Defense Health Agency (DHA)
2023.2 Small Business Innovation Research (SBIR)
Proposal Submission Instructions

INTRODUCTION

The Defense Health Agency (DHA) SBIR/STTR Program seeks small businesses with strong research and development capabilities to pursue and commercialize medical technologies.

Proposers responding to a topic in this Broad Agency Announcement (BAA) must follow all general instructions provided in the Department of Defense (DoD) Program BAA. DHA requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

The DHA Program participates in up to three DoD SBIR BAAs each year. Proposals not conforming to the terms of this BAA will not be considered. Only Government personnel will evaluate proposal submissions.

Specific questions pertaining to the administration of the DHA SBIR/STTR Program and these proposal preparation instructions shall be directed to:
DHA SBIR Program Management Office (PMO)
Email: usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@health.mil
Phone - (301) 619-5146

For technical questions about a topic during the pre-release period, contact the Topic Author(s) listed for each topic in the BAA. To obtain answers to technical questions during the formal BAA period, visit the Topic Q&A: https://www.dodsbirsttr.mil/submissions/login.

Proposers are encouraged to thoroughly review the DoD Program BAA and register for the DSIP Listserv to remain apprised of important programmatic and contractual changes.

- The DoD Program BAA is located at: https://www.defensesbirsttr.mil/SBIR-STTR/Opportunities/#announcements. Be sure to select the tab for the appropriate BAA cycle.
- Register for the DSIP Listserv at: https://www.dodsbirsttr.mil/submissions/login.

PHASE I PROPOSAL GUIDELINES

The Defense SBIR/STTR Innovation Portal (DSIP) is the official portal for DoD SBIR/STTR proposal submission. Proposers are required to submit proposals via DSIP; proposals submitted by any other means will be disregarded. Detailed instructions regarding registration and proposal submission via DSIP are provided in the DoD SBIR Program BAA.

Technical Volume (Volume 2)

The technical volume is not to exceed **20 pages** and must follow the formatting requirements provided in the DoD SBIR Program BAA. Do not duplicate the electronically-generated Cover Sheet or put information normally associated with the Technical Volume in other sections of the proposal as these will count toward the 20-page limit.

Only the electronically-generated Cover Sheet and Cost Volume are excluded from the 20-page limit. Technical Volumes that exceed the 20-page limit will be reviewed only to the last word on the 20th page. Information beyond the 20th page will not be reviewed or considered in evaluating the offeror's proposal. To the extent that mandatory technical content is not contained in the first 20 pages of the proposal, the evaluator may deem the proposal as non-compliant and score it accordingly.

Content of the Technical Volume
The Technical Volume has a 20-page limit including: table of contents, pages intentionally left blank, references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any other attachments. Refer to the instructions provided in the DoD SBIR Program BAA for full details on content of the technical volume.

Cost Volume (Volume 3)
The Phase I amount must not exceed **$250,000**. Costs must be separated and clearly identified on the Proposal Cover Sheet (Volume 1) and in Volume 3.

Please review the updated Percentage of Work (POW) calculation details included in section 5.3 of the DoD Program BAA. DHA will occasionally accept deviations from the POW requirements with written approval from the Funding Agreement Officer.

Travel must be justified and relate to the project needs for direct Research Development Test & Evaluation (RDT&E) Technology Readiness Level (TRL) increasing costs. Travel costs must include the purpose of the trip(s), number of trips, origin and destination, length of trip(s), and number of personnel.

Company Commercialization Report (CCR) (Volume 4)
Completion of the CCR as Volume 4 of the proposal submission in DSIP is required. Please refer to the DoD SBIR Program BAA for full details on this requirement. Information contained in the CCR will be considered by DHA during proposal evaluations.

Supporting Documents (Volume 5)
DHA SBIR will accept a Volume Five (Supporting Documents) as required under the DoD SBIR Program BAA.

Fraud, Waste and Abuse Training Certification (Volume 6)
DoD requires Volume 6 for submission. Please refer to the Phase I Proposal section of the DoD SBIR/STTR Program BAA for details.

