Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program	DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY 0130: *Defense Health Program* BA 2: *RDT&E*	R-1 ITEM NOMENCLATURE PE 0605145HP: *Medical Products and Support Systems Development*

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	33.073	17.116	18.976	-	18.976	25.855	39.669	42.094	42.772	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	-	18.062	8.521	13.476	-	13.476	23.955	38.769	41.194	41.872	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	-	15.011	8.595	5.500	-	5.500	1.900	0.900	0.900	0.900	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

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. 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 product development of hyperbaric oxygenation for chronic, mild traumatic brain injury (mTBI), also called post-concussion syndrome. 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 mTBI.

Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program	DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY 0130: *Defense Health Program* BA 2: *RDT&E*	R-1 ITEM NOMENCLATURE PE 0605145HP: *Medical Products and Support Systems Development*

B. Program Change Summary ($ in Millions)	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total
Previous President's Budget	33.695	17.116	18.976	-	18.976
Current President's Budget	33.073	17.116	18.976	-	18.976
Total Adjustments	-0.622	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.622	-			

Change Summary Explanation

FY 2012: Realignment from DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-$0.622 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+$0.622 million).

FY 2013: No Change

FY 2014: No Change

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program			DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY 0130: *Defense Health Program* BA 2: *RDT&E*	R-1 ITEM NOMENCLATURE PE 0605145HP: *Medical Products and Support Systems Development*	PROJECT 375A: *GDF-Medical Products and Support System Development*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
375A: *GDF-Medical Products and Support System Development*	-	18.062	8.521	13.476	-	13.476	23.955	38.769	41.194	41.872	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

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 2012	FY 2013	FY 2014
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	18.062	8.521	13.476

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 commodities delivered from 0604110HP (Medical Products Support and Advanced Concept Development). Development and demonstration activities will be conducted in the following two specific areas: development and demonstration of medical modeling and simulation systems for training/education/treatment, and medical system development and demonstration.

FY 2012 Accomplishments:

The Combat Casualty Care research area continued development on a portable anesthesia device for the Marine Corps, an integrated portable patient life support and monitoring system for expeditionary medical care, a reference device for traumatic brain injury biomarkers, and a ruggedized version of a device to measure eye tracking for the diagnosis of mild traumatic brain injury.

FY 2013 Plans:

Medical Training and Health Information Sciences (MTHIS) is focusing on producing technologies and products that will improve military relevant training with a focus on combat trauma training.

The Combat Casualty Care research area is continuing development of a TBI biomarkers reference device and complete the clinical trial of TBI biomarkers.

FY 2014 Plans:

Medical Training and Health Information Sciences (MTHIS) will focus on developing technologies and products that will improve military medicine through medic or medical provider training, technologies to reduce live tissue training, or home based training.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program		DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY 0130: *Defense Health Program* BA 2: *RDT&E*	R-1 ITEM NOMENCLATURE PE 0605145HP: *Medical Products and Support Systems Development*	PROJECT 375A: *GDF-Medical Products and Support System Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Combat Casualty Care research will continue the development effort of dried plasma and TBI biomarkers.			
Accomplishments/Planned Programs Subtotals	18.062	8.521	13.476

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 to gather data required for military and regulatory requirements prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.

E. Performance Metrics

Principal investigators will participate in In-Progress Reviews, high-level DHP-sponsored Review & Analysis meetings, submit quarterly and annual status reports, and are subjected to Program Office or Program Sponsor Representative progress reviews to ensure that milestones are being met and deliverables will be transitioned on schedule. 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 TRL 8.

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program			DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY 0130: *Defense Health Program* BA 2: *RDT&E*	R-1 ITEM NOMENCLATURE PE 0605145HP: *Medical Products and Support Systems Development*	PROJECT 399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	

COST ($ in Millions)	All Prior Years	FY 2012	FY 2013#	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	-	15.011	8.595	5.500	-	5.500	1.900	0.900	0.900	0.900	Continuing	Continuing

FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) Clinical Trial will focus on research for development of treatment modalities using HBO2 for chronic mild TBI. Four HBO2 study sites are established and fully functional. The sites consist of a hyperbaric oxygen chamber enclosed in a mobile trailer, another mobile trailer for testing and evaluation of the subjects and a third subject changing trailer. Testing in humans will be designed to evaluate and use HBO2 treatments for Service members who are symptomatic from one or more concussions at the time of post-deployment health reassessments.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	15.011	8.595	5.500

Description: HBO2 clinical trials are designed to test in humans the use of hyperbaric oxygen treatments for Service members who are symptomatic from one or more concussions at the time of post-deployment health reassessments.

FY 2012 Accomplishments:

For HBO2 therapy, the initial research study co-funded with the US Air Force was completed, analyzed and published, showing high dose HBO2 is safe and well tolerated, and that this procedure is associated with a major placebo effect but no additional benefit. A second proof of concept and outcome assessment study of low dose HBO2 is fully enrolled and nearing completion. Validation of the content of the lead post concussion outcome measure (Neurobehavioral Symptom Inventory questionnaire) was completed. A third study to confirm initial findings and evaluate cutting-edge radiologic and physiologic biomarker technology was fully approved by the Institutional Review Board. Meetings with FDA yielded a clear path for FDA clearance.

FY 2013 Plans:

The pilot study of low dose HBO2 is being completed, with analysis and results to be released. The team is working with the Navy and Veteran's Affairs (VA) researchers to analyze the results of the complementary dose ranging study also due to be completed this year. The team is completing a summary of these three studies for review by the national hyperbaric medical professional association, TRICARE, the VA and Department of Defense policymakers. A study confirming initial findings and evaluating cutting-edge radiologic and physiologic biomarker technology is to continue for 2 years. The VA is validating the Neurobehavioral

Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program		DATE: March 2013
APPROPRIATION/BUDGET ACTIVITY 0130: *Defense Health Program* BA 2: *RDT&E*	R-1 ITEM NOMENCLATURE PE 0605145HP: *Medical Products and Support Systems Development*	PROJECT 399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2012	FY 2013	FY 2014
Symptom Inventory questionnaire per FDA guidelines. A decision is being made to proceed to a FDA-regulated, phase III pivotal trial. ***FY 2014 Plans:*** HBO2 therapy treatment guidelines will be updated along with education of the end-users, as the results warrant. Integration into multi-modal TBI rehabilitation will continue. The study confirming initial findings and evaluating cutting-edge radiologic and physiologic biomarker technology will continue for 2 years. Long-term follow-up of study volunteers to evaluate durability of the improvement will continue.			
Accomplishments/Planned Programs Subtotals	15.011	8.595	5.500

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 2/3 clinical trials to gather data required for military and regulatory requirements prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.

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.