AMENDMENT TWO (2)

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	Attachment 2: Appendix I.2: FAR Clause 52.204-25

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PURPOSE OF SOLICITATION AMENDMENT

The purpose of this amendment is to:

- Provide slides, recording, and transcript of the pre-proposal conference;
- Revise Section 4.2 'Offeror Eligibility and Performance Requirements' to clarify how subcontracting limitations will be measured.
- Revise Solicitation Sections 4.12 'Registrations and Certifications' and 5.15 'Other Contract Requirements' to incorporate FAR Provision 52.204-24 *Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment,* FAR Clause 52.204-25 *Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment*, and FAR Clause 52.244-6 *Subcontracts for Commercial Items* (Aug 2019) pursuant to Pub. L. 115-232; as well as FAR Clause 52.204-14 *Service Contract Reporting Requirements*; and,
- Respond to Questions received regarding the solicitation.

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.

A recording of the pre-proposal conference and associated materials have been posted on the NIH SBIR/STTR News Flash Page https://sbir.nih.gov/engage/news and are also made available below:

- Webinar Slides
- Recording
- Transcript

Section 4.2 'Offeror Eligibility and Performance Requirements' is amended as follows:

The following statement is revised for clarification and conformity with the SBIR Policy Directive:

> For Phase I, a minimum of two-thirds of the research or analytical effort must be performed by the awardee. For Phase II, a minimum of one-half of the research or analytical effort must be performed by the awardee. The percentage of work will be measured by **total award dollars**.

Section 4.12 'Registrations and Certifications' is amended to include the following:

Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.

All offerors must complete and submit FAR Provision 52.204-24 as part of your Business Proposal, which is attached and incorporated as Solicitation APPENDIX I.1.

Section 4.16 State Assistance and Technical Assistance is amended as follows:

The following statement is **removed**:

> "If the cost of the proposed technical assistance provider is determined to be appropriate and allowable, this cost will be in addition to the base SBIR award budget established in the appropriate Topic description in Section 12."

Instead, it will be up to each Awarding Component to decide whether or not Technical and Business Assistance may be in addition to the base SBIR award budget established in the appropriate Topic description in Section 12.

For National Cancer Institute Topics, Technical and Business Assistance funds, if requested, must fall **within the budget set forth for the Topic in Section 12**. For other Awarding Components, please verify with the Contracting Office Points of contact listed in Section 10 for further guidance.

Section 5.15 Other Contract Requirements, is amended to include the following:

aa. **Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.** Contracts resulting from this solicitation will include FAR clause 52.204-25, attached and incorporated as Solicitation APPENDIX I.2.

bb. **Subcontracts for Commercial Items.** Contracts resulting from this solicitation will include FAR clause 52.244-6 (Aug 2019), which can be referenced **here.**

cc. **Service Contract Reporting Requirements.** Contracts with an estimated total value of $500,000 or greater resulting from this solicitation will include FAR clause 52.204-14, which can be referenced **here.**

General Questions

Question 1: Is a company allowed to submit more than one proposal to the same topic, assuming the proposals represent clearly different approaches, under the PHS 2020-1 SBIR Contracts solicitation?

Answer 1: Yes, a company is allowed to submit more than one proposal under the same topic, if the proposals represent separate and distinct projects.

Note that for proposal submission in eCPS, the company would need to create entirely separate submission packages. The company would go through the eCPS submission process for the 1st submission and then repeat the process for the next submission. If a company is planning to submit more than one proposal under the same topic, it is recommended that the Company differentiates between their different Phase I proposals by using a unique identifier in the file names/naming conventions. For example: if each submission has a different PI,

include the PI name in the submission file names, etc., to ensure reviewers will be aware that the submissions are different proposals from the same vendor not a duplicate submission of the same proposal.

Question 2: Can you clarify when letters of support are requested?

Answer 2: When a subcontractor or consultant collaborator is proposed, a letter must be included from each individual confirming his/her role in the project and extent of involvement; when facilities other than those of the applicant are proposed, a letter must be included stating that leasing/rental arrangements have been negotiated and will be available for the use of the SBIR applicant; and, for Phase II proposals under a Fast Track submission, letters should be included in the Finance Plan section of your Commercialization Plan.

In addition, some of the specific Topic Descriptions in Section 12 refer to additional and/or more specialized letter requirements, so check your individual Topic of interest carefully.

*All of these letters should be included in your **Technical Proposal** to ensure that they are reviewed by all reviewers.*

*In addition, costs associated with collaborators should be addressed in Appendix C of the Business Proposal, and letters that discuss or confirm financial information for collaborators can also be included in the Business Proposal to support the evaluation of the proposed project budget. For NIH Topics, please note that information submitted in the Business Proposal, however, will not be seen by all evaluators, some of whom will **only** review the Technical Proposal.*

Question 3: How should I determine and document indirect rates?