PHASE II PROPOSAL GUIDELINES

Phase II proposals may only be submitted by Phase I awardees. Phase II is the demonstration of the technology found feasible in Phase I. All DHA SBIR Phase I awardees from this BAA will be allowed to submit a Phase II proposal for evaluation and possible selection. The details on the due date, content, and submission requirements of the Phase II proposal will be provided by the DHA SBIR PMO. Submission instructions are typically sent in month five of the Phase I contract. The awardees will receive a Phase II window notification via email with details on when, how and where to submit their Phase II proposal.

Small businesses submitting a Phase II Proposal must use the DoD SBIR electronic proposal submission system (https://www.dodsbirsttr.mil/submissions/login). This site contains step-by-step instructions for the preparation and submission of the Proposal Cover Sheets, the Company Commercialization Report, the Cost Volume, the Technical Volume, Supporting Documents, and Fraud, Waste, and Abuse certificate.

The DHA SBIR Program will evaluate and select Phase II proposals using the evaluation criteria in the DoD SBIR Program BAA. Due to limited funding, the DHA SBIR Program reserves the right to limit

awards under any topic and only proposals considered to be of superior quality will be funded. Small businesses submitting a proposal are required to develop and submit a Commercialization Strategy describing feasible approaches for transitioning and/or commercializing the developed technology in their Phase II proposal. This plan shall be included in the Technical Volume.

The Cost Volume must contain a budget for the entire 24-month Phase II period not to exceed the maximum dollar amount of $1,300,000.

Budget costs must be submitted using the Cost Volume format (accessible electronically on the DoD submission site), and shall be presented side-by-side on a single Cost Volume Sheet.
DHA SBIR Phase II Proposals have six Volumes: Proposal Cover Sheets, Technical Volume, Cost Volume, Company Commercialization Report, Supporting Documents, and Fraud, Waste, and Abuse. The Technical Volume has a **40-page** limit including: table of contents, pages intentionally left blank, references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any attachments. Do not include blank pages, duplicate the electronically- generated Cover Sheets or put information normally associated with the Technical Volume in other sections of the proposal as these will count toward the 40-page limit.

Technical Volumes that exceed the 40-page limit will be reviewed only to the last word on the 40th page. Information beyond the 40th page will not be reviewed or considered in evaluating the offeror's proposal. To the extent that mandatory technical content is not contained in the first 40 pages of the proposal, the evaluator may deem the proposal as non-compliant and score it accordingly.

DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TABA)
The DHA SBIR Program **does not** participate in the Technical and Business Assistance (formerly the Discretionary Technical Assistance Program). Contractors shall not submit proposals that include Technical and Business Assistance.

The DHA SBIR Program has a Technical Assistance Advocate (TAA) who provides technical and commercialization assistance to small businesses that have Phase I and Phase II projects.

EVALUATION AND SELECTION
All proposals will be evaluated in accordance with the evaluation criteria listed in the DoD SBIR Program BAA.

Proposing firms will be notified via email to the Corporate Official of selection or non-selection status for a Phase I award within 90 days of the closing date of the BAA.

Non-selected companies may request feedback within 15 calendar days of the non-select notification. The Corporate Official identified in the firm's proposal shall submit the feedback request to the SBIR Office at usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@health.mil. Please note feedback is provided in an official PDF via email to the Corporate Official identified in the firm proposal within 60 days of receipt of the request. Requests for oral feedback will not be accommodated. If contact information for the Corporate Official has changed since proposal submission, a notice of the change on company letterhead signed by the Corporate Official must accompany the feedback request.

NOTE: Feedback is not the same as a FAR Part 15 debriefing. Acquisitions under this solicitation are awarded via "other competitive procedures". Therefore, offerors are neither entitled to nor will they be provided FAR Part 15 debriefs.

Refer to the DoD SBIR Program BAA for procedures to protest the Announcement.

