AMENDMENT 1

Defense Health Agency (DHA)
22.4 Small Business Innovation Research (SBIR)
Release 1, Proposal Submission Instructions

March 10, 2022: Topics issued for pre-release
March 24, 2022: Topics open; DHA begins accepting proposals via DSIP
April 5, 2022: Deadline for technical question submission
April 28, 2022: Deadline for receipt of proposals no later than **1:00 pm ET**

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

Broad Agency Announcement (BAA), topic, and general questions regarding the SBIR Program should be addressed according to the DoD SBIR Program BAA. 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 https://www.dodsbirsttr.mil/submissions/login

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.

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

Specific questions pertaining to the administration of the DHA SBIR Program and these proposal preparation instructions should be directed to:

DHA SBIR Program Management Office (PMO)
Email - usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@mail.mil
Phone - (301) 619-7296.

Direct Contact with Topic Authors. From March 10, 2022 to March 23, 2022, this BAA is issued for pre-release with the names of the topic authors and their phone numbers and e-mail addresses. During the pre-release period, proposing firms have an opportunity to contact topic authors by telephone or e-mail to ask technical questions about specific BAA topics. Questions should be limited to specific information related to improving the understanding of a particular topic's requirements. Proposing firms may not ask for advice or guidance on solution approach and you may not submit additional material to the topic author. If information provided during an exchange with the topic author is deemed necessary for proposal preparation, that information will be made available to all parties through Topic Q&A. After this period questions must be asked through Topic Q&A as described below.

Topic Q&A. Once DoD begins accepting proposals on March 24, 2022, no further direct contact between proposers and topic authors is allowed unless the Topic Author is responding to a question submitted during the pre-release period. However, proposers may submit written questions through Topic Q&A at https://www.dodsbirsttr.mil/submissions/login. In Topic Q&A, all questions and answers are posted electronically for general viewing. Identifying information for the questioner and respondent is not posted.

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Questions submitted through the Topic Q&A are limited to technical information related to improving the understanding of a topic's requirements. Any other questions, such as those asking for advice or guidance on solution approach, or administrative questions, such as SBIR or STTR program eligibility, technical proposal/cost proposal structure and page count, budget and duration limitations, or proposal due date WILL NOT receive a response. Refer to the Component-specific instructions given at the beginning of that Component's topics for help with an administrative question. Proposing firms may use the Topic Search feature on DSIP to locate a topic of interest. Then, using the form at the bottom of the topic description, enter and submit the question. Answers are generally posted within seven (7) business days of question submission (answers will also be e-mailed directly to the inquirer).

The Topic Q&A for this BAA opens on March 10, 2022 and closes to new questions on April 5, 2022 at 12:00 PM ET. Once the BAA closes to proposal submission, no communication of any kind with the topic author or through Topic Q&A regarding your submitted proposal is allowed. Proposing firms are advised to monitor Topic Q&A during the BAA period for questions and answers. Proposing firms should also frequently monitor DSIP for updates and amendments to the topics.

DIRECT TO PHASE II 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.

15 U.S.C. §638 (cc), as amended by NDAA FY2012, Sec. 5106, and further amended by NDAA FY2019, Sec. 854, PILOT TO ALLOW PHASE FLEXIBILITY, allows the Department of Defense to make an award to a small business concern under Phase II of the SBIR Program with respect to a project, without regard to whether the small business concern was provided an award under Phase I of an SBIR Program with respect to such project. DHA is conducting a "Direct to Phase II" implementation of this authority for this 2019.3 SBIR Announcement and does not guarantee Direct to Phase II opportunities will be offered in future Announcements. Each eligible topic requires documentation to determine that Phase I feasibility described in the Phase I section of the topic has been met.

DHA Direct to Phase II Proposals are different than traditional DHA SBIR Phase I proposals. The chart below explains some of these differences.

	STANDARD DHA SBIR PROCESS	DHA D2P2 PROCESS
PHASE 1 TYPICAL FUNDING LEVEL	$250,000	None
PHASE 1 TECHNICAL *POP DURATION	6 months	None
PHASE 2 TYPICAL FUNDING LEVEL	$1,100,000	$1,100,000
PHASE 2 TECHNICAL *POP DURATION	24 months	24 months

*POP= Period of Performance

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PROPOSAL FORMAT (60 pages maximum)

Direct to Phase II proposals must include all of the following:

a. DoD Proposal Cover Sheet (Volume 1)

b. Technical Volume (Volume 2):

Part 1: Phase I Justification (20 Pages Maximum)

Part 2: Phase II Technical Proposal (40 Pages Maximum)

c. Cost Volume (Volume 3)

d. Company Commercialization Report (Volume 4)

e. Supporting Documents (Volume 5)

f. Fraud, Waste, Abuse (Volume 6)

Cover Sheet (Volume 1). As instructed on the DoD SBIR proposal submission website, prepare a Proposal Cover Sheet, include a brief description of the problem or opportunity, objectives, effort and anticipated results. Expected benefits and Government or private sector applications of the proposed research should also be summarized in the space provided. The Project Summary of selected proposals will be submitted for publication with unlimited distribution. Therefore, the summary should not contain classified or proprietary information.

Technical Volume (Volume 2).
B. **Phase I Justification (20 Pages Maximum)**. Offerors are required to provide evidence that the scientific and technical merit and feasibility has been established as described in the topic description.

C. **Phase II Technical Objectives and Approach (40 Pages Maximum).** List the specific technical objectives of the Phase II research and describe the technical approach in detail to be used to meet these objectives.

