

**DEFENSE HEALTH AGENCY**  
**20.1 Small Business Innovation Research (SBIR) Program**  
**Direct to Phase II 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.

The 2020.1 DHA SBIR Direct to Phase II proposal submission instructions are intended to clarify the Department of Defense (DoD) instructions as they apply to DHA requirements. This Announcement is for Direct to Phase II proposals only. All Phase II proposals must be prepared and submitted through the DoD SBIR/STTR electronic submission site: <https://www.dodsbirsttr.mil/submissions/>. The offeror is responsible for ensuring that their proposal complies with the requirements in the most current version of instructions. Prior to submitting your proposal, please review the latest version of these instructions as they are subject to change before the submission deadline.

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

**1. DIRECT TO PHASE II**

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

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

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

\*POP= Period of Performance

**2. INTRODUCTION**

Direct to Phase II proposals must follow the steps outlined below:

1. Offerors must create a Proposal Cover Sheet (Volume 1) using the DoD Proposal submission system. The Cover Sheet must include a brief technical abstract of no more than 200 words that describes the proposed R&D project with a discussion of anticipated benefits and potential commercial applications. **Do not include proprietary or classified information in the Proposal Cover Sheet.** If your proposal is selected for award, the technical abstract and discussion of anticipated benefits may be publicly released on the Internet.
2. Offerors must submit a Technical Volume (Volume 2) using the DHA SBIR Direct to Phase II proposal instructions below.\*

\* NOTE: Offerors must provide documentation showing they have completed research and development to establish Phase I feasibility outlined in the topic description. The DHA will not evaluate the offeror's related Phase II proposal if it determines that the offeror has failed to demonstrate that technical merit and feasibility has been established or the offeror has failed to demonstrate that work submitted in the feasibility documentation was substantially performed by the offeror and/or the Principal Investigator (PI). Refer to the Phase I description (within the topic) to review the minimum requirements for feasibility documentation.

3. Offerors must submit a Cost Volume (Volume 3) using the on-line cost volume form on the DoD Submission Web site.

### **3. PROPOSAL SUBMISSION**

The complete proposal, i.e., DoD Proposal Cover Sheet, technical volume, cost volume, and Company Commercialization Report, must be submitted electronically at <https://www.dodsbirsttr.mil/submissions/>. Ensure your complete technical volume and additional cost volume information is included in this sole submission. The preferred submission format is Portable Document Format (.pdf).

**Complete proposals must include all of the following:**

- a. DoD Proposal Cover Sheet (Volume 1)
- b. Technical Volume (Volume 2):
  - Part 1: Phase I Justification (20 Pages Maximum)
  - Part 2: Phase II Technical Proposal (40 Pages Maximum)
- c. Cost Volume (Volume 3)

**Please note the DHA SBIR Program will not be accepting Volume Five (Supporting Documents).**

Phase II proposals require a comprehensive, detailed submission of the proposed effort. DHA SBIR Direct to Phase II periods of performance are 24 months. DHA SBIR Direct to Phase II efforts are awarded up to a maximum value of \$1,100,000 per contract award. Commercial and military potential of the technology under development is extremely important. Proposals emphasizing dual-use applications and commercial exploitation of resulting technologies are sought. 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](mailto:DoDSBIRSupport@reisystems.com) (9:00 am to 5:00 pm ET).

### **4. Direct to Phase II PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS**

**PROPOSAL FORMAT** (60 pages maximum)

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

**B. Phase I Justification (20 Pages Maximum).** Offerors are required to provide information demonstrating that the scientific and technical merit and feasibility has been established as outlined in the topic description.

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

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

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

**F. 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 Phase II effort in providing a foundation for a Phase III research or research and development effort.

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

1. What is the first product that this technology will go into?
2. Who will be your customers, and what is your estimate of the market size?
3. How much money will you need to bring the technology to market, and how will you raise that money?
4. Does your company contain marketing expertise and, if not, how do you intend to bring that expertise into the company?
5. Who are your competitors, and what is your price and/or quality advantage over your competitors?

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

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

J. **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.

K. **Cost Volume (\$1,100,000 Maximum).** A detailed, Phase II Cost Volume must be submitted online and in the proper format shown in the Cost Breakdown Guidance in Section 5.4 d of the DoD SBIR Broad Agency Announcement (BAA). Some items in the cost volume template may not apply to the proposed project. If such is the case, there is no need to provide information for each and every item. Provide enough information to allow the DHA evaluators to assess the proposer's plans to use the requested funds if the contract is awarded. Phase II proposers should provide cost data based upon a contract award date six months after submission of the Phase II proposal. Phase II contracts are awarded for a two year development and prototype production. Indicate funding requirements for "Year 1" and "Year 2" in the cost volume.