As further prescribed in FAR 33.106(b), FAR 52.233-3, Protests after Award shall be submitted to:

Ms. Samantha L. Connors SBIR/STTR Chief, Contracts Branch 8
Contracting Officer
U.S. Army Medical Research Acquisition Activity
Email: Samantha.l.connors.civ@health.mil

AWARD AND CONTRACT INFORMATION
Phase I awards will total up to $250,000 for a 6-month effort and will be awarded as Firm-Fixed-Price Purchase Orders.

Phase II awards will total up to $1,300,000 for a 24-month effort and will typically be Firm-Fixed-Price contracts. If a different contracting type is preferred, such as cost-plus, the rational as to why must be included in the proposal.

Phase I and II awardees will be informed of contracting and Technical Point of Contact upon award.

ADDITIONAL INFORMATION

RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN SPECIMENS/DATA, OR ANIMAL RESEARCH
The DHA SBIR Program highly discourages offerors from proposing to conduct Human Subjects, Human Specimens/Data, or Animal Research during Phase I due to the significant lead time required to prepare regulatory documentation and secure approval, which could substantially delay the performance of the Phase I award. While technical evaluations will not be negatively impacted, Phase I projects requiring Institutional Review Board approval may delay the start time of the Phase I award. If necessary regulatory approvals are not obtained within two months of notification of selection, the decision to award may be terminated.

Offerors are expressly forbidden to use, or subcontract for the use of, laboratory animals in any manner without the express written approval of the U.S. Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRDC ACURO to the recipient. Modifications to previously approved protocols require re-approval by ACURO prior to implementation.

Research under this award involving the use of human subjects, to include the use of human anatomical substances or human data, shall not begin until the USAMRDC's Office of Human and Animal Research Oversight (OHARO) provides formal authorization. Written approval to begin a research protocol will be issued from the USAMRDC OHARO, under separate notification to the recipient. Written approval from the USAMRDC OHARO is required for any sub-recipient using funds from this award to conduct research involving human subjects. If the Offeror intends to submit research funded by this award to the U.S. Food and Drug Administration, Offerors shall propose a regulatory strategy for review.

Non-compliance with any provision may result in withholding of funds and or termination of the award.

WAIVERS
In rare situations, the DHA SBIR Program allows for a waiver to be incorporated allowing federal facility usage for testing/evaluation. A waiver will only be permitted when it has been determined that no applicable U.S. facility has the ability or expertise to perform the specified work. The DHA SBIR

Program has the right of refusal. If approved, the DHA SBIR Program will assist in establishing the waiver for approval. If approved, the proposer will subcontract directly with the federal facility and not a third party representative.

Transfer of funds between a company and a Military Lab must meet the APAN 15-01 requirements that will be included in the Phase II submission instructions.

International Traffic in Arms Regulation (ITAR)
For topics indicating ITAR restrictions or the potential for classified work, limitations are generally placed on disclosure of information involving topics of a classified nature or those involving export control restrictions, which may curtail or preclude the involvement of universities and certain non-profit institutions beyond the basic research level. Small businesses must structure their proposals to clearly identify the work that will be performed that is of a basic research nature and how it can be segregated from work that falls under the classification and export control restrictions. As a result, information must also be provided on how efforts can be performed in later phases, such as Phase III, if the university/research institution is the source of critical knowledge, effort, or infrastructure (facilities and equipment).

END

DHA SBIR 23.2 Phase I Topic Index

DHA232-001 TITLE: Integrated Photonics-based Handheld Non-Contact Laser Near-Infrared Photoacoustic Imager

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Combat Casualty Care

OBJECTIVE: Design, build and validate a handheld non-contact Laser Near-Infrared Absorption and Photoacoustic Imager (ncNIRPA) in the form of a stand-alone lightweight handheld device, using laser-based measurements, absorption and vibrometry, having optics pathways constructed with integrated photonics technology.