Answer 3: The solicitation allows for small business to charge indirect costs at a rate of up to 40% of total direct costs without requiring that the small business negotiate an indirect rate agreement with the NIH Division of Financial Advisory Services (DFAS).

However, this does not mean that an indirect rate of 40% will be acceptable for every business.

Your business should complete a table such as the one found at the website below to be able to justify your rate (of up to 40%), and include this information in your Business Proposal:

- https://oamp.od.nih.gov/dfas/indirect-cost-branch/indirect-cost-submission/indirect-cost-definition-and-example

After reviewing the DFAS website above, if you have further questions, you are encouraged to contact the DFAS staff at dfas-idc@nih.gov for assistance in understanding how to determine an appropriate indirect rate.

Section 12 Component Instructions and Technical Topic Descriptions

NATIONAL CANCER INSTITUTE (NCI)

National Cancer Institute (NCI), Topic 399: Combinatory Treatment Utilizing Radiation to Locally Activate Systemically Delivered Therapeutics Therapeutics

Question 1: The summary states that this solicitation is intended to develop combinatory treatment modalities utilizing external ionizing radiation to locally activate or release systemically or intratumorally delivered therapeutics, including high-atomic number elements that emit auger electrons. If the drug itself does not need to be activated with radiation, can we propose to use the radiation as a neoadjuvant to essentially activate the tumor to be more receptive to the drug?

Answer 1: The NCI clarifies that using radiation as a neoadjuvant to essentially activate the tumor to be more receptive to the drug would not fall within the scope of what NCI is seeking under Topic 399. You are encouraged to consider SBIR grant opportunities.

Question 2: Would abscopal effects in various tumor models when a targeted radiotherapy agent is combined with checkpoint inhibitors without the use of external beam radiotherapy fall within scope of NIH/NCI Topic 399?

Answer 2: The NCI clarifies that this sort of combination therapy would not fall within the scope of what NCI is seeking under Topic 399. You are encouraged to consider SBIR grant opportunities.

National Cancer Institute (NCI), Topic 400: Sensing Tools to Measure Biological Response to Radiotherapy

Question 1: Would proposals that measure concentration of reactive oxygen species released by cells that have absorbed radiation be within scope for Topic 400?

Answer 1: Yes, the NCI would consider this situation as being within the scope of what type of research we would be interested in receiving under Topic 400.

National Cancer Institute (NCI), Topic 402: Artificial Intelligence-Aided Imaging for Cancer Prevention, Diagnosis, and Monitoring

Question 1: There is no mention of any specificity or sensitivity targets. Is it important to achieve production quality specificity and sensitivity in Phase I, or is the focus more on usability?

Answer 1: The sensitivity and specificity for the cancer prevention, diagnosis, and/or monitoring will depend on the clinical question and unmet need that the tool is attempting to answer. Therefore, the Topic does not set forth these requirements, and it is up to the applicant to decide a benchmark that will be meaningful for the cancer type of their choice. NCI certainly wants to see a better diagnostic outcome than existing technologies currently provide. It is important to achieve production quality, specificity and sensitivity in addition to usability in Phase I for a proof of concept. Phase II is more focused on a study/technology development toward regulatory approval.

Question 2: Could you elaborate on what level of usability study is required for Phase I?

Answer 2: A Usability study needs to demonstrate a proof of concept for Phase I and readiness for applying regulatory approval (e.g., FDA) for Phase II. Specificity, sensitivity and reproducibility as well as user interface, etc. are the key requirements here. The applicants are also encouraged to communicating with FDA regarding the requirements that are needed for clinical application, which will depend on the clinical question and unmet need that the tool is attempting to answer.

Question 3: Do we have to identify the test users in our proposal?

Answer 3: Applicants are encouraged to identify the test users in their proposal, and this may make the proposal more competitive in technical evaluation; however, it is not required and it would be permissible to find potential users during the project.

Question 4: Does the program require multiple users to test the final software prototype in detail or just the conceptual UI and underlined capability?

Answer 4: The program requires multiple users to test the final software prototype with focus on usability and application of the software to answer clinical questions. Users are not required to check how the algorithm technically works, for example.

Question 5: Would you allow Topic 402 to use AI on immunochemical results rather than imaging?

Answer 5: The scope of Topic 402 is focused on AI-aided imaging, and therefore, AI on immunochemical results rather than imaging would be not be considered for award under this contract topic. You are encouraged to consider SBIR grant opportunities.

Question 6: Would targeting tumor prognostics be considered within scope for Topic 402?

Answer 6: Yes, the scope of this solicitation does include prognostics. For this Topic, the word "monitoring" in the title is intended to include both monitoring prognosis and response of treatment.

Question 7: Would screening mammography to improve the diagnosis of breast cancer, with a specific focus on earlier detection be allowed?