1. List all key personnel by name as well as number of hours dedicated to the project as direct labor.
2. Special Tooling, Test Equipment, and Materials Costs:
  - a. Special tooling, test equipment, and materials costs may be included under Phase II. The inclusion of equipment and material will be carefully reviewed relative to need and appropriateness for the work proposed; and
  - b. The purchase of special tooling and test equipment must, in the opinion of the Contracting Officer, be advantageous to the Government and should be related directly to the specific effort.
3. Cost for travel funds must be justified and related to the needs of the project. Cost-sharing is permitted; however, cost-sharing is not required nor will it be an evaluation factor in the consideration of a proposal.

## **5. METHOD OF SELECTION AND EVALUATION CRITERIA**

A. **Evaluation Criteria.** All proposals will be reviewed for overall merit based on the evaluation criteria published in the DoD SBIR Program BAA:

1. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
2. The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development, but also the

ability to commercialize the results.

3. The potential for commercial (Government or private sector) application and the benefits expected to accrue from this commercialization.

## **6. CONTRACTUAL CONSIDERATIONS**

**A. Awards.** The number of Direct to Phase II awards will depend upon the quality the Phase II proposals and the availability of funds. Each Phase II proposal selected for award will be funded under a negotiated contract to be signed by both parties before work begins. Phase II awards will be made to Small Businesses based on results of the scientific, technical, and commercial merit of the Phase II proposal.

**B. Reports.** For incrementally funded Phase II projects an interim, midterm written report may be required (at the discretion of the awarding agency).

**C. Payment Schedule.** Per DoD SBIR Program BAA.

**D. Markings of Proprietary Information.** Per DoD SBIR Program BAA, section 5.3. DHA does not accept classified proposals.

**E. Copyrights, Patents and Technical Data Rights.** Per DoD SBIR Program BAA.

**F. Joint Ventures or Limited Partnerships.** Per DoD SBIR Program BAA.

**G. Contractor Commitments.** The information in the DoD SBIR Program BAA is applicable to the types of provisions that may be included in a Phase II contract.

## **7. 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.

## **8. FOR RESEARCH CONTAINING ANIMAL USE**

A. All research involving animals must be reviewed for compliance with Federal and Department of Defense (DoD) regulatory requirements and approved by the United States Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO) prior to initiation. All amendments to ongoing protocols must also be approved by ACURO prior to initiation. Approval by the local institutional animal care and use committee (IACUC) is required before ACURO review. Include the institutional protocol, documentation of IACUC approval, a completed ACURO appendix for research involving animals (available from ACURO's web page

[https://mrdc.amedd.army.mil/index.cfm/collaborate/research\\_protections/acuro/animal\\_appendix](https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro/animal_appendix)), and the research site's most recent USDA inspection report.

Please submit documents or questions to the electronic mailbox at [USArmy.Detrick.MEDCOM-USAMRMC.Other.ACURO@mail.mil](mailto:USArmy.Detrick.MEDCOM-USAMRMC.Other.ACURO@mail.mil).

## **9. FOR RESEARCH CONTAINING HUMAN USE**

A. All research involving humans, human data, human specimens, or cadavers must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the United States Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP) before the research begins. Submission forms and instructions are provided here:

[https://mrdc.amedd.army.mil/index.cfm/collaborate/research\\_protections/hrpo](https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo).

Please submit protocol documents to the electronic mailbox at [USArmy.Detrick.MEDCOM-USAMRMC.Other.HRPO@mail.mil](mailto:USArmy.Detrick.MEDCOM-USAMRMC.Other.HRPO@mail.mil).

## **10. REPORTING OF PHASE III COMMERCIALIZATION EFFORTS**

A. Please send any corresponding Phase III documents in PDF format to:

[usarmy.detrick.medcom-usamrnc.mbx.dhpsbir@mail.mil](mailto:usarmy.detrick.medcom-usamrnc.mbx.dhpsbir@mail.mil)

B. Reportable activities include: sales revenue from new products and non-R&D services resulting from the Phase II project; additional investment from sources other than the Federal SBIR program in activities that further the development and/or the commercialization of the Phase II technology; the portion of additional investment representing clear and verifiable investment in the future commercialization of the technology (i.e. "hard investment"); whether the Phase II technology has been used in a fielded DoD system or acquisition program and, if so, which system or program; the number of patents resulting from the contractor's participation in the SBIR/STTR program; growth in number of firm employees, and; whether the firm completed an initial public offering (IPO) of stock resulting in part from the Phase II project.

