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

<b>Appropriation/Budget Activity</b> 0130: <i>Defense Health Program I BA 2: RDT&amp;E</i>					<b>R-1 Program Element (Number/Name)</b> PE 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>							
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016 Base</b>	<b>FY 2016 OCO</b>	<b>FY 2016 Total</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
Total Program Element	3.712	2.894	3.151	3.599	-	3.599	3.653	3.879	3.943	4.013	Continuing	Continuing
010A: <i>CSI - Congressional Special Interests</i>	0.000	-	0.315	-	-	-	-	-	-	-	Continuing	Continuing
240A: <i>Infectious Disease (USUHS)</i>	0.520	0.404	0.397	0.433	-	0.433	0.440	0.471	0.480	0.490	Continuing	Continuing
240B: <i>Military Operational Medicine (USUHS)</i>	1.593	1.242	1.217	1.330	-	1.330	1.354	1.451	1.479	1.509	Continuing	Continuing
240C: <i>Combat Casualty Care (USUHS)</i>	1.599	1.248	1.222	1.836	-	1.836	1.859	1.957	1.984	2.014	Continuing	Continuing

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

For the Uniformed Services of the Health Sciences (USUHS), this program element supports basic medical research at the Uniformed Services University of the Health Sciences (USUHS). It facilitates the recruitment and retention of faculty; supports unique research training for military medical students and resident fellows; and allows the University's faculty researchers to collect pilot data towards military relevant medical research projects in order to secure research funds from extramural sources (estimated \$135 million annually). Approximately 110 intramural research projects are active each year, including 32 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the fund of knowledge intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs.

The ILIR program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of Combat Casualty Care, Infectious Diseases, Military Operational Medicine, and Chemical, Biological, and Radiologic Defense. The portfolio of research projects will vary annually because this research is investigator-initiated. Examples of typical research efforts are detailed in R-2a.

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<b>Appropriation/Budget Activity</b> 0130: <i>Defense Health Program I BA 2: RDT&amp;E</i>	<b>R-1 Program Element (Number/Name)</b> PE 0601101HP <i>I In-House Laboratory Independent Research (ILIR)</i>
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<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016 Base</b>	<b>FY 2016 OCO</b>	<b>FY 2016 Total</b>
Previous President's Budget	3.088	2.836	3.099	-	3.099
Current President's Budget	2.894	3.151	3.599	-	3.599
Total Adjustments	-0.194	0.315	0.500	-	0.500
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	0.315			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.194	-			
• Change Proposal Center for Rehabilitation Sciences (CRSR) - Project 240C	-	-	0.500	-	0.500

**Congressional Add Details (\$ in Millions, and Includes General Reductions)**

**Project:** 010A: *CSI - Congressional Special Interests*

Congressional Add: 468A – *Program Increase: Restore Core Research Funding Reduction (USUHS)*

Congressional Add Subtotals for Project: 010A

Congressional Add Totals for all Projects

<b>FY 2014</b>	<b>FY 2015</b>
-	0.315
-	0.315
-	0.315

**Change Summary Explanation**

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601101-In-House Laboratory Independent Research (-\$0.194 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.194 million).

FY 2015: Restores core research funding to the DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+\$0.315 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$0.500 million) to DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+\$0.500 million).

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2016 Defense Health Program										<b>Date:</b> February 2015		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>				<b>Project (Number/Name)</b> 010A / <i>CSI - Congressional Special Interests</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016 Base</b>	<b>FY 2016 OCO</b>	<b>FY 2016 Total</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
010A: <i>CSI - Congressional Special Interests</i>	-	-	0.315	-	-	-	-	-	-	-	Continuing	Continuing

**A. Mission Description and Budget Item Justification**  
 The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) - In-House Laboratory Independent Research (ILIR). Because of the CSI annual structure, out-year funding is not programmed.

