Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145DHA *I Medical Products and Support Systems Development*

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	82.111	15.590	17.954	15.219	-	15.219	20.295	21.589	22.022	22.462	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	44.627	13.919	17.180	14.464	-	14.464	19.421	20.654	21.068	21.489	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	25.334	0.790	0.774	0.755	-	0.755	0.874	0.935	0.954	0.973	Continuing	Continuing
500A: *CSI - Congressional Special Interests*	12.150	0.881	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force – Medical Products and Support Systems Development: This program element (PE) provides funding for system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping Department of Defense (DoD) Components that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials. These clinical trials are conducted to obtain US Food and Drug Administration approval, a requirement for use of all medical products. 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, translational 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, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. 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 medical simulation and information sciences (JPC-1), military operational medicine (JPC-5) combat casualty care (JPC-6), and clinical and rehabilitative medicine (JPC-8). The funding also supports the clinical evaluation of hyperbaric oxygenation for post-concussion syndrome (PCS). The effort encompasses development, initiation, operation, analysis, and subsequent publication of clinical trials to compare and assess the long-term benefit of hyperbaric oxygen (HBO2) therapy on Service members with PCS. As the research efforts mature, the most promising will transition to production and deployment or to industry.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145DHA *I Medical Products and Support Systems Development*

The Army Medical Command received DHP Congressional Special Interest (CSI) research funding to Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	15.906	17.954	15.219	-	15.219
Current President's Budget	15.590	17.954	15.219	-	15.219
Total Adjustments	-0.316	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.881	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.197	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 500A: *CSI - Congressional Special Interests*		
Congressional Add: *465A – Program Increase: Restore Core Research Funding Reduction (GDF)*	0.800	-
Congressional Add: *475A – Program Increase: Restore Core Research Funding Reduction (Army)*	0.081	-
Congressional Add Subtotals for Project: 500A	0.881	-
Congressional Add Totals for all Projects	0.881	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$1.197 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.197 million).

FY 2016: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+$0.881 million).

FY 2017: Realignment from DHP RDTE PE 0605145 (-$0.913 million) to DHP RDTE PE 0603115 for rebalancing JPC portfolios (+$0.913 million).

FY 2017: Realignment from DHP RDTE PE 0605145 (-$0.633 million) to DHP RDTE PE 0603115 for Breast, GYN and Prostate Cancer Centers of Excellence (+ $0.633 million).

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145DHA *I Medical Products and Support Systems Development*

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605145-Medical Products and Support Systems Development (+$0.594 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$0.594 million).

