AMENDMENT ONE (1)

Solicitation Number: PHS-2021-1

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Attachments (2): Appendix I.1: FAR Clause 52.204-24 (2020); Appendix I.2: FAR Clause 52.204-25 (2020)

Amendment Points of Contact:
George Kennedy, Contracting Officer
E-mail: kennedyg@mail.nih.gov
Phone: 240-669-5170

Tiffany Chadwick, Procurement Analyst & Contracting Officer
E-mail: tiffany.chadwick@nih.gov
Phone: 240-276-7293

OFFICE OF ACQUISITIONS
National Institute of Allergy and Infectious Diseases (NIAID)
5601 Fishers Lane, Suite 300, MSC 9821
Rockville, MD 20852

PURPOSE OF SOLICITATION AMENDMENT

The purpose of this amendment is to:

- Provide slides and recording of the pre-proposal conference;
- Revise solicitation Section 10, updating the NCI and NHLBI contracting office contact information;
- Amend solicitation Section 12, NHLBI Topic 112 *Intramyocardial Suture Annuloplasty System ("SCIMITAR" devices),* to include "MIRTH" devices;
- Provide updated form links for solicitation Appendices H.2. and H.3.:
  - *Appendix H.2 - HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM - https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/PHSHumanSubjectsAndClinicalTrialsInfo_2_0-V2.0.pdf*
  - *Appendix H.3 - STUDY RECORD, ATTACHMENT TO HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM - https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HumanSubjectStudy_2_0-V2.0.pdf*
- Incorporate *August 2020* updates in solicitation Section 5.15: FAR Clause 52.244-6 *Subcontracts for Commercial Items (Aug 2020),* Appendix I.1: FAR provision 52.204-24 *Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020),* and Appendix I.2: FAR Clause 52.204-25 *Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)*; 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#engage and are also made available below:

- Webinar Slides
- Recording

Section 5.15 Other Contract Requirements, paragraph bb is amended to update FAR clause 52.244-6 as follows:

bb. **Subcontracts for Commercial Items.** Contracts resulting from this solicitation will include FAR clause 52.244-6 (Aug **2020**), which can be referenced **here.**

Section 10 Contracting Officer Points of Contact for Questions Related to Specific Topics, National Cancer Institute (NCI) and National Heart, Lung, and Blood Institute (NHLBI), are revised as follows:

NATIONAL CANCER INSTITUTE (NCI)

Cherie Wells
Contracts Analyst (Contractor)
Office of Acquisitions, NCI
E-mail: ncioasbir@mail.nih.gov

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

Stacy Turner (primary point of contact)
Contracting Officer
Office of Acquisitions, OM, NHLBI
Phone: (301) 827-7734
E-mail: turners@nhlbi.nih.gov

Tara Knox (secondary point of contact)
Contracting Officer
Office of Acquisitions, OM, NHLBI
Phone: (301) 827-7551
E-mail: knoxt@nhlbi.nih.gov

Section 12 Component Instructions and Technical Topic Descriptions, National Heart, Lung, and Blood Institute (NHLBI), Topic 112: *Intramyocardial Suture Annuloplasty System ("SCIMITAR" devices)*, is amended to include "MIRTH" devices as follows:

National Heart, Lung, and Blood Institute (NHLBI):

Topic 112: Intramyocardial Suture Annuloplasty System (*"MIRTH" and* "SCIMITAR" devices)

Budget and number of awards: Fast-Track proposals **will** be accepted.
Direct-to-Phase II proposals **will** be accepted.

Number of anticipated awards: 1 Phase I, 1 Phase II

Budget (total costs): Phase I: **$400,000** for **12** months; Phase II: **$3,000,000** for **3** years:

It is strongly suggested that proposals adhere to the above budget amounts and project periods. Proposals with budgets exceeding the above amounts and project periods may not be funded.

Summary:

Ventricular remodeling (enlargement) is a common pathologic manifestation of cardiomyopathy and that exacerbates mechanical inefficiency of both ventricles. Ventricular remodeling contributes to mitral and tricuspid valve regurgitation and congestive heart failure. Tricuspid valve regurgitation is a common malignant disease with few attractive mechanical treatment options. Secondary tricuspid regurgitation frequently accompanies

secondary mitral valve regurgitation and confers a worse prognosis. *Secondary or "functional" mitral valve regurgitation is a common disease with few satisfactory non-surgical options.*

NHLBI has developed the *Myocardial Intramural Restraint by endovenous interstitial teTHer (MIRTH) procedure and the related* Suture via Coronary sinus with Interstitial myocardial navigation for MItral and Tricuspid Annular Reduction (SCIMITAR) procedure to accomplish *single- and* dual-valve annuloplasty via interstitial navigation of heart muscles entered through heart veins. Clinical evaluation will require the development of purpose-built *MIRTH and* SCIMITAR devices, which are similar.

This **contract** solicitation aims to support the development and commercialization of transcatheter *MIRTH and* SCIMITAR system.

