

**DEFENSE HEALTH PROGRAM (DHP)**  
**15.B Small Business Technology Transfer (STTR) Program**  
**Proposal Submission Instructions**

The DHP STTR Program seeks small businesses with strong research and development capabilities to pursue and commercialize medical technologies.

The STTR Program Management Office (PMO), located at the United States Medical Research Materiel Command (USAMRMC), manages the DHP's STTR Program. The DHP STTR Program harnesses the collective knowledge and experience of scientists and engineers, to identify and put forward research and development (R&D) topics to stimulate a partnership of ideas and technologies between innovative small business concerns (SBCs) and research institutions (RIs) through Federally-funded R&D to address DHP needs.

For technical questions about specific topics during the Pre-Solicitation period (24 Apr 2015 - 25 May 2015), contact the Topic Authors listed as POCs for each topic in the Solicitation. To obtain answers to technical questions during the formal Solicitation period, visit <https://sbir.defensebusiness.org/>. For general inquiries or problems with the electronic submission process, contact the DoD SBIR/STTR Help Desk at 1-800-348-0787 (9:00 am to 6:00 pm ET). Specific questions pertaining to the DHP STTR Program should be submitted to:

DHP STTR Program Management Office (PMO)  
[usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@mail.mil](mailto:usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@mail.mil)  
(301) 619-5047

**PHASE I PROPOSAL GUIDELINES**

Phase I proposals should address the feasibility of a solution to the topic. Due to limited funding, the DHP STTR Program reserves the right to limit awards under any topic and only proposals considered to be of superior quality will be funded. The DHP reserves the right to not fund a topic for any reason. Phase I contracts are limited to a maximum of \$150,000 over a period not to exceed six months. Awards will be made on the basis of technical evaluations using the criteria described in this DoD solicitation (see section 6.0) and availability of DHP STTR funds.

The DoD SBIR/STTR Proposal Submission system (<https://sbir.defensebusiness.org/>) provides instruction and a tutorial for preparation and submission of your proposal. Refer to section 5.0 at the front of this solicitation for detailed instructions on Phase I proposal format. You must include a Company Commercialization Report (CCR) as part of each proposal you submit. If you have not updated your commercialization information in the past year, or need to review a copy of your report, visit the DoD SBIR/STTR Proposal Submission site. Please note that improper handling of the CCR may have a direct impact on the review and evaluation of the proposal (refer to section 5.4.e of the DoD Solicitation).

Proposals addressing the topics will be accepted for consideration if received no later **6:00 a.m. ET, Wednesday, 24 June 2015**. The DHP requires your entire proposal to be submitted electronically through the DoD-wide SBIR/STTR Proposal Submission Web site (<https://sbir.defensebusiness.org/>). A hardcopy is NOT required and will not be accepted. Hand or electronic signature on the proposal is also NOT required. DHP has established a **20-page limitation** for Technical Volumes submitted in response to its topics. This does not include the Proposal Cover Sheets (pages 1 and 2, added electronically by the DoD submission site), the Cost Volume, or the CCR. The Technical Volume includes, but is not limited

to: table of contents, pages left blank, references and letters of support, appendices, key personnel biographical information, and all attachments. The DHP requires that small businesses complete the Cost Volume form on the DoD Submission site versus submitting it within the body of the uploaded Technical Volume. Proposals are required to be submitted in Portable Document Format (PDF), and it is the responsibility of submitters to ensure any PDF conversion is accurate and does not cause the Technical Volume portion of the proposal to exceed the 20-page limit. Any pages submitted beyond the 20-page limit will not be read or evaluated. If you experience problems uploading a proposal, call the DoD SBIR/STTR Help Desk at 1-800-348-0787 (9:00 am to 6:00 pm ET).

If a small business concern is selected for an STTR award they must negotiate a written agreement between the small business and their selected research institution that allocates intellectual property rights and rights to carry out follow-on research, development, or commercialization (section 10).

