Defense Health Agency (DHA)
2023.3 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.

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 format submission via DSIP are provided in the DoD SBIR Program Broad Agency Announcement (BAA). Proposals not conforming to the terms of this BAA will not be considered.

DHA requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

Only Government personnel will evaluate proposals with the exception of technical personnel from Odyssey Systems, Allied Technologies and Consulting LLC, and General Dynamics Information Technology, who will provide technical analysis in the evaluation of proposals submitted against DHA topics:

- Rapid Diagnostic for Invasive Fungal Infection
- Medical Oxygen Storage and Delivery for Deployed Joint Services' Casualty Care

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

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

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 deemed non-compliant and will not be evaluated.

Cost Volume (Volume 3)

The Phase I amount must not exceed $250,000 over a 6-month period of performance. 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)

Volume 5 is provided for proposing small business concerns to submit additional documentation to support the submission. All proposing small business concerns 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)
2. Disclosures of Foreign Affiliations or Relationships to Foreign Countries (Attachment 2)
3. Disclosure of Funding Sources (Attachment 4)

A completed proposal submission in DSIP does NOT indicate that the mandatory supporting documents have been uploaded. It is the responsibility of the proposing small business concern to ensure that the mandatory documents listed above have been uploaded and included with the proposal submission.

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.

DIRECT TO PHASE II PROPOSAL GUIDELINES

Each Direct to Phase II topic requires that proposing small business concerns provide documentation to demonstrate feasibility described in the Phase I section of the topic has been met. Feasibility documentation cannot be based upon or logically extend from any prior or ongoing federally funded SBIR or STTR work. Work submitted within the feasibility documentation must have been substantially performed by the proposing small business concern and/or the PI. If technology in the feasibility documentation is subject to Intellectual Property (IP), the proposing small business concern must either own the IP, or must have obtained license rights to such technology prior to proposal submission, to enable it and its subcontractors to legally carry out the proposed work. If the proposing small business concern fails to demonstrate technical merit and feasibility

equivalent to the Phase I level as described in the associated topic, the related Phase II proposal will not be accepted or evaluated.

Direct to Phase II proposals must include all volumes, not to exceed maximum page limit, and must follow the formatting requirements provided in the DoD SBIR Program BAA. Submissions that exceed the maximum page limit will be deemed non-compliant and will not be evaluated.

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)

Technical Volume (Volume 2):

Phase I Justification: Offerors are required to provide evidence that the scientific and technical merit and feasibility have been established as described in the topic description.

Phase II Technical Proposal:

i. Results of the current work – Discuss the objectives of your effort, the research conducted, findings or results, and estimates of technical feasibility.
ii. Technical objectives and approach – List the specific technical objectives of the Direct to Phase II research and describe the technical approach in detail to be used to meet these objectives.
iii. Work plan – The plan should indicate what is planned, how and where, a schedule of major events, and the final product to be developed.
iv. 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.
v. Relationship with future research or Research and Development – State the anticipated results of the proposed approach if the project is successful. Discuss the significance of the effort in providing a foundation for a Phase III research or research and development effort.
vi. Technology transition and commercialization strategy – Describe your company's strategy for converting the proposed SBIR research into a product or non-R&D service with widespread commercial use – including private sector and/or military markets. Note: The commercialization strategy is separate from the Commercialization Report. 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 awards.

vii. Key personnel - Identify key personnel, including the Principal Investigator, who will be involved in the effort. List directly related education and experience and relevant publications (if any) of key personnel. A concise resume of the Principal Investigator(s) must be included.

viii. Foreign Citizens – Identify any foreign citizens or individuals holding dual citizenship expected to be involved on this project as a direct employee, subcontractor, or consultant. For these individuals, please specify their country of origin, the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project. Proposing small business concerns frequently assume that individuals with dual citizenship or a work permit will be permitted to work on an SBIR project and do not report them. This is not necessarily the case and a proposal may be deemed nonresponsive if the requested information is not provided. Therefore, proposing small business concerns should report any and all individuals expected to be involved on this project that are considered a foreign national as defined in Section 3 of the BAA. You may be asked to provide additional information during negotiations in order to verify the foreign citizen's eligibility to participate on a SBIR contract. Supplemental information provided in response to this paragraph will be protected in accordance with the Privacy Act (5 U.S.C. 552a), if applicable, and the Freedom of Information Act (5 U.S.C. 552(b)(6)).

ix. Facilities/Equipment – Justify items of equipment to be purchased (as detailed in the cost proposal), 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 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.

x. 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):

The Cost Volume must contain a budget for the entire 24-month Direct to Phase II period that reflects 'year 1' and 'year 2' and not to exceed the maximum dollar amount of $1,300,000. Costs must be separated and clearly identified on the Proposal Cover Sheet (Volume 1) and in the Cost Volume (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.