**B. Accomplishments/Planned Programs (\$ in Millions)**

	<b>FY 2014</b>	<b>FY 2015</b>
<b><i>Congressional Add:</i></b> 468A – Program Increase: Restore Core Research Funding Reduction (USUHS)	-	0.315
<b><i>FY 2014 Accomplishments:</i></b> No Funding Programmed.		
<b><i>FY 2015 Plans:</i></b> FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the In-House Laboratory Independent Research (ILIR) Program Element (PE) - 0601101.		
<b>Congressional Adds Subtotals</b>	-	0.315

**C. Other Program Funding Summary (\$ in Millions)**  
 N/A

**Remarks**

**D. Acquisition Strategy**  
 N/A

**E. Performance Metrics**  
 N/A

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>				Project (Number/Name) 240A / <i>Infectious Disease (USUHS)</i>			
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
240A: <i>Infectious Disease (USUHS)</i>	0.520	0.404	0.397	0.433	-	0.433	0.440	0.471	0.480	0.490	Continuing	Continuing
A. Mission Description and Budget Item Justification												
Infectious Diseases: Immunology and molecular biology of bacterial, viral and parasitic disease threats to military operations. These threats include Bartonella bacilliformis, Clostridium difficile, Escherichia coli and their Shiga toxins, Henipaviruses (Hendra & Nipah), Hepatitis A, Helicobacter pylori, HIV, HTLV-1, Leishmaniasis, Litomosoides sigmodontis, Malaria, Neisseria gonorrhoeae, Shigella spp., Streptococcus, and Methicillin-resistant Staphylococcus aureus (MRSA).												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2014	FY 2015	FY 2016	
Title: Infectious Disease									0.404	0.397	0.433	
Description: Infectious Diseases: Immunology and molecular biology of bacterial, viral and parasitic disease threats to military operations. These threats include Bartonella bacilliformis, Clostridium difficile, E. coli and their Shiga toxins, Henipaviruses (Hendra & Nipah), Hepatitis A, Helicobacter pylori, HIV, HTLV-1, Leishmaniasis, Malaria, Neisseriae gonorrhea, Shigella spp., Streptococcus, Staphylococcus, and Typhoid fever.												
FY 2014 Accomplishments: Representative projects include the following: determination of the factors responsible for maintaining and driving the immune response against helminth, such as Litomosoides sigmodontis, (parasitic worm) infections eventually leading to effective vaccines against these infections; characterization of the alternative energy-generating pathways in C. difficile as a potential target to prevent the transmission and recurrence of Clostridium difficile infection (CDI), the leading cause of nosocomial, antibiotic-associated diarrhea; investigation of skin and soft tissue infections (SSTI) in the military population, generally caused by community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA), towards the development of novel prevention and treatment strategies; investigation of the Henipaviruses and their bat hosts towards the development of novel intervention and vaccine strategies; development of a cutaneous Leishmaniasis vaccine to prevent parasitic infection; elucidation of the natural transmission of Bartonella bacilliformis by the sand fly towards disease prevention and control; analysis of genetic factors resulting in colonization of the host intestinal tract by Escherichia coli O157:H7, the most common infectious cause of bloody diarrhea & hemorrhagic colitis; understand how antibiotic resistance mutations in Neisseria gonorrhoeae (Gc), whose infections occur at a high incidence throughout the world and in the United States and U.S. military, may influence the spread of resistant strains which subsequently threatens control methods as well as our capacity to limit the spread of human immunodeficiency virus; design of a new class of anti-viral therapeutics (HAIVA prep) for critical conditions like acute pulmonary infection (with different types of flu viruses), and for vaccination purposes in imminent flu endemics; and the health behaviors and deployment factors that are associated with acquisition of sexually transmitted diseases (STDs).												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2016 Defense Health Program			<b>Date:</b> February 2015		
<b>Appropriation/Budget Activity</b> 0130 / 2		<b>R-1 Program Element (Number/Name)</b> PE 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>		<b>Project (Number/Name)</b> 240A / <i>Infectious Disease (USUHS)</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>
<p>These projects will support the essential military mission by advancing our understanding of both the transmission and the internal mechanisms of a spectrum of pernicious and/or common diseases that may be faced by warfighters both at home and abroad. In turn, that understanding opens avenues to better control, diagnosis, and treatment of both natural and manmade biological threats.</p> <p><b>FY 2015 Plans:</b> We will continue to investigate infectious diseases that impact soldiers from the standpoint of lost “man-days” to death. We recognize that infectious disease can severely hamper combat readiness and effectiveness, and therefore we will continue to concentrate our efforts on diagnosis and treatment of those naturally occurring infectious diseases that can affect the war fighter by further development of vaccines, drugs, and diagnostic tools.</p> <p><b>FY 2016 Plans:</b> Efforts will continue within the Infectious Disease research area in FY 2016. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p>					
<b>Accomplishments/Planned Programs Subtotals</b>			0.404	0.397	0.433
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A <b>Remarks</b>  <b>D. Acquisition Strategy</b> N/A  <b>E. Performance Metrics</b> N/A					