## **PHASE II PROPOSAL GUIDELINES**

Phase II is the demonstration of the technology found feasible in Phase I. Only Phase I awardees are eligible to submit a Phase II proposal. All Phase I awardees 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 DHP STTR Program Office either during the Phase I award or by subsequent notification.

Phase II proposals will be reviewed for overall merit based upon the criteria in section 8.0 of this solicitation. STTR Phase II proposals have four Volumes: Proposal Cover Sheet, Technical Volume, Cost Volume and Company Commercialization Report. The Technical Volume has a **40-page** limit including: table of contents, pages intentionally left blank, technical references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any attachments. However, offerors are instructed to NOT leave blank pages, duplicate the electronically generated cover pages or put information normally associated with the Technical Volume in others sections of the proposal submission as these will count toward the 40-page limit. ONLY the electronically generated Cover Sheets, Cost Volume and CCR are **excluded** from the 40-page limit. As instructed in section 5.4.e of the DoD Program Solicitation, the CCR is generated by the submission website based on information provided by you through the “Company Commercialization Report” tool.

Technical Volumes that exceed the 40-page limit will be reviewed only to the last word on the 40<sup>th</sup> page. Information beyond the 40<sup>th</sup> 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.

Small businesses submitting a proposal are also required to develop and submit a technology transition and commercialization plan describing feasible approaches for transitioning and/or commercializing the developed technology in their Phase II proposal.

DHP Phase II Cost Volumes must contain a budget for the entire 24 month Phase II period not to exceed the maximum dollar amount of \$1,000,000. 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. The total proposed amount should be indicated on the Proposal Cover Sheet as the Proposed Cost. Phase II projects will be evaluated after the base year prior to extending funding for the option year. Phase II proposals should be structured as follows: the first 10-12 months (base effort) should be approximately \$500,000; the second 10-12 months of funding should also be approximately

\$500,000. The entire Phase II effort should not exceed \$1,000,000. The Phase II contract structure is at the discretion of the DHP's Contracting Officer, and the PMO reserves the option to reduce an annual budget request > \$500,000 if program funds are unavailable.

### **DISCRETIONARY TECHNICAL ASSISTANCE (DTA)**

In accordance with section 9(q) of the Small Business Act (15 U.S.C. 638(q)), the DHP STTR Program will provide technical assistance services to small businesses engaged in STTR projects through a network of scientists and engineers engaged in a wide range of technologies. The objective of this effort is to increase DHP STTR technology transition and commercialization success thereby accelerating the fielding of capabilities to Soldiers, Sailors, Airmen and Marines, and to benefit the nation through stimulated technological innovation, improved manufacturing capability, and increased competition, productivity, and economic growth.

### **RESEARCH INVOLVING ANIMAL OR HUMAN SUBJECTS**

The DHP STTR Program discourages offerors from proposing to conduct Human or Animal Subject Research during Phase I due to the significant lead time required to prepare the documentation and obtain approval, which will delay the Phase I award.

All research involving human subjects (to include use of human biological specimens and human data) and animals, shall comply with the applicable federal and state laws and agency policy/guidelines for human subject and animal protection.

Research involving the use of human subjects may not begin until the USAMRMC's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for an award will be issued from the USAMRMC, HRPO, under separate letter to the Contractor.

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

### **FOREIGN NATIONALS**

If the offeror proposes to use a foreign national(s) [any person who is NOT a citizen or national of the United States, a lawful permanent resident, or a protected individual as defined by 8 U.S.C. 1324b (a)(3) – refer to Section 3.5 of this solicitation for definitions of “lawful permanent resident” and “protected individual”] as key personnel, they must be clearly identified. For foreign nationals, you must provide 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. Please ensure no designated Privacy Act information is included in this submittal.