Project Goals:

The project goal is to develop *MIRTH (Myocardial Intramural Restraint by endovenous interstitial teTHer) and* SCIMITAR (Suture via Coronary sinus with Interstitial Myocardial navIgation for MItral and Tricuspid Annular Reduction) system implants and delivery catheters. *MIRTH creates a loop around the left ventricle inside the muscle and below the coronary arteries.* SCIMITAR creates a figure-of-eight loop around the left ventricular myocardial base and inside the right ventricular myocardial wall that narrows both mitral and tricuspid annuli. *MIRTH implantation requires device traversal in sequence from the coronary sinus, into the basal and/or mid myocardium, circumferentially around the left ventricle underneath the epicardium and deep to the endocardium, and out back into the coronary vein selected for entry.* SCIMITAR implantation requires device or guidewire traversal sequentially from the coronary sinus, through the basal interventricular septum, into the wall of the posterior right ventricle at the base, and through the basal right ventricular free wall to its anterior extent. A tension element is implanted along the *MIRTH or* SCIMITAR trajectory and countertraction is applied from the free limbs in the coronary sinus and right heart re-entry points.

The goals are to develop and commercialize specific catheter tools to accomplish a *MIRTH and* SCIMITAR annuloplasty. The tools work together as a suite of catheters.

Offerors are encouraged to include concrete milestones in their proposals, along with detailed research and development plans, risk analysis, and contingency plans, both for Phase I and Phase II.

Phase I Activities and Expected Deliverables

A phase I award would develop and test a suite of working prototypes in swine. The contracting intramural laboratory wishes to test the final prototype in vivo, and offers an earlier stage test to the contractor at no cost.

Below is a list of required characteristics for the specified device system. The system presupposes that an off-the-shelf or purpose-built guidewire has navigated the intramyocardial *MIRTH and* SCIMITAR trajectory.

- *A device to establish the MIRTH and SCIMITAR trajectories*
- Able to exchange the *MIRTH/*SCIMITAR guidewire for a permanent tension element, without contributing to or precipitating centripetal (cameral) pull-through
- Incorporating a coronary artery protection element, to protect entrapped (circumflex) coronary artery branches from extrinsic compression *(SCIMITAR only).*
- Able to deliver a tension countertraction element through the coronary sinus on one limb and the right atrial or right ventricular reentry site on the other limb
- Incorporating an adjustable intravascular lock

- Allowing early removal or at least tension interruption using transcatheter techniques as an emergency bail-out

- Preferred embodiments allow late transcatheter tension adjustment (days to months after the first implantation procedure)

- Incorporating radiopaque markers. Preferred embodiments indicate the perimeter of the implant as a reflection of applied tension

- Preferred embodiments incorporate elements to protect entrapped coronary sinus ("left ventricular") pacemaker or cardiac resynchronization therapy leads from damage, *when applicable*

- Safe for body and brain MRI at a minimum 1.5T field strength according to contemporary FDA guidelines

Offerors are advised to plan travel to NHLBI in Bethesda Maryland, and are expected to plan meeting at project initiation, mid-project to determine what iteration is necessary, and at project completion.

Consideration for transition to Phase II funding will include progress toward regulatory clearance. Consideration may include the status of the contractor's interactions with the Food and Drug Administration (FDA); therefore, contractors are encouraged to provide a detailed report of pre-IDE interactions with the FDA identifying requirements for IDE development under Phase II, including the summary of mutual understanding, if available. NHLBI encourages contractors to consider requesting designation to the FDA's Breakthrough Devices Program (https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program) during the Phase I award period.

Phase II Activities and Expected Deliverables

In addition to meeting all requirements for Phase I, a phase II award would allow commercial introduction of the device(s) together or independently as PMA devices or 510(k) devices substantially equivalent to marketed predicate devices. If this is not feasible, the phase II deliverable would be all testing and regulatory development for the device to be used in human investigation in the United States, under Investigational Device Exemption, along with devices sufficient to test in 30 human subjects.

All communications with FDA related to the contracted device must be recorded and provided to NHLBI.

The contracting DIR lab offers to perform an IDE clinical trial at no cost to the awardee. Complete IDE documentation and license and a suitable supply of clinical materials would constitute the deliverable.

End of Topic 112

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 2021-1 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.

Question 4: Appendix H.1 "Instructions, Human Subjects and Clinical Trials Information Form" refers to version 'E' of the Information Form. Can you please clarify?

Answer 4: *Appendix H provides instructions applicable to the PHS Human Subjects and Clinical Trials Information Form (OMB Number 0925-0001). The expiration date of these forms was recently updated as version F (version specific instructions are not yet available). A link to the most recent version (F) of the forms can be found at: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files, and are included here:*

Appendix H.2 - HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM - https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/PHSHumanSubjectsAndClinicalTrialsInfo_2_0-V2.0.pdf

Appendix H.3 - STUDY RECORD, ATTACHMENT TO HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM - https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HumanSubjectStudy_2_0-V2.0.pdf

Section 12 Component Instructions and Technical Topic Descriptions

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

National Center for Advancing Translational Sciences (NCATS), Topic 020: Development of Remote Rare Disease Patient Care Environment through Immersive Virtual Reality

Question 1: **This topic focuses on rare disease patients. From our initial discussions with a potential clinical partner we've learned that there is also a very significant new (due to the pandemic) need for tele-health for physical therapy and rehabilitation of outpatients, the gross majority of those being of course stroke patients. Keeping in mind the commercial viability of the potential end product, what are your thoughts on an approach which aims to develop an immersive system to serve the stroke population and other non-rare disease populations, as well as the rare disease patient populations? In our view, a system suitable for a very wide patient population would likely be lower-cost (due to the larger volumes) and thus more accessible to the rural, rare-disease patient population. Put another way, will our proposal be viewed less favorably if its focus isn't solely on rare-disease patients?**