D. **Phase II Work Plan.** Provide an explicit, detailed description of the Phase II approach. The plan should indicate what is planned, how and where the work will be carried out, a schedule of major events, and the final product to be developed. Phase II is the principal research and development effort and is expected to produce a well-defined deliverable prototype or product.

E. **Related Work.** Describe significant activities directly related to the proposed effort, including those conducted by the Principal Investigator, the proposing firm, consultants, or others. Report how the activities interface with the proposed project and discuss any planned coordination with outside sources. The proposers' awareness of the state-of-the-art in the technology and associated science must be demonstrated.

F. **Technology Transition and Commercialization Strategy.** Describe your company's strategy for converting the proposed SBIR research, resulting from your proposed Phase II contract, into a product or non-R&D service with widespread commercial use -- including private sector and/or military markets. Note that the commercialization strategy is separate from the Commercialization Report described in Section 4.L below. The strategy addresses how you propose to commercialize this research, while the Company Commercialization Report covers what you have done to commercialize the results of past

Phase II awards. Historically, a well-conceived commercialization strategy is an excellent indicator of ultimate Phase III success. The commercialization strategy must address the following questions:

1. What is the first product that this technology will go into?

2. Who will be your customers, and what is your estimate of the market size?

3. How much money will you need to bring the technology to market, and how will you raise that money?

4. Does your company contain marketing expertise and, if not, how do you intend to bring that expertise into the company?

5. Who are your competitors, and what is your price and/or quality advantage over your competitors?

G. **Key Personnel**. Identify key personnel, including the Principal Investigator, who will be involved in the Phase II effort. List directly related education and experience and relevant publications (if any) of key personnel. No Government personnel may be listed. A concise resume of the Principal Investigator(s) must be included.

H. **Facilities/Equipment**. Describe available instrumentation and physical facilities necessary to carry out the Phase II effort. Justify items of equipment to be purchased (as detailed in the cost proposal) here, including Government Furnished Equipment (GFE). All requirements for government furnished equipment or other assets, as well as associated costs, must be determined and agreed to during Phase II contract negotiations. State whether or not the facilities where the proposed work will be performed meet environmental laws and regulations of federal, state (name) and local governments for, but not limited to, the following groupings: airborne emissions, waterborne effluents, external radiation levels, outdoor noise, solid and bulk waste disposal practices, and handling and storage of toxic and hazardous materials.

I. **Consultants.** Involvement of university, academic institution, or other consultants in the project may be appropriate. If such involvement is intended, it should be described in detail and identified in the Cost Volume.

Cost Volume (Volume 3).
Complete the Cost Volume by using the on-line cost volume form on the Defense SBIR/STTR Innovation Portal (DSIP). Some items in the cost breakdown may not apply to the proposed project. If that is the case, there is no need to provide information on each and every item. What matters is that enough information be provided to allow us to understand how you plan to use the requested funds if a contract is awarded.

(1) List all key personnel by name as well as by number of hours dedicated to the project as direct labor.

(2) While special tooling and test equipment and material cost may be included, the inclusion of equipment and material will be carefully reviewed relative to need and appropriateness for the work proposed. The purchase of special tooling and test equipment must, in the opinion of the Component Contracting Officer, be advantageous to the Government and should be related directly to the specific topic. These may include such items as innovative instrumentation or automatic test equipment. Title to property furnished by the Government or acquired with Government funds will be vested with the DHA SBIR Program, unless it is determined that transfer of title to the contractor would be more cost effective than recovery of the equipment by the DoD Component.

(3) Cost for travel funds must be justified as necessary to the direct research, engineering, testing, or evaluation needs of the project.

(4) Cost sharing is permitted for proposals under this BAA; however, cost sharing is not required nor will it be an evaluation factor in the consideration of a Direct to Phase II proposal.

(5) All subcontractor costs and consultant costs, such as labor, travel, equipment, materials, must be detailed at the same level as prime contractor costs. Provide detailed substantiation of subcontractor costs in your cost proposal. Volume 5, Supporting Documents, may be used if additional space is needed.

When a proposal is selected for award, you must be prepared to submit further documentation to the Component Contracting Officer to substantiate costs (e.g., an explanation of cost estimates for equipment, materials, and consultants or subcontractors). For more information about cost proposals and accounting standards, see https://www.dcaa.mil/Guidance/Audit-Process-Overview/.

Company Commercialization Report (Volume 4).
The Company Commercialization Report (CCR) allows companies to report funding outcomes resulting from prior SBIR and STTR awards. SBIR and STTR awardees are required by SBA to update and maintain their organization's CCR on SBIR.gov. Commercialization information is required upon completion of the last deliverable under the funding agreement. Thereafter, SBIR and STTR awardees are requested to voluntarily update the information in the database annually for a minimum period of 5 years.

If the proposing firm has been awarded prior DoD and/or non-DoD Phase I and/or Phase II SBIR/STTR awards, regardless of whether the project has any commercialization to date, a PDF of the CCR must be downloaded from SBIR.gov and uploaded to the Firm Forms section of DSIP by the Firm Admin. Firm Forms are completed by the DSIP Firm Admin and are applied across all proposals the firm submits. The DSIP CCR requirement is fulfilled by completing the following:

1. Log into the firm account at https://www.sbir.gov/.
2. Navigate to My Dashboard > My Documents to view or print the information currently contained in the Company Registry Commercialization Report.
3. Create or update the commercialization record, from the company dashboard, by scrolling to the "My Commercialization" section, and clicking the create/update Commercialization tab under "Current Report Version". Please refer to the "Instructions" and "Guide" documents contained in this section of the Dashboard for more detail on completing and updating the CCR. Ensure the report is certified and submitted.
4. Click the "Company Commercialization Report" PDF under the My Documents section of the dashboard to download a PDF of the CCR.
5. Upload the PDF of the CCR (downloaded from SBIR.gov in previous step) to the Company Commercialization Report in the Firm Forms section of DSIP. This upload action must be completed by the Firm Admin.