### **PUBLIC RELEASE OF AWARD INFORMATION**

If your proposal is selected for award, the technical abstract and discussion of anticipated benefits will be publicly released via the Internet. Therefore, do not include proprietary or classified information in these sections. For examples of past publicly released DoD SBIR/STTR Phase I and II awards, visit <https://sbir.defensebusiness.org/>.

## **NOTIFICATION SCHEDULE OF PROPOSAL STATUS AND DEBRIEFS**

Once the selection process is complete, the DHP STTR Program Manager will send an email to the individual listed as the “Corporate Official” on the Proposal Coversheet with an attached letter of selection or non-selection. The notification letter referenced above will provide instructions for requesting a proposal debriefing. Small Businesses will receive a notification for each proposal that they submitted. The DHP STTR Program Manager will provide *written* debriefings upon request to offerors in accordance with Federal Acquisition Regulation (FAR) Subpart 15.5. Please read each notification carefully and note the proposal number and topic number referenced.

## **DHP STTR 15.B Topic Index**

DHP15B-001	Conversion to Universal Plasma
DHP15B-002	Laser and Lightwave Therapies for Wound Healing Application

## DHP STTR 15.B Topic Descriptions

DHP15B-001 TITLE: Conversion to Universal Plasma

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Program Endorsement: Office of the Principal Assistant for Acquisition

OBJECTIVE: To develop and/or evaluate a simple and efficient blood purification/extraction technology to selectively remove anti-A / anti-B antibodies from donor plasma resulting in the production of universal plasma.

DESCRIPTION: Demand for plasma-based therapies continues to rise. In the US alone, there were ~29 million donations of plasma in 2013<sup>1</sup>. Plasma-based therapies are also in high demand in the military. Warfighters with combat casualties often require massive plasma transfusions for trauma, shock, burn injury, and emergency surgery. Today, only Type AB blood donors, who account for only 4% of the overall donor population, are considered universal plasma donors. This greatly limits the overall plasma donor pool, and necessitates time-consuming and costly screening of non-AB plasma. The restricted donor pool poses additional logistic challenges to already complicated blood transfusion practices in the far-forward setting.<sup>2</sup> Anti-A and anti-B (IgG and IgM antibodies) found in plasma from Type A, B or O donors can mediate blood cell hemolysis if not appropriately matched. These antibodies bind to A and B blood group antigens found on the surfaces of red blood cells, lymphocytes, endothelial cells and platelets in a recipient, triggering potentially dangerous hemolytic transfusion reactions. Plasma from Type AB blood donors lack these antibodies and do not cause hemolytic reactions. Therefore, blood purification/extraction technologies that selectively remove anti-A and anti-B antibodies from plasma can potentially produce universal plasma and significantly expand the plasma donor pool. One potential solution is the passage of plasma through a small, portable, biocompatible filter that can efficiently and selectively remove anti-A and anti-B (IgG and IgM antibodies) from plasma while sparing beneficial substances in plasma such as coagulation factors and albumin. Such a filter should ideally be:

- Easy to implement with little to no supervision
- Capable of being used at the point of plasma collection or transfusion, using gravity alone with no change in standard transfusion times
- Easily stored at ambient temperature without the need of refrigeration, with a shelf-life of more than 2 years
- Devoid of biologics, antibodies or ligands that can leach or degrade over time
- Simple to manufacture and gamma sterilizable
- Easy to use and not cost prohibitive.

PHASE I: The contractor will develop and screen various chemical / synthetic modifications of the base filtration technology, optimizing anti-A and anti-B antibody removal capacity as a proof-of-concept. As the feasibility criteria for Phase I, the contractor is required to demonstrate at least 70% selective removal of anti-A and/or anti-B (IgG and IgM antibodies) from plasma, while avoiding the removal of no more than 25% of coagulation factors and beneficial substances. Beneficial substances include albumin, total IgG, certain coagulation factors, and electrolytes (Na<sup>+</sup>, K<sup>+</sup>, and Ca<sup>2+</sup>). The research plan should include a R&D concept and in vitro screening methods to support the investigation.

