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 0607100DHA *I Medical Products and Capabilities Enhancement Activities*

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	53.833	16.052	14.998	13.438	-	13.438	15.714	16.819	17.215	17.619	Continuing	Continuing
377A: *GDF-Medical Products and Capabilities Enhancement Activities*	50.115	16.052	14.998	13.438	-	13.438	15.714	16.819	17.215	17.619	Continuing	Continuing
457A: *AF Advanced Technology Development – Rapid Technology Transition*	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
700A: *CSI - Congressional Special Interests*	2.382	0.000	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 Capabilities Enhancement Activities: Funds will support (1) developmental upgrades to medical systems and products that have been fielded, are routinely used in a fixed facility, or that have been approved for full-rate production and for which procurement funding is anticipated in the current fiscal year or subsequent fiscal years, (2) testing and evaluation supporting the enhancement of fielded or procured medical systems/products and medically-related information technology systems, (3) assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and (4) analyses of clinical intervention outcomes to enhance and improve military unique Clinical Practice Guidelines. Efforts address the Military Health System Concept of Operations documents and follow-on Capabilities Based Assessments/Joint Capability Documents, appropriate Component requirements, legislative and Executive directives (e.g., National Research Action Plan, Precision Medicine Initiative, Office of Management and Budget Combat Casualty Care Assessment, National Defense Authorization Acts, etc.), and others as appropriate.

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	17.356	14.998	14.938	-	14.938
Current President's Budget	16.052	14.998	13.438	-	13.438
Total Adjustments	-1.304	0.000	-1.500	-	-1.500
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.304	-			
• Cancer Moonshot	-	-	-1.500	-	-1.500

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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 700A: *CSI - Congressional Special Interests*		
Congressional Add: *467A – Program Increase: Restore Core Research Funding Reduction (GDF)*	0.000	-
Congressional Add Subtotals for Project: 700A	0.000	-
Congressional Add Totals for all Projects	0.000	-

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-$1.304 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$1.304 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) PE 0607100-Medical Products and Capabilities Enhancement Activities (-$2.291 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Caree (+$2.291 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-$0.358 million) to USU DHP RDT&E PE 0603115 Breast, GYN and Prostate Cancer Centers of Excellence (+$0.358 million).

FY 2018: Realignment from DHP RDTE PE 0607100-Medical Products and Capabilities Enhancement Activities, Project 377 GDF (-$1.500 million) to DHP RDTE PE 0603115-Medical Technology Development, Uniformed Services University, Project 478 Applied Proteogenomics Organization Learning and Outcomes (APOLLO) Consortium (+$1.500 million) to support the White House-directed Cancer Moonshot initiative.

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 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 377A / *GDF-Medical Products and Capabilities Enhancement Activities*	

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
377A: *GDF-Medical Products and Capabilities Enhancement Activities*	50.115	16.052	14.998	13.438	-	13.438	15.714	16.819	17.215	17.619	Continuing	Continuing

A. Mission Description and Budget Item Justification

The goal of the Medical Products and Capabilities Enhancement Activities is to test, evaluate, and support enhancement of existing medical products and medically-related IT systems within the Joint Program Committee (JPC) research areas of Medical Simulation and Information Sciences, Infectious Diseases, Combat Casualty Care, Military Operational Medicine, and Clinical and Rehabilitative Medicine. Additionally, funding supports the investigation of clinical intervention outcomes to support, enhance, and improve militarily unique Clinical Practice Guidelines. Program Element (PE) 6.7 efforts are short-term, high-impact projects. It is an intramural research program focused on the evaluation of new commercial medical capabilities suitable for theater, the testing of a fielded capability to function in an expanded or altered operationally-relevant environment, and investigating the potential to incorporate emerging medical or non-medical technologies into fielded medical systems.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities	16.052	14.998	13.438
Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year.			
FY 2016 Accomplishments: 1- Analyzed data on the population prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine and provided recommendations on primaquine use to treat malarial relapse; 2- initiated patient enrollment in study to assess whether a current method of monitoring traumatic brain injury (TBI) patients may worsen clinical outcomes; 3- initiated patient enrollment on the effectiveness of the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/mild TBI; 4- collected data for comparison of a commercially available device measuring injury specific biomarkers (biological indicators) of acute kidney injury versus the current standard of practice; 5- began subject recruitment for assessment on the use of a marksmanship trainer, the Conflict Kinetics (CK) Gunfighting Gym, as a potential tool/metric to measure neurocognitive (cognitive functions associated with particular areas of the brain) status/mental performance; 6- evaluated technologies designed to fabricate custom ear pieces for hearing protection; 7- collected retrospective data and began a prospective study evaluating the efficacy of a peripheral nerve block to correct heterotopic ossification (abnormal bone growth outside of the skeleton), which can occur after battlefield injuries, severe burn injuries and following amputation; 8- continued evaluations of junctional and extremity tourniquets to stop excessive bleeding; 9- evaluated commercial spatial mosquito repellents for efficacy in wind tunnel and semi-field tests to provide data to the Repellents Committee of the Armed Forces Pest Management Board; 10- designed improved, affordable versions of hoistable rescue litter that make patient securing procedure faster and easier and improve patient access; and 11- began evaluation of			