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>				Project (Number/Name) 240B / <i>Military Operational Medicine (USUHS)</i>			
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
240B: <i>Military Operational Medicine (USUHS)</i>	1.593	1.242	1.217	1.330	-	1.330	1.354	1.451	1.479	1.509	Continuing	Continuing
A. Mission Description and Budget Item Justification												
Military Operational Medicine: Sustainment of individual performance; mapping and managing deployment and operational stressors; cognitive enhancement; use of dietary and nutritional supplements and military and medical training readiness.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2014	FY 2015	FY 2016	
Title: Military Operational Medicine									1.242	1.217	1.330	
Description: Military Operational Medicine: Sustainment of individual performance; mapping and managing deployment and operational stressors; cognitive enhancement; and military and medical training readiness.												
FY 2014 Accomplishments: Representative projects will include the following: refinement of a single item post traumatic stress disorder (PTSD) screening tool for use in the DOD Primary Care system; understanding and attenuating deleterious effects of tobacco, alcohol, stress and their interactions upon military personnel; forecasting levels of full or threshold PTSD, depression, health and alcohol problems within the military population; determination of the unique proteomic signature for the diagnosis and assessment of the neuro-immune response to traumatic brain injury (TBI) towards early assessment of the disease in the military and veteran population; understanding the determinants of health promoting behaviors towards preventing obesity in both active duty military and their family members; identifying signaling pathways that control satiety and dietary triggers towards prevention of obesity; implementation of a neuromuscular routine that minimizes musculoskeletal injury in military academy cadets; study the relationship between previous ankle injury, a common event in military populations, and future serious injury, such as ACL injury as musculoskeletal injury (MSK-1) is the #1 cause of lost and limited duty in the U.S. military; evaluation of suicidal behaviors within recent suicide deaths of active duty service members to aid in identification and prevention efforts; determination of the psychosocial and biomedical risks and protective factors for heart failure and ischemia within the military and veteran population; and the determination of non-invasive neurological biomarkers for heat intolerance using in vivo Magnetic Resonance Imaging (MRI) and Spectroscopy (MRS).												
These studies support the essential military mission by enhancing and protecting the health, performance and fitness of soldiers throughout the deployment cycle. These studies strive to increase our understanding of and ability to manipulate the physiological mechanisms of stress and immunity, human sleep and seasonal cycles, and neurological changes necessary for short- and long-term memory. Their discoveries should enable warfighters to stay awake longer with fewer detriments to performance; lead to better strategies for enhancing and preserving memory and reasoning capabilities under battle conditions; help understand												

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2014</b>	<b>FY 2015</b>
<p>and ultimately prevent and treat neuropsychiatric illnesses such as depression and PTSD; and assist deployed troops and their families better prepare for and contend with common, significant stressors related to the deployment cycle.</p> <p><b>FY 2015 Plans:</b> Our efforts will concentrate on biomedical solutions that protect and enhance the health, performance, and fitness of our soldiers. Our focus will continue to be to understand stress as it is related to performance and health. We will also study performance in environmental extremes. Our goal is to lay the ground work that will establish platforms that build biomedical products and solutions that mitigate risk to soldiers and protect them from “head to toe” both on the battlefield and at home.</p> <p><b>FY 2016 Plans:</b> Efforts will continue within the Military Operational Medicine research area in FY 2016. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		1.242	1.217
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
N/A			
<b>E. Performance Metrics</b>			
N/A			

