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Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency **Date:** February 2016

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0601117DHA I <i>Basic Operational Medical Research Sciences</i>
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COST (\$ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	10.805	8.282	9.558	6.444	-	6.444	6.917	7.699	8.608	8.913	Continuing	Continuing
100A: <i>CSI - Congressional Special Interests</i>	2.237	1.578	2.161	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
371A: <i>GDF-Basic Operational Medical Research Sciences</i>	8.568	6.704	7.397	6.444	-	6.444	6.917	7.699	8.608	8.913	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Basic Operational Medical Research Sciences: This program element (PE) provides support for basic medical research directed toward greater knowledge and understanding of the fundamental principles of science and medicine that are relevant to the improvement of Force Health Protection. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research and Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include military infectious diseases (JPC-2), military operational medicine (JPC-5), and combat casualty care (JPC-6). Funds in this PE are for basic research that promises to provide important new approaches to complex military medical problems. As the research efforts mature, the most promising efforts will transition to applied research (PE 0602115) or technology development (PE 0603115) funding.

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B. Program Change Summary (\$ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	7.481	7.397	9.417	-	9.417
Current President's Budget	8.282	9.558	6.444	-	6.444
Total Adjustments	0.801	2.161	-2.973	-	-2.973
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1.578	2.161			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.777	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-1.161	-	-1.161
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-1.812	-	-1.812

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

Project: 100A: *CSI - Congressional Special Interests*

Congressional Add: 461A – *Program Increase: Restore Core Research Funding Reduction (Army)*

Congressional Add Subtotals for Project: 100A

Congressional Add Totals for all Projects

	FY 2015	FY 2016
	1.578	2.161
	1.578	2.161
	1.578	2.161

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$0.777 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.777 million).

FY 2015: Restore core research funding to the DHP RDT&E, PE 06011117-Basic Operational Medical Research Sciences (+\$1.578 million).

FY 2016: Restore core research funding to the DHP RDT&E, PE 06011117-Basic Operational Medical Research Sciences (+\$2.161 million).

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Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i>
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FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$1.161 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+\$1.161 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$1.812 million) to DHP RDT&E, PE 0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+\$1.812 million).

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Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency **Date:** February 2016

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i>	Project (Number/Name) 100A / <i>CSI - Congressional Special Interests</i>
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COST (\$ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
100A: <i>CSI - Congressional Special Interests</i>	2.237	1.578	2.161	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2015 DHP Congressional Special Interest (CSI) funding was directed toward restoral of core research initiatives in PE 0601117 - Basic Operational Medical Research Sciences. Because of the CSI annual structure, out-year funding is not programmed.

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

	FY 2015	FY 2016
<i>Congressional Add:</i> 461A – Program Increase: Restore Core Research Funding Reduction (Army)	1.578	2.161
<i>FY 2015 Accomplishments:</i> FY 2015 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0601117. Funds supported basic research in military operational medicine (Project 371A).		
<i>FY 2016 Plans:</i> FY 2016 DHP Congressional Special Interest (CSI) was directed toward the restoral of core research initiatives in PE 0601117. Funds supported basic research in military operational medicine (Project 371A).		
Congressional Adds Subtotals	1.578	2.161

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 2017 Defense Health Agency										Date: February 2016		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 060117DHA / <i>Basic Operational Medical Research Sciences</i>				Project (Number/Name) 371A / <i>GDF-Basic Operational Medical Research Sciences</i>			
COST (\$ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
371A: <i>GDF-Basic Operational Medical Research Sciences</i>	8.568	6.704	7.397	6.444	-	6.444	6.917	7.699	8.608	8.913	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Basic Operational Medical Research Sciences: Basic research described here focuses on enhancement of knowledge to support capabilities identified through the Joint Capabilities Integration and Development System (JCIDS) process and sustainment of DoD and multi-agency priority investments in science, technology, research, and development as stated in the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, and the National Strategy for Combating Antibiotic Resistance. This project supports basic research managed by the Joint Program Committees (JPCs) in the following areas: 1- Military infectious diseases (JPC-2) research develops protection and treatment products for military relevant infectious diseases. Basic research efforts in this area support a task in bacterial diseases. 2- Military operational medicine (JPC-5) research focuses on the development of medical countermeasures against operational stressors, prevention of physical and psychological injuries during training and operations, and maximizing the health, performance and fitness of Service members. Basic research efforts in this area support tasks in musculoskeletal injury; brain health and performance risk; behavioral health, wellness and resilience; warfighter physical performance; nutrition and weight balance; psychiatry and clinical psychology disorders; sensory performance, injury and protection; blunt, blast and accelerative injury; environmental toxicant exposure; and aircrew health and performance. 3- Combat casualty care (JPC-6) research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through enroute and facility care. Basic research efforts in this area support the task for hemorrhage, shock, and coagulopathy (inability of blood to clot normally) of trauma.

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

	FY 2015	FY 2016	FY 2017
Title: Project 371 GDF – Basic Operational Medical Research Sciences	6.704	7.397	6.444
Description: Provide support for basic medical research directed toward attaining greater knowledge and understanding of fundamental principles of science and medicine relevant to the improvement of medical care in operationally relevant environments.			
FY 2015 Accomplishments: FY 2015 Accomplishments: Military infectious diseases research supported antimicrobial countermeasures to discover antibacterial agents for biofilms (a group of microorganisms in which cells stick to each other on a surface), characterize and detect multi-drug resistant organisms (MDROs), identify MDRO biomarkers (biological indicators of health outcomes and disease) and new targets. These laboratory studies helped provide an understanding of the mechanisms that make organisms infectious and mechanisms that render the human body response effective to prevent diseases caused by infectious agents.			

