

**Office Of The Secretary Of Defense (OSD)  
Deputy Director Of Defense Research & Engineering  
Deputy Under Secretary Of Defense (Science & Technology)  
Small Business Innovation Research (SBIR)  
FY2004.1 Program Description**

## **Introduction**

The Deputy Under Secretary of Defense (Science & Technology) SBIR Program is co-sponsoring four topics in biomedical technology for military health systems, with Defense Health Affairs. The Army Medical Research Command and the Office of Naval Research are participating in the OSD program this year. The service laboratories act as our OSD Agent in the management and execution of the contracts with small businesses. The Army and Navy laboratories, often referred to as a DoD Component acting on behalf of the OSD, invite small business firms to submit proposals under this Small Business Innovation Research (SBIR) program solicitation. In order to participate in the OSD SBIR Program this year, all potential proposers should register on the DoD SBIR website as soon as you can, and should follow the instruction for electronic submittal of proposals. It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at <http://www.dodsbir.net/submission>. If you experience problems submitting your proposal, call the help desk (toll free) at 1-866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The DoD SBIR Proposal Submission Website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report.

**We WILL NOT accept any proposals that are not submitted through the on-line submission site.** The submission site does not limit the overall file size for each electronic proposal, there is only a page limit. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. If you wish to upload a very large file, it is highly recommended that you submit prior to the deadline submittal date, as the last day is heavily trafficked. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

Firms with strong research and development capabilities in science or engineering in any of the topic areas described in this section and with the ability to commercialize the results are encouraged to participate. Subject to availability of funds, the DUSD(S&T) SBIR Program will support high quality research and development proposals of innovative concepts to solve the listed defense-related scientific or engineering problems, especially those concepts that also have high potential for commercialization in the private sector. Objectives of the DUSD(S&T) SBIR Program include stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The guidelines presented in the solicitation incorporate and exploit the flexibility of the SBA Policy Directive to encourage proposals based on scientific and technical approaches most likely to yield results important to DoD and the private sector.

The topic descriptions in the Defense Health Biomedical technology area, that follow this program overview section, are listed below:

OSD04-DH01	Fractured Femur Simulator (Army TATRC)
OSD04-DH02	Non-invasive Metabolic Monitoring (Army MRMC)
OSD04-DH03	Development of Improved FDA-Approved Intravenous Hemostatic Agents (Army MRMC)
OSD03-DH04	Portable Near Infrared Technology for Detection of Traumatic Brain Injuries in Operational Environments (Navy ONR)

## Description of the OSD SBIR Three Phase Program

Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR Program and will typically be one half-person year effort over a period not to exceed six months, with a dollar value up to \$100,000. We plan to fund 3 Phase I contracts, on average, and downselect to one Phase II contract per topic. This is assuming that the proposals are sufficient in quality to fund this many. Proposals should concentrate on that research and development which will significantly contribute to proving the scientific and technical feasibility of the proposed effort, the successful completion of which is a prerequisite for further DoD support in Phase II. The measure of Phase I success includes technical performance toward the topic objectives and evaluations of the extent to which Phase II results would have the potential to yield a product or process of continuing importance to DoD and the private sector, in accordance with Section 4.3.

Subsequent Phase II awards will be made to firms on the basis of results from the Phase I effort and the scientific and technical merit of the Phase II proposal in addressing the goals and objectives described in the topic. Phase II awards will typically cover 2 to 5 person-years of effort over a period generally not to exceed 24 months (subject to negotiation). Phase II is the principal research and development effort and is expected to produce a well defined deliverable prototype or process. A more comprehensive proposal will be required for Phase II.

Under Phase III, the DoD may award non-SBIR funded follow-on contracts for products or processes, which meet the component mission needs. This solicitation is designed, in part, to encourage the conversion of federally sponsored research and development innovation into private sector applications. The small business is expected to use non-federal capital to pursue private sector applications of the research and development.

This solicitation is for Phase I proposals only. Any proposal submitted under prior SBIR solicitations will not be considered under this solicitation; however, offerors who were not awarded a contract in response to a particular topic under prior SBIR solicitations are free to update or modify and submit the same or modified proposal if it is responsive to any of the topics listed in this section.