Answer 1: *While NCATS cannot necessarily predict how reviewers will view a proposal that does not exclusively focus on rare diseases, NCATS would not view it less favorably at all, as NCATS understands there could be a broader audience for any proposed solution especially in light of the boom in tele-health during the COVID-19 pandemic. For NIH Awarding Components, the peer review technical evaluation panel will also determine whether each proposal is technically acceptable, meaning that it demonstrates sufficient technical understanding and capabilities to perform the technical objectives set forth in the solicitation. Please refer to 6 Method of Evaluation in the solicitation.*

Question 2: **RFP, Section 3.2, Research Involving Human Subjects, pg. 14. The solicitation states:**

"All research involving human subjects, to include use of identifiable human biological specimens and human data, shall comply with the applicable federal and state laws and agency policy/guidelines for human subject protection." There is a lack of clarity on whether contractor personnel testing a virtual reality gaming environment that collects their biometrics by contractor personnel would be considered Human Subjects research? Specifically, this is with respect to a Phase I for National Center for Advancing Translational Sciences Topic 20 which is Development of Remote Rare Disease Patient Care Environment through Immersive Virtual Reality for which the proof-of-principle prototype would not yet be used on patients.

Answer 2: *NCATS refers interested offerors to NIH's policies on conducting human subjects research: https://grants.nih.gov/policy/humansubjects/research.htm.*

Question 3: **RFP, Section 12, General, pg. 64. Topic 20 provides a list of Phase I deliverable including a set of prototype requirements that are quite extensive. The description of Phase II, then says "build the prototype according to the specifications developed in Phase I." Can the government clarify whether the phase I list of the deliverables refers to delivery of prototype specifications or requires the development of all of the described deliverables as part of a working prototype?**

Answer 3: *The thought of Phase 1 vs Phase 2 would be that of a proof of concept framework versus a fully functional prototype. A specification alone for Phase 1 would most likely not be adequate but NCATS also recognizes that the duration and funding provided during this phase may not be enough for a fully functional prototype. Ideally, Phase 1 could be used to develop a demonstratable framework to act as the foundation for the completion of a fully functional prototype in Phase 2.*

Question 4: **We are interested in responding to the SBIR solicitation, 020 "Development of Remote Rare Disease Patient Care Environment through Immersive Virtual Reality". Are the overall Phase I Activities and Expected Deliverables concept designs and plans for prototyping in Phase II? Or are they actual product development tasks that must be built during Phase I? (We are trying to understand if there is considerable development work involved within the Phase I, or if the primary Phase I task is to create systems plans and designs for the Phase II prototype).**

Answer 4: *Please see Answer 3 to Question 3 above.*

Question 5: Clarification on Phase I deliverables:

• Does this product need to be WebXR or a VR application?

• What is the reasoning behind using Unity Game Engine? Can this be done in Unreal?

• Can you provide a more detailed definition of sensing capabilities for runtime health analytics? Can you provide an example of what this means?

Answer 5: Clarification on Phase I deliverables:

• Does this product need to be WebXR or a VR application?

The product could be WebXR or a VR application based upon the offerors proposed technical approach.

• What is the reasoning behind using Unity Game Engine? Can this be done in Unreal?

The reasoning behind using Unity Game Engine is intended to be exemplary; this could be done in Unreal or another engine based upon the Offerors proposed technical approach.

• Can you provide a more detailed definition of sensing capabilities for runtime health analytics? Can you provide an example of what this means?

Sensing capabilities for runtime health analytics is specific to the type of sensing to be integrated with the overall platform. One example could be heart rate monitoring.

Question 6: Can you provide some examples of the intended patient-specific health metrics? Are the activities within the application meant to be rare disease-specific or generalized procedures and actions? - as referenced in bullet #4 of the project goals category a. Can you provide some examples of rare diseases that this solution should be able to address? Is the expectation that this solution should be all encompassing?

Answer 6: This depends on the offerors proposed technical approach and the types of sensing to be integrated. The activities within the application can be generalized procedures and actions. As an example, there could be a gait analysis built in to track patients with rare diseases that have an impact on patient mobility. There are too many rare diseases for this to be all encompassing so that is not the intent.

Question 7: What is the definition of "multi-modal" of this solicitation? - as referenced in the first sentence of the summary?

Answer 7: The definition of "multi-modal" means multiple types of data being collected/analyzed.

Question 8: What is the intended fidelity and range of functionality of the avatars that will be used to represent patients in the virtual environments?

Answer 8: The intended fidelity and range of functionality of the avatars that will be used to represent patients in the virtual environments depends on the application under development and is specific to the offerors proposed technical approach.

Question 9: If required by the proposal and requested technology, are we able to request additional funds if necessary?

Answer 9: It is strongly suggested that proposals adhere to the above budget amounts and project periods. Proposals with budgets exceeding the above amounts and project periods may not be funded.

National Center for Advancing Translational Sciences (NCATS), Topic 021: Platform for Rapidly Deployable Autonomous Laboratory

Question 1: Are all tasks listed for Phase 1 required to be included in the proposal or is a subset acceptable?

