

DEFENSE HEALTH AGENCY
20.1 Small Business Innovation Research (SBIR) Program
Proposal Submission Instructions

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://sbir.defensebusiness.org/topics/>.

Specific questions pertaining to the DHA SBIR Program should be submitted to the DHA SBIR Program Management Office (PMO) at:

E-mail - usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@mail.mil
Phone - (301) 619-7296

PHASE I PROPOSAL SUBMISSION

Follow the instructions in the DoD SBIR Program BAA for program requirements and online proposal submission instructions.

DHA SBIR Phase I Proposals have three Volumes: Proposal Cover Sheets, Technical Volume and Cost Volume [Note: the Company Commercialization Report will NOT be available or required for the 20.1 BAA]. **Please note that the DHA SBIR will not be accepting a Volume Five (Supporting Documents) as noted at the DoD SBIR website.** The Technical Volume has a 20-page limit including: table of contents, pages intentionally left blank, references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any other attachments. Do not duplicate the electronically generated Cover Sheets or put information normally associated with the Technical Volume in other sections of the proposal as these will count toward the 20-page limit.

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

Companies submitting a Phase I proposal under this BAA must complete the Cost Volume using the on-line form, within a total cost not to exceed \$250,000 over a period of up to six months.

The DHA SBIR Program will evaluate and select Phase I proposals using the evaluation criteria in Section 6.0 of 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.

Proposals not conforming to the terms of this BAA, and unsolicited proposals, will not be considered. Awards are subject to the availability of funding and successful completion of contract negotiations.

RESEARCH INVOLVING ANIMAL OR HUMAN SUBJECTS

The DHA SBIR Program discourages offerors from proposing to conduct human subject or animal research during Phase I due to the significant lead time required to prepare regulatory documentation and secure approval, which will significantly delay the performance of the Phase I award.

The offeror is 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's (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. Furthermore, modifications to already approved protocols require 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 authorization that the research protocol may proceed. Written approval to begin 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.

PHASE II PROPOSAL SUBMISSION

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

Small businesses submitting a Phase II Proposal must use the DoD SBIR electronic proposal submission system (<https://www.dodsbirsttr.mil/submissions/>). This site contains step-by-step instructions for the preparation and submission of the Proposal Cover Sheets, the Company Commercialization Report, the Cost Volume, and how to upload the Technical Volume. For general inquiries or problems with proposal electronic submission, contact the DoD SBIR/STTR Help Desk at (1-703-214-1333) or Help Desk email at DoDSBIRSupport@reisystems.com (9:00 am to 5:00 pm ET).

The DHA SBIR Program will evaluate and select Phase II proposals using the evaluation criteria in Section 8.0 of 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. DHA Topic DHA201-002 is a candidate for a potential Jumbo award under the Phase II award process. Awardees under this topic may be awarded up to \$3,000,000.

Small businesses submitting a proposal are required to develop and submit a Commercialization Strategy (please refer to DoD Instructions, section 7.4) describing feasible approaches for transitioning and/or commercializing the developed technology in their Phase II proposal. This plan should 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 \$1,100,000. These costs must be submitted using the Cost Volume format (accessible electronically on the DoD submission site), and may be presented side-by-side on a single Cost Volume Sheet.

DHA SBIR Phase II Proposals have four Volumes: Proposal Cover Sheets, Technical Volume, Cost Volume and Company Commercialization Report. The Technical Volume has a 40-page limit including: table of contents, pages intentionally left blank, references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any attachments. Do not include blank pages, duplicate the electronically generated Cover Sheets or put information normally associated with the Technical Volume in other sections of the proposal as these will count toward the 40-page limit.

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

PHASE II ENHANCEMENTS

The DHA SBIR Program has a Phase II Enhancement Program which provides matching SBIR funds to expand an existing Phase II contract that attracts investment funds from a DoD Acquisition Program, a non-SBIR government program or eligible private sector investments. Phase II Enhancements allow for an existing DHA SBIR Phase II contract to be extended for up to one year per Phase II Enhancement application, and perform additional research and development. Phase II Enhancement matching funds will be provided on a dollar-for-dollar basis up to a maximum \$550,000 of SBIR funds. All Phase II Enhancement awards are subject to acceptance, review, and selection of candidate projects, are subject to availability of funding, and successful negotiation and award of a Phase II Enhancement contract modification.

