Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145HP *I Medical Products and Support Systems Development*

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	42.313	14.415	26.649	15.906	-	15.906	20.094	21.805	22.236	22.685	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	23.780	9.262	12.694	15.051	-	15.051	19.239	20.905	21.319	21.750	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	18.533	5.153	1.805	0.855	-	0.855	0.855	0.900	0.917	0.935	Continuing	Continuing
500A: *CSI - Congressional Special Interests*	0.000	-	12.150	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This Program Element (PE) funds 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 the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the strategy and initiatives described in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully 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 Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees, established for the Defense Health Program Research, Development, Test and Evaluation funding. 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 2016 Defense Health Program	Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0605145HP *I Medical Products and Support Systems Development*

B. Program Change Summary ($ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	18.976	14.499	19.534	-	19.534
Current President's Budget	14.415	26.649	15.906	-	15.906
Total Adjustments	-4.561	12.150	-3.628	-	-3.628
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	12.150			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-4.561	-			
• Realignment - Project 375A	-	-	-3.628	-	-3.628

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2014	FY 2015
Project: 500A: *CSI - Congressional Special Interests*		
Congressional Add: *465A – Program Increase: Restore Core Research Funding Reduction (GDF)*	-	5.000
Congressional Add: *475A – Program Increase: Restore Core Research Funding Reduction (Army)*	-	7.150
Congressional Add Subtotals for Project: 500A	-	12.150
Congressional Add Totals for all Projects	-	12.150

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$4.561 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+$4.561 million).

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

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support System Development (-$3.628 million) to DHP RDT&E PE 0604110-Medical Products Support and Advanced Concept Development (+$3.628 million).

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

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
375A: *GDF-Medical Products and Support System Development*	23.780	9.262	12.694	15.051	-	15.051	19.239	20.905	21.319	21.750	Continuing	Continuing

A. Mission Description and Budget Item Justification

Activities conducted are intended to support system development and demonstration prior to initial full rate production and fielding of commodities.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	9.262	12.694	15.051

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 2014 Accomplishments:

Medical Simulation and Information Sciences focused on the advanced development and validation of technologies and products to improve military medicine through healthcare provider training, technologies to reduce and refine dependency on use of live tissue for training, and technologies that facilitate home-based training. Initiated an evaluation of the effectiveness of currently commercialized or advanced prototype simulation systems versus currently accepted training models for military use.

Combat Casualty Care medical products in this PE are grouped under the Hemorrhage and Resuscitation and Neurotrauma portfolios. Under Hemorrhage and Resuscitation: Continued the Spray Dried Plasma advanced development effort. Under Neurotrauma: Conducted clinical trials evaluating two point-of-care devices for use in conjunction with a biomarker-specific diagnostic assay system for traumatic brain injury. These clinical trials provided data supporting an application for licensure by the US Food and Drug Administration (FDA).

FY 2015 Plans:

Medical Simulation and Information Sciences will continue an evaluation of the effectiveness of currently commercialized or advanced prototype simulation systems versus currently accepted training models for military use. Year 2 of this effort will focus on comparison validation studies between commercially available systems versus currently used live tissue training models. These efforts support the advanced development of technologies to reduce and refine the use of live tissue for training.

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Combat Casualty Care medical products in this PE are grouped under the Hemorrhage and Resuscitation and Neurotrauma portfolios. Under Hemorrhage and Resuscitation: Initiate two Phase II clinical trials supporting the advanced development of a Spray Dried Plasma product. Under Neurotrauma, continue development on a state of the art lightweight Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System (BANDITS) portable device to diagnose mild, moderate and severe TBI. ***FY 2016 Plans:*** Medical Simulation and Information Sciences will continue an evaluation of the effectiveness of currently commercialized or advanced prototype simulation systems versus currently accepted training models for military use/live tissue training models. Year 3 of this effort will evaluate FY 2015 data and provide recommendations to refine and re-evaluate commercially available simulator products. These efforts support the advanced development of technologies to reduce and refine the use of live tissue for training. Combat Casualty Care medical products in this PE are grouped under the Hemorrhage and Resuscitation and Neurotrauma portfolios. Under Hemorrhage and Resuscitation: Conduct a Milestone B decision for the Spray Dried Plasma product and continue clinical trials. Continue collecting data to support the FDA submission of a whole blood pathogen reduction device, which will be used to reduce pathogens in battlefield-collected whole blood units intended for transfusion.			
Accomplishments/Planned Programs Subtotals	9.262	12.694	15.051

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Test and evaluate medical procedures and prototype devices in government-managed Phase 2 clinical trials in order to gather data to meet military and regulatory (FDA and 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. Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with DoD Regulation 5000 series. 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 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145HP / *Medical Products and Support Systems Development*	Project (Number/Name) 399A / *Hyperbaric Oxygen Therapy Clinical Trial (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
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	18.533	5.153	1.805	0.855	-	0.855	0.855	0.900	0.917	0.935	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. 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. 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	5.153	1.805	0.855
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 2014 Accomplishments: HBO2 had four (4) clinical trials in various phases of execution. Results of completed FY14 studies may impact HBO2 therapy guidelines for end users. Completed enrollment on an evaluation of radiologic and physiologic biomarker technology. Study volunteers will be followed for one year to assess the durability of the HBO2 responses. Submitted a manuscript of initial HBO2 study findings for publication. Initiated the development of a database to document the effects of HBO2 treatment on normal healthy volunteers. Initiated recruitment for a long-term follow-up study of HBO2 subjects. Collaborated with Veterans Affairs as they continued validating a Neurobehavioral Symptom Inventory questionnaire.			
FY 2015 Plans: HBO2 has three (3) on-going clinical trials in various phases of execution. Prepare final clinical study report, which will include the initial findings related to the HBO2 therapy. Continue evaluation of cutting-edge radiologic and physiological biomarker technology and begin 6 month and 12 month subject follow-ups. Continue enrollment of a study to establish a database documenting the effects of HBO2 treatment on normal healthy participants. Complete recruitment and participant surveys for a long-term follow-up study of HBO2 subjects, and begin analyzing survey responses.			
FY 2016 Plans:			

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

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
HBO2 will have two (2) on-going clinical trials in various phases of execution. Will submit final report and associated manuscript on a study to confirm the initial findings related to the response to HBO2 therapy. Will complete subject enrollment and begin data analysis related to the establishment of a database on the effects of HBO2 treatment on normal healthy participants			
Accomplishments/Planned Programs Subtotals	5.153	1.805	0.855

C. Other Program Funding Summary ($ in Millions)

N/A

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 regulation 5000.

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

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
500A: *CSI - Congressional Special Interests*	-	-	12.150	-	-	-	-	-	-	-	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) 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 2014	FY 2015
Congressional Add: 465A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2014 Accomplishments:*** No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Products and Support Systems Development Program Element (PE) - 0605145.	-	5.000
Congressional Add: 475A – Program Increase: Restore Core Research Funding Reduction (Army) ***FY 2014 Accomplishments:*** No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Products and Support Systems Development Program Element (PE) - 0605145.	-	7.150
Congressional Adds Subtotals	-	12.150

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

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

E. Performance Metrics

N/A