For Phase II, no separate solicitation will be issued and no unsolicited proposals will be accepted. Only those firms that were awarded Phase I contracts, and have successfully completed their Phase I efforts, will be invited to submit a Phase II proposal. Invitations to submit Phase II proposals will be released at or before the end of the Phase I period of performance. The decision to invite a Phase II proposal will be made based upon the success of the Phase I contract to meet the technical goals of the topic, as well as the overall merit based upon the criteria in section 4.3. DoD is not obligated to make any awards under Phase I, II, or III. DoD is not responsible for any money expended by the proposer before award of any contract. For specifics regarding the evaluation and award of Phase I or II contracts, please read the front section of this solicitation very carefully. Every Phase II proposal will be reviewed for overall merit based upon the criteria in section 4.3 of this solicitation, repeated below:

- a. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
- b. 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.
- c. The potential for commercial (defense and private sector) application and the benefits expected to accrue from this commercialization.

In addition, the OSD SBIR Program has a *Phase II Plus* Program, which provides matching SBIR funds to expand an existing Phase II that attracts investment funds from a DoD acquisition program or Private sector investments. ***Phase II Plus*** allows for an existing Phase II OSD SBIR effort to be extended for up to one year to perform additional research and development. ***Phase II Plus*** matching funds will be provided on a one-for-one basis up to a maximum \$250,000 of SBIR funds. All ***Phase II Plus*** 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 Plus*** contract modification.

The Fast Track provisions in section 4.0 of this solicitation apply as follows. Under the Fast Track policy, SBIR projects that attract matching cash from an outside investor for their Phase II effort have an opportunity to receive interim funding between Phases I and II, to be evaluated for Phase II under an expedited process, and to be

selected for Phase II award provided they meet or exceed the technical thresholds and have met their Phase I technical goals, as discussed Section 4.5. Under the Fast Track Program, a company submits a Fast Track application, including statement of work and cost estimate, within 120 to 180 days of the award of a Phase I contract (see the Fast Track Application Form on [www.dodsbir.net/submission](http://www.dodsbir.net/submission)). Also submitted at this time is a commitment of third party funding for Phase II. Subsequently, the company must submit its Phase I Final Report and its Phase II proposal no later than 210 days after the effective date of Phase I, and must certify, within 45 days of being selected for Phase II award, that all matching funds have been transferred to the company. For projects that qualify for the Fast Track (as discussed in Section 4.5), DoD will evaluate the Phase II proposals in an expedited manner in accordance with the above criteria, and may select these proposals for Phase II award provided: (1) they meet or exceed selection criteria (a) and (b) above and (2) the project has substantially met its Phase I technical goals (and assuming budgetary and other programmatic factors are met, as discussed in Section 4.1). Fast Track proposals, having attracted matching cash from an outside investor, presumptively meet criterion (c). However, selection and award of a Fast Track proposal is not mandated and DoD retains the discretion not to select or fund any Fast Track proposal.

### **Follow-On Funding**

In addition to supporting scientific and engineering research and development, another important goal of the program is conversion of DoD-supported research and development into commercial products. Proposers are encouraged to obtain a contingent commitment for private follow-on funding prior to Phase II where it is felt that the research and development has commercial potential in the private sector. Proposers who feel that their research and development have the potential to meet private sector market needs, in addition to meeting DoD objectives, are encouraged to obtain non-federal follow-on funding for Phase III to pursue private sector development. The commitment should be obtained during the course of Phase I performance. This commitment may be contingent upon the DoD supported development meeting some specific technical objectives in Phase II which if met, would justify non-federal funding to pursue further development for commercial purposes in Phase III. The recipient will be permitted to obtain commercial rights to any invention made in either Phase I or Phase II, subject to the patent policies stated elsewhere in this solicitation.