List all key personnel by name as well as number of hours dedicated to the project as direct labor. Special Tooling, Test Equipment, and Materials Costs.

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

Supporting Documents (Volume 5): A completed proposal submission in DSIP does NOT indicate that the mandatory supporting documents have been uploaded. It is the responsibility of the proposing small business concern to ensure that the mandatory documents listed above have been uploaded and included with the proposal submission.

1. Contractor Certification Regarding Provision of Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Attachment 1) MANDATORY
2. Disclosures of Foreign Affiliations or Relationships to Foreign Countries (Attachment 2) MANDATORY
3. Verification of Eligibility of Small Business Joint Ventures (Attachment 3), if applicable
4. Disclosure of Funding Sources (Attachment 4) MANDATORY
5. Other supporting documentation

PHASE II PROPOSAL GUIDELINES
Phase II proposals may only be submitted by Phase I awardees from this BAA. Phase II is the demonstration of the technology found feasible in Phase I. The details on the due date, content, and submission requirements of the Phase II proposal will be provided by the DHA SBIR PMO typically in month five of the Phase I contract.

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.

Technical Volumes that exceed the 40-page limit will be deemed non-compliant and will not be evaluated.

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

The DHA SBIR Program highly discourages offerors from proposing a federal facility use waiver during Phase I due to the significant lead time required to prepare documentation and secure approval, which could substantially delay the performance of the Phase I award.

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 following APAN 15-01 requirements (the full text of this notice can be found at https://usamraa.health.mil/SiteAssets/APAN%2015-01%20Revised%20Feb%202018.pdf):

(1) The DoD Intramural Researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the Extramural Research project. This letter must be provided to the Extramural Organization for inclusion in the proposal or application.

(2) The DoD Intramural Researcher must also coordinate with his/her local Resource Manager Office (or equivalent) to prepare a sound budget and justification for the estimated costs. Where there are no DoD-established reimbursement rates [e.g., institution review board (IRB) fees, indirect cost rates, etc.], the Military Facility's RM office (or equivalent) must provide details of how the proposed rates were determined. The DoD Intramural Researcher must use the budget and justification form enclosed in APAN 15-01 when developing the estimated costs and provide it to the Extramural Organization for inclusion in the proposal or application.

(3) The Extramural Research proposal or application must include a proposed financial plan for how the Military Facility's Intramural Research costs will be supported [i.e., directly funded by DoD, resources (other than award funds) provided by the Awardee to the Military Facility, or award funds provided by the Awardee to the Military Facility (in accordance with the requirements below)].

(4) The DoD Intramural Researcher should also coordinate with his/her technology transfer office.

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 23.3 Topic Index

DHA233-001 TITLE: Rapid Diagnostic for Invasive Fungal Infection

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Military Infectious Disease

OBJECTIVE: Develop a technical solution or device for the identification of an Invasive Fungal Wound Infections in a Military Treatment Facility or lower Role of Care within 24 hours.

DESCRIPTION: Trauma-related invasive fungal wound infections (IFIs) are associated with significant morbidity and mortality (8-12% mortality). Early identification and treatment are critical to prevent loss of limb and/or loss of life. Traditional identification methods can be delayed and insensitive and are heavily dependent on clinical and microbiological expertise. At presentation for clinical treatment, differential diagnoses for deep necrotizing wounds leans heavily towards infections caused by multi-drug resistant (MDR) bacteria. During initial wound assessment, clinicians must have a heightened sense of IFI suspicion, often requiring a high degree of expertise, in order to clinically differentiate between bacteria or fungal infections. Current clinical laboratory diagnostics involve direct examination of cultures and histopathology of collected wound tissue specimens. Fungal cultivation, the current standard diagnostic method, has numerous disadvantages including, but not limited to a low sensitivity (only 50% of the patients present positive fungal cultures) and long growth time. These factors delay patient treatment and consequently lead to longer hospital admissions and higher hospital costs. Clinical laboratory diagnosis can take, at best, between 24-72 hours or at worst, 6-8 weeks, to positively confirm and identify an IFI. The benefit of fungal isolation from tissue culture includes direct evaluation of clinically relevant characteristics such as antifungal resistance and species identification. However, fungal speciation through culture requires considerable expertise for identification.

Currently, there are no commercially available products that can quickly and accurately clinically diagnose the presence of a wound-IFI as well as quickly speciate and determine antifungal drug susceptibility. Many IFI's go undiagnosed due to the high level of clinical and microbiological experiences required. The envisioned system would employ a technology using an innovative engineering approach that enables infection identification. In addition to the primary objective of determining the causative agent of an ongoing IFI, such a device would also enable prospective monitoring of patients at risk for IFI, such as severely immunocompromised individuals, enabling early treatment before the occurrence of overt symptoms. If adapted to a DOD product the proposed technology is envisioned to be utilized at the Role 3 or potentially Role 2+ alongside analogous bacteriological diagnostics in a prolonged field care type environment occurring during Large Scale Combat Operations.