DESCRIPTION: Exposure of military to explosions and explosive weapons frequently leads to blast injury, concussions and subconcussions comprising mild traumatic brain injury (mTBI), that has accompanying deleterious and sometimes long-term debilitating effects [1]. More than 449,000 U.S. servicemen suffered from TBIs since 2000, with 82% mTBI [2]. mTBI is often accompanied by intracranial hemorrhage and hematoma containing oxygenated hemoglobin (Hb) and deoxygenated Hb (deoxyHb), that are detectable by NIRS [3]. This project's objective is to employ state-of-the-art technology to produce a novel handheld non-contact laser NIR photoacoustic (PA) imager (ncNIRPA) [4] with real-time imaging capabilities exceeding conventional NIRS devices, and using eye-safe lasers. NIRS devices designed previously, eg. The InfraScan (InfraScan Inc. Philadelphia PA), are limited to a single optode for signal acquisition from a single head location at a time, and require repeated scalp contact [5]. Head burns or trauma complicate use of such NIRS devices. The ncNIRPA imager is a non-contact device. It is directed towards the skull but separated from it, will employ a pulsed NIR laser that is able to detect abnormal accumulation of deoxyHb, producing acoustic vibrations that can be detected through Laser Doppler Vibrometry (LDV), which, in turn, will enable PA imaging [6].

PHASE I: The main goal of Phase I is a feasibility study in the development of a handheld ncNIRPA device. The device laser beam pathways are to be implemented using integrated photonics. Initially, to prove feasibility, a physical, electronics, optical and circuit design of the final handheld ncNIRPA product should be completed as the first deliverable. The major components will include the laser diodes, silicon photonics for laser transmit and receive components, computer processor(s), circuit board, rechargeable battery, transmission antenna, an on/off power switch and display screen. It must be capable to reconstruct an image in near-real-time, i.e. >= 2 Hz, and store DICOM-formatted [8] images. The ncNIRPA should be designed to operate by battery for a minimum threshold of two hours prior to battery recharging or replacement. The physical design of the ncNIRPA must have a form factor of approximately the width and height of a cellphone and be appropriate for the rigors of battlefield use. A second deliverable is a CAD computer model of the imager, accompanied by a physical mock-up of the scanning device. If time
permits, a schematic should be developed of the image acquisition and reconstruction software methodology, identifying useful existing software or software to be programmed.

PHASE II: The overall objective of Phase II is to produce a fully operational prototype handheld ncNIRPA imager factor that can acquire images from a human head in tests, archive and display the images on the device itself and on external devices so one can retrieve the images from the archive and redisplay them. The first deliverable of Phase II is to produce prototype hardware based on the electronics and optical design of Phase I. This task will produce the first deliverable, a true-size prototype of the ncNIRPA that acquires LDV signals that can be observed on an oscilloscope. The next aim is the programming and testing of software for the imager. The aim of this stage is to produce a second deliverable that is an enhanced form of the first deliverable, now replete with fully operational software for the acquisition of LDV signals, reconstruction of greyscale images, and transmission of the images to an external handheld computer. All image data must be compliant with DICOM standards. Laser power deposition must be demonstrated to not exceed FDA guidelines. The next goal is the production of a fully

functional prototype ncNIRPA imager in the desired form factor, complete with the computer software needed to perform signal acquisition and all functions for display, archiving and retrieving the acquired images. This device should be demonstrated to acquire NIR PA images from a healthy human head, under an IRB-approved research protocol. The human subject volunteers should represent a range of cultural backgrounds exhibiting different hair pigments and other hair qualities. The third deliverable is to provide one fully functional prototype, accompanied by validation test reports and other relevant reports and designs, and a proposed regulatory strategy that includes a clear plan on how FDA clearance will be obtained. Early FDA coordination may be considered to assist with regulatory strategy, analysis of manufacturability and commercialization strategy.