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 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 377A / *GDF-Medical Products and Capabilities Enhancement Activities*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
commercially available surgical pneumatic tourniquets (used during orthopedic and plastic/reconstructive surgeries to produce a relatively bloodless operative field) for military operational suitability to inform selection of replacement for currently fielded discontinued models. ***FY 2017 Plans:*** Solicit, review, and make awards for intramural proposals consistent with the intent of PE 6.7. For previously funded efforts: continuing patient recruitment for a study assessing whether a current method of monitoring TBI patients may worsen clinical outcomes; continuing patient enrollment and data analysis on the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/ mild TBI; continuing data collection on comparison of a commercially available device measuring injury specific biomarkers of acute kidney injury versus the current standard of practice; completing assessment and provide recommendations on the use of a marksmanship trainer, the CK Gunfighting Gym, as a potential tool/metric to measure neurocognitive status/mental performance and provide a plan to translate the tests designed for the larger CK platform to smaller platforms; continuing data collection on the efficacy of a peripheral nerve block during corrective surgery for heterotopic ossification, a condition which can occur after battlefield injuries, severe burn injuries, and following amputation; building and testing improved, affordable versions of hoistable rescue litter that will make patient securing procedure faster and easier and will improve patient access; completing the testing of commercially available surgical pneumatic tourniquets for military operational suitability and make a recommendation to replace currently fielded discontinued models; beginning adaptation of the current (paper) pain management workbook into an interactive, mobile application software (app) to increase accessibility and engagement among patients for optimizing pain management and treatment; initiate enrolling TBI patients to determine whether a commercially available, non-invasive cerebral blood flow monitor can predict progression of TBI, potentially transforming TBI care in deployed settings. ***FY 2018 Plans:*** Will solicit, review, and make awards for intramural proposals consistent with the intent of PE 6.7. For previously funded efforts: will continue patient recruitment and begin data analysis for a study assessing whether a current method of monitoring TBI patients may worsen clinical outcomes; will complete patient enrollment and continue data analysis on the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/ mild TBI; will complete data collection and data analysis on comparison of a commercially available device measuring injury specific biomarkers of acute kidney injury versus the current standard of practice; will complete data collection and analysis on the efficacy of a peripheral nerve block during corrective surgery for heterotopic ossification, a condition which can occur after battlefield injuries, severe burn injuries, and following amputation; will complete adaptation of the current (paper) pain management workbook into an interactive, mobile app to increase accessibility and engagement among patients for optimizing pain management and treatment and will conduct patient usability testing of the app; will continue enrolling TBI patients and begin			

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 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	**Project (Number/Name)** 377A / *GDF-Medical Products and Capabilities Enhancement Activities*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
data analysis to determine whether a commercially available, non-invasive cerebral blood flow monitor can predict progression of TBI, potentially transforming TBI care in deployed settings.			
Accomplishments/Planned Programs Subtotals	16.052	14.998	13.438

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

The PE 6.7 Program Manager solicits proposals annually with two submission deadlines. Civilian and military intramural DoD laboratory investigators are eligible to apply. Awardees may collaborate with extramural (e.g., academia or industry) entities. Submitted proposals undergo a two-level review – one technical and one programmatic. A technical assessment of the proposals is solicited from the respective subject matter experts within the JPCs and the advanced development community. Following this, a programmatic review is performed by senior Service experts representing the science and technology base and advanced development. After the programmatic review, funding recommendations are forwarded to the Director, Research, Development and Acquisition, Defense Health Agency or their designee for final approval prior to award.

E. Performance Metrics

Principal Investigators will provide quarterly reports and a final report. Performance is measured based on the number of products for which testing either certifies use in a given environment (e.g., sufficiently ruggedized, airworthiness testing) and/or results in a recommendation of a specific product, and delivery of an enhanced product or knowledge product. The benchmark performance metric for research supported in this PE will be the enhancement of a maturity level that is typical of TRL 9.

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 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	Project (Number/Name) 457A / *AF Advanced Technology Development – Rapid Technology Transition*	

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
457A: *AF Advanced Technology Development – Rapid Technology Transition*	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Air Force - Medical Products and Capabilities Enhancement Activities: Funds support a developmental upgrade to a medical product that has been fielded and for which procurement funding is anticipated subsequent fiscal years.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: AF Advanced Technology Development – Rapid Technology Transition	0.000	0.000	-
Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year. ***FY 2016 Accomplishments:*** Complete enhancements and modifications to the XSTAT-30 Advanced Junctional Non-Compressible Hemorrhage Control Agent product, submit data package to the FDA regulatory approval process for predicate devices and transition the enhanced device to military operational use. ***FY 2017 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

$1.1M FY15/17 Defense Health Program – Air Force Procurement funds

D. Acquisition Strategy

Cost-plus Fixed Fee contract award to performer via the Army-Natick Soldier Systems Research Development and Execution Center contracting activity.

E. Performance Metrics

N/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 0607100DHA / *Medical Products and Capabilities Enhancement Activities*	Project (Number/Name) 700A / *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
700A: *CSI - Congressional Special Interests*	2.382	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

No FY 2016 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0607100 - Medical Products and Capabilities Enhancement Activities.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: 467A – Program Increase: Restore Core Research Funding Reduction (GDF)	0.000	-
FY 2016 Accomplishments: No Funding Programmed.		
Congressional Adds Subtotals	0.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A