The technology is not limited to but may consider, the factors below:

1) The technology must include a plan for FDA clearance
2) Detection and identification of IFI via built-in antigen tests, nucleic acid assays, VOC sniffers, chemical/molecular detector, photonics …etc. must be contiguous in one platform with minimal user training
3) Technology should have the ability to distinguish between common clinical fungal agents of infection with no downstream analysis required. Examples include, but are not limited to:
Order Mucorales, Aspergillus sp, Fusarium sp., +/- Scedosporium sp., and agents of phaeohyphomycosis
4) Technology should be capable of operating continuously or successively in a high throughput as well as an on-demand between samples with minimal number of steps
5) The ability to determine antifungal drug susceptibility is preferred but optional
6) Engineering solutions overall should require minimum logistical support, should be compatible with applications in wet/dry environments, and stable in long term storage including hot (~100°C) and cold temperature (-20°C)

7) Ease of use, technology should be operable with little training or background with unambiguous primary output

Technologies with the following features are not the primary focus of this topic
1. Microscopy based automated or manual morphology description methods
2. Methods involving staining and/or adhesive tape
3. Established methods involving mass spectrometry workflow
4. Technologies involving radioactive agents

PHASE I: Given the short duration of Phase I and the high order of technology integration required, Phase I should focus on system design and development of proof-of-concept prototypes that address the diagnostic capability requirement. Proposals may include early versions diagnostic systems that may combine "classes" of applications into different "sets" of designs. At the end of this phase, fabricated prototypes should demonstrate detection along a continuum of growth as feasibility, proof-of-concept and establish reasonable qualitative identification, using relevant testing platforms for the proposed technology. This phase should down-select promising design with sufficient performance specification superior to current standards in the laboratory. Evaluation of the product's durability for detecting IFI and must include data for 6, 12, 18, and 24 hours of in vitro testing at a minimum. The above time points do not represent system application on subjects but used as a benchmark and quantify efficacy of detection of infection.

PHASE II: During this phase, the lead integrated system should be further refined from proof-of-concept and begin planning compatibility with CLIA standards for the clinical laboratory. Further optimization of the technology for earlier and more robust detection of infection at a traumatized wound bed should be demonstrated during this phase. Qualitative and quantitative outcomes of product with regards to quantification of spores/hyphae, identification of invading organism, and/or characteristics of such as anti-fungal susceptibility if feasible. This testing should be controlled and in rigorous conditions. Accompanying application instructions and simplified procedures should be drafted in a multimedia format for use and integration of the product into market. At this stage, offers may begin developing plans and documents for quality control material, training materials, proficiency assessment tools and materials, device verification and validation documents, supporting material for Individualized Quality Control Plan for easy adoption of technology as a nonwaived test. Price estimate and comparison analysis for new designs relative to current fielded equipment shall be provided to forecast the potential cost of the product and commercial viability. The offeror shall articulate the regulatory strategy and provide a clear plan on how FDA clearance will be obtained.

PHASE III DUAL USE APPLICATIONS: The ultimate goal of this phase is to secure an FDA approved device to commercialize a technology enabling the early detection of fungi. Additional use cases may be included in order to derive, extend, or complete the funded innovation. The growing use of immunosuppressive drugs to treat various diseases such as HIV will likely increase the incidence of IFIs in civilian populations. The global market for fungal therapeutics is expected to grow from $7.2 Billion in 2021 to $10 billion by 2030. The clinical diagnostic space will be critical in leveraging this growing market segment. Alternatively, further development, testing and evaluation of the product developed in phase II of this SBIR can be supported by BARDA, CDMRP, JWMRP, and other DOD opportunities. Once developed and demonstrated, the technology can be used commercially in both civilian and military settings to save lives. If the product is transitioned into Acquisition Programs of Record, the Government retains the right to harmonize design with other relevant products.