FY 2018: No changes.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 375A / *GDF-Medical Products and Support System Development*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
375A: *GDF-Medical Products and Support System Development*	44.627	13.919	17.180	14.464	-	14.464	19.421	20.654	21.068	21.489	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Support Systems Development: Activities conducted in this project are intended to support system development and demonstration prior to initial full rate production and fielding of commodities. Medical products and support systems development is managed by the following Joint Program Committees (JPCs). 1- The Medical Simulation and Information Sciences JPC seeks to improve military medical training through informatics based training and education. This involves simulation, educational gaming, and health-focused and objective training metrics. Within this JPC, the Combat Casualty Training Initiative supports the testing and evaluation of innovative medical simulation technologies with the goal of improving healthcare access, availability, continuity, cost effectiveness, quality, and patient safety through improved decision-making. 2 - The Military Operational Medicine JPC supports the testing and evaluation of real-time physiological (normal function of living organisms and their parts) status monitoring in order to provide actionable patient information. 3- The Combat Casualty Care JPC seeks Food and Drug Administration (FDA) approval of methods, drugs and devices through human clinical trials. Within this JPC, advanced product development to improve the quality of care is ongoing within the areas of hemorrhage, shock, and coagulopathy of trauma. In addition, the traumatic brain injury (TBI) neurotrauma and brain dysfunction area is validating TBI therapeutics and testing new imaging techniques, battlefield devices for operational decision making, and behavioral physiologic assessment tools for mild TBI. 4- The Clinical Rehabilitation Medicine JPC seeks FDA approval of fast-acting, easily dispensed oral battlefield pain management products that have minimal side effects.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	13.919	17.180	14.464
Description: GDF-Medical Products and Support Systems Development: Activities conducted are intended to support system development and demonstration prior to initial full rate production and fielding of medical commodities delivered from 0604110HP (Medical Products Support and Advanced Concept Development). Development and demonstration activities will be conducted in the following areas: medical modeling and simulation systems for training/education/treatment, rapid screening for fresh whole blood, and Spray Dried Plasma and TBI biomarker (biological indicator) point of care devices.			
FY 2016 Accomplishments: Medical simulation and information sciences efforts continued evaluations of the effectiveness of commercially available or advanced prototype simulation systems and currently used live tissue training models. This work supports the knowledge product researching the reduction and refinement of the use of live tissue for training. Combat casualty care hemorrhage and resuscitation research: Completed a human safety study in humans in support of a FDA Biologic License Application for a spray-dried plasma product. For the spray-dried plasma product, coordinated preparation of a			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375A / *GDF-Medical Products and Support System Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
human safety, dose and initial efficacy trial; initiated planning for clinical trials to confirm safety and effectiveness of the product in diverse populations. Combat casualty care neurotrauma research: Continued clinical trial to evaluate novel biomarker-based TBI diagnostics and point of care diagnostic devices. ***FY 2017 Plans:*** Medical simulation and information sciences efforts work toward updating several serious medical games and transitioning them to the advanced developer. Military operational medicine is validating, through end-user field testing, a system-on-a-chip ultra-low power physiologic status monitoring system. Combat casualty care hemorrhage and resuscitation research: For the spray-dried plasma product, initiating clinical trials to confirm safety and effectiveness in diverse populations. Combat casualty care neurotrauma research: Continued clinical trial to evaluate novel biomarker-based TBI diagnostics and point of care diagnostic devices; downselecting a point of care diagnostic device. ***FY 2018 Plans:*** Medical simulation and information sciences efforts will support the Special Operation Forces (SOF) with additional training for prolonged field care to support anti access and area denial requirements. Military operational medicine will continue the testing of a real-time physiological status monitoring system that integrates refined algorithms and respective sensors into actionable real-time physiological status, health, and readiness information. Combat casualty care hemorrhage and resuscitation research: For the spray-dried plasma product, will continue clinical trials to confirm safety and effectiveness in diverse populations. Will continue human clinical studies to confirm safety and effectiveness of valproic acid, a drug to prolong survival following severe hemorrhage. Combat casualty care neurotrauma research: Will support validation of downselected point of care device to assess and monitor TBI casualties in the far forward field environment. Clinical and rehabilitative medicine will seek FDA approval for Sufentanil, a rapid acting pain medication with minimal side effects.			
Accomplishments/Planned Programs Subtotals	13.919	17.180	14.464

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375A / *GDF-Medical Products and Support System Development*