### **Contact with DoD**

General informational questions pertaining to proposal instructions contained in this solicitation should be directed to the topic authors and point of contact identified in the topic description section. Proposals should be electronically submitted. Oral communications with DoD personnel regarding the technical content of this solicitation during the pre-solicitation phase are allowed, however, proposal evaluation is conducted only on the written submittal. Oral communications during the pre-solicitation period should be considered informal, and will not be factored into the selection for award of contracts. Oral communications subsequent to the pre-solicitation period, during the Phase I proposal preparation periods are prohibited for reasons of competitive fairness. Refer to the front section of the solicitation for the exact dates.

### **Proposal Submission**

Proposals shall be submitted in response to a specific topic identified in the following topic description sections. The topics listed are the only topics for which proposals will be accepted. Scientific and technical information assistance may be requested by using the DTIC SBIR Interactive Technical Information System (SITIS).

It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at <http://www.dodsbir.net/submission>. If you experience problems submitting your proposal, call the help desk (toll free) at 866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The proposal submission website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report. We **WILL NOT accept any proposals which are not submitted through the on-line**

**submission site.** The submission site does not limit the overall file size for each electronic proposal, only the number of pages are limited. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

The following pages contain a summary of the technology areas, which are followed by the topics.

**Office Of The Secretary Of Defense (OSD)  
Deputy Director Of Defense Research & Engineering  
Deputy Under Secretary Of Defense (Science & Technology)/Defense Health Program  
Biomedical Technology Focus Area**

The Department of Defense is aggressively pursuing unified Force Health Protection strategies to protect Service members and their family members from health hazards associated with military service. Toward that end, DoD is undertaking strategies that promote healthy units and communities while improving both force morale and war fighting capabilities.

The operational force is exposed to health threats throughout the operational continuum, from CONUS fixed facilities (garrison, base, ashore) through deployment, employment, and redeployment. DoD is developing policy and procedures to assess occupational and environmental health threats for all locations. A comprehensive record of current health—and of past health events and resultant exposure levels—will be maintained for as many as 100,000 U.S. military personnel over their entire military-service cycle (the Millennium Cohort Study).

When Force Health Protection capabilities are fully implemented, commanders will have a more complete view of potential health threats. Integration of assessments from health databases and other assessments from intelligence (e.g., about land mines, directed enemy fire, fratricide) and safety (e.g., about injuries, vehicle accidents, explosives, aviation mishaps) will provide a framework for identifying future medical technology capabilities necessary for Force Health Protection.

Ensuring the health of the force encompasses several key capabilities:

- To provide FDA-approved prevention, diagnosis and treatment items for disease and injury;
- To mobilize, deploy and sustain field medical services and support for any operation requiring military services;
- To maintain and project the continuum of healthcare resources required to provide for the health of the force;
- To operate in conjunction with beneficiary healthcare; and
- To develop training systems which provide realistic rehearsal of emergency medical and surgical procedures and unit-level medical operations.

These capabilities comprise an integrated and focused approach to protect and sustain DoD's most important resource—its Service members and their families—throughout the entire length of service commitment. Three broad capability areas of particular interest are tools and techniques for risk communication, for epidemiology research, and for delivery of health education and training unique to DoD functions. These are described in more detail below:

**Health Risk Assessment and Communication Decision Tools:** Risk analysis is a science-based process that strives to reflect the realities of nature as accurately as possible. The Department experienced significant challenges in determining and communicating risk on illnesses among Gulf War veterans, such as that for the anthrax vaccination program, as well as other deployments. A decision support tool is needed that produces a likelihood index of risk based on epidemiological, intelligence, environmental exposure, and health information concerning deployed forces.

**New Methods to Monitor Health Status:** Monitoring of health status during deployments is necessary to determine etiologic factors of deployment related health change. Health monitoring should be for a sharply limited set of physiologically based indicators, and should yield an unambiguous interpretation of health status.

**Force Health Distributed Learning Tools:** Developing and maintaining diagnostic and treatment skills among military physicians—as well as lifesaving buddy- and self-aid skills among other military personnel and laymen—are important aspects of first-response capabilities. Advanced distributed learning and other computer-based training technology should enable all responders to assist in providing health care in emergency situations involving chemical, biological, radiological, and nuclear events as well as traumatic injury, and should assist medical professionals to maintain clinical knowledge and skills.