This version of the CCR, uploaded to DSIP from SBIR.gov, is inserted into all proposal submissions as Volume 4.

During proposal submission, the proposer will be prompted with the question, "Do you have a new or revised Company Commercialization Report to upload?." There are three possible courses of action:

a. If the proposing firm has prior DoD and/or non-DoD Phase I and/or Phase II SBIR/STTR awards, and DOES have a new or revised CCR from SBIR.gov to upload to DSIP, select YES.

- If the user is the Firm Admin, they can upload the PDF of the CCR from SBIR.gov directly on this page. It will also be updated in the Firm Forms and be associated with all new or in-progress proposals submitted by the firm. If the user is not the Firm Admin, they will receive a message that they do not have access and must contact the Firm Admin to complete this action.
- WARNING: Uploading a new CCR under the Firm Forms section of DSIP or clicking "Save" or "Submit" in Volume 4 of one proposal submission is considered a change for ALL proposals under any open BAAs or CSOs. If a proposing firm has previously certified and submitted any Phase I or Direct to Phase II proposals under any BAA or CSO that is still open, those proposals will be automatically reopened. Proposing firms will have to recertify and resubmit such proposals. If a proposing firm does not recertify or resubmit such proposals, they will not be considered fully submitted and will not be evaluated.

b. If the proposing firm has prior DoD and/or non-DoD Phase I and/or Phase II SBIR/STTR awards, and DOES NOT have a new or revised CCR from SBIR.gov to upload to DSIP, select NO.

- If a prior CCR was uploaded to the Firm Forms, the proposer will see a file dialog box at the bottom of the page and can view the previously uploaded CCR. This read-only access allows the proposer to confirm that the CCR has been uploaded by the Firm Admin.
- If no file dialog box is present at the bottom of the page that is an indication that there is no previously uploaded CCR in the DSIP Firm Forms. To fulfill the DSIP CCR requirement the Firm Admin must follow steps 1-5 listed above to download a PDF of the CCR from SBIR.gov and upload it to the DSIP Firm Forms to be included with all proposal submissions.

c. If the proposing firm has NO prior DoD and/or non-DoD Phase I and/or Phase II SBIR/STTR awards, the upload of the CCR from SBIR.gov is not required and firm will select NO. The CCR section of the proposal will be marked complete.

While all proposing firms with prior DoD and/or non-DoD Phase I and/or Phase II SBIR/STTR awards must report funding outcomes resulting from these awards through the CCR from SBIR.gov and upload a copy of this report to their Firm Forms in DSIP, please refer to the Component-specific instructions for details on how this information will be considered during proposal evaluations.

Supporting Documents (Volume 5).
Volume 5 is provided for proposers to submit additional documentation to support the Coversheet (Volume 1), Technical Volume (Volume 2), and the Cost Volume (Volume 3).

All proposers are REQUIRED to submit the following documents to Volume 5:

1. Contractor Certification Regarding Provision of Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Attachment 1) (REQUIRED)
2. Foreign Ownership or Control Disclosure (BAA Attachment 2) (Proposers must review Attachment 2: Foreign Ownership or Control Disclosure to determine applicability)

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Any of the following documents may be included in Volume 5 if applicable to the proposal.
Refer to Component-specific instructions for additional Volume 5 requirements.

1. Letters of Support
2. Additional Cost Information
3. Funding Agreement Certification
4. Technical Data Rights (Assertions)
5. Lifecycle Certification
6. Allocation of Rights
7. Other

Fraud, Waste and Abuse Training (Volume 6).
The Fraud, Waste and Abuse (FWA) training is required for Phase I and Direct to Phase II proposals. FWA training provides information on what represents FWA in the SBIR/STTR program, the most common mistakes that lead to FWA, as well as the penalties and ways to prevent FWA in your firm. This training material can be found in the Volume 6 section of the proposal submission module in DSIP and must be thoroughly reviewed once per year. Plan ahead and leave ample time to complete this training based on the proposal submission deadline. FWA training must be completed by one DSIP firm user with read/write access (Proposal Owner, Corporate Official or Firm Admin) on behalf of the firm.

TECHNICAL AND BUSINESS ASSISTANCE (TABA)
The DHA SBIR Program does not participate in the Technical and Business Assistance. Contractors should 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 II award within 90 days of the closing date of the BAA.

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 should be submitted to:

Ms. Samantha Connors
SBIR/STTR Chief, Contracts Branch 8
Contracting Officer
U.S. Army Medical Research Acquisition Activity
Phone: (301)-619-6979
Email: Samantha.l.connors.civ@mail.mil

AWARD AND CONTRACT INFORMATION
Phase II awards is likely to be awarded as a Firm Fixed contract with the Contracting Officer Representative and other contracting staff identified.

