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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605502HP I <i>Small Business Innovation Research (SBIR) Program</i>
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COST (\$ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
Total Program Element	63.347	47.882	-	-	-	-	-	-	-	-	Continuing	Continuing
470A: <i>Small Business Innovation Research (SBIR) (Army)</i>	63.347	47.882	-	-	-	-	-	-	-	-	Continuing	Continuing

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. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	-	-	-	-	-
Current President's Budget	47.882	-	-	-	-
Total Adjustments	47.882	-	-	-	-
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	47.882	-			

Change Summary Explanation

FY 2014: Realignment to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$19.205 million) from the following DHP PEs:
 DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (-\$0.194 million);
 DHP RDT&E, PE 0601117-Basic Operational Medical Research Sciences (-\$0.269 million);
 DHP RDT&E, PE 0602115-Applied Biomedical Technology (-\$1.793 million);
 DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (-\$0.077 million);
 DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (-\$0.020 million);
 DHP RDT&E, PE 0603115-Medical Technology Development (-\$17.961 million);
 DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$11.165 million);
 DHP RDT&E, PE 0605013-Information Technology Development (-\$2.164 million);
 DHP RDT&E, PE 0605023-Integrated Electronic Record (iEHR) (-\$0.574 million);

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0130: Defense Health Program I BA 2: RDT&E	PE 0605502HP I Small Business Innovation Research (SBIR) Program	
DHP RDT&E, PE 0605025-Theater Medical Information Program - Joint (TMIP-J) (-\$3.889 million); DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-\$4.561 million); DHP RDT&E, PE 0606105-Medical Program-Wide Activities (-\$4.291 million); DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.924 million).		
FY 2015: No Change.		
FY 2016: No Change.		

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program										Date: February 2015		
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
470A: Small Business Innovation Research (SBIR) (Army)	63.347	47.882	-	-	-	-	-	-	-	-	Continuing	Continuing

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 2014	FY 2015	FY 2016
Title: Small Business Innovation Research (SBIR) Program	47.882	-	-
Description: The program funds small business proposals chosen to enhance military medical research and information technology research. The following reflects the FY14 research area topics sought for proposals.			
FY 2014 Accomplishments: For FY14 (DHP SBIR 15.1), sixteen topics were developed for solicitation of biomedical technology SBIR proposals. Funding for each topic was based on the merits of responses to solicitations. Topics include: (1) a simulation-based system to provide psychomotor (cognitive functions causing physical movement) skills training to advanced health care providers in the performance of a Lateral Canthotomy and Cantholysis (LCC) procedure (a surgical technique at corner of the eyes where upper and lower eyelids meet); (2) develop and demonstrate video overlay capability of virtual augmented reality technology, also known as VIPAAR, on a mobile Android Smart device (also known as an End User Device (EUD)) over a military tactical network; (3) demonstrate a prototype medical concierge application that will improve patient, employee, and visitor engagement with Military Health System Military Treatment Facilities (MTFs); (4) develop a toolset for analyzing the security properties of interconnected medical devices in an Integrated Clinical Environment (ICE) architecture; (5) develop new controls for securing in an integrated clinical environment from malicious threats, which minimizes impacts on clinical workflows and usability, and promotes patient safety using a model-based approach; (6) develop a sensitive, specific, rapid, portable, field friendly assay to determine whether a tick or pool of ticks is infected with the <i>Borrelia burgdorferi</i> bacterium, the causative agent for Lyme disease; (7) develop a small molecule to target at least one of the, but preferably multiple, multidrug-resistant bacteria that pose the greatest threat to military populations, specifically methicillin-resistant <i>Staphylococcus aureus</i> (MRSA), <i>Acinetobacter baumannii</i> , <i>Enterobacter</i> species (<i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i>), and <i>Pseudomonas aeruginosa</i> ; (8) demonstrate a prototype system that will successfully predict the incidence of human infectious disease;			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015
<p>(9) develop a non-invasive, wearable passive dosimeter that can be stored indefinitely until analysis is required;</p> <p>(10) develop and demonstrate new techniques to separate/enrich oxygen from air using minimal power to provide supplemental oxygen for injured soldiers under field conditions;</p> <p>(11) demonstrate that a kinetic pathway model of blood platelet physiology and biochemistry can be used to simulate the deleterious effects of storage upon isolated platelets within 5-7 days, and to develop a prototype program or a commercially viable software product for improved blood product storage;</p> <p>(12) develop a biosensor technology capable of measuring specific analytes in blood, continuously, in real-time;</p> <p>(13) develop novel cryoprotectants (a substance that prevents damage to cells during freezing), cryotherapeutics (therapy using cold), and cryopreservation (process where cells susceptible to damage caused by chemical reactivity or time are preserved by cooling to sub-zero temperatures) protocols that will permit clinically effective banking of large complex vascularized composite tissues such as vital organs and limbs;</p> <p>(14) develop a capability to solve one of the remaining barriers towards true banking of organs and vascularized composite tissues – optimal rewarming methods of large cryopreserved tissues;</p> <p>(15) develop objective measurement tool for the detection of noise-induced hearing loss and a smart algorithm for monitoring; and</p> <p>(16) develop a novel intraocular visualization tool to improve surgical outcomes following complex ocular trauma.</p> <p>FY 2015 Plans: No funding programmed. The DHP SBIR program is funded in the year of execution.</p> <p>FY 2016 Plans: No funding programmed. The DHP SBIR program is funded in the year of execution.</p>			
Accomplishments/Planned Programs Subtotals		47.882	-
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
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.			
E. Performance Metrics			
The number of Phase I awards supporting innovative technology development. The number of Phase II and III awards leading to technology transition.			