Answer 7: As stated in our contract solicitation, proposals focused on sharing and archiving imaging information, radiation therapy treatment planning, or mammography will not be considered within scope for this solicitation.

Question 8: Would it be considered responsive to propose AI methods that are intended to support cancer clinical trials rather than direct patient care?

Answer 8: It is considered to be within scope if the AI methods are intended to support cancer clinical trials that are related to cancer prevention, diagnosis, prognosis or treatment.

Question 9: Would it be considered responsive to propose informatics capabilities to enable novel methods for training and disseminating AI algorithms -- either as the central focus of the proposal or as a secondary aim linked with a clinical application?

Answer 9: Any awards made under this Topic will not support standalone training and dissemination of AI algorithms. These are not the central focus or aims of this Topic. The main focus is to target or help with cancer prevention, diagnosis, and monitoring (of prognosis or treatment). However, it would be acceptable for the AI aided imaging tool to include functions that could help train users and disseminate the tools to potential users.

Question 10: The Topic Description states "Products addressing cancers of the brain, cervix, colon, head and neck, lung, prostate, and rare cancers as well as childhood cancers are particularly encouraged for this topic." We have clinical data on breast cancer patients, although we could divert our focus to prostate cancer. Will you consider breast cancer in scope under Topic 402? Or should we rather divert our focus towards Prostate only?

Answer 10: Either prostate cancer or breast cancer would be considered for award under Topic 402. Having more patient data could potentially make a proposal more competitive during technical evaluation, which may counterbalance the stated preference for certain specified cancers.

Question 11: We intend to develop an AI-based platform for oncology clinical decision support targeting solid tumors. Due to data availability, we initially plan to develop and benchmark the tool for breast cancer. However, we envision the product should be easily adaptable to target to other cancers and intend to do so once a MVP is developed for breast cancer. Would such a technology be responsive to the call? Would it be preferred that we start begin with lung cancer instead?

Answer 11: This technology would be within scope for what the NCI would consider for award under Topic 402. Having more patient data could potentially make a proposal more competitive during technical evaluation, which may counterbalance the stated preference for certain specified cancers.

Question 12: Are Whole Slide Images (WSI) of microscopy slides from Digital Pathology scanners considered applicable for this topic?

Answer 12: Yes, Whole Slide Images (WSI) of microscopy slides from Digital Pathology scanners are considered applicable for this Topic.

National Cancer Institute (NCI), Topic 403: Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research

Question 1: Due to the emphasis of the slide-based "histological context" and "spatial context', it appears that Topic 403 is geared towards solid cancers. Could you please confirm this? We are working with suspension cells in heme onc indications, so this information would help us rule out 403?

Answer 1: Topic 403 is geared towards solid cancer; however, if the model of the heme onc indications involve "spatial context" i.e cell-cell interaction (cancer cells in a complex with other cells involved), then the project would still be considered to fall within the scope of Topic 403.

National Cancer Institute (NCI), Topic 404: Subcellular Microscopy and -Omics in Cancer Cell Biology

Question 1: Regarding Topic 404, would it be possible to receive additional information on the "non-sequencing based omic technologies"? What would be acceptable non-sequencing approaches for genomic and transcriptomic analysis, or are there specific sequencing technologies that do not qualify under this Topic?

Answer 1: Acceptable non-sequencing approaches for genomic or transcriptomic analysis may include (but are not limited to) hybridization, biosensor, or PCR based approaches, as well as approaches focused on genome architecture or copy number as the endpoint. Also acceptable are technologies that utilize sequencing steps to read out, for example, barcodes or tags.

Generally, technologies that directly sequence and provide as the assay endpoint genomic or transcriptome sequence information should be within the scope of Topic 403.

Question 2: Regarding Topic 404, would it be possible to receive additional information on the "non-sequencing based omic technologies"? What would be acceptable non-sequencing approaches for genomic and transcriptomic analysis, or are there specific sequencing technologies that do not qualify under this Topic?

Answer 2: Acceptable non-sequencing approaches for genomic or transcriptomic analysis may include (but are not limited to) hybridization, biosensor, or PCR based approaches, as well as approaches focused on genome architecture or copy number as the endpoint. Also acceptable are technologies that utilize sequencing steps to read out, for example, barcodes or tags.

Generally, technologies that directly sequence and provide as the assay endpoint genomic or transcriptome sequence information should be within the scope of Topic 403.

National Cancer Institute (NCI), Topic 406: Software for Patient Navigation Through the Cancer Care Continuum

Question 1: As we reviewed the funding opportunity, it was not entirely clear to us whether we could define "cancer care continuum" to focus on the transition to survivorship, and I was hoping you could shed some light. Do you know if we could?