We have chosen the following topics and Service Laboratory Executive Agents to manage the SBIR topics in this technology area:

OSD04-DH01 Fractured Femur Simulator (Army TATRC)  
OSD04-DH02 Non-invasive Metabolic Monitoring (Army MRMC)  
OSD04-DH03 Development of Improved FDA-Approved Intravenous Hemostatic Agents (Army MRMC)  
OSD03-DH04 Portable Near Infrared Technology for Detection of Traumatic Brain Injuries in Operational Environments (Navy ONR)

*All of the OSD FY04.1 SBIR topics are on the following pages.*

### **OSD 04.1 Topic List**

OSD04-DH1 Fractured Femur Simulator  
OSD04-DH2 Non-invasive Metabolic Monitoring  
OSD04-DH3 Development of Improved FDA-Approved Intravenous Hemostatic Agents  
OSD04-DH4 Portable Near Infrared Technology for Detection of Traumatic Brain Injuries in Operational Environments

## OSD 04.1 Topic Descriptions

OSD04-DH1

TITLE: Fractured Femur Simulator

TECHNOLOGY AREAS: Biomedical

**OBJECTIVE:** To develop a proof-of-concept, design, develop, build and demonstrate a Personal Computer (PC)-based simulation training system to demonstrate various human femur fractures, to assist in the training of military and civilian health care professionals, i.e., physicians, nurses, and combat medics, to diagnose and treat fractures appropriately.

**DESCRIPTION:** This topic falls into a category of “virtual workbench”, “part-task” simulators. In a “part-task” simulation, rather than simulate an entire mission or procedure from start to finish, certain part(s) of a mission / procedure are simulated, e.g., those that are most difficult, most dangerous, least-encountered, highest-risk, etc. The system should promote the acquisition and maintenance of skills in this and other minimally invasive surgical techniques and provide a level of training not possible using the traditional medical training methods currently in use.

The use of a fractured femur simulator should provide health care providers hands-on experience in managing various types of fractures without risk to a human patient. Fractures of the femur include but are not limited to: femoral neck (intracapsular); intertrochanteric; subtrochanteric; femoral shaft; supracondylar. Fractures can be spiral or transverse, comminuted (broken into pieces), open, or uncomplicated. Femoral fractures can damage major arteries, veins and nerves as well as muscle, skin and related tissues. Fracture management includes knowledge of the mechanism of injury and age-specific differences in injuries; emergent care and splinting/traction; operative (debridement and external/internal fixation) and non-operative treatment options; complications (vascular and nerve injury, infection, etc); pain management and rehabilitation.

Although various types of medical simulators either exist or are under development, there is no realistic model for fractured femurs. For example, given a simulator, health care providers could assess the fracture (modality/mechanism of injury, patient age, X-ray and CT for diagnosis and management) and apply treatment modalities (such as traction and fixation). This simulator should also be able to replicate femoral, popliteal and posterior tibial pulses.

The following performance objectives should be met:

1. Simulator should provide visual and tactile feedback consistent with the visualization and manipulation of the fractured femur to include at least femoral and popliteal pulses as well as the appearance of an open fracture. Better methods for photo-realistic texture mapping to minimize graphic “seam” artifacts should be explored.
2. Techniques for simulation of physiological events should be explored. Integrate realistic modeling of local tissue surface deformation.
3. Realistic lighting simulation should be explored to simulate moist/bleeding tissue surfaces and resulting lighting effects.
4. Real-time collision processing should be explored to detect local collisions with instruments and traction devices. Representations of the physics of external and internal fixators and associated instruments for real-time simulation with tactile feedback should be investigated.
5. Integrate a computer-based geometric model of the femur that can display the different types of fractures and the result of traction/fixation.
6. Integrate the physics processing, device tracking, multimedia, and graphics rendering that will be applicable to all complex real-time environments.
7. Include fluoroscopic and 3-D transparent views for demonstrating real-time position of the external and/or internal fixators. Techniques to eliminate or at least minimize the on-screen appearance of fluoroscope “flutter” should be explored.
8. Of particular interest are technologies and techniques that present the user with multiple patient conditions and complications that might be encountered during management.

9. Of particular interest are technologies and techniques that allow the user to “treat” the condition presented by the simulation. Treatment should be based on clinical protocols developed and accepted by credentialed orthopedic and trauma surgeons. Examples of treatment: traction, external fixation (pins/wires), internal fixation (plates, intramedullary nails). Non-operative treatment should be reserved for children and complicated adult patients. (see references)

10. Cases and treatment should be based on embedded metrics for performance assessment and training.

11. User interface should contain a module that allows the teaching, rehearsal, testing and results tracking of the user.

12. Didactic content should encompass peri-procedural aspects of emergent orthopedic and trauma surgery, including patient preparation, local or general anesthesia, indications and contraindications, complications, and patient recovery, rehabilitation and follow-up.

PHASE I: Phase I will develop a feasibility concept and plan for developing and /or applying various innovative simulation technologies to the management and treatment of human femur fractures.

PHASE 2: Phase 2 will develop and demonstrate a working functional prototype of the human femur surgical simulator. The interface platform will enable the integration of individual patient cases and therapeutic treatment. The simulation should include approximately six patient cases presenting an array of complications.

PHASE III DUAL-USE COMMERCIALIZATION: The focus will be on commercializing a human femur simulation training system that is fieldable in both the military and civilian arenas.

#### REFERENCES:

(1)Jha, Ashish K., Duncan, Bradford W., Bates, David W. Simulator-Based Training and Patient Safety.

(2) Olympio, Michael A. Simulation Saves Lives. American Society of Anesthesiologists Newsletter, October 2001.

(3) Raemer, Daniel B., Barron, Deborah M., Use of Simulators for Education and Training in Nonanesthesia Health Care Domains, Uses of Simulators for Education, 1997.

(4) Salas, Eduardo; Bowers, Clint A., Rhodenizer, Lori; It is How How Much You Have but How You Use It: Toward a Rational Use of Simulation to Support Aviation Training; The International Journal of Aviation Psychology, 8(3), 197-208.

(5) Satava, Richard M., Advanced Simulation Technologies for Surgical Education; American College of Surgeons

KEYWORDS: Modeling, simulation, surgical metrics, medical skills training, human femur training.

OSD04-DH2

TITLE: Non-invasive Metabolic Monitoring

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: The objective is the development and testing of a non-invasive monitor for glucose, lactate and other metabolic analytes.

DESCRIPTION: The determination of metabolic parameters non-invasively can provide a useful gauge of physiological activity and health in a variety of circumstances. This solicitation is not limited to determination of glucose, the metabolic marker of primary choice, but rather extends to possibilities that include lactate and other metabolic analytes. The actual measurements of these metabolites need to be performed non-invasively. They can be made transdermally, using spectrophotometry e.g., NIR, other novel imaging technologies, expired breath gas analysis, saliva, tear or pheromone biochemistry. A useful monitor must provide a means of accounting for variables that impact or confound the metabolite measurement and useful in-put and out-put interpretation.

PHASE I: Conduct research to determine the feasibility and efficacy of the technology to determine a metabolic metabolite non-invasively. Determine the variables, physiologic and phenotypic, that impact on the measurement

and construct report software appropriate to accounting for their affect on metabolite concentrations and their interpretation. The metabolite concentration measurements need to be referenced to standard clinical laboratory measurements, e.g., the normal blood glucose range of 70 to 110 mg/dL. Proof of concept for this research will be accomplished through compliance with the characteristics stated above.

PHASE II: The research developed in Phase I will be refined and individual elements will be optimized. A minimum of one prototype device will be developed and tested for safe and reliable output of metabolite monitoring. Software development will provide for report functions of the metabolite concentrations and demonstrate the device capability to account for all of the impacting variables determined in Phase I. Feasibility of production of a hand-held and/or portable unit will be explored and, if feasible, the prototype device should be of sufficient durability for use in military-type field situations.