D. Acquisition Strategy

Test and evaluate medical procedures and prototype devices in government-managed Phase 2 and Phase 3 clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, and quarterly and annual status reports and is subject to Program Office or Program Sponsor Representatives progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with DoD Instruction 5000 series on the Operation of the Defense Acquisition System. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of Technology Readiness Level 8 and/or the achievement of established Key Performance Parameters.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	25.334	0.790	0.774	0.755	-	0.755	0.874	0.935	0.954	0.973	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials focus on research related to the development of treatment modalities using HBO2 for chronic post-concussion syndrome after mild traumatic brain injury (mTBI). Three HBO2 human clinical trials were designed to evaluate the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments: 1- A pilot phase II (narrow population safety and effectiveness) study of hyperbaric oxygen for persistent post-concussive symptoms after mild traumatic brain injury (HOPPS), 2- Brain Injury and Mechanisms of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (BIMA), and 3- Development of Normative Datasets for Assessments Planned for Use in Patients with Mild Traumatic Brain Injury (Normal). A fourth retrospective study, Long Term Follow-up (LTFU), is focused on the lessons learned from long-term follow-up of subjects enrolled in the Department of Defense (DoD) primary HBO2 trials. To support these protocols, four HBO2 study sites were established within the Military Health System. Each of the research sites consisted of a hyperbaric oxygen chamber enclosed in a mobile trailer, a second mobile trailer for testing and evaluation of the subjects, and a third subject staging trailer. This information is intended to inform DoD policy decisions regarding the use of HBO2 therapy as a treatment for mTBI.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	0.790	0.774	0.755
Description: The HBO2 clinical trials are designed to test the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments.			
FY 2016 Accomplishments: Completed data accession phase of two on-going HBO2 clinical trials (BIMA and Normal). Completed Subject Matter Expert (SME) analysis of brain scan data and monitoring devices (baseline Holter monitor, Eyetracker, electroencephalogram, individual and longitudinal computerized tomography, individual and longitudinal magnetic resonance imaging, and looming functional magnetic resonance imaging). Along with the LTFU study results, this information was published in a peer-reviewed journal special edition. The BIMA study outcomes data and comparative data from the Normal study subject population were submitted for SME evaluation. Continued development of the final clinical study report, statistical report, draft primary manuscript, and corresponding materials for scientific presentation and journal submissions.			
FY 2017 Plans: Continue collaboration with subject matters experts to complete the BIMA and Normal trial final clinical study report, statistical report, and primary manuscript. Draft clinical study and statistical reports for submission to the US Food and Drug Administration. Consolidate BIMA study data for inclusion in the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
system. Prepare manuscripts reporting the Normal study comparative findings. Finalize a meta-analysis that identified common trends and findings across the four DoD-sponsored trials evaluating HBO2 effects on mTBI. ***FY 2018 Plans:*** Submit the final clinical study and statistical reports for the BIMA/Normal studies to the FDA. Publish the BIMA / Normal study primary manuscript and other peer-reviewed manuscripts detailing outcome measure findings. Transfer mTBI study data into the FITBIR informatics system. In response to positive meta-analysis findings, develop and implement a multi-Service protocol designed to evaluate a potential dose-response improvement in combat-related PTSD symptoms secondary to HBO2 exposure. Beyond targeting identification of an optimal oxygen exposure dose, this protocol will assess the time to onset, duration and magnitude of the symptom improvements previously seen. Concurrently, the protocol will evaluate the relative contribution of placebo and Hawthorne influences previously ascribed to the DoD-sponsored HBO2 trials.			
Accomplishments/Planned Programs Subtotals	0.790	0.774	0.755

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

The acquisition outcome of this effort is a knowledge product, with the results intended to inform DoD mTBI treatment and reimbursement policies. The decision to pursue FDA registration/off-label application of an existing drug-device combination product will be made as part of a formal decision by leadership after the DoD HBO2 trial results are reviewed. If future work using HBO2 proves beneficial in the treatment of PTSD this knowledge product would inform DoD treatment and reimbursement policies.

E. Performance Metrics

The HBO2 Program Management Office monitors the performance of contracts through review of monthly, yearly and final progress reports to ensure that milestones are met, deliverables will be transitioned on schedule and within budget and in accordance with DoD Instruction 5000. The HBO2 Executive Committee meets bi-monthly to evaluate the direction of the science, discuss future actions, and resolve any current or potential issues or areas of concern.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 500A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
500A: *CSI - Congressional Special Interests*	12.150	0.881	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2016 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0605145 - Medical Products and Support Systems Development. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 465A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2016 Accomplishments:*** FY 2016 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0605145. Funds supported product testing for combat casualty care (Project 375A).	0.800	-
Congressional Add: 475A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2016 Accomplishments:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0605145. Funds supported efforts for the Hyperbaric Oxygen Therapy Clinical Trials (Project 399A).	0.081	-
Congressional Adds Subtotals	0.881	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A