Answer 1: Yes, the NCI would describe survivorship as a part of the cancer care continuum. The transition to survivorship would fall within the scope of what NCI is looking for in response to Topic 406, and in fact, the NCI would specifically encourage this, as the NCI finds that this has been relatively neglected in the patient navigation world, which has historically focused on the early part of cancer care continuum.

Question 2: Is there a list pf examples of existing software systems/tools/solutions that proposed solution design must take into consideration of in terms of cyber-security and protecting patient's privacy?

Answer 2: It is the offeror's responsibility to research existing solutions in the marketplace, and to describe in brief plans to address these two important areas during the Phase I or II project period. The primary focus in Phase I should be functionality of the product to assist patient navigation, and to address all listed deliverables, but cyber-security and patient privacy cannot be neglected.

Question 3: For Phase I, Goal #3 (securely transmit information), what are some target health-IT systems that NIH NCI would like us to securely transmit information with?

Answer 3: Any of the existing electronic health record software platforms now in use in the U.S. Epic would be one example.

Question 4: Is the secure transmittal of information intended for communication or also data aggregation about patient care?

Answer 4: It is for improvement of communication between patient, patient navigator, and the health care team. The purpose is to improve clinical cancer care. It is not for research across institutions (data aggregation) on patient care.

Question 5: Can we get some examples of category of organizations for proposed solution to 1) conduct needs assessment of Nos and cancer patients 2) have usability study of the proposed tools?

Answer 5: It is the offeror's responsibility to identify such organizations that will be responsible for these key aspects of the study, via subcontract agreement, as necessary.

Question 6: Do we have to have the cancer care delivery site already selected in our proposal?

Answer 6: Yes, you must identify the site in your proposal.

Question 7: How much "interoperability" is required for Phase II?

Answer 7: The solicitation does not provide a quantitative target, so you have some flexibility here. The more interoperability there is, the better, in general. The offeror can choose the number of health care delivery sites at

which interoperability will be demonstrated in Phase II, depending on available budget and time. A minimum of 1 is required.

Question 8: Which health-IT systems (clinical, administrative, public health) would NIH NCI like to integrate a PN system with?

Answer 8: *This is the offeror's (your) choice depending on the strengths of your small business, the potential market impact, the potential impact on clinical cancer care, and other considerations for the best possible response to the goals of the solicitation. The tools solicited in Topic 406 are for use by the whole cancer clinical care community.*

Question 9: The announcement refers to the role of a navigator being filled by various types of individuals, including, "Nurses, social workers, and lay persons." Can NCI please provide clarity as to the definition of the roles: what are the qualifications (or credentials) of the navigators that NCI expects to participate in the needs assessment and usability study?

Answer 9: *For both the needs assessment and usability study, two types of participants are required: experienced patient navigators, and patients. The offeror should document participant qualifications as navigators or patients in progress report deliverables submitted during the project. Experience rather than credentials is what should be documented. In the case of a patient, this could take the form of a short narrative describing the patient's healthcare journey from symptoms through diagnosis, treatment, follow care etc. In the funding proposal, the offeror should disclose specific plans for recruitment of participants and documentation of their qualifications.*

Question 10: Must the end user of our IT assistance have the title "patient navigator"? Or can the solution assist with the kinds of tasks a PN does but may be conducted by a nurse or someone else with a different title?

Answer 10: *The user can be anyone who helps patients successfully manage the cancer care continuum (help with making appointments and with communication with the health care professionals who are part of the care team, all as described in the solicitation), regardless of title. As mentioned in the solicitation, individuals who take the role of navigators can be laypersons, who quite possibly may not have the formal title of "navigator" within the health care setting.*

Question 11: Do we have to use the cancer care delivery site's Patient Navigators or can we use our own?

Answer 11: *This is not stated in the solicitation. However, given the desire to demonstrate integration of the software tool with that delivery site's health IT systems, using the delivery site's own navigators seems like it would be the best option in most cases.*

Question 12: The usability study activity of Phase 1 indicates that a minimum of 25 "users" shall participate. With the flexibility of the solicitation stating that solutions can be designed for patients or navigators, is there a requirement that the 25 users be a certain percentage of patients or navigators, depending on for whom the solution is designed?

Answer 12: *This should be driven by the extent to which your solution will be used by navigators and/or patients.*

Question 13: What (if any) qualitative or quantitative measures exist to measure performance over existing tools, to see if a new method or solution would be a significant improvement over current approaches?

Answer 13: *For this product, there will be no substitute for collection of feedback on the product from patients, navigators, the health care team, and anyone else who has eyes on the patient experience as he/she travels the cancer care continuum. Your challenge is to document benefit linked to use of your product, using whatever means you choose. This includes software usability testing in Phase I, and a validation study in Phase II. You could also in theory do a head-to-head comparison with a competing product, but in this space it is not clear that there is presently a leading product to compare to.*

National Cancer Institute (NCI), Topic 407: Cloud-Based Software for the Cancer Research Data Commons

Question 1: Is there a preferred analytics platform? SaaS?