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ADDITIONAL INFORMATION

RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN SPECIMENS/DATA, OR ANIMAL RESEARCH

Prior to contract award when an IRB is indicated, proposers must demonstrate compliance with relevant regulatory approval requirements that pertain to proposals involving human subjects, human specimens, or research with animals. If necessary 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 US 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 Research Protections (ORP) provides formal authorization. Written approval to begin a research protocol will be issued from the USAMRDC ORP, under separate notification to the recipient. Written approval from the USAMRDC ORP is also required for any sub-recipient that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRDC ORP. Non-compliance with any provision may result in withholding of funds and or termination of the award.

CYBERSECURITY CONSIDERATIONS

Appropriate cybersecurity considerations should be implemented at Phase III (or earlier if specified) for the potential transition of software and connected devices to be considered for future fielding. For initial information, please see the below reference to the DoD Cybersecurity Reference and Resource Guide.

DoD Cybersecurity Reference and Resource Guide
https://dodcio.defense.gov/Portals/0/Documents/Cyber/2019%20Cybersecurity%20Resource%20and%20Reference%20Guide_DoD-CIO_Final_2020FEB07.pdf

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.

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DHA SBIR 22.4 Topic Index
Release 1

DHA224-D001	Remote Frostbite Prevention System
DHA224-D002	Therapeutic Modalities for the Mitigation of Neck/Back Pain during Flight Operations
DHA224-D003	Adaptive Technology to Optimize Rehabilitation of Lower Extremity Musculoskeletal Injuries throughout Recovery

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DHA224-D001 TITLE: Remote Frostbite Prevention System

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: Develop a wireless, readily-scalable, real-time skin temperature sensing system that end-users can use to identify cold stressed workers with hands, feet, and other extremities that are at risk of freezing cold injury.

DESCRIPTION: Workers exposed to cold stress, e.g., recreational hikers, mountain climbers, snow cleanup crews, construction workers, police officers and firefighters, as well as baggage handlers, landscaping services, and electrical, oil and gas workers (https://www.osha.gov/winter-weather/cold-stress) are at risk of freezing cold injuries, i.e., frostbite, a localized cold injury resulting from tissue freezing. Infantry personnel training in cold temperatures for extended periods of time are also at risk of frostbite. Frostbite can force a quick shift from the work at hand to the care and evacuation of the injured individual. Although frostbite can occur at the nose, ears, cheeks, chin and groin, the most concerning is freezing injury to hands and feet. Hands and feet are particularly vulnerable to freezing injury due to peripheral vasoconstriction and reduced blood flow, high rates of heat loss due to high surface-to-volume ratios, and limited local metabolic heat production. Hands and feet become numb at ~8°C; tissue freezing starts at skin temperatures of −1 to −4°C. The inherent difficulty evacuating casualties from remote areas, the limited medical treatments for frostbite, and the potentially disabling effects of frostbite all underscore the need for a suitable and effective frostbite prevention system. The commercial marketplace currently lacks a system that can be used in cold field conditions to wirelessly monitor groups of workers, identify those individuals with extremities at risk of freezing, and direct appropriate risk-mitigating interventions (e.g., change socks and/or mittens, don additional protective clothing, increase physical activity level, seek a warm environment).

PHASE I: An advanced, innovative system is sought that end-users can use in cold field conditions to wirelessly monitor groups of workers and identify individuals with extremities at risk of freezing cold injury. The proposed solution should be feasible and have scientific, technical, and commercial merit. A rigorous argument showing that to a solution will be viable and risk-mitigated needs to be presented. Evidence of this proposed solution would be a proof-of-concept prototype, drawings, etc. Vendor will provide a plan for practical deployment of the proposed approach, to include how the prototype could be developed and demonstrated at large scale. An ideal system will be rugged, lightweight, simple to use and sustain, cost-effective, tolerant of cold/wet and extreme cold conditions, and provide valid data during multi-day use in austere field environments. All body-worn sensors will need to be unobtrusive. The methodology proposed will enable the detection of skin temperatures without direct visual or physical skin examination by the end-users. The approach should focus on monitoring skin temperatures on the hands and feet where severe frostbite typically occurs (e.g., fingers, toes) but could optionally be extended to other areas (e.g., ears, nose, chin).

This topic is accepting Direct to Phase II (DPII) proposals ONLY. Proposers submitting a DPII proposal must provide documentation to substantiate that the scientific and technical merit and feasibility described above has been met and describes the potential commercial applications. Documentation should include all relevant information including, but not limited to: technical reports, test data, prototype designs/models, and performance goals/results.

PHASE II: Building on prior accomplishments, the offeror will design and engineer a wireless, readily deployable, multi-point real-time skin temperature sensing system that end-users can easily use to monitor tens to hundreds of cold weather workers, and identify individuals with extremities (e.g., fingers, thumbs,

toes, foot pads) that are at risk of freezing cold injury. An early objective should be a demonstration that convincingly shows the prototype system is suitable for remotely detecting imminent frostbite from a distance.

Evidence that the system will be easy to use and provide valid data under mild to extreme cold conditions (0°C to −60°C) is necessary. Body-worn temperature sensors should be unobtrusive and acceptable to the individual wearer and not hinder the worker's ability to perform their jobs. A low-powered, lightweight, handheld device capable of receiving wirelessly transmitted skin temperature data from 50-to-500 body-worn skin temperature sensors over distances of 3-to-10 meters is necessary. Temperature needs to be monitored on the feet (e.g., under toe pads, ball of foot, lateral foot pad, heel pad, lateral edge of foot), and hands (e.g., finger tips, thumb, lateral edge of hand), the areas of highest risk of freezing injury. The system design should readily support scaling to applications where skin temperature would be monitored in hundreds of individuals.

