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**Department of Defense
Fiscal Year (FY) 2016 President's Budget Submission**

February 2015



Defense Health Program

Defense Wide Justification Book Volume 1 of 1

Defense Health Program

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Defense Health Program • President's Budget Submission FY 2016 • RDT&E Program

Table of Volumes

Defense Advanced Research Projects Agency..... Volume 1

Missile Defense Agency..... Volume 2

Office of the Secretary Of Defense..... Volume 3

Chemical and Biological Defense Program.....Volume 4

Defense Contract Management Agency..... Volume 5

DoD Human Resources Activity..... Volume 5

Defense Information Systems Agency.....Volume 5

Defense Logistics Agency.....Volume 5

Defense Security Cooperation Agency..... Volume 5

Defense Security Service..... Volume 5

Defense Technical Information Center.....Volume 5

Defense Threat Reduction Agency.....Volume 5

The Joint Staff..... Volume 5

United States Special Operations Command..... Volume 5

Washington Headquarters Service..... Volume 5

Operational Test and Evaluation, Defense..... Volume 5

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Defense Health Program • President's Budget Submission FY 2016 • RDT&E Program

- Defense Geospatial Intelligence Agency..... (see NIP and MIP Justification Books)**
- Defense Intelligence Agency..... (see NIP and MIP Justification Books)**
- National Security Agency.....(see NIP and MIP Justification Books)**

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Defense Health Program • President's Budget Submission FY 2016 • RDT&E Program

Volume 1 Table of Contents

Comptroller Exhibit R-1..... Volume 1 - v
Program Element Table of Contents (by Budget Activity then Line Item Number).....Volume 1 - vii
Program Element Table of Contents (Alphabetically by Program Element Title).....Volume 1 - ix
Exhibit R-2's..... Volume 1 - 1

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**Defense Health Program
Fiscal Year (FY) 2016 Budget Estimates
RDT&E Programs**

Appropriation: RDT&E, Defense Health Program (\$s M)

Date: March 2015

Program		Budget	FY 2014	FY 2015	FY 2016	FY 2016	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	
R-1 Line Element	Item	Activity	Actual ¹	Enacted ²	Base	OCO	Total Request	Estimates	Estimates	Estimates	Estimates	
Item No	Number											
1	0601101	In-House Laboratory Independent Research (ILIR)	2	2.894	3.151	3.599	0.000	3.599	3.653	3.879	3.943	4.013
2	0601117	Basic Operational Medical Research Sciences	2	5.805	9.059	7.397	0.000	7.397	9.417	10.395	10.666	10.889
3	0602115	Applied Biomedical Technology	2	59.968	73.201	58.251	0.000	58.251	68.797	80.447	83.982	89.223
4	0602787	Medical Technology (AFRRI)	2	1.139	1.241	1.222	0.000	1.222	1.242	1.331	1.356	1.383
5	0603002	Medical Advanced Technology (AFRRI)	2	0.284	0.310	0.305	0.000	0.305	0.310	0.332	0.338	0.345
6	0603115	Medical Technology Development	2	1109.743	1201.188	231.051	0.000	231.051	250.488	267.321	265.167	267.228
7	0604110	Medical Products Support and Advanced Concept Development	2	296.634	150.822	103.443	0.000	103.443	129.137	140.826	146.781	149.354
8	0605013	Information Technology Development	2	44.451	21.696	19.312	0.000	19.312	19.679	23.582	21.386	21.813
9	0605023	Integrated Electronic Health Record (iEHR)	2	19.912	68.267	9.216	0.000	9.216	8.125	0.000	0.000	0.000
10	0605025	Theater Medical Information Program - Joint (TMIP-J)	2	23.783	22.042	22.100	0.000	22.100	22.140	22.180	22.619	23.071
		Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)	2	0.000	91.394	438.376	0.000	438.376	260.501	0.000	0.000	0.000
12	0605039	DoD Medical Information Exchange and Interoperability	2	0.000	0.000	11.000			0.000	0.000	0.000	0.000
13	0605145	Medical Products and Support Systems Development	2	14.415	26.649	15.906	0.000	15.906	20.094	21.805	22.236	22.685
14	0605502	Small Business Innovation Research (SBIR) Program	2	47.882	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
15	0606105	Medical Program-Wide Activities	2	68.277	44.042	41.567	0.000	41.567	25.156	23.731	24.182	24.665
16	0607100	Medical Products and Capabilities Enhancement Activities	2	15.097	17.474	17.356	0.000	17.356	17.647	19.663	20.037	20.439
Total Budget Activity 2				1710.284	1730.536	980.101	0.000	980.101	836.386	615.492	622.693	635.108

Notes:

- 1.) FY 2014 actual includes congressional additions, reductions, and statutory reductions for FFRDC/SBIR.
- 2.) FY 2015 enacted includes congressional additions, reductions, and statutory reductions for FFRDC/SBIR.