TECHNICAL AND BUSINESS ASSISTANCE (TABA)

The DHA SBIR Program does not participate in the Technical and Business Assistance (formally the Discretionary Technical Assistance Program). 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.

DHA SBIR 20.1 Topic Index

DHA201-001	Diagnostic Platform for Rapid Identification of Pathogens in Infected Wounds that is Useable in a Battlefield Environment
DHA201-002	Radioprotector Medical Countermeasure to Prevent the Effects of Acute Radiation Syndrome
DHA201-003	Nano-synthetic Materials Smart System Enabling Sensor Discovery and Fabrication

DHA SBIR 20.1 Topic Descriptions

DHA201-001 TITLE: Diagnostic Platform for Rapid Identification of Pathogens in Infected Wounds that is Useable in a Battlefield Environment

TECHNOLOGY AREA(S): Biomedical

RESEARCH & TECHNOLOGY AREA(S):

ADVANCED CAPABILITIES:

ACQUISITION & SUSTAINMENT AOR:

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition- USAMRDC

OBJECTIVE: Develop state-of-the-art diagnostic technology for rapid identification of pathogens in infected wounds that can be used to triage injured warfighters and guide clinical decisions in a modern battlefield environment.

DESCRIPTION: U.S. military service members who are medically evacuated from theatre due to combat-related injuries have sustained high impact insults such as explosions, gunshot wounds and motor vehicle accidents, leading to significant skin and soft tissue injuries that may be frequently contaminated. A large proportion of these service members are at increased risk for infectious complications of their traumatic injuries, and the most common infections involve skin and soft tissue, wound infections, and osteomyelitis and sepsis if not treated in a timely manner. *Acinetobacter baumannii* has been identified as one of the most frequently associated organisms with skin and soft tissue infections among wounded warriors, occurring in 35% of wound infections. Within this 35%, up to 90% of the culture isolates were assessed to be antimicrobial resistant (AMR) [1]. Community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA) is a well-recognized cause of skin and soft tissue infections (SSTI) in US military hospitals with a reported prevalence of 68% to 70% in selected military hospital emergency rooms [2]. High rates of MRSA skin and soft tissue infections have been observed among soldiers in training [3,4]. In addition to skin and soft tissue infection, MRSA is the most frequently isolated organism late in infection in traumatically injured service members [5]. Late infection in this population often results in limb salvaging amputation [6]. *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* are responsible for significant morbidity and mortality among both civilian and military populations, often colonizing mucosal surfaces, wounds, and foreign devices such as catheters and endotracheal tubes with biofilms that are highly resistant to antibiotic penetration and clearance by the immune system. In civilian and veteran populations these same types of infections frequently occur in individuals that have skin and soft tissue and prosthetic joint infections [4,5]. In a patient infected with multi-drug resistant organisms, the treatment choices often become limited due to waning approvals of new antibiotics [6]. Frequently, these patients are hospitalized for prolonged periods of time and subsequently experience multiple episodes of hospital readmissions related to infectious complications of their wound or orthopedic implants. In addition to increased patient morbidity, provision of medical care for service members with infected traumatic wounds can be very costly and lead to intense resource utilization.

Early diagnosis of infection in injured warfighters could provide early guidance to caregivers. Treatment of chronic infections are less successful, so the goal is to improve early detection and rapid intervention before the infection is established and progressing. Current diagnostic systems are complex with often multiple steps from sample processing to interpretation, are often restricted to fixed laboratories, require cold chain for reagents, and not available to front line users. This effort seeks to support development of novel approaches to detect infected wounds at the bedside or in the field to rapidly inform medics and early caregivers on best approaches to wound and infection management.

PHASE I: Selected contractor determines the feasibility of the concept by developing a prototype diagnostic assay that has the potential to meet the broad needs discussed in this topic description. Currently there are no FDA-

cleared, field-capable assays that can be used to rapidly identify the most common bacterial pathogens causing wound and sepsis infections as described in references 1-6 (to include but not limited to the ESKAPE group of pathogens: *Enterococcus* spp., *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Enterobacter* spp, and *Escherichia coli*), as well as an ability to determine the respective antibiotic susceptibility of the detected pathogen to guide treatment decisions for wound infections in injured warfighters. Development of an assay for the detection of bacterial infections with MDR bacteria is therefore a high priority. In some infections, a possibility of multiple pathogens and bacterial strains can be present within a single sample, so the assay must be sensitive and specific enough to identify each pathogen.