REFERENCES:

1. Tribble DR, Ganesan A, Rodriguez CJ. Combat trauma-related invasive fungal wound infections. Curr Fungal Infect Rep. 2020 Jun;14(2):186-196. doi: 10.1007/s12281-020-00385-4. Epub 2020 Apr 16. PMID: 32665807; PMCID: PMC7360332.
2. Ganesan, Anuradha, et al. "Molecular detection of filamentous fungi in formalin-fixed paraffin-embedded specimens in invasive fungal wound infections is feasible with high specificity." Journal of clinical microbiology 58.1 (2019): e01259-19. https://doi.org/10.1128/JCM.01259-19
3. Mendonca, Alexandre, et al. "Fungal infections diagnosis–Past, present and future." Research in Microbiology 173.3 (2022): 103915. https://doi.org/10.1016/j.resmic.2021.103915
4. Kozel, Thomas R., and Brian Wickes. "Fungal diagnostics." Cold Spring Harbor perspectives in medicine 4.4 (2014): a019299. doi:10.1101/cshperspect.a019299
5. Terrero-Salcedo, David, and Margaret V. Powers-Fletcher. "Updates in laboratory diagnostics for invasive fungal infections." Journal of Clinical Microbiology 58.6 (2020): e01487-19. https://doi.org/10.1128/JCM.01487-19

KEYWORDS: Infection, Diagnosis, Trauma, Fungal Pathogen, Clinical Device

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DHA233-002 TITLE: Novel Fieldable Device for Detection of Sleep Microarousals

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Military Operational Medicine

OBJECTIVE: Develop a fieldable, wearable device that detects microarousals during sleep.

DESCRIPTION: It is well known that Soldiers consistently fail to obtain the 7-9 hours of nightly sleep that is recommended by National Sleep Foundation (Watson et al., 2015). In fact, more than 62% of Soldiers average less than 6 hours of sleep per night (Troxel et al., 2015). This is over double what is found in the civilian population, as 28% of civilians average less than 6 hours of sleep per night, thus, a majority of Soldiers are chronically sleep restricted– a situation that reduces the military's competitive edge. Sleep loss of this magnitude negatively impacts virtually every aspect of performance, health, and readiness. However, even in carefully controlled laboratory studies of sleep loss in health young adults, there exists a spectrum of responses to the same amount of sleep loss, such that roughly 1/3 are resilient to sleep loss and another third are more vulnerable as measured by next day performance (Reifman et al., 2018). Therefore, total sleep time itself does not fully predict performance even in tightly controlled laboratory studies. Additionally, outside of the laboratory, military members encounter many disruptions to sleep, including noise, light, and extreme and fluctuating temperatures. These disruptions are only expected to intensify during multi-domain operations where the battlefield will be progressively more lethal and complex. However, currently available fieldable sleep measurement devices (e.g., watches from Garmin, Fitbit, Apple and rings from Oura) struggle to fully capture smaller disruptions to sleep continuity and can only provide reliable total sleep time measures (Chinoy et al., 2021). For these reasons, there exists a need for a fieldable, wearable device than can measure more than total sleep time. Both the DoD and the consumer market need an unobtrusive, wearable device that can reliably measure sleep continuity – a metric that may predict next day performance and health associated outcomes better than total sleep time.

One measure of disrupted sleep continuity is the accumulation of cortical microarousal events across a sleep period. These are moments of brief biological waking activity with a rapid return to sleep (< 15 seconds). These events are not detected with current wearable sleep tracking technology (e.g., watches and rings) but they provide an important datapoint associated with altered daytime functioning (Martin et al., 1996; Stepanski et al., 1987) and negative health outcomes including cardiovascular health and increased diabetes risk (Taylor et al., 2016; Stamatakis and Punjabi 2010). Currently microarousals can only be identified by a trained technologist using polysomnographic equipment in a laboratory setting. However, with the increasing sophistication of wearable devices, including dry electroencephalographic electrodes and increased onboard processing power, it stands to reason that consistent measurement of microarousals could be possible with a fieldable wearable device.

This proposal aims to first develop a novel wearable device that measures sleep microarousals in Phase I and then validate the device and determine if microarousals collected by the device are related to next day performance on militarily relevant outcomes in Phase II. If fielded, the technology may require secured communication methods.

PHASE I: The objective is to develop a novel wearable device that measures sleep microarousals. The current sleep measurement devices that are on the market can only accurately predict total sleep time and struggle to capture issues with sleep continuity. No current wearable devices can measure microarousals during sleep to our knowledge. Therefore, there is a need for a fieldable device that can measure this important aspect of sleep that is associated with negative health outcomes and altered daytime functioning. This phase will demonstrate the feasibility of producing a demonstration of microarousal detection on a wearable device.

Requirements for Phase I device:
• Wearable on the body (e.g., placed on the forehead or on a limb)
• Comfortable and unobtrusive – should not interfere with sleep
• No user interaction needed (e.g., prepping skin, adding electrodes, adding gel) – device should be able to put on by user and then left alone
• Wireless – small rechargeable battery lasting at least 12 hours (lithium ion is minimum standard)
• Ability to toggle between saving data on device or wirelessly transmitting to local device using military telecommunication standards
• Onboard detection of microarousals in real-time – preliminary design and validation can be completed with simulated data

PHASE II: The objective is to demonstrate that sleep microarousals can be detected with a novel wearable device and determine feasibility for prediction of next day cognitive performance. This phase will involve testing of the microarousal device created in Phase I to prove it can be used to reliably measure microarousals during sleep. Additionally, performers should determine if microarousals measured during sleep by the device are found to relate to next day cognitive performance.
During this phase, performers will build off the results from Phase I and execute human subject research prototype development where participants wear the novel microarousal detection device overnight and then perform militarily relevant tasks the next day.