Deliverables will include a minimum of 250 sensors that are designed for easy integration with socks, and gloves or glove liners, and three handheld devices that receive, store, interpret data, and display "risk of cold injury" alerts. The handheld device receiving data from body-worn temperature sensors will have software algorithms that generate alerts when skin temperatures indicate one or more workers are at risk of frostbite. The alert would identify the individual and the extremity (left/right hand, left/right foot) at risk of freezing injury.

Each temperature sensing element will weigh less than 0.5 grams, have a temperature resolution of 0.2°C or better. Temperature sensors should preferably be reusable, machine washable, easily adhered to or embedded in the user's garments, and capable of withstanding extended exposure to sweat and immersion in water. The real-time skin temperature sensing system developed will need to be open architected, i.e., have open communication standards, readily modifiable firmware, and be capable of hosting third party algorithms. If experimentation with human test volunteers is planned, the offeror must provide a clear plan for compliance with all applicable rules and regulations regarding the use of human subjects, to include Institutional Review Board approval(s).

PHASE III: Expected users of the technology are individuals and small-to-large groups of cold-weather workers such as mountain climbers, snow removal crews, indoor and outdoor fishery workers, construction workers, utility workers, oil and gas workers, first responders, infantry soldiers, as well as baggage handlers, landscaping services, and electrical, oil and gas workers.

Ease of use in field environments is an important characteristic of the desired technological solution. The developed technology should be durable and readily applicable in resource-limited cold field conditions, be designed for at least 72 hours of use, and tolerate storage in cold conditions for months-long periods of time. The offeror should consider final procurement cost as well as system operation and maintenance costs, creation of instruction manuals, definition of replacement/warranty policies, and training requirements for users.

A user manual is a necessary deliverable. This manual should describe how the wearer wears the system and how the person doing the monitoring uses the receiver device. Specifically the manual should include use of the software necessary to enable this product to be used.
Phase III work will concentrate on product maturation and successful applications of the technology to commercial and military use. Phase III shall provide production planning and marketing strategy for potential procurement by commercial and recreational entities responsible for performance and safety cold-stressed workers. Application of this frostbite prevention technology to military use in cold weather training environments is also desired. The final product is expected to be used for safety monitoring and is

not expected to have diagnostic capabilities. If the final product has diagnostic capabilities, all Federal Drug Administration review and certification requirements must be met.

REFERENCES:

1. Pozos RS (ed.). Section II: cold environments. In: Pandolf KB, Burr RE, eds. Medical aspects of harsh environments, Volume 1. Falls Church, VA: Office of the Surgeon General; 2001:311-566. <https://medcoe.army.mil/borden-tb-med-aspects-harsh-environ-vol1>\

2. Sullivan-Kwantes W, Dhillon P, Goodman L, Knapik JJ. Medical Encounters during a Joint Canadian/U.S. Exercise in the High Arctic (Exercise Arctic Ram), Military Medicine, Volume 182, Issue 9-10, September 2017, Pages e1764–e1768, https://doi.org/10.7205/MILMED-D-16-00390]

3. Sullivan-Kwantes W, Haman F, Kingma BRM, Martini S, Gautier-Wong E, Chen KY, Friedl KE. Human performance research for military operations in extreme cold environments. J Sci Med Sport. 2020 Dec 15:S1440-2440(20)30832-X. doi: 10.1016/j.jsams.2020.11.010. Epub ahead of print. PMID: 33358087 < https://www.sciencedirect.com/science/article/pii/S144024402030832X>

KEYWORDS: Freezing cold injury, frost nip, cold exposure

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DHA224-D002 TITLE: Therapeutic Modalities for the Mitigation of Neck/Back Pain during Flight Operations

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: Design, build, and demonstrate a portable, ergonomically appropriate, and powered device for the relief of neck/back pain during long-haul flight operations. The proposed device shall: 1) not employ lithium-ion batteries in conjunction with the enriched oxygen environment of the aircraft cockpit/cabin; 2) provide relief on-demand as needed via on/off switch; 3) require no manipulation on the part of the aircrew outside turning on or off; 4) be compatible for use across all current-generation flight seats independent of platform type (fixed-wing ejection seat (FWES), fixed-wing non-ejection seat (FWNES), or rotary-wing/tilt rotor (RW/TR) and aircrew position (cockpit vs cabin); and finally, 5) not interfere with the operation of flight, safety, and life-support gear. Additionally, the proposed device may: 1) provide heat at targeted areas; 2) be obtainable without a prescription.

Finally, the device shall be considered by NAVAIR (or other SYSCOMs and DoD Service Components) and the Aeromedical Community for use inside the cockpit/cabin.

DESCRIPTION: Neck/back pain is a significant problem in aircrew of the US Navy (USN) and US Service Branches; prevalent across all platforms including fixed-wing ejection-seat (FWES), fixed-wing non-ejection-seat (FWNES), and rotary wing/tilt rotor (RW/TR)[9, 13]. It accounts for an extensive burden in time and resources to the US and international partners in Europe with numerous investigations and projects aimed at solving the problem, demonstrated by a comprehensive report to the North Atlantic Treaty Organization (NATO) in 2019 and highlighting the universal aspect of this problem[9]. Neck/back pain is cited multiple times in the aircrew surveys designed to identify crew concerns, requirements, and capability gaps. In the RW community alone, over 10,000 aircrew reported neck, back, leg pain, and injury ranging from temporary annoyance, pain-related in-flight distraction, decreased operational performance, to temporary or permanent grounding, and in some cases early medical retirement. The annual cost from lost time due to neck, back, and leg pain across the Department of Defense (DoD) was $25M, while disability payments was $129M annually[11]. Back and neck pain directly affects aircrew performance and crew resource management (CRM) inside the cabin resulting in fatigue or pain-related mishaps due to human error and costing roughly $248M DoD-wide in annual damage costs[12].

