer 11: Phase I is intended to be proof-of-concept to demonstrate feasibility of objectively measuring symptoms of withdrawal in newborns. The project goals listed are those that are thought to be helpful for clinical assessment; however they may not all be feasible/compatible with technology. Thus, some of the work expected in Phase I is to explore options for optimal design.*

*The device should be used for a single infant, whether it is for repeated use or used for a specified time then replaced over the full-length of stay is dependent on the design. The design should consider issues such as extraneous noise originating from other sources other than newborn of interest; movement from being held or changed or moved; whether swaddled; and, best placement. Even when swaddled, increased muscle tone and tremors would still be observed. Sterilization is not required but should be considered, dependent on design. It is expected that the readout could be a mobile device or room-based unit. Wireless communication over 50 feet should be considered. Optimum data transmission, analysis, and evaluation would occur continuously; however this is also dependent on design of the device. Additionally, view of data history would be helpful for clinical staff.*

*As no device currently exists to capture symptoms objectively, work related to decoding sensor data does not exist. It is envisioned that the device will aid clinical staff in developing treatment protocols in the future.*

## **NATIONAL CENTER FOR EMERGING ZONOTIC AND INFECTIOUS DISEASES (NCEZID)**

### ***NCEZID, Topic 020: Novel Coatings/Surfaces on Indwelling Medical Devices to Prevent Biofilms***

**Question 1: If very new, novel approaches are presented such as including biological molecules in a catheter coating, the production /commercial viability would not be clear until the end of Phase I and perhaps even Phase II. How do we address this? My company specializes in medical device coatings with active antimicrobials and additives.**

*Answer 1: This Phase I solicitation states that proposals are to provide information on an available pathway forward towards commercialization. Consider the statement regarding commercialization potential included in this topic and the Technical Evaluation Criterion set forth in Section 6.3 of the solicitation when deciding what information and content to include in your proposal.*

## **OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR)**

### ***OPHPR, Topic 003: Rapid Test for Simultaneous Detection of Influenza (types A and B) and Streptococcus (Group A)***

**Question 1: The stated goal is to develop a rapid test for use in the field. However, the description for this topic seems focused entirely on reagents. Is this reagent focus a requirement?**

*Answer 1: As mentioned in the announcement, the applicant interested in the development of the kit for one-step simultaneous detection of influenza (Types A and B) and Streptococcus (Group A), can develop new reagents, or use or modify reagents already available in the market and the research community. So the reagents (new or already available) are a component of the kit.*

End of Amendment 2