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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
240C: <i>Combat Casualty Care (USUHS)</i>	1.599	1.248	1.222	1.836	-	1.836	1.859	1.957	1.984	2.014	Continuing	Continuing
A. Mission Description and Budget Item Justification												
Combat Casualty Care: Ischemia and reperfusion injury, traumatic brain and peripheral nerve injury, neural control of pain, endotoxic shock, cryotherapy, malignant hyperthermia, inflammation, soman induced neuropathology and wound healing, and the advancement of rehabilitative care for service members with combat related injuries, particularly those with orthopaedic trauma, limb loss and neurological complications.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2014	FY 2015	FY 2016	
Title: Combat Casualty Care									1.248	1.222	1.836	
Description: Combat Casualty Care: Ischemia and reperfusion injury, traumatic brain and peripheral nerve injury, neural control of pain, endotoxic shock, cryotherapy, malignant hyperthermia, inflammation, and wound healing.												
FY 2014 Accomplishments: Representative projects will include: investigation of synaptic plasticity in temporal lobe epilepsy and possible development of novel therapies; determination whether BMP-2 is a effective therapy to promotes recapitulation of the meninges surrounding the spinal cord; understanding the contribution of inflammation to post-injury loss of function after traumatic brain and spinal cord injury; investigate the underlying mechanisms involved in heart failure and drug-induced arrhythmias; identifying how the formation of nerve cell circuits in the brain are affected by psychological stress and traumatic brain injury; analysis of the underlying mechanisms responsible for the development of tolerance following the chronic use of opiates for severe pain; development of psychological interventions to be used with military health care providers who experience post-traumatic stress symptoms to prevent burn-out; and development of accurate millisecond-level assessment tools and computer based analyses to assist in the evaluation and assessment of traumatic brain injury.												
These studies also support the essential military mission by further exploring the mechanism of pain control for an established treatment; providing the groundwork for effective treatments to limit nerve damage and encourage regeneration; and identifying a possible cause for life-threatening complications due to the combination of exertion and injury common under heavy battlefield conditions.												
FY 2015 Plans: Our efforts will concentrate on diagnosis and treatment for our wounded warriors to reduce mortality and morbidity resulting from injuries on the battlefield. We will study physical and biological determinants of brain injury and post-traumatic stress disorder. In												



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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2014</b>	<b>FY 2015</b>
<p>addition, we will also focus on rehabilitation for amputees and pain management. Our goal is to understand how to best care for soldiers who have suffered any type of physical or mental traumatic injury in the field.</p> <p>We will continue to foster the four research focuses in FY2015 that will support advances in clinical and rehabilitation strategies. New research studies will advance inter-service rehabilitation research that is relevant to the care of injured service members and to provide the necessary platform for transferring novel technologies into the clinical practice at the MTFs.</p> <p>Our proposed research for FY15 and beyond seeks to extend our current projects for the following three years as part of a broader effort to establish a post-injury monitoring project to follow patients with orthopedic and extremity trauma for succeeding years as they move through their life course.</p> <p><b><i>FY 2016 Plans:</i></b> Efforts will continue within the Combat Casualty Care research area in FY 2016. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p> <p>We will continue to foster the four research focuses in FY2016 that will support advances in clinical and rehabilitation strategies. In particular, efforts in FY2016 have the potential to benefit all DoD sites with an instrumented gait analysis laboratory that care for patients with lower extremity injury. While the current focus of this program is to provide a long-term follow-up/outcome measure for evaluating patients with amputations and limb salvage, the Gait Quality Index (GQI) we are developing may be applied to any patient population with a lower extremity injury and/or gait deviation. The GQI provides a tool to evaluate patients across various DoD sites with a standardized three-component score, allowing for improved multi-site collaboration in research.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		1.248	1.222
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			