Requirements for Phase II human subject research prototype development:
• Overnight PSG recordings collected during sleep while individual is wearing device developed in Phase I
• Cognitive performance must be tested the next day following the sleep recording
• Cognitive performance datasets should include at least one militarily relevant outcome metric and must contain a measure of vigilance (can count as militarily relevant outcome)
• Data should come from healthy adults under 50 (i.e., surrogates of the active duty population including leaders)
• Data should be collected on at least 20 individual adults
• Data from the device should be able to detect American Academy of Sleep Medicine (AASM) defined microarousals with 85% accuracy compared to polysomnography (https://aasm.org/clinical-resources/scoring-manual/)
• Data from the device should be tested to ascertain if it can predict next day cognitive performance with 85% accuracy and is significantly better at predicting performance than using total sleep time alone.
Performers should provide a statement assessing the feasibility of the device for the prediction of next day performance and any recommendations for follow-up validation studies.

Following the conclusion of Phase II, four prototype devices and associated datasets containing the requirements listed above should be delivered to the DoD.

PHASE III DUAL USE APPLICATIONS: Following successful completion of Phase II, a fieldable device that can measure sleep microarousals will be available. If preliminary feasibility testing in Phase II indicates that the device has the potential to predict next day cognitive performance, further validation testing will occur in Phase III to verify that the device can reliably predict next day cognitive performance.

This device holds great utility in both the commercial market and within the DoD. Commercially a device of this nature would be a game changer for companies that rely on the current state of performance modeling to schedule workers with high risk jobs such as pilots, truck drivers, and law enforcement. Current performance models rely on total sleep time which does not accurately reflect the quality of sleep and therefore does not accurately predict performance. These companies could easily give workers the

microarousal detection device to wear during sleep and utilize data from the device to make scheduling decisions. Indeed, employee tracking to increase productivity is becoming more and more accepted in industry (https://www.nytimes.com/interactive/2022/08/14/business/worker-productivity-tracking.html). Additionally, outside of industry commercialization, the rapidly growing sleep device consumer market would embrace this device as a more accurate way to measure sleep and also test the efficacy of different sleep interventions within the home. Software and algorithms developed under this SBIR could also potentially be applied to existing wearable devices and sold and licensed as a severable entity. Applications within the DoD are similar to industry but also the information provided by this device could potentially be incorporated into the MRDC-developed 2B-Alert Performance Prediction algorithm to replace the current app's onboard reaction time test (i.e., the Psychomotor Vigilance Test, PVT) that provides individualized performance prediction. This would be a large improvement because the PVT requires the user to interface with the app directly to take the test multiple times a day. The device proposed here is a non-invasive and passive wearable. The technology created with this SBIR could also potentially be integrated into existing wearables and scheduling tools, such as 2B-Alert.

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KEYWORDS: Sleep, Performance, Wearable, Device, Total Sleep Time, Microarousal

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DHA233-003 TITLE: Operator State Monitoring: Minimally Intrusive Monitoring of Peripheral and Cerebral Blood Oxygen as Well as Pulse and Respiratory Rates in Future Vertical Lift Aircrew

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Military Operational Medicine

OBJECTIVE: Develop and demonstrate nonintrusive technology to monitor cerebral blood oxygen, pulse oximetry, pulse rate, respiration rate, and possible impact trauma of Army aviators during flight.

DESCRIPTION: The Army's Future Vertical Lift (FVL) program, which includes SOCOM, is developing aircraft with dramatically expanded performance envelopes that will increase environmental stress on aircrew personnel during flight (1). The enhanced performance capabilities of FVL aircraft and their consequent stresses on the Army aviator will require near real-time actionable information characterizing the aviator's physiological status, information that must be obtained without adversely impacting aviator performance in any way for the duration of the mission (3). With the increased speed, agility, and altitude of the FVL aircraft, blood oxygen levels are an increasingly crucial parameter to monitor.