Answer 1: *No, there is no preferred analytics platform. Applicants decide what platform to be used based on the need of their potential users.*

Question 2: What is the anticipated size of the production population?

Answer 2: This is also open for applicants to propose. For reference, applicants may take a look at the Genomic Data Commons Data Portal site, as an example: https://portal.gdc.cancer.gov/.

National Cancer Institute (NCI), Topic 409: Software for Automated Analysis of Images for Improved Cancer Health

Question 1: The description says that we should specify the use case. Is that completely wide open for any use case related to improving cancer health, or is there any additional guidance available about what is interesting?

Answer 1: The use case is open to anything cancer related as stated in the solicitation: "multiple aspects of cancer prevention and control from primary prevention such as improved evaluation of interventions to encourage physical activity, to enhanced epidemiological studies, to automation in monitoring of symptoms and response to treatment for disease affecting physical performance, to improved compliance with cancer treatments or physical rehabilitation regimens."

Question 2: Is it a requirement to "create or identify an open access image data source," or just a possible task that the offeror can choose to include?

Answer 2: The quoted deliverable is a requirement.

Question 3: Would an in-home system that could quantitatively assess clinical outcomes fit with this Topic, or are there other areas we should be focusing on?

Answer 3: The NCI agrees that this project would fall within the scope of what type of research we would be interested in receiving under Topic 409.

Question 4: Can we focus on individuals from 60-80 years of age for our Phase I product and testing or do we need to include a wider demographic?

Answer 4: The external peer review group performing the technical evaluation will assess acceptable compliance with the NIH Policy on Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects. Please justify the age-appropriate inclusion or exclusion of individuals in your proposal.

Question 5: Two of the systems mentioned in the solicitation, TraxSales and TRAF-SYS, use additional non-imaging hardware to accomplish their objectives. Should our solution be an imaging only solution or are we expected to interface with other hardware devices?

Answer 5: The focus of this solicitation is the development of image analysis software.

Question 6: One of the deliverables for the Phase I program under topic 409 is to conduct a usability study with 15 users. Could you elaborate on what level of usability study is required for Phase I? Is this a usability study for the user interface or for the image extraction itself? For instance, in activity monitoring, are we testing how well the system assesses the person being monitored or how well it reports those results to the person monitoring?

Answer 6: Phase 1 usability testing should focus on the functional prototype as stated in the 4th deliverable.

Question 7: Does the program requires multiple users to test the final software prototype in detail or just the conceptual UI and underlined capability?

Answer 7: The program requires multiple users to test the final software prototype. The offeror may include iterative testing that would involve a conceptual UI and capability.

Question 8: Do we have to identify the test users in our proposal?

Answer 8: Applicants are encouraged to identify the test users in their proposal, and this may make the proposal more competitive in technical evaluation; however, it is not required and it would be permissible to find potential users during the project.

National Cancer Institute (NCI), Topic 410: Cancer Clinical Trials Recruitment and Retention Tools for Participant Engagement

Question 1: What would be considered good testing of the feasibility of the Phase I effort, given the funds and timeframe of Phase I?

Answer 1: The offeror will need to decide the kind of testing they would perform. Expected Phase I activities and deliverables include:

- *Demonstrate feasibility and usability with a pilot user testing. Provide a report on the results of the first round of usability testing and the approach to modify the platform based on this user feedback. Offerors shall provide a technical evaluation and quality assurance plan with specific detail required for use.*
- *Demonstration that the tool, technology, or product can be adapted to multiple clinical trials at a price point that is compatible with market success and widespread adoption by the clinical research community.*

So, it is important to demonstrate feasibility and usability of the tool in pilot testing. It's expected that offerors will demonstrate that the approach they are proposing is user friendly and can enhance cancer clinical trial recruitment and/or retention.

The solicitation also lays out some of the expectations based on type of tool that is being developed:

- *If clinic-facing for recruitment, it should help identify protocol barriers to recruitment and present options for addressing the challenge(s), effective recruitment strategies, potentially integrate with electronic medical records, and allow for tracking of screening efforts. If clinic-facing for retention, it should enhance patient engagement, potentially integrate with electronic medical records, and allow for tracking of retention efforts. If participant-facing for recruitment, it should be designed to engage potential participants, help them understand details of a given trial, and be easily adaptable for different trials. If participant-facing for retention, it should be designed to engage enrolled participants, help them adhere to protocol requirements and communicate with clinic staff in an effective and efficient manner, and be easily adaptable for different trials.*

Question 2: Should we prioritize the budget for generalizability or proof of efficacy?

Answer 2: For the Phase I study, we would like to see some pilot testing for feasibility and usability and for that it should be fine to do it in a few cancers – 2 to 3 should be sufficient.