PHASE III DUAL USE APPLICATIONS: To add value, an aim would be to develop training software, sample input and manuals for the system. Due to the device's small size and likely modest price, the main target for the product is the mass commercial pre-hospital market, i.e., primary care physicians, clinics, and EMT use. Military use would primarily be in Roles One and Two. The regulatory strategy shall be refined and implemented for FDA submission and approval for technical use as an US device. In conjunction with FDA submission, the contractor may develop scaled up manufacturing of the technology that follows FDA quality regulations. Utility is enhanced if the device was easily able to transmit images from phone internet application(s), enabling teleradiology and potentially integrate with artificial intelligence.

REFERENCES:

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2. Agimi Y, LE Regasa, KC Stout, Incidence of traumatic brain injury in the US Military, 20102014. Mil Med 184(5-6) e233-41 (2019).
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4. Hosseinaee Z, M Le, K Bell, P Haji Reza, Towards non-contact photoacoustic imaging [review], Photoacoustics 20, 100207 (2020)
5. Calingo A, Innovative Scanner Designed to Save Marines' Lives on the Battlefield, Marine Corps Systems Command, https://www.marines.mil/News/News-Display/Article/1181027/innovative-scanner-designed-to-save-marines-lives-on-thebattlefield, 12 May 2017.
6. Binte A, E Attia, G Balasundaram, M Moothanchery, US Dinisha, R Bi, V Ntziachristos M Olivoa, A review of clinical photoacoustic imaging: Current and future trends, Photoacoustics 16, 100144 (2019)
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KEYWORDS: near-infrared, laser, vibrometry, photonics, imager, photoacoustic, hemorrhage, hematoma, intracranial, portable, non-contact, medical imaging

DHA232-002 TITLE: Integrated Photonics-based Portable Non-Contact Laser Vital Signs Monitor

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Combat Casualty Care

OBJECTIVE: Design, build, and validate results of a non-contact Laser Vital Signs Monitor (ncLVSM) in the form of a stand-alone lightweight portable cellphone-sized self-steering laser vibrometry device, constructed using integrated photonics.

DESCRIPTION: Main vital signs (VS) consist of core body temperature (Tc), heart rate (HR; pulse), respiratory rate (RR) and blood pressure (BP) An extended set includes oxygen saturation (SpO2), level of consciousness, and pain. VS of battlefield wounded are critical for Medic's triage at the point-of-injury (POI) and monitoring during prolonged field care (PFC). Standard manual means for monitoring VS are inefficient when first responders are focused on priorities of hemorrhage cessation and wound care. One approach is to use non-contact VSMs. Non-contact VSMs have been developed recently with optical, radar, thermal, and Laser Doppler Vibrometry (LDV) technology, and passive and active acoustic sensing. These devices suffer an innate limitation due to steering and localization control, requiring either manual direction or a restriction in the subject's position (e.g. [1]). The ncLVSM created in this project will use integrated photonics-based optical, laser, and LDV technology [2] capable of steering using computer vision and learned-sensing control. LDV can make non-contact vibration measurements of a surface struck by a laser [3]. It was shown [4] that LDV with manual steering can record a patient's Arterial Waveform (AWF) when signal is acquired from a body pulse point. Analysis of the AWF signal [5,6] yields HR and BP (as systolic BP (SBP) and diastolic BP (DBP)). The patient's RR is interrogated from signals acquired from chest expansions. The Tc is computed from the HR using for example the ECTemp algorithm [7] or another multi-wavelength thermography technique. The ncLVSM will include an onboard camera and computer, then use computer vision incorporating pose recognition [8-10] to steer the interrogation laser beams. Pulse points are located by morphing a gender-specific standard anatomy surface mesh with labeled pulse points onto the patient's body surface, with locations adjusted for movement by tracking software. ncLVSM is intended to operate hands-free, for example, attached to the front of a first-responder's jacket, helmet, or unmanned aerial vehicle.