PHASE II: Based on the results from Phase I, the selected contractor provides up to 3 Initial lots of 250 prototype assays each to the COR. These initial lots will be evaluated for sensitivity and specificity using a diversity set of bacterial strains for evaluation in vitro, then if efficacious for analysis of samples (blood and tissue, or directly) from preclinical animal infection studies. Can coordinate with WRAIR/NMRC for assistance with preclinical evaluation if needed. Feedback regarding the sensitivity/specificity of each lot of prototype assays will be provided to the contractor. This data will then be used to optimize each subsequent lot of assays. The goal In Phase II is the development of a prototype assay that provides 85% sensitivity and 85% specificity when compared to current bacterial culture and antibiotic susceptibility testing methods. Once sensitivity and specificity requirements have been met in preclinical tests, the selected contractor will confirm the performance characteristics of the assay (sensitivity, specificity, positive and negative predictive value, accuracy and reliability) using clinical specimens. The regulatory strategy for using different types of clinical specimen should be clearly described in the Phase II proposal. Human use protocols for using clinical specimen should be approved by Institutional Review Board (IRB) of all participating institutes. The elected contractor will require a Federal-Wide Assurance of Compliance before government funds can be provided for any effort that requires human testing or uses of clinical samples. The selected contractor will also conduct stability testing of the prototype device in Phase II. Stability testing will follow both real-time and accelerated (attempt to force the product to fail under a broad range of temperature and humidity conditions and extremes) testing in accordance with FDA requirements. The assay must be rapid (<30 min), soldier-friendly (i.e., easy to operate), inexpensive, portable, and stable (no requirement of refrigeration). The assay should be at least 85% as sensitive and specific as current (non-deployable, non-FDA cleared) assays and sera, plasma, whole blood, or other types of specimen can be used without sample processing. The data package plan required for application to the U.S. Food and Drug Administration will be prepared at the end of phase II.

PHASE III DUAL USE APPLICATIONS: During this phase the performance of the assay should be evaluated in a variety of field studies that will conclusively demonstrate that the assay meets the requirements of this topic. The contractor may coordinate with WRAIR/NMRC to set up field testing sites. The selected contractor shall make this product available to potential military and non-military users throughout the world. Military applications: MDR bacterial infections occur worldwide. The diagnosis of these wound infections and sepsis cases are often delayed, because the currently available tests, mostly reliant on bacterial culture or high-complexity nucleic acid amplification, are not field-capable, not rapid, and can vary considerably among different laboratories even when using the same procedure or method. With the availability of an easy and rapid assay developed under this topic, wounded and ill soldiers can be treated in a timely manner in any military medical organization (such as a Battalion Aid Station, a Combat Support Hospital, Forward operation base, or a fixed medical facility). The contractor should coordinate with WRAIR/NMRC to establish a National Stock Number (NSN) for potential inclusion in into appropriate "Sets, Kits and Outfits" that are used by deployed medical forces. Civilian applications: MDR bacterial infections occur in communities and hospitals, in wounds, skin and soft tissue infections, pneumonia, and blood stream infections. We envision that the contractor that develops the rapid diagnostic assay and will be able to sell and/or market this assay to a variety of civilian medical organizations, and that this market will be adequate to sustain the continued production of this device.

REFERENCES:

1. Davis, K.A., et al., Multidrug-resistant *Acinetobacter* extremity infections in soldiers. *Emerg Infect Dis*, 2005. 11(8): p. 1218-24.
2. Morrison-Rodriguez, S.M., et al., Community-associated methicillin-resistant *Staphylococcus aureus* infections at an Army training installation. *Epidemiol Infect*, 2010. 138(5): p. 721-9.