PHASE II: The contractor will down select the optimal filtration technology developed in Phase I and target anti-A and anti-B (IgG and IgM antibodies) removal of >90%, while removing no more than 10% of coagulation factors and beneficial substances. The Phase II research plan should incorporate a detailed product design specification and plan for custom tooling, manufacturing, and final delivery of a prototype

filtration/extraction device. The contractor shall furthermore demonstrate device compatibility with gamma sterilization.

PHASE III: The contractor will conduct an animal safety and efficacy study. The device should be tested for ISO 10993 biocompatibility and immunohematological compatibility testing and be compatible with standard hospital transfusion and blood filtration equipment. The contractor will be required to apply for IDE approval from the FDA to run a small human pilot trial. This device could expand the plasma donor pool and alleviate substantial donor transfusion restrictions in definitive care, combat casualty care, and austere environments globally.

REFERENCES:

1. <http://www.pptaglobal.org/plasma/plasma-collection>
2. Spinella, PC; Dunne, J; Beilman, GJ, O'Connell, RJ; Borgman, MA; Cap, AP and Rentas, F. Constant challenges and evolution of US military transfusion medicine and blood operations in combat. *Transfusion*. 05/2012; 52(5):1146-53.

KEYWORDS: transfusion, universal plasma, donor antibody, anti-A antibody, anti-B antibody, purification

DHP15B-002 TITLE: Laser and Lightwave Therapies for Wound Healing Application

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Program Endorsement: Office of the Principal Assistant for Acquisition

OBJECTIVE: Investigate and validate alternative approaches for wound healing such as laser and lightwave treatments.

DESCRIPTION: Since 8 December 2007, the war in the Middle East has seen over 30,000 soldiers injured in combat with the majority of these injuries occurring the last few years [1]. Despite the type of the injury, the majority of the wounded have suffered some degree of soft tissue injury which needs to be addressed. Since these soldiers endure harsh conditions and their wounds are much more likely to become infected while in the field, early treatment is critical. Many colonized wounds harbor bacterial loads that can eventually lead to infections that not only can result in significant delays in healing (affecting troop deployment) but also increase rates of morbidity and mortality. Furthermore, wound healing is a complex process that involves a series of events including initial clotting, inflammation, granulation tissue formation, epithelialization, collagen synthesis, and finally tissue remodeling. Finding the optimal treatment for various types of wounds would also save time and money by allowing Warfighters to return to service as quickly as possible. Treatments that may be effective at stimulating one type of injury may not be effective on a different type of injury. For example, a diabetic wound ulcer not healing because of dead necrotic tissue and lack of blood flow may benefit significantly from a stimulatory laser or lightwave treatment rather than a standard antimicrobial wound care dressing treatment. Laser and lightwave therapies have been used as an adjunctive treatment in acute wound healing at military treatment facilities (MTFs) in treating superficial epidermal injuries such as contractures or for reducing scarring in Warfighters. Typically, a laser or lightwave technology is placed over a wounded area, and the photon energy from the light stimulates the healing process. The heat brings blood to the wound and increases circulation, which expedites recovery. Several MTFs currently use pulsed dye lasers (PDL) and excimer lasers for epidermal treatments. PDLs typically use a concentrated beam of light while an excimer laser uses a combination of a noble gas (argon, krypton, or xenon) and a reactive gas (fluorine or chlorine) to