PHASE I: The main goal of Phase I is a feasibility study in the development of a portable ncLVSM device. The ncLVSM must be designed to acquire data to compute the Tc, HR, RR and BP as SBP and DBP. The major components of the ncLVSM are to include the laser diode, silicon photonics for laser transmit and receive components, camera, computer processor(s), circuit board, rechargeable battery, transmission antenna, on/off power switch and small alphanumeric display screen. A thermally sensitive camera is an optional feature for nighttime pose recognition. As the first deliverable, a physical, electronics, optical, photonics and circuit design of the final ncLVSM product is to be completed to prove feasibility. The designs may include commercial components accompanying custom-designed photonics components. The physical design of the ncLVSM must have a form factor of approximately the width and height of a cellphone, must be appropriate for rugged civilian or battlefield applications, and must operate throughout the range of arctic to desert temperatures. The ncLVSM should operate by battery for a minimum of two hours of combined time use prior to battery recharging or replacement. Innovation is encouraged in each design aspect to create a lighter, more rugged, longer charged device. The device is to contain a computer processor(s) capable of performing the computations necessary to redirect the laser beam for locating and tracking a pulse point in case of movement. The VS should be computed at approximately 1Hz, displayed on the device, transmitted to external devices in real-time, and stored for later download. A second deliverable is a CAD computer model of the device, accompanied by a physical 3D printed model of the device. A third deliverable is a schematic description of the data acquisition process and software for each task. Existing software and planned software in the scheme should be indicated. A practically attainable AWF analysis methodology must be described.

PHASE II: The overall objective of Phase II is to produce one fully operational portable ncLVSM prototype. The prototype device must perform these tasks: recognize the subject body form; recognize the body pose; morph the body surface mesh of standard anatomy into the form of the patient; locate the pulse points on the patient from labels on the standard body mesh; acquire AWF VS; acquire signal from chest expansions; display the VS; store the information; decide if information is to be transmitted to an external device; and, continuously repeat this process. The first goal of Phase II is to produce a prototype hardware based on the silicon photonics and electronics design of Phase I. The emphasis should be focused on hardware integration and operation during this stage. This task will produce the first deliverable, a functioning prototype of the ncLVSM that acquires observable LDV signals from an inanimate phantom. The project then requires the design and programming of software operations detailed above. A second deliverable is the demonstration of the fully functional prototype ncLVSM in the desired cellphone form factor, complete with the computer software needed to perform signal acquisition and all functions for computation, display, data storage and transmission. Laser power deposition must be demonstrated to not exceed FDA guidelines. The ncLVSM must be demonstrated to acquire data from a human subject, under an IRB-approved research protocol. Subject movement should be included to demonstrate operation in non-static conditions. The third deliverable consists of 1) Providing one fully functional prototype ncLVSM device, accompanied by details of the electronics and integrated photonics design. 2) All software code that includes validation test reports and other relevant reports. 3) A regulatory strategy that reflects a clear plan on how FDA clearance will be obtained.

Early FDA coordination may be considered to assist with the regulatory strategy for obtaining approval for use as a medical monitoring device.

PHASE III DUAL USE APPLICATIONS: An aim would be to develop training software, sample input and create manuals for the system. Due to the device's small size and likely modest price, the main target for the product is the mass commercial market, i.e. primary care physicians, clinics, and EMT use. ncLVSM use when mounted on an UAV, to provide an unmanned triage capability, is another application for both the military and civilian markets. This phase shall include FDA submission with the goal of FDA approval. In conjunction with FDA submission, the contractor can develop scaled up manufacturing of the technology that follows FDA quality regulations. Utility is enhanced if the device was easily able to transmit VS data in a manner to be accessible to phone internet application(s), enabling telemedicine and potentially integrating with artificial intelligence.

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KEYWORDS: Laser, vibrometry, vital signs, biosensor, photonics, portable, self-steering, noncontact, monitor.

DHA232-003 TITLE: Medical Simulations for Extreme Cold Weather Environments

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Combat Casualty Care

OBJECTIVE: Develop and test proof-of-concept systems for training military medics to identify and treat various injuries in extreme cold weather environments.