Answer 1: For Phase 1 it would be ideal to consider designing a framework that could support all the required tasks even if some tasks are more functional/mature than others. It could be fair to consider Phase 1 as the development of some minimally viable product.

Question 2: On Page 67 "Infrastructure" section the phrase "demonstrate access (via an executed license)", what does "executed license" mean aside from legally acquired software?

Answer 2: *An "executed license" has no other meaning, aside from legally acquired software. NCATS would like to ensure an offeror has at their expense licensed access to the cloud provider proposed.*

Question 3: **Will NIH require or attempt to connect and demonstrate the SBC solutions on its own physical infrastructure and instrumentation? If so, to what security requirements will the solution and/or personnel be subject? If there is no requirement, can SBC use and DEMO any instrumentation of choice in its own segmented networks/WAN?**

Answer 3: *NCATS does not require or attempt to connect and demonstrate the SBC solutions on its own physical infrastructure and instrumentation. The SBC can use and demo instrumentation of an offeror's choice in its own segmented network/WAN.*

Question 4: **On Page 67 "Integration" section, is the purpose of the AI/ML model to arrive at the right parameters for experiments? Will NIH require and provide specific datasets for training and/or validation?**

Answer 4: *This is specific to the application proposed by interested offerors, but the example arriving at the right parameters for an experiment is a good example.*

Question 5: **Page 68 first paragraph "Provide cost estimates to develop": Does the cost estimate apply to only the end-to-end POC. If not, should the costing for the proposed architecture include components which would span into Phase 2?**

Answer 5: *The cost estimate applies only to the end-to-end POC.*

Question 6: **Page 67: For Cloud VRO requirements, does NIH require any specific data format, model, or standard? We will be using open source and industry standard protocols wherever possible.**

Answer 6: *For Cloud VRO requirements, NCATS does not require any specific data format, model, or standard; however, this shall be based on an offerors proposed technical approach. NCATS anticipates a mixture of open source and industry standard protocols will be utilized.*

Question 7: **How may milestones be acceptable throughout the project? What is the mechanism to release payment periodically? Is work done via milestone acceptable for payment release?**

Answer 7: *The number of milestones is up to the offerors proposed technical approach. Payments on fixed price contracts may be made based on the satisfactory completion, receipt and acceptance of contract deliverables. Payments on cost-reimbursement contracts may be made pursuant to receipt of proper invoices of allowable costs incurred which may submitted no more frequently than on a monthly basis unless otherwise authorized by the contracting officer.*

NATIONAL CANCER INSTITUTE (NCI)

General Questions applicable to all NCI topics:

Question 1: **Would early stage (e.g. R21 level) projects with little to no preliminary data and significant development risk (but high reward) be of interest in response to this solicitation? Preparing and submitting a contract package is a significant effort for us.**

Answer 1: *No preliminary data are required; however, to be most competitive for award, considering the significant amount of proposals that may be submitted, some preliminary data is often included in a Phase I proposal.*

Question 2: Do we need a commercialization plan, or do we have to commit to commercialization now?

Answer 2: *For Phase I, you should provide enough information that the reviewers can judge the merit of the commercial potential. A detailed commercialization plan is not required. See the evaluation criteria in Section 6.3 for what the reviewers will be using to scoring commercial potential. Also see Section 8.8(a)(7) for instructions on how to address potential commercial application.*

If you do plan to apply for Phase I and Phase II together (Fast Track), then the Phase II proposal does need a strong commercialization plan that details market, any regulatory/reimbursement details, barriers to entry and competitive landscape.

Question 3: Who owns the products created as part of this SBIR?

Answer 3: All products are owned by the company/founders. See the SBIR Policy Directive at https://www.sbir.gov/sites/default/files/SBIR-STTR_Policy_Directive_2019.pdf for a full discussion of data rights – in particular the "SBIR/STTR Data Rights Clause" that begins on Page 187 of that document.

Question 4: Can you point us to previous (similar) contracts that have been awarded and lists of awardees?

Answer 4: You may find abstracts of contracts funded by the NIH by searching the NIH Reporter database. https://projectreporter.nih.gov/reporter.cfm or search federal-wide SBIR awards at https://www.sbir.gov/sbirsearch/award/all .

Question 5: Does the PI require a PhD qualification?

Answer 5: No but should have the appropriate experience to lead the project.

National Cancer Institute (NCI), Topic 414: Synthetic Biology Gene Circuits for Cancer Therapy

Question 1: We are working on using bacteriophage to engineer commensal bacteria present in the tumor microenvironment to produce localized anti-tumor compounds. Please let me know if this is a suitable approach to meet the goals of this contract.

Answer 1: Yes, it is within the scope of the topic.

Question 2: Our delivery method allows for precise control of the therapeutics over timing, dose, and location as needed.

Answer 2: The listed deliveries are required. Feel free to deliver more within the budget.

Question 3: To clarify, are approaches in which genetically engineered bacteria are injected into, for example, a solid tumor acceptable?

Answer 3: It is not excluded by the topic.

Question 4: Is there a minimum quantified standard of efficacy that must be achieved in cell lines or animal models in Phase I?

Answer 4: See Phase I deliverables "Demonstrate (optional) increased efficacy and/or decreased toxicity as compared with standard-of-care for the cancer indication in appropriate animal model(s)."