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Defense Health Program • President's Budget Submission FY 2016 • RDT&E Program

Program Element Table of Contents (by Budget Activity then Line Item Number)

Budget Activity 02: RDT&E
Appropriation 0130: Defense Health Program

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Line Item	Budget Activity	Program Element Number	Program Element Title	Page
1	02	0601101HP	In-House Laboratory Independent Research (ILIR).....	Volume 1 - 1
2	02	0601117HP	Basic Operational Medical Research Sciences.....	Volume 1 - 11
3	02	0602115HP	Applied Biomedical Technology.....	Volume 1 - 17
4	02	0602787HP	Medical Technology (AFRRI).....	Volume 1 - 39
5	02	0603002HP	Medical Advanced Technology (AFRRI).....	Volume 1 - 53
6	02	0603115HP	Medical Technology Development.....	Volume 1 - 63
7	02	0604110HP	Medical Products Support and Advanced Concept Development.....	Volume 1 - 169
8	02	0605013HP	Information Technology Development.....	Volume 1 - 183
9	02	0605023HP	Integrated Electronic Health Record (iEHR).....	Volume 1 - 265
10	02	0605025HP	Theater Medical Information Program - Joint (TMIP-J).....	Volume 1 - 275
11	02	0605026HP	Information Technology Development - DoD Healthcare Management System Modernization (DHMSM).....	Volume 1 - 281
12	02	0605039HP	PE 0605039HP / DoD Medical Information Exchange and Interoperability.....	Volume 1 - 287
13	02	0605145HP	Medical Products and Support Systems Development.....	Volume 1 - 293
14	02	0605502HP	Small Business Innovation Research (SBIR) Program.....	Volume 1 - 301

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Defense Health Program • President's Budget Submission FY 2016 • RDT&E Program

Budget Activity 02: RDT&E
Appropriation 0130: Defense Health Program

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Line Item	Budget Activity	Program Element Number	Program Element Title	Page
15	02	0606105HP	Medical Program-Wide Activities.....	Volume 1 - 305
16	02	0607100HP	Medical Products and Capabilities Enhancement Activities.....	Volume 1 - 323

UNCLASSIFIED

UNCLASSIFIED

Defense Health Program • President's Budget Submission FY 2016 • RDT&E Program

Program Element Table of Contents (Alphabetically by Program Element Title)

Program Element Title	Program Element Number	Line Item	Budget Activity	Page
Applied Biomedical Technology	0602115HP	3	02.....	Volume 1 - 17
Basic Operational Medical Research Sciences	0601117HP	2	02.....	Volume 1 - 11
In-House Laboratory Independent Research (ILIR)	0601101HP	1	02.....	Volume 1 - 1
Information Technology Development	0605013HP	8	02.....	Volume 1 - 183
Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)	0605026HP	11	02.....	Volume 1 - 281
Integrated Electronic Health Record (iEHR)	0605023HP	9	02.....	Volume 1 - 265
Medical Advanced Technology (AFRRI)	0603002HP	5	02.....	Volume 1 - 53
Medical Products Support and Advanced Concept Development	0604110HP	7	02.....	Volume 1 - 169
Medical Products and Capabilities Enhancement Activities	0607100HP	16	02.....	Volume 1 - 323
Medical Products and Support Systems Development	0605145HP	13	02.....	Volume 1 - 293
Medical Program-Wide Activities	0606105HP	15	02.....	Volume 1 - 305
Medical Technology (AFRRI)	0602787HP	4	02.....	Volume 1 - 39
Medical Technology Development	0603115HP	6	02.....	Volume 1 - 63
PE 0605039HP / DoD Medical Information Exchange and Interoperability	0605039HP	12	02.....	Volume 1 - 287
Small Business Innovation Research (SBIR) Program	0605502HP	14	02.....	Volume 1 - 301
Theater Medical Information Program - Joint (TMIP-J)	0605025HP	10	02.....	Volume 1 - 275

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>							
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	3.712	2.894	3.151	3.599	-	3.599	3.653	3.879	3.943	4.013	Continuing	Continuing
010A: <i>CSI - Congressional Special Interests</i>	0.000	-	0.315	-	-	-	-	-	-	-	Continuing	Continuing
240A: <i>Infectious Disease (USUHS)</i>	0.520	0.404	0.397	0.433	-	0.433	0.440	0.471	0.480	0.490	Continuing	Continuing
240B: <i>Military Operational Medicine (USUHS)</i>	1.593	1.242	1.217	1.330	-	1.330	1.354	1.451	1.479	1.509	Continuing	Continuing
240C: <i>Combat Casualty Care (USUHS)</i>	1.599	1.248	1.222	1.836	-	1.836	1.859	1.957	1.984	2.014	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services of the Health Sciences (USUHS), this program element supports basic medical research at the Uniformed Services University of the Health Sciences (USUHS). It facilitates the recruitment and retention of faculty; supports unique research training for military medical students and resident fellows; and allows the University's faculty researchers to collect pilot data towards military relevant medical research projects in order to secure research funds from extramural sources (estimated \$135 million annually). Approximately 110 intramural research projects are active each year, including 32 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the fund of knowledge intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs.