## **DHA SBIR Direct to Phase II 20.1 Topic Index**

DHA201-D001	Field-Expedient, Antimicrobial/Anti-Biofilm Hydrogel or Hydrogel-like Wound Dressing Designed for Large Burn Wounds
DHA201-D002	Optimize Performance and Mitigate Falls in Warfighters with Lower Limb Trauma and/or Loss

## DHA SBIR Direct to Phase II 20.1 Topic Descriptions

DHA201-D001      TITLE: Field-Expedient, Antimicrobial/Anti-Biofilm Hydrogel or Hydrogel-like Wound Dressing Designed for Large Burn Wounds

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 field-expedient, antimicrobial, hydration-providing wound dressing for acute care of large burn wounds.

DESCRIPTION: In future battlespace scenarios, mission-impactful increases in the numbers of burned casualties and in burn wound severity in terms of burn depth and size may be anticipated compared to recent conflicts. The projected operational paradigm also suggests that casualty evacuation may be delayed in the future fight, creating conditions in which burn injury treatments to save lives, hasten return to combat effectiveness, and improve functional recovery must be provided out of hospital for a period of days or longer, under degraded circumstances in the absence of surgical capability (i.e., prolonged field care). This prolonged care context will preclude the current standard of care for burn injuries, defined as evacuation from Theater to the San Antonio Military Medical Center Burn Center for definitive treatment. Currently only minimal burn wound management tools are available in the prehospital environment, consisting primarily of silver-containing wound dressings to prevent/minimize infection until evacuation to surgical care. There remains in the marketplace a lack of proven, clinically effective, acute burn wound treatment technologies, for example, to not only reduce infection but also promote healing of severe burn injuries. Furthermore, the prevalence of known and emerging weapon systems capable of thermal, electrical, and novel mechanisms of burn injury underscores a need for applicability of advanced acute burn care tools to mass casualty situations, potentially in dense urban environments, where the care capability and capacity of available medical providers may be rapidly overwhelmed. These circumstances underscore a critical necessity for the development of novel, advanced, effective, easy to use therapies for acute management of severe burns under austere, prolonged prehospital care to save lives, preserve combat readiness in the operational environment, and optimize long-term recovery and functional outcomes for burned Service members.

PHASE I: Advanced, innovative, topical solutions (e.g., dressings) for acute stabilization of large-sized, deep partial-thickness and full-thickness burn wounds are sought. Prevention of fluid loss, antimicrobial activity (to include anti-biofilm activity), and acceleration of wound healing are important qualities for the product to be developed. The candidate technology will demonstrate properties suggesting ease of use of the ultimate product by lower skilled responders under austere, prehospital conditions. Severe burns are defined as deep partial thickness and full thickness burn injuries. The technology developed will eventually be required to be incorporated into a therapeutic product that is highly mobile with low logistic burden (weight, power, cube) for field use under prolonged care. The minimum end goal of Phase I is readiness of an innovative, novel, candidate technology for acute care of severe burn for proof-of-concept studies in an established, combat-relevant animal model of severe burn.

PHASE II: Using the novel burn wound healing material developed in Phase I, the Offerer must design and engineer the candidate material /dressing formulation and demonstrate feasibility of use in austere environments by unskilled individuals for acceleration of large size (>15% total body surface area), deep partial thickness or full thickness burn wound healing in the absence of grafting. Initial prototypes and proof of principle of the material's ability to control gram-negative and/or gram-positive infections using standard microbiological tests must be demonstrated in a time



frame of use relevant to prolonged field care conditions.

The Offeror must conduct a proof-of-concept evaluation of the technology compared to standard of care silver-containing dressings available in the marketplace in appropriate combat-relevant, animal model(s) of large-sized, deep-partial thickness or full-thickness burn wound. Efficacy in preventing/managing infection and potentiating healing in vivo is a priority.

Topical treatments which are thin, conformable, breathable, non-toxic (safe), and bio-absorbable are sought. The ultimate product should also be self-administrable in the field, functional immediately upon application, provide a barrier to fluid loss, prevent or reduce infection, and potentially reduce blood loss. In addition, the product should be easily removed (i.e., dressing changes) without causing damage to the wound bed or not require active removal (i.e., left in place as self-shed or biodegradable).