Question 5: Is our method allowed to be specific for a singular or small subset of cancer cell type(s) or genotype(s)/mutation(s)?

Answer 5: Yes, but the clinical impact will be evaluated by the reviewers as well in addition to technical soundness.

National Cancer Institute (NCI), Topic 417: Quantitative Imaging Software Tools for Cancer Diagnosis and Treatment Planning

Question 1: Would a software product for radiopharmaceutical therapy that not only performs treatment planning using dosimetry but also determines when the optimal time points to image a patient is responsive to this contract topic.

Answer 1: Yes

Question 2: We propose to research AI enabled quantitative imaging software which will use conditional adversarial neural network architecture to train on ever growing dataset of endoscopy videos for early detection of the presence of polyps. The model we will build will also be equipped with an explainable AI capability to provide factors contributing to the detection thereby aiding future training and diagnosis. Research into the proposed AI

enabled software will determine whether real-time assessment of endoscopic video images of colorectal polyps is possible with AI. Would this be within the scope of this Topic?

Answer 2: Based on the information given, this topic seems appropriate for this Topic.

National Cancer Institute (NCI), Topic 421: Quantitative Biomimetic Phantoms for Cancer Imaging and Radiation Dosimetry

Question 1: We are developing an artificial intelligence (AI) system that may generate digital breast phantom images that are very similar to realistic human breast images (MRI, CT, etc.). The generated digital breast phantoms can be used to perform simulation for breast-cancer detection and can serve as the training data for AI algorithms for breast imaging. Would our project (producing digital phantoms, not physical phantom) be considered within the scope of this Topic?

Answer 1: Digital phantoms and physical phantoms both may be responsive to the contract topic.

National Cancer Institute (NCI), Topic 422: Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research and Precision Medicine

Question 1: Are activities that develop spatial sequencing technologies with micro-region resolution responsive to the contract solicitation?

Answer 1: Activities that only develop spatial sequencing technologies with micro-region resolution would NOT be within the scope of this Topic. However, if the technology can also provide spatial information on which sequence comes from which cell, even it does not cover the whole section, it would likely be considered within the scope of this Topic.

Question 2: Would isolation of a tissue section core of 25 microns be considered single-cell resolution sequencing? If not, would 20 microns? Or 15 microns?

Answer 2: Being able to sequence an isolated core of tissue with a diameter of 15, 20, 25 microns is not the goal of this contract Topic. The goal of the Topic is to be able to generate sequence information from a cell or a few cells (may not be the whole genome) in the context of neighboring cells (i.e. you can take out samples to analyze, but must retain the spatial information of where the samples came from in a section; and there must be multiple samples to satisfy the requirement of allowing comparison of information from neighboring cells).

Question 3: Would development of DBiT-seq technology for compatibility with FFPE processing as well as development of new microfluidic chips that increase the region of interest, and automation of spatial post transcription modification be within the scope of this Topic?

Answer 3: This sounds like something that is within the ballpark of what the Topic is seeking; however, you should do a careful compatibility check on what you propose to do against the goals, activities, and deliverables set forth for this Topic in the solicitation.

National Cancer Institute (NCI), Topic 423: Software to Address Social Determinants of Health in Oncology Practices

Question 1: Does the applicant need to identify and list in the Phase I application all oncology practices they intend to interview/ collaborate with?

Answer 1: Yes- this will be important information to provide.

Question 2: Is there a preference on the types of oncology practices applicant should collaborate with, such as:

(a) Geography (same city vs. different cities), or

(b) Ownership structure (e.g., hospital vs. physician owned vs private-equity/ financial investor)

Answer 2: *There is no preference as long as the offeror has a future scalability plan that takes into account the diversity of oncology practices that will be potential customers.*

Question 3: What type of commitment (documents, specific language) do you want to see from the practices at the time of the application?

Answer 3: *A letter of commitment to work on the project would be ideal. Time commitment and financial remuneration should be included.*

Question 4: Is there a minimum number of types of cancer that need to be represented in the pilot testing?

Answer 4: *No - NCI does not have a preference on the number or types of cancer. The offeror needs to work with the oncology practices to ascertain the number and types of cancer that make the most sense to address.*

Question 5: Given that the different types and stages of cancer have different impact on the patients, are there specific requirements regarding types of cancer and cancer stages that need to be represented in the pilot testing?

Answer 5: *No – the previous answer applies here, also.*

Question 6: Can we include in the budget payments to patients, clinicians etc. for participation in the pilot testing?

Answer 6: *Yes*

Question 7: Is there a maximum limit to number of SDH measures that can be included in the software?

Answer 7: *No - NCI has no preference on maximum limit. This should be ascertained by working with the people who will use the measures – the members of the oncology practice team.*

Question 8: In addition to the listed SDH instruments, can we add other relevant tests: for e.g. psychological tests for cognitive abilities/self-esteem/stress management?

Answer 8: *The primary research focus must be SDH. There is no prohibition of research on other relevant tests, but there is risk that pulling the focus too far from SDH may be evaluated as a weakness if the additional tests are perceived to be a detriment to the success of the primary research focus.*

National Cancer Institute (NCI), Topic 424: Digital Tools to Improve Health Outcomes in Pediatric Cancer Survivors

Question 1: For the required capabilities discussed in this Topic description, is it expected that Phase I will fully implement, or, instead, demonstrates the proof of concept?