3. Burns, T.C., et al., Microbiology and injury characteristics in severe open tibia fractures from combat. *J Trauma Acute Care Surg*, 2012. 72(4): p. 1062-7.
4. Hospenthal, D.R., et al., Guidelines for the prevention of infections associated with combat-related injuries: 2011 update: endorsed by the Infectious Diseases Society of America and the Surgical Infection Society. *J Trauma*, 2011. 71(2 Suppl 2): p. S210-34.
5. Campoccia, D., L. Montanaro, and C.R. Arciola, The significance of infection related to orthopedic devices and issues of antibiotic resistance. *Biomaterials*, 2006. 27(11): p. 2331-9.
6. Ventola, C.L., The antibiotic resistance crisis: part 1: causes and threats. *P T*, 2015. 40(4): p. 277-83.

KEYWORDS: Wound Infections, ESKAPE, AMR, Diagnostic

DHA201-002 TITLE: Radioprotector Medical Countermeasure to Prevent the Effects of Acute Radiation Syndrome

TECHNOLOGY AREA(S): Biomedical

RESEARCH & TECHNOLOGY AREA(S):

ADVANCED CAPABILITIES:

ACQUISITION & SUSTAINMENT AOR:

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition- USAMRDC

OBJECTIVE: To provide a radioprotector medical countermeasure (MCM) to the Joint Force with effective prophylactics to recover from and survive Acute Radiation Syndrome (ARS) resulting from ionizing radiation exposure. In concert with resuscitative intervention and supportive care, MCMs would improve survival and reduce recovery times for the individual contributing to a higher level of unit readiness.

DESCRIPTION: The current Joint Force requires Medical Counter Measures (MCMs) against threats to sustain the full range of military operations. The Joint Force must effectively protect the maximum number of personnel against the greatest number of hazards as far forward as possible, and sustain the casualty from the point of exposure to the point of definitive care. These MCMs will be administered at the lowest echelon of health care possible. They will work in concert with other medical products to lessen performance degradation and increase survival for the individual contributing to a higher level of unit readiness.

The Department of Defense requires MCMs for Acute Radiation Syndrome (ARS) that are safe and effective prophylaxes and therapeutics. To be effective, any prophylaxes must be available to Joint Force personnel prior to ionizing radiation (IR) exposure. It will reduce the likelihood of developing severe adverse health effects associated with ARS to increase survival. Prophylaxes would be administered to the Joint Force prior to operating in a known, high risk Ionizing Radiation (IR) environment.

ARS encompasses a spectrum of pathophysiologic changes caused by exposure to high doses of penetrating radiation in a relatively short time period. Injuries sustained depend on the dose and extent of radiation exposure (e.g., whole- or partial-body). Radiation exposures exceeding 2 Gray (Gy) in adults can result in the depletion of hematopoietic stem cells and cellular progenitors in the bone marrow, which may lead to severe neutropenia, thrombocytopenia, and death from infection or hemorrhage. Higher radiation doses can cause gastrointestinal (GI) complications, including mucosal barrier breakdown, bacterial translocation, and loss of GI structural integrity, which can lead to rapid death. Individuals who survive ARS may suffer from the delayed effects of acute radiation

exposure (DEARE), which can include pulmonary, renal, cardiovascular, immunological, and cutaneous complications occurring weeks to months after radiation exposure.

There are three FDA-approved post-exposure therapeutic drugs to treat the hematopoietic subsyndrome of ARS. There are no FDA-approved prophylactic MCMs for IR exposures resulting in ARS. Future pharmaceuticals will be used in concert with the most appropriate and cost effective mix of existing protocols for treating radiation injuries and could be used at any role of care. Together, future pharmaceuticals and existing medical management protocols (e.g., supportive care, antioxidants, antiemetics, antibiotics, colony stimulating factors, blood/bone marrow transplants, isolation) will provide the means to effectively treat the maximum number of personnel.

For the purpose of this effort, the terms “MCM(s)” and “drug(s)” will include drugs, biologics, and cellular therapies. The objective of a prophylactic MCM is to reduce the likelihood of developing severe adverse health effects associated with ARS to increase survival. The prophylactic MCM must work in concert with other medical products to lessen performance degradation and increase survival for an individual contributing to a higher level of unit readiness. A prophylactic MCM will need to be given pre-exposure, pre-symptomatic and be administered at the lowest echelon of health care possible to the Joint Force (age range of 18 - 62 years) prior to operating in a known, high risk irradiated environment. To achieve this effect the method of administration must be tailored to optimize ease of administration in an operational environment.