PHASE III: DUAL-USE APPLICATION: The devise, procedures, and interpretive software will be tested in clinical studies of sufficient size to demonstrate an effective, reliable and safe system capable of producing data comparable to that using standard clinical laboratory procedures. The completed device will prove useful in a variety of clinical, therapeutic and experimental applications. The device will be capable of being integrated with other physiologic monitoring systems to provide a medical capability in the treatment and monitoring metabolites of patients in a variety of circumstances.

#### REFERENCES:

Koschinsky T, Heinemann L. Sensors for glucose monitoring: technical and clinical aspects. *Diabetes Metab Res Rev* 2001 Mar-Apr; 17(2): 113-23.

Klonoff D.C., Current, Emerging and Future Trends in Metabolic Monitoring. *Diabetes: Technologies and Therapeutics*, vol. 4, No. 5, 2002.

KEYWORDS: Saliva, Glucose, Lactate, Breath-analysis, Transdermal, Metabolic Monitoring

OSD04-DH3

TITLE: Development of Improved FDA-Approved Intravenous Hemostatic Agents

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To develop improved FDA-approved intravenous hemostatic agent for testing in combat-relevant animal models of severe hemorrhage. If successful, this hemostatic agent would proceed to clinical trials for treatment of severe intracavitary hemorrhage.

DESCRIPTION: Noncompressible hemorrhage (i.e., hemorrhage not accessible to direct pressure) continues to be a primary cause of death in both military and civilian trauma<sup>1,2</sup>. For example, intravenous administration of recombinant factor VIIa (rFVIIa) shows great promise in reducing the bleeding associated with noncompressible hemorrhage in coagulopathic trauma patients<sup>3,4,5</sup>. However, treatment with rFVIIa may be prohibitive in certain circumstances due to its great expense, requirement for frequent re-dosing, short half-life, reduced activity at low blood pH (pH<7.1) and marginal effectiveness when used as a sole agent for hemostasis. It is therefore desirable to use new drug discovery techniques based on rapid computer modelling to produce a more potent and pharmacoeconomically advantageous intravenous hemostatic agent. The project will develop and test a prototype intravenous hemostatic agent with priority given to modification of existing constructs for FDA-approved drugs that demonstrate greater efficacy and has the potential to be produced at less cost than similar agents that are currently available. Additionally, the putative agent must be at least as safe as currently available drugs for similar use.

Phase I: Design and develop a computer-generated construct of a putative hemostatic agent that is likely to promote hemostasis under conditions of severe hemorrhage even in the presence of coagulopathy. Successful completion of Phase I will result in development of a computer-generated molecule that could reasonably proceed to animal testing. If possible, preliminary "proof-of-concept" experimentation either in cell-based or whole animal models is desired for demonstration of efficacy.

Phase II: Synthesize the putative hemostatic agent and perform preclinical whole animal testing in animal models of severe trauma. Requirements for successful completion of this phase include: 1) a well-controlled animal study using a standard model of severe venous/parenchymal injury; and, 2) a well-controlled animal study using a standard model of arterial injury. Each study should be performed with sufficient group sizes to demonstrate statistical significance. Additionally, it is required that synthesis and delivery of the candidate drug be shown to be less expensive, more efficacious than and as safe as currently available FDA-approved hemostatic agents. Successful completion of Phase II will result in a hemostatic agent that is ready for entry into clinical studies.

PHASE III DUAL-USE COMMERCIALIZATION: Because of the high incidence of life-threatening hemorrhage associated with both military and civilian trauma, a less costly, FDA-approved hemostatic agent would have wide applicability in trauma centers throughout the world. Such an agent would decrease the significant mortality secondary to uncontrolled hemorrhage and has the potential to decrease adverse sequelae subsequent to hemorrhage.