Medical grounding is responsible for significant detrimental impacts to squadron operational tempo (OPTEMPO), costs from physical therapy or surgery, and loss of the aircrewman to early retirement by medical separation; all resulting in a fiscal burden of over $161M in the Navy RW/TR community alone[12]. These costs reflect 10-year-old helicopter data, which are only a fraction of current costs across all platforms[12]. More importantly, the US Navy Aviator training pipeline is rigorous and requires significant investment of time and money. Depending on the platform, training a single new USN Aviator can take over 2 years and over $11 million as these aviators have the additional task of landing on moving carriers and amphibious assault ships compared with their USAF colleagues[8]. Coupled together, neck/back pain is a costly problem within the USN.

The Defense Health Agency (DHA) is a joint, integrated Combat Support Agency that enables the Army, Navy, and Air Force medical services to provide a medically ready force and ready medical force to Combatant Commands in both peacetime and wartime[7]. Neck/back pain is not isolated to the USN; the US Army, Air Force (USAF), Marine Corps (USMC), and Coast Guard (UCG) have their own aviation (rotary and fixed-wing) and operating common platforms that experience high prevalence of neck/back pain[3, 10]. Likewise, IT is ubiquitous throughout USN Systems Commands (SYSCOMS) including Naval

Sea Systems Command (NAVSEA)[11]. Officers and sailors in communities such as surface warfare and submarine warfare and manning watch-stations and consoles for radar, sonar, UUV, and ROV operators all experience neck/back pain; however, they don't have the same operating environment exposures or constraints inherent to military aviation. This critical problem requires "outside the box thinking" and new approaches through modalities in the form of a device that can treat and alleviate neck/back pain during actual in-flight operations. The DHA and its joint mission objectives is vitally suited to address this global military affliction.

The severe impacts described necessitate the implementation of preventive measures to mitigate and alleviate pain before it becomes debilitating and results in medical grounding. Currently, treatments for neck/back pain within the USN and the DoD consist of rest, pharmacological intervention, seat cushions/material solutions, physical therapy (PT) and surgery. The final two are both expensive therapies in terms of fiscal and time. Additionally, there are the second and third order effects of grounding for recovery or even permanent. Furthermore, as a preventable pathology, PT for neck/back pain severely drains valuable manpower, time and resources from more serious injuries sustained from either combat or mishaps. This is especially pertinent when it is not secondary to a more serious pathology or injury.

Concomitantly, these mitigation strategies often aren't available because the resources are consumed by combat, trauma, or mishap-related injuries. As a result, potentially preventable injuries go untreated until they become severe and/or permanent. Neck/back pain are sometimes a physical pathology is due to individual anatomy, pre-existing conditions that are exacerbated by flying, sometimes they are truly over-use/chronic injuries that might have been prevented through early intervention. It is important to note that this proposal is not meant as a replacement to clinical intervention as these remain essential for treatment. The device may not actually address physical pathology, however, it is a modality that can help alleviate pain during flight operations, improving aircrew CRM and safety.

Several studies demonstrate low-cost, non-invasive exercises targeting the muscles of the shoulders, neck, and core significantly reduced in-flight neck/back pain in rotary wing aviators[1, 2]. While these exercises are often used by physical therapists for during clinical treatment, the results have not yet been promulgated as official guidance through instruction documents such as the Naval Air Training and Operating Procedures Standardization (NATOPS)[4]. Furthermore, neck/back pain starts inside the aircraft during operation. Unfortunately, the interior space of an aircraft cabin or cockpit preclude performing these exercises due to the limited range of motion for the aircrew due to flight gear and being harnessed in the seat.

The ultimate goal of this SBIR proposal is to tackle this ubiquitous problem as an "all hands on deck" approach. By leveraging industry to develop an innovative and beneficial device solution for the prevention of musculoskeletal injuries at the source; neck and back pain during active flight operations. Employment of an in-cabin device to augment preventive measures for musculoskeletal injury in conjunction with current clinical therapies will significantly reduce the enormous health and fiscal burden neck/back pain inflicts on the Navy and DoD. More importantly, it will allow DHA and Navy Medicine to refocus efforts to higher priority areas like combat casualty care and traumatic injury while also helping the Line combat pilot and aircrew shortages due to medical groundings and separations.

PHASE I: Advanced, innovative solutions for acute alleviation of neck and back pain during operation of vehicle/machinery such as aircraft are sought. Design can include, but not limited to, common, commercially-available devices such as a conventional contact-style massager or transcutaneous electrical nerve stimulation (TENS). FDA may be required if the proposed solution is a TENS design. Delivery of pain relief despite limited range of motion for the operator in a seated position and minimal interaction are important qualities for the product to be developed. The candidate technology will demonstrate a portable, ergonomically appropriate, and powered device for the relief of neck/back pain during long-haul

flight, driving, or heavy machinery operations. The technology developed will eventually be required to be adapted to a flight environment on military aircraft with special emphasis on naval environments featuring moisture and salt. Highly desirable criteria include: not powered by lithium-ion batteries, and will not interfere with potentially worn safety gear. Successful proposers will show feasibility of an innovative, novel, candidate technology for mitigating neck and back pain during operational conditions including flight, driving, and heavy machinery like cranes/excavators.