Expected users of the technology are medical providers (including those who are not burn care specialists), non-providers (i.e., medics), and untrained personnel (i.e., "buddy care") in austere operational environments. Field-expediency is an important characteristic of the desired technological solution. Field-expediency standards for the expected use profile of the developed technology require that the candidate solution must be readily applicable in dirty, harsh, resource limited, prehospital conditions for up to 72 hours of prolonged care prior to surgical intervention, as well as durable during storage for long periods of time and during use. Reasonable cost is also key.

Other required Phase II deliverables include: biocompatibility, cytotoxicity and immunogenicity analysis, and the demonstration of acceleration of burn wound healing over standard of care in both uninfected and infected wounds. During Phase II product safety/toxicity and stability using FDA standardized models performed under appropriate Good Laboratory Practice (GLP) conditions must be demonstrated. A detailed description of any additional studies, strategy for clinical studies, and transition pathway of the novel product into clinical practice must be addressed. Development and discussion of a plan for the potential regulatory pathway for the material for ACURO and HRPO and approval is required.

Additional objectives, which are desirable but not required, are that the technology demonstrates eschar-stabilizing, anti-inflammatory, and local pain analgesic properties. Efficacy in preventing/treating acute infection and accelerating healing of other traumatic soft tissue injuries in addition to severe burn wounds would be advantageous, while effectiveness specifically in acute management of large-size, severe burn injuries is paramount and required.

**PHASE III DUAL USE APPLICATIONS:** Phase III efforts should include focus on technology transition, preferably commercialization of SBIR research and development. The product developed is intended to be suitable for use and potential procurement by all of the Services for primary use in the field/prehospital environment, including austere, prolonged care scenarios. Realization of a dual-use technology applicable to both the military and civilian use is preferred. Therefore, the successful transition path of the technology is expected to include close engagement with military medical acquisition program managers (USAMMDA) during product commercialization to ensure appropriate product applicability for military field deployment. The minimum goal of Phase III is to finalize all pre-clinical testing and validation of a material for treatment of large, deep-partial thickness and/or full thickness burn wounds that can receive regulatory approval. In this phase the Offeror, in consultation with the FDA, may conduct a small, pilot, large animal validation study to establish safety/toxicity in an appropriate Good Laboratory Practice (GLP) model relevant to combat burn, and demonstrate appropriate product stability. Efforts leading to FDA approval require execution of Phase II plans on regulatory pathway, including identifying relevant patient population for clinical testing to evaluate safety and efficacy and GMP manufacturing of sufficient materials for evaluation. The end state of Phase III consisting of preclinical research is completion of appropriate studies required to receive FDA approval for the conduct of human clinical trials. Alternatively, dependent on the end state of Phase II of the program, the most desirable Phase III effort would consist of human clinical trials designed to demonstrate a product with the appropriate indications for treatment of large, deep-partial thickness and/or full thickness burns under prolonged care in austere environments. Human trials must demonstrate safety and efficacy of the product with the described desirable characteristics to promote burn wound healing and provide infection control. Demonstration that the novel technology yields improved results over standard of care for the parameters described in the "OBJECTIVE" and "DESCRIPTION" sections above is the ultimate goal of this SBIR program announcement. Phase III studies designed as human comparative effectiveness trials with competitive technologies under conditions relevant to the prolonged care combat environment are also sought.

REFERENCES:

1. TRADOC Pamphlet 525-3-1, The U.S. Army in Multi-Doman Operations; 6 DEC 2018; [https://www.tradoc.army.mil/Portals/14/Documents/MDO/TP525-3-1\\_30Nov2018.pdf](https://www.tradoc.army.mil/Portals/14/Documents/MDO/TP525-3-1_30Nov2018.pdf)
2. JTS Clinical Practice Guideline: Burn Care (CPG ID: 12); 11 MAY 2016; [https://jts.amedd.army.mil/assets/docs/cpgs/JTS\\_Clinical\\_Practice\\_Guidelines\\_\(CPGs\)/Burn\\_Care\\_11\\_May\\_2016\\_ID12.pdf](https://jts.amedd.army.mil/assets/docs/cpgs/JTS_Clinical_Practice_Guidelines_(CPGs)/Burn_Care_11_May_2016_ID12.pdf)

KEYWORDS: Burn, Hydrogel, Antimicrobial, Anti-inflammatory, Healing, Topical

DHA201-D002      TITLE: Optimize Performance and Mitigate Falls in Warfighters with Lower Limb Trauma and/or Loss

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 and demonstrate a technology that can be easily implemented in a clinical setting to provide advanced fall-mitigation training and accelerate recovery to the highest possible levels of performance for Warfighters with lower limb trauma and/or loss.