Answer 1: *Proof of concept is expected in Phase I, full implementation expected in Phase II.*

Question 2: What is the expected scope of the environmental scan of relevant, existing software systems and apps? Eg, are you looking for a high-level review with key features, market penetration etc., or detailed evaluation of each system uncovered?

Answer 2: *Be as thorough as possible*

Question 3: Are the "identified gaps", resulting from the environmental scan, meant to inform the nature and features of the functional prototype or are you expecting us to propose the detail of the functional prototype in our submitted proposal?

Answer 3: *Detail of the prototype should be presented in the proposal. The environmental scan will serve to improve what is initially proposed.*

Question 4: There is a request to "Conduct a pilot usability testing of the prototype tool with at least 25 potential users". Are we correct in assuming that these users could be either patients or clinicians?

Answer 4: *Should include both patients and clinicians.*

Question 5: In the presentation of Phase I findings and demonstrate functional prototype to an NCI Evaluation Panel, are you expecting a feature complete prototype or is a function demonstrator

sufficient?

Answer 5: Demonstration of a functional prototype is expected and the end of Phase I.

Question 6: How important, for this particular topic, is it to evidence our ability to commercialize the product that we develop?

Answer 6: Important.

Question 7: Must IRB approval be obtained prior to proposal submission?

Answer 7: Not expected prior to submission

National Cancer Institute (NCI), Topic 425: Information Technology Tools for Automated Analysis of Physical Activity, Performance, and Behavior from Images for Improved Cancer Health

Question 1: Topic NIH / NCI 425 describes capturing and using visual information (still and video) to gather data on things such as walking speed, timing data, physical performance, and other in-home monitoring and behavior. Would a proposal be considered within the scope of the Topic if it proposed alternate ways to gather these same kinds of data? For instance, would a more secure, anonymous, and non-intrusive way to report highly precise time-and-motion data be considered in the place of a visual system?

Answer 1: No, the contract topic is specifically focused on processing of images to improve cancer health. It is recommended that the company consider a grant application instead.

National Cancer Institute (NCI), Topic 427: De-Identification Software Tools and Pipelines for Cancer Imaging Research

Question 1: Is viewing the radiology and .wsi images part of the desired solution or only de-identification?

Answer 1: If the question is whether you need a viewer for the de-identified images, the response would be no, you do not need to develop /build a viewer as long as other commercially available viewers can be used to view the de-identified images.

Question 2: What percentage of the imaging for this Topic is .wsi vs DICOM?

*Answer 2: There is no specified percentage. The Topic description says "The goal of this concept is to support the development of software tools that comprehensively de-identify images by removing PHI and PII from image files generated by clinical imaging **and/or** WSI modalities while retaining metadata relevant to providing interoperability." You can do 100% of one modality if you prefer and can justify it.*

Question 3: What are the requirements around the size of the dataset used? i.e. can we perform Phase I with 1000 exams (or 1TB worth of data)? Can this be more? Can this be less?

Answer 3: You should be able to convincingly represent that the data set you have selected can prove that you can remove the PHI. We have not assigned a limit for the size of dataset.

Question 4: In Phase II it is our understanding that the NIH will leverage the tool with a dataset procured by the NIH (i.e. not the same dataset that was provided/tested in Phase I). Can you confirm?

Answer 4: This is what we plan to do.

National Cancer Institute (NCI), Topic 429: Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-Based Therapies

Question 1: Regarding "Provide proof of collaboration with an engineer(s), immunologist(s) and clinician(s) that has experience developing high throughput systems and/or treating patients with autologous cell-based cancer therapies", is it required to provide one collaboration from these three field

experts, or three collaborations covering all three fields?

Answer 1: This requirement could be met through a single collaboration or multiple, depending on the existing expertise within the company. The deliverable in question is directly tied to the project goal that states, "Proposals submitted under this topic must involve a collaboration between technology developers and clinical researchers with experience developing and treating patients with autologous cell-based cancer therapies." It is the Government's position that such a collaboration is important for the success of the technology, and therefore a critical element of each proposal.

Question 2: Would a project focused on the development of a cryopreservation solution be within the scope of this Topic?

Answer 2: The goal of the solicitation is to encourage the development of technologies that will improve the speed and cost of autologous cell production. The solicitation is looking for technologies that will enable high-throughput cell production. One of the major activities and deliverables in phase I is to, "Develop an early prototype device or technology for integrated high throughput autologous-cell manufacturing that include specifications designed to substantially reducing the speed, as well as any cost savings based on the new manufacturing approach."

It is unlikely that a proposal focused solely on the development of a cryopreservation solution would meet all of the necessary activities and deliverables described in the solicitation.

Question 3: Is the Topic specifically looking for an end-to-end system or could a project be for accelerating realization of our system that when used for cell separation, wash and concentration in the overall cell manufacturing process can dramatically speed availability of emerging autologous cell-based therapies?

Answer 3: To meet several deliverables in the solicitation, a cell therapy product would need to be produced and evaluated.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

National Heart, Lung, and Blood Institute (NHLBI), Topic 111: Oxygen Delivery Device Innovations

Question 1: Regarding the project goals and device features, a total weight of 5 pounds is listed. Does this 5 pound weight goal include a battery, or is it separate of a battery? We ask as portable lithium ion batteries can often weigh 2-3 pounds.