Question 3: Our work would involve expanding our existing platform. We think it is important to describe the already existing functionality so it is clear how the contracted work will result in a platform that meets and exceeds the contract specs. It looks to us that a description of our existing platform may belong in the "Related Research or R&D" section in the Phase 1 proposal. Is this appropriate, or do you have different suggestions about how to incorporate this information?

Answer 3: Yes, Related Research or R&D would be appropriate. Some of it would probably also fit into Detailed Approach and Methodology if discussion of previous activities are critical to explaining what is being proposed.

National Cancer Institute (NCI), Topic 411: De-Identification Software Tools for Cancer Imaging Research

Question 1: Could you provide more information about the de-identification needs of TCIA, specifically what kind of information it is that you would like removed? Is NCI interested in identifying/removing/redacting things like fillings, implants, jewelry, and hand-written notes on images? How could we use images that have the PHI present without the proper permissions that are required in being able to view such data?

*Answer 1: Please note that the TCIA example was just that – an **example** of where such tools are needed. The NCI does not plan to purchase or endorse tools that are produced as a result of this contract topic. These research topics are meant for companies to develop technologies that can be commercialized and have a market other than (or beyond) the NCI. TCIA image sets are publicly available and can be used to test your product. We are looking for tools that could be commercialized for various end-users. It may be useful to work together with universities or imaging centers to get different types of imaging data to validate your software.*

Question 2: Who would be the primary end-user(s) of this software beyond the PHI reviewer on, say, the TCIA data curation team?

Answer 2: *The primary end-users are decided by the company. We envision that this could be used by image registries, CROs etc. The company is expected to identify potential users and develop a commercial feasibility analysis for the product. The solicitation mentions some potential users but NCI does not plan to purchase and cannot endorse any tool that was developed as a result of funding from this contract.*

Question 3: **What is the process to get sample images from NCI data sets from the TCIA database as mentioned in the contract solicitation?**

Answer 3: *The TCIA database link is: https://www.cancerimagingarchive.net/ . All images can be downloaded for free. TCIA contains only deidentified images. The TCIA database was provided as an example of users for such a product. The NCI does not plan to purchase or endorse any product developed under this contract.*

Question 4: **What are the image formats?**

Answer 4: *Whole slide imaging and CT are preferred but other images can be considered.*

Question 5: **The deliverables suggest that the primary goals of Phase I are to identify a wide range of WSI and CT filetypes and gain access to a large set of examples for a Phase II deep dive. Are those accurate measures of success for Phase I or should we focus more heavily on PHI scrubbing during Phase I?**

Answer 5: *The focus is on scrubbing PHI from any modality, preferably WSI and/or CT. If it can be extended to other modalities, it can be validated later.*

Question 6: **Should the proposed solution update and integrate with the functionality of an existing software tool(s) (if so, which one(s)?) or should the solution provide a custom independent software for de-identification and data scrubbing?**

Answer 6: *There are no preferences. Both solutions are acceptable. If you do plan to integrate with an existing tool belonging to another vendor, please provide letters of support indicating that the vendor will work with you.*

Question 7: **How does the government want to redact the information?**

Answer 7: *The method that is chosen to redact PHI is up to the potential offeror to propose. All reasonable methods to remove the PHI and still retain all metadata fields will be considered.*

Question 8: **Who would you recommend that we should contact to understand the origin/context/requirements of this specific topic further?**

Answer 8: *All information for the topic is present in the solicitation. You can reach out to institutions or organizations that use large imaging data sets to get a sense of end users and their requirements. Please note that NCI or TCIA does not plan to purchase or endorse any product developed under this contract.*

National Cancer Institute (NCI), Topic 412: Software Enabling Data Integration from Wearable Sensors for Cancer Patients

Question 1: **Is there specific hardware (e.g., FitBit) that the government has in mind?**

Answer 1: *There is no specific hardware that is preferable.*

Question 2: **Is the hardware expected to communicate with the system real-time or via periodic data downloads?**

Answer 2: *It is preferred that the hardware communicates with the system real-time for periodic data downloads, depending on the interval of periodic downloads.*

Question 3: **What are considered external sensor platforms? Bio-/sensor platforms are still being incubated in the device and sensor research laboratories and not at the stage for "use for out of clinic patient monitoring." Are the terms "external sensor platforms" and "bio-/sensor platforms." used interchangeably in the solicitation?**

Answer 3: *The platforms that can be envisioned cover all ambient (in home) sensing platforms and wearable sensing tools. Anything, within this broad class of tools, which allows for real-world data generation to drive an understanding of patients / people in an ambulatory setting for cancer research would be considered within scope for Topic 412.*

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

National Institute on Alcohol Abuse and Alcoholism (NIAAA), Topic 018: Alcohol Biosensor Development for Continuous Alcohol Consumption Monitoring

Question 1: Would you consider measuring the alcohol concentration in the interstitial fluid (ISF) of a human subject responsive to this topic?