This topic is accepting Direct to Phase II (DPII) proposals ONLY. Proposers submitting a DPII proposal must provide documentation to substantiate that the scientific and technical merit and feasibility described above has been met and describes the potential commercial applications. Documentation should include all relevant information including, but not limited to: technical reports, test data, prototype designs/models, and performance goals/results.

PHASE II: Develop a working prototype that mitigates neck/back pain and is suitable for use in the flight environment and during operations. It is desirable that the performer produces a prototype that meets the requirements listed below as well as begin to validate the use of the prototype using human participants. Through this testing and evaluation process, the performer should make iterative refinements to the prototype. Required Phase II deliverables will include a working prototype, and a report about the overall project progress.

While devices for relieving neck/back pain are mature technologies and available commercially in various forms, neither device have been designed to operate in conjunction with aircrew flight and safety gear or within the unique confines of an aircraft cabin (hypobaric pressure, oxygen-enriched, temperature). Specific considerations to naval environments (moisture and salt) and flight worthiness must incorporated in order to meet mil-standards for required for approval and use. Mil-standard 810 (MIL-STD-810) describes “Environmental Engineering Considerations and Laboratory Tests”[6]. Flight worthiness requirements for crew systems are instructed in chapter 9 of the DoD Handbook 516 (MIL-HDBK-516) “Airworthiness Certification Criteria”[5].

Furthermore, seating dimensions for the variety of USN aircraft may need to be provided but, generally, the dimensions are fairly common between different platforms. The following table displays area dimensions for the seat pan, back rest, and head rest for the different seating positions in RW and TR aircraft including the H-60, V-22, AH-1, and CH-47. Furthermore, Martin-Baker Aircraft Co. Ltd. produces most of the ejection seats for USN FWES aircraft.

Aircraft and Seat Position								
	Units	MH-60S Gunner Seat	MH-60S Troop Seat	H-60 Pilot Seat, Armored	V-22 Troop Seat	V-22 Pilot, Armored	H-1/AH-1 Pilot Seat, Armored	CH-47 Troop Seat
Seat Pan Width	[in]	19	19.5	18.5	17.5	19.5	17.5	18
Seat Pan Length	[in]	17	14.5	15	16	16	15.5	13.5
Back Rest Width	[in]	18	19	19	17.5	17	17.5	15.5
Back Rest Height	[in]	24	26	24	26	22	25	34
Head Rest Width	[in]	11	N/A	10	N/A	N/A	9	integrated
Head Rest Height	[in]	7.5	N/A	8	N/A	N/A	8	integrated

AMENDMENT 1

Related to the previous consideration, operation of a device inside the unique, confined, pressurized, and oxygen-rich environment of the cockpit/cabin requires several critical characteristics be developed and ***shall*** be incorporated into design concepts developed in Phase I to comply with standard operation procedures and safety protocols. These characteristics are as follows:

1. This cockpit/cabin interior of FWES and FWNES aircraft are pressurized and oxygen-enriched. Aviators/aircrew flying in these platforms wear masks that deliver on average 95% O2 at any given time. NATOPS instruction forbids the operation of equipment powered by lithium-ion batteries inside the cockpit/cabin[4].

2. The cockpit/cabin of most USN aircraft are extremely space limited, particularly in the cockpit. Moreover, aviators/aircrew are strapped by harness into the seat with limited maneuverability and range of motion. To compensate for the limited space within aircraft, the device shall be designed to require no sustained manipulation to operate beyond turning on/off. The device design must be small and portable, either as a chairback-style or wearable under the flight equipment. Outside of an on/off switch to power on/off, the device shall be "set it and forget it" in its method of operation and delivery of relief.

   Location of power switch shall be intuitively located and not require line of sight or upper body movement to operate to allow for quick termination should necessity (high-intensity operations or maneuvers) require. If proposed device is a wearable system, switch will need to be routed and secured to the flight suit in such a way as to preventing a snag hazard.

3. All aircraft platforms feature a variety of seat types and aviators/aircrew sit in different positions depending on their job and role. The device shall be designed to be ergonomically appropriate and compatible for operation across all current generation flight seats. It should be compatible for use in all flight platforms in the USN inventory including FWES, FWNES, and RW/TR. It shall be capable of operation independent of seating position whether in thecockpit, cabin, jump seat, or other.

4. The operating environment of cockpit/cabin places significant cognitive loading on the aircrew performing the operation procedures required to fly the highly complex and capable aircraft of the fleet. As such, aviators/aircrew must rely on CRM to maintain safe operating conditions and prevent mishaps. Unexpected stimuli from the device could disrupt CRM and interfere with flight operations particularly in a high-intensity situation like combat maneuvering.

   Therefore, the device must incorporate into its design an on/off switch easily accessible to the aircrew to allow for on-demand delivery of relief and cessation when no longer needed or required by necessity.
5. Finally, the device shall not interfere with flight, safety, or life-support gear/equipment either during normal or emergency operations. Device proposals designed as a wearable must be water-tight in event of submersion to prevent the risk of electric shock. All devices must be designed to withstand typical naval environment exposures such as salt and moisture as well as be rugged enough for use in a military capacity. Additionally, any proposed device must not interfere with aircrew emergency egress.

Furthermore, the following considerations ***may*** also be incorporated into any device proposal.

1. Most neck/back pain involve some element of muscle spasms. Heat therapy is well documented to be beneficial in relieving neck/back pain by increasing the delivery of blood and oxygen, and

facilitating stretching of muscle fibers. Accordingly, the device may be designed to deliver heat through the contact elements.