The ILIR program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the areas of Combat Casualty Care, Infectious Diseases, Military Operational Medicine, and Chemical, Biological, and Radiologic Defense. The portfolio of research projects will vary annually because this research is investigator-initiated. Examples of typical research efforts are detailed in R-2a.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>
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B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	3.088	2.836	3.099	-	3.099
Current President's Budget	2.894	3.151	3.599	-	3.599
Total Adjustments	-0.194	0.315	0.500	-	0.500
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	0.315			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.194	-			
• Change Proposal Center for Rehabilitation Sciences (CRSR) - Project 240C	-	-	0.500	-	0.500

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 010A: *CSI - Congressional Special Interests*

Congressional Add: 468A – *Program Increase: Restore Core Research Funding Reduction (USUHS)*

Congressional Add Subtotals for Project: 010A

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	-	0.315
Congressional Add Subtotals for Project: 010A	-	0.315
Congressional Add Totals for all Projects	-	0.315

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601101-In-House Laboratory Independent Research (-\$0.194 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.194 million).

FY 2015: Restores core research funding to the DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+\$0.315 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$0.500 million) to DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+\$0.500 million).

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 010A / <i>CSI - Congressional Special Interests</i>
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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
010A: <i>CSI - Congressional Special Interests</i>	-	-	0.315	-	-	-	-	-	-	-	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) - In-House Laboratory Independent Research (ILIR). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 468A – Program Increase: Restore Core Research Funding Reduction (USUHS)	-	0.315
FY 2014 Accomplishments: No Funding Programmed.		
FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the In-House Laboratory Independent Research (ILIR) Program Element (PE) - 0601101.		
Congressional Adds Subtotals	-	0.315

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>				Project (Number/Name) 240A / <i>Infectious Disease (USUHS)</i>			
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
240A: <i>Infectious Disease (USUHS)</i>	0.520	0.404	0.397	0.433	-	0.433	0.440	0.471	0.480	0.490	Continuing	Continuing

A. Mission Description and Budget Item Justification

Infectious Diseases: Immunology and molecular biology of bacterial, viral and parasitic disease threats to military operations. These threats include Bartonella bacilliformis, Clostridium difficile, Escherichia coli and their Shiga toxins, Henipaviruses (Hendra & Nipah), Hepatitis A, Helicobacter pylori, HIV, HTLV-1, Leishmaniasis, Litomosoides sigmodontis, Malaria, Neisseria gonorrhoeae, Shigella spp., Streptococcus, and Methicillin-resistant Staphylococcus aureus (MRSA).

B. Accomplishments/Planned Programs (\$ in Millions)

Title: Infectious Disease	FY 2014	FY 2015	FY 2016
Description: Infectious Diseases: Immunology and molecular biology of bacterial, viral and parasitic disease threats to military operations. These threats include Bartonella bacilliformis, Clostridium difficile, E. coli and their Shiga toxins, Henipaviruses (Hendra & Nipah), Hepatitis A, Helicobacter pylori, HIV, HTLV-1, Leishmaniasis, Malaria, Neisseriae gonorrhea, Shigella spp., Streptococcus, Staphylococcus, and Typhoid fever.	0.404	0.397	0.433
FY 2014 Accomplishments: Representative projects include the following: determination of the factors responsible for maintaining and driving the immune response against helminth, such as Litomosoides sigmodontis, (parasitic worm) infections eventually leading to effective vaccines against these infections; characterization of the alternative energy-generating pathways in C. difficile as a potential target to prevent the transmission and recurrence of Clostridium difficile infection (CDI), the leading cause of nosocomial, antibiotic-associated diarrhea; investigation of skin and soft tissue infections (SSTI) in the military population, generally caused by community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA), towards the development of novel prevention and treatment strategies; investigation of the Henipaviruses and their bat hosts towards the development of novel intervention and vaccine strategies; development of a cutaneous Leishmaniasis vaccine to prevent parasitic infection; elucidation of the natural transmission of Bartonella bacilliformis by the sand fly towards disease prevention and control; analysis of genetic factors resulting in colonization of the host intestinal tract by Escherichia coli O157:H7, the most common infectious cause of bloody diarrhea & hemorrhagic colitis; understand how antibiotic resistance mutations in Neisseria gonorrhoeae (Gc), whose infections occur at a high incidence throughout the world and in the United States and U.S. military, may influence the spread of resistant strains which subsequently threatens control methods as well as our capacity to limit the spread of human immunodeficiency virus; design of a new class of anti-viral therapeutics (HAIVA prep) for critical conditions like acute pulmonary infection (with different types of flu viruses), and for vaccination purposes in imminent flu endemics; and the health behaviors and deployment factors that are associated with acquisition of sexually transmitted diseases (STDs).			