Answer 1: Measuring alcohol in interstitial fluid is considered an improvement over sweat-based techniques. Note that the solicitation requires "innovative, original approaches to alcohol quantification". Since NIAAA already supports small business grants developing microneedle techniques (NIH RePORT, https://projectreporter.nih.gov/reporter.cfm), technologies and approaches that propose to measure alcohol in interstitial fluid will need to be novel, creative, and distinct from devices already under development.

National Institute on Alcohol Abuse and Alcoholism (NIAAA), Topic 019: Data Science Tools for Accelerating Alcohol Research

Question 1: The solicitation states that the "generation of new primary data is not supported by this topic." We plan to incorporate drug prediction in our approach. Can we run a small, targeted validation study?

Answer 1: Yes, a targeted validation study is within the scope of the topic.

Question 2: Is there a set of expectations on the number of data types included for the Phase I? The Topic covers a wide breadth of data types.

Answer 2: The number of data types is dependent upon the research question or problem. There are no specified minimum or maximum number of data types, However, NIAAA is very interested in approaches that combine more than one type of data.

Question 3: Is it that you are looking for an offeror to build a research tool so that other researchers can make better use of the data in NIAAA databases?

Answer 3: One possible research tool may enable better (easier) use of databases within the NIAAA mission. The databases may be managed by NIAAA, but they may also be public databases or those from individual alcohol researchers.

Question 4: Would this tool be hosted on a server controlled by NIAAA?

Answer 4: No, it is not expected that the tool would be hosted on a served controlled by NIAAA. The tool may be hosted by an extramural investigator or another group involved in alcohol research.

Question 5: We are thinking of proposing a machine learning infrastructure where we learn a model and allow other researchers to investigate the features of that model and visualize why it makes the predictions it does for different people. Would such a proposal be responsive?

Answer 5: Yes, a machine learning infrastructure, as described above, would be within the scope of the Topic. Consultation with NIAAA-supported extramural researchers (recipients of NIAAA grants) is strongly recommended.

Question 6: The Topic Description for Topic 019 does not discuss Phase II. Does this mean that this Topic will not have the opportunity to move on to Phase II, or that Phase II will be defined upon completion of Phase I?

Answer 6: Phase II Activities and Deliverables for this Topic will be defined upon completion of Phase I.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

National Institute of Allergy and Infectious Diseases (NIAID), Topic 081: Adjuvant Development for Vaccines against Infectious or Immune-mediated Diseases

Question 1: We are developing a novel material that has little or no immunostimulatory activity by itself, but when a ligand is attached, it generates a significant and sustained immunostimulatory effect. Would the solicitation support a project to further develop this material?

Answer 1: *The purpose of the solicitation is to support the preclinical development of novel vaccine adjuvants. The solicitation will support formulation activities, which could include optimizing the adjuvant for use with a platform technology. The solicitation will not support the development of platform or delivery technologies that have no immunostimulatory or tolerogenic activity themselves (e.g., nanoparticles to optimize delivery of antigens, microneedle patches). NIAID does support the development of platforms and delivery technologies through other funding mechanisms, such as R43/R44 SBIR grants.*

National Institute of Allergy and Infectious Diseases (NIAID), Topic 086: Development of rapid fungal diagnostics for select endemic dimorphic fungi

Question 1: **A potential offeror has a relationship with a foreign Hospital where histoplasmosis is hyperendemic and particularly high in incidence due to the geography of the country and due to high rates of untreated/undiagnosed HIV/AIDS. The number of cases of histoplasmosis at this hospital is far higher in density than at any site we evaluated in the United States (allowing diagnostic studies to be completed expeditiously), and there is a high rate of tuberculosis, which is difficult to distinguish clinically from histoplasmosis and an outstanding control population scientifically and medically (which is not really accessible in the United States at these levels).**

Could we seek approval to continue working with this site as a subcontract site to enroll patients with suspected histoplasmosis for testing using our breath diagnostic device?

Answer 1: *Section 4.2 - Offeror Eligibility and Performance Requirements reads:*

For both Phase I and Phase II, all research or research and development work must be performed by the SBC and its subcontractors in the United States.

Based on rare and unique circumstances, deviations from these performance requirements may occur, and must be approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager/Coordinator.

The offeror must demonstrate in their proposal the unique nature, population and need to perform their work with foreign subcontractor(s).

NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)

NCEH, Topic 002: Web-Based Platform for Flooding Vulnerability and HealthCare Access

Question 1: **What types of existing products inspired the contract?**

Answer 1: *The CDC is not aware of existing web-based platforms that would fulfil this need, and did not base the contract language on any existing products.*

Question 2: **What are the preferred datasets an applicant should combine to create this product?**

Answer 2: *The CDC is aware of relevant datasets from the American Hospital Association, the Urgent Care Association, and Healthcare Ready. These datasets contain geographic location of healthcare infrastructure such as hospitals. We are aware of relevant flood datasets from EPA and FEMA. These datasets will likely be adequate, but the contractor may identify different relevant or useful datasets.*

Question 3: **Which is the most accurate final use case:**

a. Members of the public and first responders will use the product will make real-time navigation decisions to arrive safely to a healthcare facility during a disaster

b. Disaster Response Organizations (Red Cross) and Public Health Departments will use the product to plan for shelters and/or additional aid facilities.

c. Hospital Administrators will use the product prior to and during a disaster to determine alternative healthcare facilities for ICU and other patients.

Answer 3: *The product could potentially be useful for all of these cases. The priority is to provide scientifically robust risk information that will facilitate healthcare agencies to develop preparedness plans to improve resilience to extreme weather events, which aligns closely with option "c."*

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)

NCIRD, Topic 034: Accelerating Time to Detection of Legionella in Environmental Samples

Question 1: The solicitation clearly states it is unlawful to enter into contracts or grants requiring Essentially Equivalent Effort. The solicitation defines Essentially Equivalent Work as follows: "Work that is substantially the same research, which is proposed for funding in more than one contract proposal or grant application submitted to the same Federal agency or submitted to two or more different Federal agencies for review and funding consideration; or work where a specific research objective and the research design for accomplishing the objective are the same or closely related to another proposal or award, regardless of the funding source."

We wish to respond to topics for two different CDC institutes (NCEZID and NCIRD) and need advice to avoid double-dipping and to get better insight into "essentially equivalent work".

Answer 1: While it is permissible, with proposal notification, to submit identical proposals or proposals containing a significant amount of essentially equivalent work for consideration under numerous federal solicitations for the NIH/CDC SBIR program, it is unlawful to enter into contracts or grants requiring essentially equivalent effort. Submitting proposals with essentially equivalent work is permissible with appropriate disclosures on the forms found in Appendix A and Appendix C of the solicitation. However, CDC cannot award contracts to proposals where a specific research objective and the research design for accomplishing the objective are the same or closely related to another proposal or award. If two or more proposals with essentially equivalent effort are approved to move forward for potential funding by the Agency, only one can be awarded.

Question 2: One of the deliverables is "Develop a protocol to validate the assay in the field". Can you give us some guidance on the definition of "fieldability"? Does the assay have to be completed in the field using minimal resources? What kind of limited resources will you foresee for this assay?

Answer 2: The ideal assay for this proposal would require minimal technical expertise or extra equipment. It wouldn't necessarily need to be literally completed in the field (i.e., on the roof of a building next to a cooling tower), but it should not require laboratory space. The final assay should be as self-contained as possible and easy enough for a facilities manager or other water technician to use. Portability would be considered a plus.

Question 3: Does a proposal based on PCR have a very poor chance of being selected because CDC is really interested in developing technologies that are NOT PCR based?

Answer 3: A PCR-based assay would be well within the scope of this proposal. We are interested in speed, simplicity, and portability (if possible). We are less interested in the exact mechanism as long as the final assay can reliably identify viable Legionella bacteria in water samples.

Question 4: What we would like to do is PCR for legionella but only amplify DNA from live legionella. Is CDC looking for something else besides this fairly obvious approach?

Answer 4: A PCR-based assay as you describe would be well within the scope of this proposal. We are interested in speed, simplicity, and portability (if possible). We are less interested in the exact mechanism as long as the final assay can reliably identify viable Legionella bacteria in water samples.

End of Amendment 2

Attachment 1: Appendix I.1

52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.

REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

(a) Definitions. As used in this provision—

Covered telecommunications equipment or services, Critical technology, and Substantial or essential component have the meanings provided in clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Contractors are not prohibited from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) Representation. The Offeror represents that—

It [ ] will, [ ] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation.

(d) Disclosures. If the Offeror has responded affirmatively to the representation in paragraph (c) of this provision, the Offeror shall provide the following information as part of the offer—

(1) All covered telecommunications equipment and services offered (include brand; model number, such as original equipment manufacturer (OEM) number, manufacturer part number, or wholesaler number; and item description, as applicable);

(2) Explanation of the proposed use of covered telecommunications equipment and services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b) of this provision;

(3) For services, the entity providing the covered telecommunications services (include entity name, unique entity identifier, and Commercial and Government Entity (CAGE) code, if known); and

(4) For equipment, the entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known).

(End of provision)

Attachment 2: Appendix I.2

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

(a) Definitions. As used in this clause—

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means-

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means-

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled—

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in Federal Acquisition Regulation 4.2104.

(c) Exceptions. This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)