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

	FY 2015	FY 2016	FY 2017
<p>Military operational medicine research continued studies to develop predictive models of repeated low level blast exposures in order to understand the mechanisms of injury and optimal exposure conditions, and identified potential biomarkers of pulmonary exposure to toxic substances from burn pit emissions, natural dust from Afghanistan, and the interactions between pollutants, which are associated with adverse health outcomes and lung disease. Studies in nutrition and dietary supplements assessed dietary status of different Service member populations. Additional studies identified novel targets for promotion of sleep quality, and refined algorithms that predict the effects of fatigue countermeasures, such as caffeine and naps, to optimize Warfighter physical and cognitive performance. Research continued in Posttraumatic Stress Disorder (PTSD) to identify and understand neural systems and mechanisms underlying PTSD vulnerability, disease progression, and identification of potential intervention targets for pharmacologic and stimulation approaches. These efforts supported the Precision Medicine Initiative.</p> <p>Combat casualty care basic research made progress towards identifying underlying pathophysiologic (functional changes associated with injury) mechanisms associated with coagulopathy of trauma, and towards identifying potential diagnostic and therapeutic targets of coagulopathy of trauma.</p> <p>FY 2016 Plans: FY 2016 Plans:</p> <p>Military infectious diseases research supports basic research laboratory studies in bacterial diseases prevention, treatment, and management to develop antibacterial agents targeting biofilms and MDRO s, and host and microbial biomarkers for early detection of infection. Outcomes from FY 2015-16 laboratory studies identify bacterial targets for prevention/treatment of diseases caused by bacterial agents. These studies are in alignment with the National Strategy for Combating Antibiotic Resistance.</p> <p>Military operational medicine research is identifying mechanisms and characterizing behavioral effects in small animal models resulting from low level repeated blast exposure, is characterizing the biomechanical responses of brain tissue resulting from direct transmission of blast waves through the skull using computational modeling that will guide the development of interventions for mitigating blast-induced brain injury. Starting studies to understand brain mechanisms associated with substance abuse problems that affect adult decision making and behavioral health. Beginning studies to examine the relationship of pre-accession factors such as personal mental health, familial mental health, and factors promoting resilience both with self-reported, and official post-deployment mental diagnoses after high-conflict deployments. Starting studies to identify gender-specific factors that impact military task performance, defining minimal physical requirements for entry into physically demanding military occupations, investigating applications of novel interventions and their neurobiological impact via animal models to evaluate effectiveness in treating PTSD symptoms, conducting basic studies to define medical standards for noise injury criteria , and identifying novel interventions to promote sleep quality and nonpharmacological approaches to reduce the need for sleep in order to sustain Warfighter readiness. Studies to examine the effects of inadequate nutrition on gut microbiota composition and function. Studies to identify biomarkers of toxicity to complex chemical mixtures and particulates using an in vitro model system. Combat casualty care</p>			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2015	FY 2016	FY 2017
<p>basic research is identifying the molecular and cellular mechanisms involved in abnormal bleeding due to coagulopathy of trauma that occurs following severe trauma. The results from these studies will be used to generate diagnostics and therapeutic targets for further development.</p> <p>FY 2017 Plans: Military infectious diseases research will support multi-year basic research laboratory studies in bacterial diseases prevention, treatment, and management in discovery and development of antibacterial agents for biofilms and MDROs, detection of MDROs, and biomarkers. Successful approaches will be selected for continued funding. New studies will be initiated to address the remaining gaps related to infection caused by MDROs. These studies will support the National Strategy for Combating Antibiotic Resistance.</p> <p>Military operational medicine research will characterize the biomechanical responses of brain tissue in animal models due to the indirect mechanism of blast waves (through the vasculature) using computational modeling that will guide the development of interventions for mitigating blast-induced brain injury. Will identify the role of individual and unit climate factors on aggression. Will begin studies to understand the basic mechanisms underlying psychological resilience to inform potential future intervention and assessment work. Will perform epidemiological studies to identify the nature of the substance abuse problem in the military and possible unique contributing and protective factors. Will continue PTSD research on genetic vulnerabilities, disease models and mechanisms, and identification of intervention targets for pharmacologic treatment approaches. Will establish mechanisms of electrical stimulation of the brain on wakefulness and cognitive processes. Will identify physiological factors that may affect the performance of female Warriors.</p> <p>Combat casualty care basic research will continue to identify the molecular and cellular mechanisms involved in abnormal bleeding due to coagulopathy of trauma that occurs following severe trauma. These findings will be used to generate diagnostic and therapeutic targets for further development. The Systems Biology Program in coagulopathy of trauma will be completed. Focus will shift toward exploiting findings to develop specific diagnostics and therapeutics for coagulopathy of trauma.</p>				
Accomplishments/Planned Programs Subtotals		6.704	7.397	6.444
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				

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E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with basic science funding is the attainment of a maturity level that is typical of Technology Readiness Level 2 or the equivalent for knowledge products.