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240A / <i>Infectious Disease (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>These projects will support the essential military mission by advancing our understanding of both the transmission and the internal mechanisms of a spectrum of pernicious and/or common diseases that may be faced by warfighters both at home and abroad. In turn, that understanding opens avenues to better control, diagnosis, and treatment of both natural and manmade biological threats.</p> <p>FY 2015 Plans: We will continue to investigate infectious diseases that impact soldiers from the standpoint of lost “man-days” to death. We recognize that infectious disease can severely hamper combat readiness and effectiveness, and therefore we will continue to concentrate our efforts on diagnosis and treatment of those naturally occurring infectious diseases that can affect the war fighter by further development of vaccines, drugs, and diagnostic tools.</p> <p>FY 2016 Plans: Efforts will continue within the Infectious Disease research area in FY 2016. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p>			
Accomplishments/Planned Programs Subtotals	0.404	0.397	0.433

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240B / <i>Military Operational Medicine (USUHS)</i>
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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
240B: <i>Military Operational Medicine (USUHS)</i>	1.593	1.242	1.217	1.330	-	1.330	1.354	1.451	1.479	1.509	Continuing	Continuing

A. Mission Description and Budget Item Justification

Military Operational Medicine: Sustainment of individual performance; mapping and managing deployment and operational stressors; cognitive enhancement; use of dietary and nutritional supplements and military and medical training readiness.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Title: Military Operational Medicine</p> <p>Description: Military Operational Medicine: Sustainment of individual performance; mapping and managing deployment and operational stressors; cognitive enhancement; and military and medical training readiness.</p> <p>FY 2014 Accomplishments: Representative projects will include the following: refinement of a single item post traumatic stress disorder (PTSD) screening tool for use in the DOD Primary Care system; understanding and attenuating deleterious effects of tobacco, alcohol, stress and their interactions upon military personnel; forecasting levels of full or threshold PTSD, depression, health and alcohol problems within the military population; determination of the unique proteomic signature for the diagnosis and assessment of the neuro-immune response to traumatic brain injury (TBI) towards early assessment of the disease in the military and veteran population; understanding the determinants of health promoting behaviors towards preventing obesity in both active duty military and their family members; identifying signaling pathways that control satiety and dietary triggers towards prevention of obesity; implementation of a neuromuscular routine that minimizes musculoskeletal injury in military academy cadets; study the relationship between previous ankle injury, a common event in military populations, and future serious injury, such as ACL injury as musculoskeletal injury (MSK-1) is the #1 cause of lost and limited duty in the U.S. military; evaluation of suicidal behaviors within recent suicide deaths of active duty service members to aid in identification and prevention efforts; determination of the psychosocial and biomedical risks and protective factors for heart failure and ischemia within the military and veteran population; and the determination of non-invasive neurological biomarkers for heat intolerance using in vivo Magnetic Resonance Imaging (MRI) and Spectroscopy (MRS).</p> <p>These studies support the essential military mission by enhancing and protecting the health, performance and fitness of soldiers throughout the deployment cycle. These studies strive to increase our understanding of and ability to manipulate the physiological mechanisms of stress and immunity, human sleep and seasonal cycles, and neurological changes necessary for short- and long-term memory. Their discoveries should enable warfighters to stay awake longer with fewer detriments to performance; lead to better strategies for enhancing and preserving memory and reasoning capabilities under battle conditions; help understand</p>	1.242	1.217	1.330

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240B / <i>Military Operational Medicine (USUHS)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
and ultimately prevent and treat neuropsychiatric illnesses such as depression and PTSD; and assist deployed troops and their families better prepare for and contend with common, significant stressors related to the deployment cycle.			
<i>FY 2015 Plans:</i> Our efforts will concentrate on biomedical solutions that protect and enhance the health, performance, and fitness of our soldiers. Our focus will continue to be to understand stress as it is related to performance and health. We will also study performance in environmental extremes. Our goal is to lay the ground work that will establish platforms that build biomedical products and solutions that mitigate risk to soldiers and protect them from “head to toe” both on the battlefield and at home.			
<i>FY 2016 Plans:</i> