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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2015 Defense Health Program **Date:** March 2014

<b>Appropriation/Budget Activity</b> 0130: Defense Health Program I BA 2: RDT&E	<b>R-1 Program Element (Number/Name)</b> PE 0605502HP I Small Business Innovation Research (SBIR) Program
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COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
Total Program Element	36.040	27.307	19.205	-	-	-	-	-	-	-	Continuing	Continuing
470A: Small Business Innovation Research (SBIR) (Army)	36.040	27.307	19.205	-	-	-	-	-	-	-	Continuing	Continuing

# The FY 2015 OCO Request will be submitted at a later date.

**A. Mission Description and Budget Item Justification**

The Small Business Innovation Research (SBIR) program was established in the Defense Health Program (DHP), Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2001, and is funded in the year of execution. The objective of the DHP SBIR Program includes 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 program funds small business proposals chosen to enhance military medical research and information technology research.

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO</b>	<b>FY 2015 Total</b>
Previous President's Budget	-	-	-	-	-
Current President's Budget	27.307	19.205	-	-	-
Total Adjustments	27.307	19.205	-	-	-
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	27.307	19.205			

**Change Summary Explanation**

FY 2013: Realignment to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$27.307 million) from the following DHP PEs:  
 DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (-\$0.025 million);  
 DHP RDT&E, PE 0601117-Basic Operational Medical Research Sciences (-\$0.271 million);  
 DHP RDT&E, PE 0602115-Applied Biomedical Technology (-\$1.622 million);  
 DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (-\$0.032 million);  
 DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (-\$0.004 million);  
 DHP RDT&E, PE 0603115-Medical Technology Development (-\$8.356 million);  
 DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$8.378 million);  
 DHP RDT&E, PE 0605013-Information Technology Development (-\$4.605 million);

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0130: Defense Health Program / BA 2: RDT&E		PE 0605502HP / Small Business Innovation Research (SBIR) Program
<p>DHP RDT&amp;E, PE 0605145-Medical Products and Support Systems Development (-\$2.889 million);</p> <p>DHP RDT&amp;E, PE 0606105-Medical Program-Wide Activities (-\$0.833 million);</p> <p>DHP RDT&amp;E, PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.292 million).</p>		
<p>FY 2014: Realignment to DHP RDT&amp;E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$19.205 million) from the following DHP PEs:</p> <p>DHP RDT&amp;E, PE 0601101-In-House Laboratory Independent Research (-\$0.086 million);</p> <p>DHP RDT&amp;E, PE 0601117-Basic Operational Medical Research Sciences (-\$0.170 million);</p> <p>DHP RDT&amp;E, PE 0602115-Applied Biomedical Technology (-\$1.309 million);</p> <p>DHP RDT&amp;E, PE 0602787-Medical Technology (AFRRI) (-\$0.034 million);</p> <p>DHP RDT&amp;E, PE 0603002-Advanced Technology (AFRRI) (-\$0.009 million)</p> <p>DHP RDT&amp;E, PE 0603115-Medical Technology Development (-\$8.144 million);</p> <p>DHP RDT&amp;E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$3.705 million);</p> <p>DHP RDT&amp;E, PE 0605013-Information Technology Development (-\$1.207 million);</p> <p>DHP RDT&amp;E, PE 0605023-Integrated Electronic Record (iEHR) (-\$0.574 million);</p> <p>DHP RDT&amp;E, PE 0605025-Theater Medical Information Program - Joint (TMIP-J) (-\$0.993 million);</p> <p>DHP RDT&amp;E, PE 0605145-Medical Products and Support Systems Development (-\$0.531 million);</p> <p>DHP RDT&amp;E, PE 0606105-Medical Program-Wide Activities (-\$2.033 million);</p> <p>DHP RDT&amp;E, PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.410 million).</p>		
<p>FY 2015: No Change.</p>		

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program										Date: March 2014		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605502HP / Small Business Innovation Research (SBIR) Program				Project (Number/Name) 470A / Small Business Innovation Research (SBIR) (Army)			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
470A: Small Business Innovation Research (SBIR) (Army)	36.040	27.307	19.205	-	-	-	-	-	-	-	Continuing	Continuing
# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
Small Business Innovation Research (SBIR): The SBIR program was established in the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2001, and is funded in the year of execution. The program funds small business proposals chosen to enhance military medical research and information technology research.												
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2013	FY 2014	FY 2015
Title: Small Business Innovation Research (SBIR) Program										27.307	19.205	-
Description: The program funds small business proposals chosen to enhance military medical research and information technology research. The following reflects the FY12 research area topics sought for proposals.												
FY 2013 Accomplishments:												
For FY13 (DHP SBIR 13.2), seventeen area topics were developed for solicitation of biomedical technology SBIRs proposals. Funding for each research area topic was based on the merits of responses to solicitations. Topics include development of a simulation-based training system to assist teaching the use of intraosseous (injection directly into bone marrow) devices to administer fluid to patients; long-lasting disposable insecticidal/repellant fabric barrier for personal or area protection against biting arthropods (tick and flea); militarized formulation and Environmental Protection Agency registerable attractive targeted sugar bait for insect vector control; rapid identification of microbial pathogens from food, water and environmental samples; sporozoite (infectious stage of a unicellular organism) vaccine administration method; development of a vector arthropod (tick and flea) pitfall or sticky trap with CO2 attractant; a software tool to assess injury risk and maximum allowable exertions for repetitive forceful one hand and two hand shoulder push/pull motions; a software tool to assess injury risk associated with mechanical exposures from wearing head supported mass; a human body model for computational assessment of blast injury and protection; visual evoked potentials (electrical signals initiated by strobe flash) for TBI diagnosis; immediate application cranioplasty (surgical repair of a defect of a skull) during decompressive craniectomy (removal of part of the skull to allow swelling) for head injuries; a point-of-care device for diagnosis of platelet injury in trauma patients; tailored wound dressing for the treatment of burns; a universal device for performing cricothyrotomies (an incision made through the skin and membrane to establish an airway during life-threatening situations); development of technologies that address the complex architecture of the face during the treatment of severe facial burn injury; and assistive technology sensor platform.												
FY 2014 Plans:												

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
DHP SBIR 14.1 Topic Index					
<p>DHP14-001 - Reducing the Burden on Military Tactical Networks by Lowering the Impact of Digital Medical Image Transmissions.  OBJECTIVE: Seek methodologies and emerging technologies to reduce the burden on the military's tactical networks derived from the transmission of digital medical imagery.</p> <p>DHP14-002 - Computer-Generated, Synthetic Medical Images and Complex Narratives for Use in Healthcare Informatics Research.  OBJECTIVE: As a first objective, conduct basic and applied research surrounding new technologies to computer-generate completely synthetic, complex, medical text narratives for subsequent use in clinical informatics research and healthcare information technology feasibility studies. As a second objective, conduct basic and applied research surrounding new technologies to computer-generate completely synthetic medical images for subsequent use in clinical informatics research and healthcare information technology feasibility studies. If the research is successful, computer-generated synthetic medical text and images could then be made available to the government and/or other private researchers through commercial or open source licensing agreements.</p> <p>DHP14-003 - Mobile Application for Improved Sleep through Sleep Hygiene Training Feedback.  OBJECTIVE: Design, develop and deploy a mobile application which provides sleep hygiene training feedback and cueing to improve sleep quantity and quality.</p> <p>DHP14-004 - Rapid Indicator of Potential for Weight Gain/Loss &amp; Trending.  OBJECTIVE: Develop a commercial; off the shelf test for daily assessing an individual's biochemical modality for weight loss or gain potential before the weight change is observable (as measured on a scale in pounds).</p> <p>DHP14-005 - Development of a Multiplex Bioassay for Early Predictors of Multiple Organ Injury.  OBJECTIVE: Define and develop existing, validated, pre-clinical biomarkers of organ-specific injury that correlate with diverse types of injury to include but not limited to systemic toxicity. Define and resolve issues involved with the use of a diverse set of biomarkers with a single multiplexed methodology. Define and resolve issues related to the isolation and use of diverse biological samples to include but not limited to plasma and urine. Develop a prototype multiplex biomarker assay and algorithm specific and sensitive to diverse and common types of organ injury to include but not limited to kidney, liver, heart, and lung.</p> <p>DHP14-006 - Application of a Wireless Finger-mounted Ultrasound Transducer and Imaging Platform.</p>					