The literature identifies well-established differences in the spectra of arterial (i.e., oxygenated) blood verses venous (i.e., deoxygenated) blood (5). This difference in spectra underlies conventional pulse oximetry, which is widely used to monitor the percent oxygen saturation of peripheral blood. Such conventional pulse oximetry measurements are typically limited to measuring blood oxygen in tissue that can be transilluminated, such as the finger or earlobe. However, it has been well established that, for any of a large number of reasons, peripheral blood oxygen saturation can differ markedly from the blood oxygen saturation in the central nervous system (5). Thus, current pulse oximetry technology, limited to peripheral blood oxygen saturation, is incapable of monitoring cerebral blood oxygen levels. Moreover, the increased physiological stresses that FVL aircraft will impose make peripheral blood oxygen saturation an even less reliable and trustworthy indicator of cerebral blood oxygen. Clearly, for the FVL aviator, precise monitoring of central blood oxygen is far more important than approximations extrapolated from peripheral oxygen saturation measurements. Thus, there is a need for technology that provides reliable measures of central blood oxygen. Recent developments in near infrared transcranial spectroscopy (NIRS) suggest a way forward to meet this need.

Furthermore, the capabilities of FVL aircraft make it essential to determine quickly and reliably whether the pilot is in some way compromised, traumatized, incapacitated, unresponsive, or possibly even dead. Because of these contingencies, there is a need for technology to monitor respiration rate, pulse rate, as well as physiological transients such as the possible occurrence of 'hydrostatic shock,' a pressure wave that can indicate the occurrence of a blunt force trauma or even a penetrating wound. While the hydrostatic shock may not itself produce tissue damage, the detection of such a shock would be important for operator state monitoring (OSM) and interpreting the ensemble of OSM signals. Thus, the technology being developed here should support potential integration with current and projected near-term OSM innovations (4).

To meet specific Army aviation requirements and to integrate with existing Army kits and equipment, significant engineering and algorithm development is anticipated. Additionally, the technology will need to be hardened to mitigate the rotary-wing vibration environment. Furthermore, software enhancements are likely necessary to integrate with the Army's specific software frameworks and possible fusion and/or comparison with other OSM data, flight information, and other factors. If fielded, the technology may require secured communication methods.

PHASE I: Given its short duration, Phase I will not incorporate human testing but will focus on the identification, design and development of an initial proof-of-concept prototype to record such essential physiological OSM parameters as peripheral blood oxygen saturation, cerebral blood oxygen, respiration rate, heart rate and other relevant metrics as well as the identification of pathways for the implementation of hydrostatic shock detection consequent to blunt force or penetrating trauma. To accelerate product development during this phase, an expert workshop targeting OSM in military and civilian aviation will clarify current and emerging near term needs and technology. The proposed prototype Phase I designs should have a compact, low profile, minimally intrusive footprint potentially compatible with the Army helicopter pilot's current helmet.

PHASE II: Phase II will be devoted to the construction, refinement, characterization, and demonstration of the functionality of prototypes designed in Phase I. During Phase II, hydrostatic shock detection capability will be incorporated into the candidate prototype form factors. Essential signal processing, database management, analysis, and display software will be designed and developed. Norms, standards, or 'Red Lines' for the prototype's physiological signals will be demonstrated. Simultaneous displays of cerebral blood oxygen, pulse oximetry, heart rate, and respiration rate for near-real time aviator self and supervisory monitoring will be developed. Additionally, during Phase II, functionality during surrogate mission simulations lasting up to 8 hours in at least 6 Warfighters will be demonstrated. A strategy and plan for FDA approvals will be developed and initiated, and a plan for self and crewmate monitoring will be formulated. Additional candidate OSM variables to interface with the prototype will be identified. Four copies of the prototype devices are to be delivered to USAARL for further test and evaluation.

PHASE III DUAL USE APPLICATIONS: The end-state of this work is an FVL-enabling technology that monitors, in real-time, the medical and physiological status of the pilot and aircrew. This goal is closely aligned with initiatives and goals within the PEO Aviation office to improve aviator safety and situational awareness by reducing cockpit workload and stress. As the technology developed here demonstrates capability within FVL aircraft, it will be integrated into PEO Aviation's enduring fleet aircraft, and more broadly into aircraft platforms across the DoD. Notably, this technology supports the achievement of a validated requirement for FVL aircraft to include operator state monitoring interfaces that enable supervised autonomy. The developer will identify public and private sector funding to support additional necessary R&D as well as the FDA approval plan as required. The developer will be encouraged to coordinate with USAARL to acquire a limited air worthiness certification to enable flight tests and evaluations of the viable prototype(s) as this technology is transitioned to the Army, other DoD partners, and to the private sector, including commercial aviation.

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Note: USAARL publications are available for the USAARL Science Information Center: usarmy-usaarl-sic@health.mil, 334-255-6067

KEYWORDS: Future Vertical Lift, Army Aviators, Physiological monitoring, Cerebral oximetry, Respiration, Pulse oximetry, Operator state monitoring

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DHA233-004 TITLE: Technology to Drive 60-day Runtimes in Wearable Devices

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Military Operational Medicine

OBJECTIVE: Invent and/or develop hardware and embedded software technologies integrated onto a self-powered on-body sensor. The wearable device should include physiological and environmental sensing, recording, and processing that should operate off a non-AC/DC power supply. The device shall be capable of a minimum of 60-day runtime and be able to operate in disconnected, i.e., no cloud or SaaS support, military relevant environments. The developed wearable devices will require additional DoD relevant security measures.