Answer 1: The weight of the battery should be included in the final product as part of the oxygen delivery system.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

National Institute of Allergy and Infectious Diseases (NIAID), Topic 087: Point-of-Care HIV Viral Load, Drug Resistance, and Adherence Assays

Question 1: Do we need to propose assays for all three functions (Viral Load, Drug Resistance, and Adherence)?

Answer 1: No, the Offeror can propose assays for one, two, or three functions.

Question 2: For the HIV Viral Load Monitoring, what is meant by "The technology should include the capacity to connect results to healthcare providers?" Does this mean an electronic readout and a device or computer input that can transmit information?

Answer 2: Yes

Question 3: For the Viral Load Monitoring, what is specifically meant by "semiquantitative"?

Answer 3: A semi-quantitative test is similar to a qualitative test in that it does not measure the precise quantity

of a HIV, but the results are expressed as an estimate of how much of a detected substance (RNA, p24) is present. As an example, a semi-quantitative assay for HIV RNA, while not giving an exact quantitative result, might give a result of target not detected, detected below 1000 copies per mL (cpm), above 1000 cpm, above 10000 cpm, etc.

Question 4: The topic description says that HIV RNA or other biomarkers (e.g. p24, immune markers) should be measured. Can HIV particles or coat proteins be measured?

Answer 4: Yes, if scientifically justified.

Question 5: Is there a specific limit on cost of the Viral Load or Adherence assays?

Answer 5: For HIV drug resistance monitoring, the initial target cost should be of $100 or less. For the other functions, the assay should be cost-effective.

Question 6: For the Adherence Monitoring assay, how much sample prep or manipulation is allowed before entering the device? How quickly are results needed, and how quantitative do they need to be?

Answer 6: We did not specify sample preparation, results turnaround time, and quantitation. However, we expect the Offeror to perform market research and only propose devices with commercial value that outperform existing devices.

National Institute of Allergy and Infectious Diseases (NIAID), Topic 092: Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases

Question 1: Is it acceptable to use model antigens to test the efficacy of novel adjuvant candidates in Phase I?

Answer 1: Using antigens that are not associated with and infectious or immune-mediated disease, other than for select studies when immunological reagents are not available for the disease model, is strongly discouraged since the data generated will not provide strong support for Phase II proposals with a specific infectious or immune-mediated disease.

Question 2: Is NIAID interested in protein-based adjuvants and are there any concerns that offerors should be aware of?

Answer 2: NIAID supports the discovery and development of several protein adjuvants derived from various pathogens. A major consideration is the potential induction of neutralizing antibodies, which may interfere with repeated use of such an adjuvant.

Question 3: Are there any restrictions regarding the starting substrates (protein / peptide / small molecule libraries) for screening for adjuvant candidates?

Answer 3: There are no restrictions.

National Institute of Allergy and Infectious Diseases (NIAID), Topic 093: Production of Adjuvants Mimics

Question 1: What defines an adjuvant that "mimics those with a favorable clinical track record"? For example, would the reformulation of imiquimod as an injectable for inclusion in vaccines be acceptable?

Answer 1: Repurposing an existing adjuvant (being used topically as a stand-alone product) for a new use, would not meet the requirements of the announcement. The offeror has to be able to point to results from clinical trials (showing immunogenicity and safety in vaccines) and describe what aspect they are mimicking (includes the chemistry of the core molecule and the formulation).

National Institute of Allergy and Infectious Diseases (NIAID), Topic 094: Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models

Question 1: Can a previous Phase I awardee for this topic apply for the topic again? Or maybe a direct to Phase II?

Answer 1: *The offeror may apply again to the Topic for a Phase 1 if the work proposed is not essentially equivalent to their previous Phase 1 in other words, a new effort. The offeror may also choose to submit a direct Phase 2 proposal to the Topic as a progression of the work performed under the previously awarded Phase 1 or for any other work (separate proposal) they feel meets the Phase 2 requirements.*

National Institute of Allergy and Infectious Diseases (NIAID), Topic 095: Improving Technologies to Make Large-scale High Titer Phage Preps

Question 1: Is a generalized approach that can be applicable to any bacteria preferred, or would specific procedures for specific ESKAPE pathogen bacteriophage cocktails be relevant?

Answer 1: *A generalized approach that can be applicable to any bacteria would be preferred. Having said that we realize that is likely to be a big ask and we would certainly be interested in specific procedures for specific ESKAPE pathogens. We would strongly discourage the development of a procedure that relied on a property that was unique to the particular ESKAPE pathogen because it is unlikely that such a procedure could be developed to be useful for other pathogens.*

Question 2: Do production and purification need to be addressed in Phase I?

Answer 2: *No, but it should be clear that the developed procedure would be compatible with production and purification in Phase 2.*

Question 3: Does stabilization need to be addressed along with manufacturing/purification in Phase I?

Answer 3: *No, but it should be clear that the developed procedure would be compatible with stabilization being addressed in Phase 2.*

Question 4: Can you please define "large-scale"?