DESCRIPTION: Even after participating in advanced rehabilitation and receiving state-of-the-art prosthetic and orthotic devices, Warfighters with lower limb trauma and/or loss are still at risk for falls. Warfighters with lower limb trauma and/or loss are often young and capable of high performance at the time of their injuries, and may be at increased risk of injury causing falls following rehabilitation due to their continued active lifestyle, sometimes including remaining on active duty and deployment [1].

Previous research on fall mitigation training has demonstrated success. However this research is often conducted on cost prohibitive systems requiring significant space and operator training [2-3]. These systems are not feasible for use in a clinical setting. A solution is sought that is clinically accessible, and easy to use for both clinicians and patients. As a use-case example, a regimen for the technology could be prescribed by a physical therapist based on individual patient needs and goals, executed by a physical therapy assistant or technician, and completed by the patient over the course of their treatment.

PHASE I: Conceptualize and design an innovative solution for a technology that optimizes the performance and mitigates the risk of falls in Warfighters with lower limb trauma and loss. The technology must be feasible for use in clinical settings and easy to use by clinical staff. The required Phase I deliverables will include: 1) a research design for engineering the device and 2) a preliminary prototype with limited bench-top testing to demonstrate proof-of-concept evidence, and 3) evidence that the technology, used in a clinical setting by a trained clinician, will result in the mitigation of falls and improved performance in those with lower limb trauma and/or loss. Other supportive data may also be provided during this 6-month Phase I effort.

PHASE II: Design, develop, test, finalize and validate the practical implementation of the prototype system that implements the Phase I methodology towards a technology that can be easily implemented in a clinical setting to

provide advanced fall-mitigation training and accelerate recovery to the highest possible levels of performance for Warfighters with lower limb trauma and/or loss, over this Phase II effort. A plan for meeting FDA requirements toward regulatory approval is required. Plans for translation in rehabilitation clinics including end-user requirements, training and use guidelines/documentation, and operating standards are required. The testing and practical implementation of the prototype technology should be relevant to Warfighters who have experienced lower limb trauma and/or loss, and are undergoing rehabilitation to meet their goals. These patients are often young and active and may have the desire to remain on active duty. Roughly 15-20% of Warfighters with major limb trauma from the most recent conflicts remained on active duty following discharge from rehabilitation. Some re-deployed to theater. Others who separated from the military have engaged in high demand occupations (police, fire fighter, first responder, etc.). The developed technology should be implemented as part of the rehabilitation process and should result in outcomes related to mitigation of falls and increased performance or participation in injured Warfighters with lower limb trauma and/or loss.

**PHASE III DUAL USE APPLICATIONS:** Work with commercial partners, military subject matter experts (e.g. a military treatment facility that treats patients with limb trauma and/or loss), and/or the civilian marketplace to move towards a final commercial product. Ensure that the final product can be incorporated into clinical practice including ease of use, appropriate coding/billing, cost/benefit, and training, education, socialization, and outreach. While the technology should be focused on optimizing performance and mitigating falls in Warfighters with limb trauma and loss, there are other military, veteran and civilian populations that may benefit. The military's highest priority is readiness. Musculoskeletal injuries are one of the greatest factors limiting readiness. There is potential that this technology could extend to Warfighters with lower limb musculoskeletal injuries (e.g. chronic ankle instability, knee/ankle tendon or ligament injury, etc.) to accelerate recovery and return to duty. Additionally, it is envisioned that this technology could be applied within VA and civilian rehabilitation facilities to mitigate falls and improve performance, participation and quality of life for patients with stability and mobility issues following injury/illness.

#### REFERENCES:

1. Felcher, S. M., Stinner, D. J., Krueger, C. A., Wilken, J. M., Gajewski, D. A., Hsu, J. R., & Skeletal Trauma Research Consortium (STReC). (2015). Falls in a young active amputee population: a frequent cause of rehospitalization?. *Military medicine*, 180(10), 1083-1086.
2. Grabiner, M. D., Bareither, M. L., Gatts, S., Marone, J., & Troy, K. L. (2012). Task-specific training reduces trip-related fall risk in women.
3. Sheehan, R. C., Rábago, C. A., Rylander, J. H., Dingwell, J. B., & Wilken, J. M. (2016). Use of perturbation-based gait training in a virtual environment to address mediolateral instability in an individual with unilateral transfemoral amputation. *Physical therapy*, 96(12), 1896-1904.

**KEYWORDS:** Stability, Limb Loss, Limb Trauma, Performance, Falls, Rehabilitation