DESCRIPTION: Wearable devices offer the DoD novel information to support readiness of Service Members, informing health and safety risks (1,2). The DoD lacks the ability for continuous remote physiological monitoring to inform readiness metrics under austere military conditions due to power supply limitations of commercially available wearable devices. Addressing this gap will support feedback to the individual Service Member for improved individual performance and resilience, personnel wellness across the unit, and ultimately, to inform and support decisions affecting training, readiness, and mission planning (3).

This funding opportunity announcement solicits applications that address the development of a hardware and software technology to extend the runtime of wearable devices through the development of a self-powered on-body sensor that collects physiological data and operates in a disconnected military relevant environment. The development of this innovative technology will
greatly improve the ability to field wearable devices for long periods of time where recharging may not be operationally feasible. While the innovation is within the development of a self-powering approach to extend wearable devices to a 60-day runtime, this must be done in conjunction with a robustly tested sensor suite so to ensure the data collected are high quality. Additionally, operational environments that involve movements, such as maritime, where induced environmental motion make detection of activity levels or sleep periods especially challenging should be addressed in sensor selection. If fielded, the technology may require secured communication methods.

PHASE I: Phase I proposals should present a plan for the design, development, and fabrication of a an on-body wearable, physiological sensor that operates on a non-AC/DC power source with up-to-date sensors for data capture and analysis. The proof-of-concept should demonstrate a 60-day or greater runtime without the need to connect and recharge from a power source. The proof-of-concept device should include emerging sensing innovations, numerous sensor transducers, and sufficient processing to extract multivariate/multimodal sensing biomarkers and health status summary information. Applicants should also present a clearly defined plan to improve any existing capabilities to support disconnected military relevant environments. Phase I will result in a proof of concept for testing and refinement in Phase II. Preference for made in U.S.A. compliance. A detailed definition of the device requirements will be provided to the successful Phase I demonstrations to proceed to Phase II.

PHASE II: Phase II will focus on prototype development and refinement of the proof-of-concept on-body sensor developed in phase I. The accomplishment of a 60-day runtime will be demonstrated in Phase II. Additionally, the developed wearable will need to be interoperable with existing DoD wireless infrastructure. The wearable devices will need to manage wireless transmission of health and readiness status information over a wireless link while maintaining an extended runtimes of 60-days or greater. Interface specifications will need to be provided to the DoD to define and develop appropriate wireless interfaces in existing data infrastructure. The prototype devices should have sufficient on-device memory storage to retain weeks' worth of summary information and synchronize the saved information to the DoD support infrastructure. Applicants should also provide a detailed plan that will outline the

verification and validation of the wearable device and sensing capabilities. The wearable device should provide at a minimum but not limited to, heart-rate, hear-rate variability, activity/motion, and asleep/awake health status information. Applicants should also provide a detailed plan that will occur for testing and evaluation (to include data type, frequency, and structure).

PHASE III DUAL USE APPLICATIONS: Phase III will focus on the best performing prototype with intent to inform commercialization and future DoD procurement. Proposals should lay out a plan for longitudinal evaluation of their Phase II product in an operational environment. For Phase III, 50 prototypes will be delivered for testing in ongoing demonstrations with Navy Surface Force ships. This evaluation will consist of a cross comparison of the prototype function across two (or more) ships of different class and where appropriate include Marines and other service members embarked on warships (e.g., Destroyer vs. Amphibious Assault Ship) across the Operational Deployment Cycle/Optimized Fleet Response Plan Cycle. In Phase III performers shall outline the ability to mass produce, support, and service the developed wearable devices.

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KEYWORDS: Wearable monitoring, biometrics, remote data capture, self-powered sensor, energy storage, physiological sensors, military readiness, non- AC/DC power source

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DHA233-D001 TITLE: Medical Oxygen Storage and Delivery for Deployed Joint Services' Casualty Care

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

OBJECTIVE: Develop a composite, or other, lightweight, low ballistic hazard oxygen cylinder/tank for medical grade oxygen in deployed environments. Meet/exceed D Cylinder volume; improve upon logistics by reducing weight and making cylinders self-stackable and interlocking.