2. Once Aeromedically-approved and to provide maximum flexibility, it is recommended the device be obtainable without a prescription from a medical official.

PHASE III: Using the results and progress made during Phase II, a Phase III effort would complete any remaining work necessary to have the proposed solution meet the performance parameters described in this topic, demonstrate its performance in a military-relevant environment, and become production ready. The final design solution should be easily adaptable for occupations experiencing significant neck/back pain including long-haul truckers and dock crane operators. These professions experience a commonality of environmental or occupational constraints including vibration, non-ergonomic seating, restricted mobility, and prolonged sitting. A device to mitigate neck/back pain during operational hours would benefit these civilian operators.

The device shall be considered by NAVAIR (or other SYSCOMs and DoD Service Components) and the Aeromedical Community for use inside the cockpit/cabin.

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KEYWORDS: Therapeutic Modalities, Neck/Back Pain, Flight Operations

AMENDMENT 1

DHA224-D003 TITLE: Adaptive Technology to Optimize Rehabilitation of Lower Extremity Musculoskeletal Injuries throughout Recovery

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: To develop a technology (e.g. brace, exoskeleton) that adapts to facilitate recovery throughout rehabilitation of service members with lower extremity musculoskeletal injury to enable return to duty throughout rehabilitation of service members with lower extremity musculoskeletal injury to enable return to duty.

DESCRIPTION: The DoD lacks capability to optimally and rapidly rehabilitate injured Warfighters to duty. Over 1 million medical encounters and roughly 10 million days of limited duty occur annually as a result of injuries and injury-related musculoskeletal conditions, affecting over half of Soldiers each year (U.S. Army Public Health Center. 2018. 2018 Health of the Force, https://phc.amedd.army.mil/topics/campaigns/hof). Military recruits engaged in training are at a higher risk of suffering an injury, with the majority of injuries occurring in the lower limb (Andersen, KA, et al. 2016. Musculoskeletal Lower Limb Injury Risk in Army Populations. Sports medicine - open, 2, 22.). Specifically, injuries to the ankle-foot complex account for one the highest proportions of musculoskeletal injuries in conventional and special warfare combatants (Teyhen, DS, et al. 2018, Incidence of Musculoskeletal Injury in US Army Unit Types: A Prospective Cohort Study. Journal of Orthopaedic and Sports Physical Therapy, 48, 749). Depending on the severity of the injury, rehabilitation times can extend across weeks, months, and even years. The rehabilitation needs of the Warfighter change during this time, to include the level of support, stabilization, assistance, and/or resistance of essential exoskeleton or bracing technology. The DoD is limited in available technology that is responsive or can be tuned to meet these changing needs of the Warfighter throughout the rehabilitation process to facilitate return to duty. A solution is sought that is clinically accessible, easy to use for both clinicians and patients, and has the potential to be applicable across various ankle injuries to promote Warfighter return to duty.

PHASE I: Completed Phase I efforts should demonstrate innovative solutions for a technology that can be worn about the lower limb (e.g. exoskeleton, brace, etc.) and adapt, respond, or be modified to meet changing needs of the end user throughout the rehabilitation process. Solutions are intended to be used within the operational environment, training environment, and/or clinical care setting. The developed technology should be implemented as part of the rehabilitation process and should result in improved outcomes and/or accelerated recovery and/or cost savings resulting from use of a single technology as opposed to fabrication or purchase of multiple devices throughout recovery.

This topic is accepting Direct to Phase II (DPII) proposals ONLY. Proposers submitting a DPII proposal must provide documentation to substantiate that the scientific and technical merit and feasibility described above has been met and describes the potential commercial applications. Documentation should include all relevant information including, but not limited to: technical reports, test data, prototype designs/models, and performance goals/results.

PHASE II: Design and develop the practical implementation of the prototype system that implements the previously completed Phase I methodology towards a technology that can respond, adapt, or be modified to meet the changing needs of the service member with lower extremity injury throughout the recovery process. Mechanical and/or biomechanical outcomes are key to demonstrating the capabilities of the design. The testing and practical implementation of the prototype system should be relevant to Warfighters who have experienced lower limb musculoskeletal injuries in training or operational settings.

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Technology intended to support rehabilitation of patients with spinal cord injury and neurological conditions is not permitted but new applications of existing technologies are acceptable. The investigator shall also describe in detail the transition plan for the Phase III effort. A plan for meeting FDA requirements toward regulatory approval is also required.

PHASE III: Test, finalize and validate the prototype and product to respond, adapt, or be modified to meet the changing needs of the service member with lower extremity injury throughout the recovery process. Investigators shall work with commercial partners, military partners, and/or the civilian marketplace (i.e. sports medicine) to move towards a final commercial product that will promote optimal recovery throughout the rehabilitation process. Ensure that the final product can be incorporated into clinical practice including ease of use, appropriate coding/billing, cost/benefit, and training, education, socialization, and outreach. The military's highest priority is readiness and musculoskeletal injuries are one of the greatest factors limiting readiness. Technology that has the potential to span a range of lower limb musculoskeletal injuries to accelerate recovery and return to duty is desirable. Additionally, it is envisioned that this technology could be applied within VA and civilian rehabilitation facilities. Regulatory approval to ensure that the commercialized product will meet FDA requirements must be considered.

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KEYWORDS: Musculoskeletal, Lower Extremity, Ankle, Injury, Brace, Exoskeleton, Rehabilitation