Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency											Date: February 2016	
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 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	56.728	25.383	16.787	17.954	-	17.954	15.219	20.295	21.589	22.022	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	33.042	11.585	15.051	17.180	-	17.180	14.464	19.421	20.654	21.068	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	23.686	1.648	0.855	0.774	-	0.774	0.755	0.874	0.935	0.954	Continuing	Continuing
500A: *CSI - Congressional Special Interests*	0.000	12.150	0.881	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 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 (FDA) 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 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, 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 Defense Health Program (DHP) sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1) and combat casualty care (JPC-6). The work includes development and demonstration of medical modeling and simulation systems for training/education/treatment, and medical system development and demonstration. 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: PB 2017 Defense Health Agency	Date: February 2016
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 Restore Core Research Funding Reduction. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	14.499	15.906	20.094	-	20.094
Current President's Budget	25.383	16.787	17.954	-	17.954
Total Adjustments	10.884	0.881	-2.140	-	-2.140
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	12.150	0.881			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.266	-			
• Rebalance Joint Program Committees	-	-	-0.913	-	-0.913
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-0.633	-	-0.633
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-0.594	-	-0.594

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 500A: *CSI - Congressional Special Interests*		
Congressional Add: *465A – Program Increase: Restore Core Research Funding Reduction (GDF)*	5.000	0.800
Congressional Add: *475A – Program Increase: Restore Core Research Funding Reduction (Army)*	7.150	0.081
Congressional Add Subtotals for Project: 500A	12.150	0.881
Congressional Add Totals for all Projects	12.150	0.881

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$1.266 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.266 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+$12.150 million).

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

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).

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 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 375A / *GDF-Medical Products and Support System Development*	

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
375A: *GDF-Medical Products and Support System Development*	33.042	11.585	15.051	17.180	-	17.180	14.464	19.421	20.654	21.068	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 following Joint Program Committees (JPCs). 1- Medical Simulation and Information Sciences (JPC-1). This 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 JPC-1, 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-Military Operational Medicine (JPC-5). This JPC supports the testing and evaluation of real-time physiological status monitoring in order to provide actionable patient information. 3- Combat Casualty Care (JPC-6). This JPC seeks FDA approval of methods, drugs and devices through human clinical trials. Within JPC-6, 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	11.585	15.051	17.180
Description: GDF-Medical Products and Support Systems Development (GDF-MPSSD): 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 point of care devices.			
FY 2015 Accomplishments: Within JPC-1, the Medical Simulation task area released an intramural solicitation/made awards for research to perform validation studies comparing commercially available or advanced prototype simulation systems and currently used live tissue training models. This work supported the advanced development of technologies to reduce and refine the use of live tissue for training. The intramural Tactical Combat Casualty Care Training for Readiness project modified and integrated existing technologies to improve training for non-medical personnel/Combat Life-Savers and started effectiveness studies to evaluate the technologies versus previous models/tools.			

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 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 2015	FY 2016	FY 2017
Within JPC-6, related to hemorrhage, clinical trials were initiated in support of a Spray Dried Plasma product. These included dosing studies and studies assessing safety and effectiveness. In addition, documentation was prepared to begin the FDA approval process. Within the Neurotrauma area, development continued on the lightweight Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System (BANDITS), a portable device to diagnose mild, moderate and severe TBI. In addition, advanced development continued on two platforms for measuring biomarkers for TBI. ***FY 2016 Plans:*** Within JPC-1, the Medical Simulation task is continuing evaluations of the effectiveness of commercially available or advanced prototype simulation systems and currently used live tissue training models. This work supports the advanced development of technologies to reduce and refine the use of live tissue for training. In addition, evaluate data and provide recommendations to refine and re-evaluate commercially available simulator products. Within JPC-6, related to hemorrhage, the Spray Dried Plasma product is scheduled for a Milestone B decision on the Spray Dried Plasma product and planning will begin on clinical trials to confirm safety and effectiveness of the product in diverse populations. Within the Neurotrauma area, the BrainScope clinical sites will complete final close-out activities and perform data analysis. Advanced development will continue on two platforms for measuring biomarkers for TBI. ***FY 2017 Plans:*** Within JPC-1, the Medical Simulation task will perform functional, specification and tolerance testing of Beta prototypes and curricula processes through anatomically correct and responsive simulation systems with the intent of transitioning to the pre-manufacturing stage. Within JPC-5, military operational medicine will sponsor end-user field testing to validate a system-on-a-chip ultra-low power physiologic status monitoring system that integrates refined algorithms into actionable real-time physiological status health information. Within JPC-6, clinical trials confirm safety and effectiveness in diverse populations will begin for the Spray Dried Plasma product. In addition, Neurotrauma will prepare for Milestone C decision, and FDA approval related to platforms for measuring biomarkers for TBI.			
Accomplishments/Planned Programs Subtotals	11.585	15.051	17.180

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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 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: PB 2017 Defense Health Agency			Date: February 2016
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 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
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	23.686	1.648	0.855	0.774	-	0.774	0.755	0.874	0.935	0.954	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials will focus on research for development of treatment modalities using HBO2 for chronic post-concussion syndrome (PCS) after mild TBI. HBO2 human clinical trials are 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. Four HBO2 study sites are established within the Military Health System. Each of the research sites consists 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 changing trailer.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	1.648	0.855	0.774
Description: 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 2015 Accomplishments:*** Prepared final clinical report on study which described initial findings related to the HBO2 therapy. Continued evaluation of radiologic and physiological biomarker technology, and began 6 month and 12 month subject follow-ups. Completed one of three on-going HBO2 clinical trials in various phases of execution. Continued enrollment to establish a database to document the effects of HBO2 treatment on normal healthy participants. Completed recruitment and participant surveys for long-term follow-up study of HBO2 subjects, and began analyzing survey responses. ***FY 2016 Plans:*** Complete two on-going HBO2 clinical trials. Submit final reports and manuscripts. Complete enrollment, begin data analysis, and establish a database to document the effects of HBO2 treatment on normal healthy participants. Complete evaluation of radiologic and physiological biomarker technology, and on-line 6 month and 12 month subject follow-ups. ***FY 2017 Plans:*** Will prepare final reports on two clinical trials. Will consolidate and format HBO2 data from three different HBO2 studies for inclusion into the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system.			
Accomplishments/Planned Programs Subtotals	1.648	0.855	0.774

C. Other Program Funding Summary ($ in Millions)

N/A

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 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

Off-label use of an existing technology. The product is a knowledge product, with initial results to affect TBI treatment policy/reimbursement policy. Decision to pursue FDA registration will be made as part of a formal acquisition decision after the initial results are reviewed.

E. Performance Metrics

The HBO2 Program Management Office Integrated Product Team monitors performance of contracts through review of monthly, yearly and final progress reports to ensure that milestones are being met, deliverables will be transitioned on schedule and within budget and in accordance with DOD Instruction 5000.

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 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 500A / *CSI - Congressional Special Interests*	

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
500A: *CSI - Congressional Special Interests*	0.000	12.150	0.881	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 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 2015	FY 2016
Congressional Add: 465A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2015 Accomplishments:*** FY 2015 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). ***FY 2016 Plans:*** 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).	5.000	0.800
Congressional Add: 475A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2015 Accomplishments:*** FY 2015 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). ***FY 2016 Plans:*** 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).	7.150	0.081
Congressional Adds Subtotals	12.150	0.881

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

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 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 500A / *CSI - Congressional Special Interests*

E. Performance Metrics

N/A