DESCRIPTION: The ability to store and deliver oxygen to patients requiring supplemental oxygen is an essential capability for deployed medical facilities and personnel that provide treatment primarily to combat casualties who incur traumatic injuries. Oxygen storage is a necessity to successful battlefield medicine, but also presents some of the largest logistical challenges and combustible hazards. The U.S. military's current oxygen storage capability is to use oxygen cylinders that are made primarily from metal. The current oxygen cylinders are heavy, highly combustible, and require a large cube space for storage and transportation. These characteristics limit the organizations' ability to support far-forward combat operations in multi-domain operations where supply and resupply operations are anticipated to be greatly hindered. Due to these constraints, the U.S. military seeks to develop a composite (or of similar material), lightweight, low ballistic hazard oxygen storage and delivery cylinder. The desired cylinder must meet the size and valve/regulator connector specifications of a standard D cylinder, while meeting or exceeding the volume capability; the cylinder meet FDA requirements for medical use. The cylinder should be a reduced weight compared to that of a D cylinder and feature a stackable and/or an interlocking feature. The valve/regulator connector may be of the same material as used in current D cylinders or may be of novel material so long as oxygen quality/purity, and both cylinder functionality and durability are uncompromised. The desired cylinder should also be fitted with connections that are compatible with existing U.S. military oxygen refilling equipment for a D cylinder. The characteristics of the desired oxygen storage capability will greatly improve weight, logistic, and ballistic hazard considerations.

PHASE I: This topic is intended for technology proven ready to move directly into Phase II. Therefore, the offeror must be able to demonstrate that its desired oxygen storage and delivery device has already met the scientific, technical, and feasibility accomplished for a Phase I-like effort.
Proof of feasibility shall include:
• Description of all relevant information including, but not limited to: technical objectives and reports, test data, product demonstrations, prototype designs/models, patents, and performance goals/results.
• Test and analysis results that the device meets or will meet all parameters (size, weight, volume, lower ballistic hazard, stack/interlock capability as an integrated or add-on feature, compatibility with existing refilling capability, etc.).
• Commercialization strategy including costs and schedule; regulatory strategy and status; FDA plan; transition to government roadmap; preliminary materials selection including MSDSs.
• Effectiveness in a deployed setting which includes static, dismounted medical units as well as medical transportation vehicles (ground and rotary-, tilt-rotor or fixed-wing).

PHASE II: Phase II will consist of further development, refinement, and optimization of the desired oxygen storage and delivery device to demonstrate its utility and validating the prototype(s) through relevant testing. The offeror shall test the prototypes in simulated environments in accordance with relevant standards for transportation, safety, and quality. For example, MIL-STD-810H is used by the military to determine viability in harsh environments. The initial phase of testing shall also include analysis to ensure the prototype meets size, weight, and ability to stack/interlock as described by the offeror. Once met, testing and evaluation shall involve refinement and more rigorous testing in laboratory studies to determine probability of ballistic hazard, and to ensure there is no degradation of oxygen purity

over time. All testing must be conducted in compliance with all applicable standards and regulations in a qualified facility. The offeror shall define and document all relevant regulatory strategies based on the regulatory body (e.g., FDA, DOT, OSHA), demonstrating a clear plan for approvals. Additionally, the offeror will identify appropriate commercialization partners (ex. manufacturing, marketing, etc.) to facilitate technology transition into the commercial market after approval is attained. Seven (7) prototype devices shall be delivered to the Government for environmental testing and user evaluations.
Deliverables will include:
- Design drawings and schematics
- Material Safety Data Sheets (MSDSs) for planned manufacturing materials
- Scientific analysis of ballistic hazard
- Regulatory strategy and pathway, as needed, to include a clear plan of how all regulatory body requirements will be achieved
- Prototype devices, quantity seven (7), for Government evaluation

PHASE III DUAL USE APPLICATIONS: The technology developed under this SBIR effort will have applicability to both civilian and military emergency medicine, and commercialization strategies should be developed to ensure both markets are being addressed. Phase III will consist of finalizing the device design and delivering manufactured devices (in their final form) for military-relevant testing such as airworthiness/performance testing (e.g., Joint Enroute Care Equipment Test Standards [JECETS], AR 70-62) and other Regulatory Body-related testing (ex. FDA, DOT, OSHA) under design freeze. The device will be functional for use by medics, physician assistants, nurses, and physicians in far forward environments (roles 1-3 of care and en route care, including ambulances), as well as civilian first responders, Life Flight teams, and others requiring transportable oxygen to care for patients. In addition to regular monthly reporting, the performer will be required to provide status updates to the Government team, apprising of commercialization efforts, highlighting potential interest from the civilian marketplace. Phase III will also include developing and finalizing training methods and protocols for the new device. Additionally, the regulatory package should be in its final form ready for submission to the Regulatory Agency(ies) including all relevant test data, where applicable.

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KEYWORDS: Medical oxygen, Oxygen storage, Oxygen delivery, Oxygen storage safety, Oxygen ballistic hazard, D cylinder, Composite D cylinder, FDA, Combat Casualty Care

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