#### REFERENCES:

1. Bellamy RF. The causes of death in conventional land warfare: Implications for combat casualty care research. *Mil. Med.* 1984; 149:55-62.
2. Sauaia A, Moore FA, Moore EE, Moser KS, Brennan R, Read RA, Pons PT. Epidemiology of trauma deaths: A reassessment. *J. Trauma* 1995; 38:185-193.
3. Hedner U. NovoSeven as a universal haemostatic agent. *Blood Coagul Fibrinolysis.* 2000; 11 Suppl 1:S107-11.
4. Martinowitz U, Kenet G, Segal E, Luboshitz J, Lubetsky A, Ingerslev J et al. Recombinant Activated Factor VII for Adjunctive Hemorrhage Control in Trauma. *J Trauma.* 2001;51:431-439.
5. O'Neill PA, Bluth M, Gloster ES. Successful Use of Recombinant Activated Factor VII for Trauma-Associated Hemorrhage in a Patient without Preexisting Coagulopathy. *J Trauma.* 2002;52:400-405.

KEYWORDS: intravenous hemostasis, noncompressible hemorrhage

OSD04-DH4

TITLE: Portable Near Infrared Technology for Detection of Traumatic Brain Injuries in Operational Environments

TECHNOLOGY AREAS: Biomedical, Sensors, Electronics, Battlespace, Human Systems

OBJECTIVE: Develop portable, accurate near infrared (NIR) spectroscopy and imaging systems for subdural hematoma detection, suitable for deployment into operational settings.

DESCRIPTION: Closed head injuries are still a major concern in the dangerous work environments soldiers face when stationed at sea or in the battlefield. Even in non-military urban settings, acute head trauma is a leading cause of death and injury. The emergence of subdural/intracranial hematomas following blunt force head trauma can lead to life threatening complications including brain damage, disability and death particularly if the injury is not detected immediately after an event. An acute subdural hematoma (SDH) is a collection of rapidly clotting blood below the inner layer of the brain membrane (dura) but external to the brain. In operational or remote settings, immediate evaluation of these injuries following a closed head event is limited to the assessment tools at hand. Ships at sea and forward deployed hospitals are not equipped with technologies such as magnetic resonance imaging (MRI) and computer aided tomography (CAT) scans. These technologies are the standard tools for determining the presence of subdural hematomas - but their excessive size, lack of portability and cost prohibit their use in operational environments. Near infrared wavelengths of light can be used non-invasively to penetrate through the skull and detect/image blood beneath the skull surface and in the cortical layer of the brain. This affords medical teams an opportunity to "see" below the skull and make rapid assessments of patient status. Devices using near infrared spectroscopy have the advantage of being relatively inexpensive due to recent advances in near infrared sources and detectors. This topic seeks to push the development of these imaging systems for use in operational/mobile settings. The development of imaging devices using near infrared spectroscopy will offer the

military medical community an opportunity to detect subdural hematomas on site and should afford medical workers more time to make critical decisions about whether or not a patient needs to be evacuated from the current location.

PHASE I: Conduct studies to determine feasibility of portable imaging system using near infrared spectroscopy to detect hematomas. Evaluate the design considerations for a near infrared imaging device that could be used by a variety of medical workers.

PHASE II: Develop prototype device for use in ambulatory environments, including evaluation of requirements for use in ship or mobile hospital units. Conduct testing to determine usability and accuracy.

PHASE III DUAL USE COMMERCIALIZATION: The development of portable NIR imaging devices has applications in both military and commercial settings. The NIR devices under development in this topic will provide information about patient status currently unavailable in remote hospital locations. The technologies under development will find commercial applications in mobile medical environments such as mobile trauma centers, ambulances and rescue helicopters.

#### REFERENCES:

1. Zhang, Q., H. Ma, et al. (2000). "Study of near infrared technology for intracranial hematoma detection." *Journal of Biomedical Optics* 5(2): 206-13.
2. Heaton, L, M Smith, et al (2000) "Handheld four wavelength retinal vessel oximeter" *Ophthalmic Technologies X Proceedings of SPIE Vol 3908*

KEYWORDS: Closed head injury, Acute subdural hematoma (SDH), Near infrared spectroscopy, Imaging systems, operational/mobile settings