DESCRIPTION: During Operations Enduring Freedom and Iraqi Freedom, Army Combat medics centered a great deal of their training on injuries due to improvised explosive devices and gunshot wounds (Dougherty, Mohrle, Galarneau, Woodruff, Dye, and Quinn, 2009). The focus of this topic is training military medics for extreme cold weather environments. Two parallel areas of concern are hardening simulations to withstand extreme cold and providing training for non-battlefield injuries such as hypothermia and frostbite (Army Public Health Center, 2022).

Highlighting the need across the services for a more collaborative approach to extreme cold warfighting capabilities, the DoD established the Ted Stevens Center for Arctic Security Studies on 9 June 2021 (DoD Fact Sheet, 2021.)

Medics need to be able to identify what an injury is as well as know how to treat it. The former requires cognitive understanding and diagnostic ability, while the latter requires hands-on practice. Current patient simulators and part task trainers often fail in extreme cold due to shortened battery life, simulated skin becoming fragile, fluids (e.g., simulated blood) freezing, and electronics failing (J. Pederson, personal communications, September 12, 2022). Diagnosis and treatment cannot be limited to “point of injury”, but should include prolonged care, should the medic be required to treat the patient for extended periods of time.

PHASE I: Phase I will result in proof-of-concept “breadboard” training systems for two or more extreme cold weather injuries that will operate in an extreme cold environment. Phase I of this effort will begin with a detailed analyses of various types of extreme cold weather injuries, difficulties treating injuries in extreme cold, and weather-related materiel issues (e.g., fluids, electronics, simulated tissue). Each analysis should include how best to train medics to initially diagnose and treat the injury, as well as what to expect from the injury over the course of 24 – 72 hours. Each analysis should also explore how best to train both diagnosis and treatment (e.g., part-task trainer, moulage on human standard patients, AR/VR/MR, or combinations). The resulting training proof-of-concept system should demonstrate solutions to the problems found during the initial analyses conducted at the start of this Phase I.

PHASE II: Successful Phase II offeror(s) will develop proof-of-concept systems as described in Phase I into well-defined, tested, and documented systems that can train military medical caregivers to diagnose and treat selected extreme environment injuries, both at point of injury and in a prolonged care situation. Note that prolonged care does not necessarily imply field conditions; a patient can spend prolonged time in a Battalion Aid Station or Forward Surgical Hospital. Resulting systems must be designed with affordability, training effectiveness and usability, in terms of reduced instructor workload, in mind. Phase II will also explore linkages to the Synthetic Training Environment (Synthetic Training Environment, 2021). As pertinent to the Phase II prototype, offerors should also examine and rate leading human physiology engines on their ability to simulate physiological reactions to extreme cold. Offerors will provide a technical approach for integrating physiology engines into the prototype system during Phase III.

During Phase II, the utility and maturity of the system should be demonstrated to military medical instructors. A training effectiveness evaluation using a relevant population should also be performed at a relevant military medical training center/schoolhouse. Ideally, the Phase II system should be

demonstrated at a cold-weather exercise, such as Arctic Edge or Cold Response.

PHASE III DUAL USE APPLICATIONS: During Phase III, the offeror will "harden" the system, ensuring it adheres to the latest Department of Defense cyber security requirements. In addition, user improvement suggestions gathered during Phase II shall be incorporated, as deemed appropriate by the Phase III funding customer. The resulting system will be well documented. Working with the Defense Medical Modeling and Simulations Office, the Ted Stevens Center for Arctic Security Studies, and service organizations involved in cold weather and extreme environments (e.g., 11th Airborne Division, 10th Mountain Division, Marine Corps Mountain Training Center, Fort McCoy's Cold Weather Operations Course), the topic proponent will seek potential funding partners.
In parallel to working with transition partners, Phase III should include pursuing commercialization opportunities. Emergency medical facilities in austere environments involving high altitude and/or extreme cold could benefit from the same technologies. Civilian organizations training/certifying Wilderness Emergency Medical Technicians are potential customers.

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KEYWORDS: Medical modeling and simulation, extreme weather medical training, cold weather medical training