PHASE I: Offerors must propose proof-of-concept experiments to demonstrate the efficacy of proposed ARS prophylactic MCM against a relevant susceptible cell populations such as hematopoietic progenitors. Demonstration of efficacy in some form of an in vivo model is also acceptable, but not required for Phase I. Technologies of interest include, but are not limited to, drugs, but can include biologics or cellular therapies. Exit criteria for successful completion of Phase I research would be the demonstration of efficacy at the LD70/30 or greater radiation dose levels. The LD70/30 represents a radiation dose that would result in 70% mortality over 30 days in vehicle treated mice. Information garnered from Phase I experiments may be more qualitative than quantitative.

PHASE II: With successful completion of Phase I experiments, Phase II would further evaluate the medical countermeasure (MCM) in a small animal study. A Phase II effort will test effective prophylactic ARS MCMs at the LD70/30 dose level or greater in an appropriate animal model. In these studies, the MCM would be administered to animals prior to radiation exposure. The animal model should be of sufficient size and scope to demonstrate a statistically significant increase in survival in animals receiving the MCM. The SBIR Phase II studies shall include experiments of a manner that facilitates the collection of non-clinical GLP pharmacokinetic (PK) and pharmacodynamic (PD) data. The PK and PD information will be of paramount importance to inform subsequent Phase III studies. Optimized formulation studies involving development of a preparation of the drug should be conducted during this phase II effort. Responders to this SBIR should provide a test plan for in vivo evaluation prior to the start of Phase II studies.

PHASE III DUAL USE APPLICATIONS: Phase III studies would further refine the animal model and the compound/drug dosing regimen. The goal would be to work toward FDA approval of a MCM for one or more radioprotector MCMs against ARS. The studies in Phase III should support FDA approval/ licensure to include entry into clinical studies, cGMP manufacturing scale up, and pivotal efficacy studies. FDA licensure/approval is not necessary for the project to be deemed successful. One means for the offeror to document progress is through a Technology Readiness Assessment (TRA) of the technology using the harmonized Quantitative Technology Readiness Level (QTRL) guidance document as described by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). A second means for demonstrating success is the establishment of funding and partnering with commercial companies (if necessary) to facilitate bringing the product to market.

Successful radioprotector MCM products directed against ARS will clearly have use by other government agencies, hospitals/ emergency departments, first responders, and others providing responses to nuclear and radiation dispersal incidents.

REFERENCES:

1. Rosen E, Day R and Singh V. New Approaches to Radiation Protection. *Frontiers in Oncology*, Vol 4, Issue 381, 2014.

2. Singh V, Newman V, Berg A and MacVittie T. Animal Models for Acute Radiation Syndrome Drug Discovery. *Expert Opinion on Drug Discovery*, Vol 10, Issue 5, 2015.

3. Joint Project Manager Medical Countermeasure Systems Broad Agency Announcement (BAA) for Medical Chemical Biological Radiological and Nuclear (CBRN) Countermeasure Developmental Studies. Attachment 1 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Harmonized Q-TRL List for Medical MCMs, MCS-BAA14-01, December 2013.

KEYWORDS: Radioprotectors, Prophylaxes, Medical Countermeasures (MCM), Acute Radiation Syndrome (ARS), Ionizing Radiation (IR), Sub-syndromes

DHA201-003 TITLE: Nano-synthetic Materials Smart System Enabling Sensor Discovery and Fabrication

TECHNOLOGY AREA(S): Biomedical

RESEARCH & TECHNOLOGY AREA(S):

ADVANCED CAPABILITIES:

ACQUISITION & SUSTAINMENT AOR:

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition- USAMRDC

OBJECTIVE: Develop a smart system of the rapid discovery, development, and evaluation of nano-synthetic detecting materials as sensors for Synthetic Tissue, Organ, Nerve and Skin (STONeS). These discovered novel sensor materials will be used to fabricate new detectors that demonstrate “murmuration behavior” that record properly/improperly performed emergent procedures, useful in medical simulation training with additional potential utility seen in forward medical operational environments.