Answer 4: *Large-scale refers to sufficient material to support clinical trials (at a minimum 100 1 ml vials containing 109 PFUs) and/or commercial production.*

Question 5: Can you also specifically address whether the scale relates to:

a. the fermentation volume, and if so, what volume(s) qualifies as large-scale (e.g., ~5L vs ~1,000L); and/or,

b. the anticipated number of doses, and if so, what quantities qualify as large-scale (e.g., millions of doses for stock piling vs thousands for a personalized pharmacy approach)?

Answer 5: *The scale should be justified in the proposal based on manufacturing and commercialization plans.*

Question 6: Can you please define "high titer"?

Answer 6: *High titer should be justified in the proposal based on currently achievable titers. Advancements that would allow for higher titer stocks that meet safety standards are encouraged.*

Question 7: Can you also specifically address with respect to titers:

a. Is there a specific endpoint titer that is desired?

b. What is the minimum titer that qualifies as "high titer"?

Answer 7: *See response to Question 6 above.*

Question 8: Can you please clarify what standard of purity is desired?

Answer 8: *Assume the purity standards for parenteral administration.*

Question 9: Can you please clarify the post-contract intent for use of technologies resulting from the contract?

Answer 9: *SOPs outlining the methods developed should be delivered to the government.*

National Institute of Allergy and Infectious Diseases (NIAID), Topic 096: Development of priority diagnostics for

Chagas disease

Question 1: It is a must that the POC assay can detect Chagas at both the acute and chronic phases?

Answer 1: Yes. It is expected that the POC assay will be appropriate for use during both the acute and chronic phases. Though it is acceptable if it is optimized for one phase or the other.

Question 2: Will the proposal deem acceptable for review if a rapid and easy to use POC test is highly sensitive and specific for either acute or chronic phase infection?

Answer 2: As above, it should be appropriate for both phases though it may be more sensitive for one phase or the other.

Question 3: Is PCR or isothermal amplification assay an acceptable approach?

Answer 3: Yes

National Institute of Allergy and Infectious Diseases (NIAID), Topic 099: Rapid, Point-of-Care Diagnostics for Hepatitis C Virus

Question 1: Does the test have to distinguish between different genotypes of HCV?

Answer 1: No, the test does not have to distinguish between different genotypes but should be able to detect an active HCV infection regardless of infecting genotype.

Question 2: Does the assay have to be quantitative (i.e. to determine viral load)?

Answer 2: No.

Question 3: If there is a non-consumable component, what would the limit on its cost be?

Answer 3: Limit on cost for non-consumable components will not be strictly defined but should be scaled appropriately for the socioeconomic status of the population for it's intended use in order to facilitate better accessibility and acceptability of the tests. Offerors may consult the literature for non-consumable component cost recommendations for use in low/middle and high income countries.

Question 4: What are the minimum expected performance metrics in terms of sensitivity/detection limit and specificity?

Answer 4: The test performance should be the same or better than similar FDA-approved diagnostic tests currently available for HCV, however offerors may propose activities that determine or optimize the test performance as part of Phase I or Phase II activities.

Question 5: The project goal states that "the diagnostic should be able to detect all HCV genotypes". Do we need to report the specific genotype (1 through 6)?

Answer 5: No, the test does not need to report the specific genotype.

CDC/NATIONAL CENTER FOR EMERGING ZOONOTIC AND INFECTIOUS DISEASES (NCEZID)

NCIRD, Topic 027: Interactive Phone-Based Video Game to Promote Handwashing Behavior Among Children

Question 1: Are we allowed to submit a proposal that offers options for the game portion of the application (e.g., endless runner, puzzle game, etc.)?

Answer 1: Yes

Question 2: When teaming with another company, can each send their own primed concept? A is prime while B is sub. And B is prime while A is sub?

Answer 2: 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 3: Are there requirements to support iOS and Android devices? If so, is this a requirement for Phase 1?

Answer 3: This would not be a requirement for Phase 1.

Question 4: Are there requirements to support both Phone and Tablet devices?

Answer 4: This would not be a requirement. The prototype should work on one of these platforms, the preference would be for a tablet as those are often used by children for reading and other games.

Question 5: Can you better define "complete, functional, prototype" found on page 134 when describing the Expected Deliverable of topic 027? Is this learning toward the vertical slice / proof of concept or is it the full product in an early stage with rough animations for instance instead of final animations?

Answer 5: The preference is a full product in an early stage with rough animations instead of final animations. We would like something that is functional enough that it could be tested among end users to ensure that it is meeting their needs, is usable, acceptable, etc.

End of Amendment 1

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 2020)

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in the provision at 52.204-26, Covered Telecommunications Equipment or Services—Representation, or in paragraph (v) of the provision at 52.212-3, Offeror Representations and Certifications-Commercial Items.

(a) Definitions. As used in this provision—

Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, 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. Nothing in the prohibition shall be construed to—

(1) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

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

(c) Procedures. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(d) Representation. The Offeror represents that—

(1) 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. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that—

It □ does, □ does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds "does" in paragraph (d)(2) of this section.

(e) Disclosures. (1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has

responded “will” in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment—

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(ii) For covered services—

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded “does” in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment—

(A) 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);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

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

(ii) For covered services—

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(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 2020)

(a) Definitions. As used in this clause—

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

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).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

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

(b) Prohibition. (1) 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 FAR 4.2104.

(2) Section 889(a)(1)(B) 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, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses 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 FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(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)