excite molecules at various wavelengths. Compared to gases and most solid state lasing media, a dye can generally be used for a much wider range of wavelengths. There are a number of other commercial lasers and lightwave devices on the market today which have potential for wound healing application. Furthermore, several researchers continue to work on various novel developmental device efforts for process optimization and alternative treatment modalities [2]. Animal modeling studies have suggested laser and lightwave therapy can be beneficial in treating more invasive wounds such as acute burns, partial thickness, full thickness, musculoskeletal injuries, degenerative damage, and chronic wounds [3, 4]. Very few controlled studies have explored the idea of using lasers or light wave therapies for dermis or subcutaneous thickness injuries in humans [5, 6]. It is the goal of this topic to explore the feasibility of developing or adapting an existing device that can meet the military need of accelerating the wound healing process for deep dermal injuries (dermis, subcutaneous, and muscular). The device should function by means of laser or lightwave energy. The device should be accessible by trained medical personnel in a military treatment facility. Finally, the device should demonstrate a clear improvement in wound healing as compared to the control therapy. Design of such a system to accelerate wound healing injuries using up-to-date computer, laser, and mechanical engineering technologies is expected to be technically challenging, and will require innovative and creative approaches to meet the technical goals. Significant flexibility in formulating an approach will be considered.

**PHASE I:** Develop design of an automated laser or lightwave wound healing system. Electronic engineering plans should be generated that allow 3-dimensional, rotational views of all components of the proposed system. A document describing the proposed operation and functionality of the system should also be generated. Furthermore, this phase should include a plan for development, clinical validation, regulatory strategy, concept of the proposed device, and a literature search to support feasibility.

**PHASE II:** Develop and demonstrate efficacy of a working prototype based on Phase I work suitable for FDA clinical trials. Conduct in-depth statistically significant testing in an appropriate animal model to show functionality, safety, toxicity, effectiveness, for deep dermal wounds (eg, second degree burns, partial thickness injuries, full thickness injuries, ulcers, etc.). Identify clinical sites for validation and primary investigators and have preliminary talks with FDA regarding regulatory path (at least pre-IDE, preferably IDE). Finalize plans pivotal trial protocol.

**PHASE III:** Design, develop, and conduct a pivotal clinical trial. The purpose is to create further indications, establish human safety and effectiveness in a clinical setting with the goal of gaining additional FDA clearance for the use of the device in wound management. Expanding the indications would pave the way for future uses in the healing of all types of tissue to include muscle, tendon and bone. In addition, emphasis on the treatment of deep pain would be addressed. The device indication would be expanded to include not just definitive care but to combat casualty care and austere environments.

#### REFERENCES:

1. <http://siadapp.dmdc.osd.mil/personnel/casualty>
2. Light-activated sutureless closure of wounds in thin skin. Yang P, Yao M, DeMartelaere SL, Redmond RW, Kochevar IE. *Lasers Surg Med.* 2012 Feb;44(2):163- 7. doi: 10.1002/lsm.21137. Epub 2011 Dec 13.
3. Asheesh G, Dai T, Hamblin MR. Effect of red and near-infrared wavelengths on low-level laser (light) therapy-induced healing of partial-thickness dermal abrasion in mice. *Lasers Med Sci.* Published online 26 April 2013.

4. Usumez A, Cengiz B, Oztuzcu S, Demir T, Hamdi Aras M, Gutknecht N. Effects of laser irradiation at different wavelengths (660, 810, 980, and 1,064 nm) on mucositis in an animal model of wound healing. *Lasers Med Sci*. Published online 01 May 2013.
5. Low-Level Laser Therapy Facilitates Superficial Wound Healing in Humans: A Triple-Blind, Sham-Controlled Study. Hopkins JT, McLoda TA, Seegmiller JG, David Baxter G. *J Athl Train*. 2004 Sep;39(3):223-229.
6. Visible light-induced healing of diabetic or venous foot ulcers: a placebo-controlled double-blind study. Landau Z, Migdal M, Lipovsky A, Lubart R. *Photomed Laser Surg*. 2011 Jun;29(6):399-404. doi: 10.1089/pho.2010.2858. Epub 2011 Jan 9.

**KEYWORDS:** Laser, Lightwave, Clinical Wound Healing, Burn, Trauma, FDA, Medical device