DESCRIPTION: Applying appropriate STONeS sensors into mannequins or part-task trainers to provide feedback signals can mimic close-to-real-life response, ensuring surgical procedural accuracy and improving training efficiency and fidelity for military medical service members. STONeS sensor enabled part-task trainers will increase training availability and accessibility, while decreasing overall training cost. Demand for the application of nanosensors in medical simulation training is rising as nanotechnology-enabled sensors to provide a faster, more accurate and sensitive detection, and therefore it enables new solutions in physical, chemical, and biological sensing STONeS applications. The diversity of nanosensor technologies and applications requires a broad diversity of nanomaterials. However, ideal sensing materials to satisfy the capability gaps remaining in civilian and military medical simulation have yet to be revealed in practice. To accelerate this sensor development, DHA considers R&D efforts in autonomous detection to enable the broad, application-driven discover of nano-synthetic material to be both necessary and urgent. Currently there is no similar effort available to provide an effective solution.

The goal of this topic is to create a nanomaterial synthetic platform with innovative methodology strategies to quickly discover novel nanomaterials as sensor materials to develop nanosensors fit for at least one of the following STONeS capabilities:

- Detection of touch
- Detection of pressure
- Detection of stretch

- Detection of disruption and closure
- Monitoring temperature
- Monitoring gases
- Monitoring humidity
- Monitoring liquids
- Monitoring radiation.

PHASE I: A feasibility study that demonstrates the scientific, technical, and commercial merit of the methodology. Identify and define the right approaches to establish a high throughput automatic nanomaterial synthetic and screening platform to rapidly discover appropriate STONeS sensing materials.

Required Phase I deliverables will include:

- Prove deep understanding and review of current nano-synthetic sensing material applications in STONeS.
- Develop a methodology to enable high throughput nanomaterial synthetic system.
- Develop approaches for application-driven discovery for sensing material for STONeS properties and targets.
- Provide proof of concept data and support the technical feasibility.
- Prove the proposed technology has advantages over the current technologies in use.

PHASE II: Phase II effort will culminate in a well-defined deliverable prototype based upon the Phase I proof of concept work, with an expectation of comprehensive development, detailed demonstration, and final validation. The prototyped high throughput platform should be utilized to produce at least two novel discoveries of nanomaterials. The characteristics of the new STONeS nanomaterials are expected to have some of the following features:

- Printable
- Flexible and/or Stretchable
- Scalable
- Unobtrusive
- Reliable
- Inexpensive
- Wireless
- Low-voltage and/or self-power

Required Phase II deliverables:

- Produce prototype hardware and software based upon Phase I work.
- Develop, test and validate the prototyped high throughput nano-synthetic material platform.
- Provide a detailed plan for nano-synthetic material discovery procedures.
- Provide practical implementation for nano-synthetic material discovery.
- Develop processes, select appropriate applications and demonstrate at least two productions as novel discoveries of nanosensing materials for STONeS applications.

PHASE III DUAL USE APPLICATIONS: Phase III work will be a continued R&D effort with the potential to transition to the advanced developer or the genesis of an advanced manufacturing capability. It's expected to be a novel nanosensors development using Phase II discovered nanomaterials. All sensors developed will improve the use of STONeS in medical simulation training with important military and commercial impact. It can also have the potential to become an important large nano-synthetic sensing material database/library commercially available to significantly accelerate the sensor discovery and development. The discovery and fabrication of these new sensors will be benefit in both training and operational environment such prolong field care, telemedicine, and the future autonomous systems.

REFERENCES:

1. Meital Segev-Bar, et al., A Tunable Touch Sensor and Combined Sensing Platform: Toward nanoparticle-based Electronic Skin. ACS Applied Materials & Interfaces. 2013

2. Carlos Garcia Nunez, et al., Energy autonomous electronic skin, *npj Flexible Electronics*. 2019
3. David Escobar-Castillejos, et al., A Review of Simulators with Haptic Devices for Medical Training. *J Med Syst* (2016)
4. Yancong Qiao, et al., Multilayer Graphene Epidermal Electronic Skin. *ACS Nano*. 2018.
5. Donghee Son, et al., nanomaterials in Skin-inspired Electronics: Toward Soft and Robust Skin-like Electronic Nanosystems. *ACS Nano*. 2018.
6. Yicong Zhao, et al., Mechanisms and materials of Flexible and Stretchable Skin Sensors. *Micromachines*. 2017.
7. Sumit Majumder, et al., Wearable Sensors for Remote Health Monitoring. *Sensors*. 2017

KEYWORDS: Nanotechnology, Nanosynthetic Material, Sensor