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p><b>OBJECTIVE:</b> The objective of this topic is to develop and demonstrate a wearable finger-mounted ultrasound transducer and ultrasound imaging platform that uses wireless connectivity for image display and operator interface functions on common commercially available hand held platforms. Medics in isolated environments are now conducting FAST exams in the field to determine internal injuries before casualties are transported out of the area and current wired handheld ultrasound transducer/probes are too large and bulky to be used in the combat environment. Medics need a finger-mounted probe to slide under body armor to examine casualties and have the capability to transmit ultrasound images wirelessly from a wearable finger probe to a SMART device which is connected to a secure communication network that can further transmit these images to a Medical Officer in the rear area. This research will incrementally advance the state of the art for point of injury care and on attended casualty evacuation vehicles such that the final demonstration shows proof-of-concept feasibility for medical information exchange and telementoring from any location on the battlefield.</p> <p>DHP14-007 - Non-Invasive, Head-Mounted Measures of Vestibular Function.  <b>OBJECTIVE:</b> Develop and test a single head-mounted device capable of measuring vestibular function to include assessment of vestibular-ocular, vestibular-auricular, vestibular-perceptual and vestibular spinal reflexes.</p> <p>DHP14-008 - Mobile Applications/Web-Based Management Solutions for Hearing Injuries.  <b>OBJECTIVE:</b> Develop a mobile, web-based application that assists/guides patients with hearing loss and tinnitus through aural rehabilitation therapy (improving signal identification and speech in noise function) and provides tinnitus management. The program will identify best practice applications for servicemen struggling to habituate to the effects of hearing loss and tinnitus. Possible solutions are to incorporate components of cognitive-behavioral therapy (CBT), tinnitus masking (TM), tinnitus retraining therapy (TRT), neuromodulation (NM) along with introducing aural rehabilitation therapy (ART) (J. A. Henry, Schechter, et al., 2006a, 2006b). The tool will identify users with ear-level devices (hearing aids, noise generators, cranial nerve stimulators, and combination instruments) and accommodate and improve effective use of such devices. The tool(s) applications will be compatible with networks and telemedicine data flows within the DOD/VA community to protect information security by preventing the exchange or transmission of personally identifiable information.</p> <p>DHP14-009 - Technologies That Reconstruct or Regenerate Vascular Tissue in the Extremities After Traumatic Injury.  <b>OBJECTIVE:</b> This effort is to develop a new innovative technology that may include the use of novel biomaterials, nanotopologies, cellular/tissue-based strategies or biologics, to reconstruct and regenerate vascular tissue in the extremities after traumatic injury.</p> <p>DHP14-010 - Upper Limb Assistive and Rehabilitation Orthotic Device.</p>					

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
<p>OBJECTIVE: To develop a rehabilitation and assistive technology that enhances and/or returns upper limb motor function losses due to traumatic combat injuries. Develop a portable and easy to use hand worn assistive device that is applicable in daily life and outdoor activities. The device should have biomimetic motion application and structural similarity to biological hand. The device should also be safe to use, relatively light weight, affordable, scalable, and have low power consumption and a wireless capability for data transfer.</p> <p>DHP14-011 - Technologies to Train Myoelectric Prosthesis Users for Optimal Functional Outcomes.</p> <p>OBJECTIVE: The objective of this effort is to develop a new tool or technology that can optimize training outcomes for myoelectric prostheses.</p> <p><b>FY 2015 Plans:</b> No funding programmed. The DHP SBIR program is funded in the year of execution.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		27.307	19.205
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
Test and evaluate commercially developed prototypes funded by the SBIR program to ensure military and regulatory requirements are met prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.			
<b>E. Performance Metrics</b>			
The number of Phase I awards supporting innovative technology development. The number of Phase II and III awards leading to technology transition.			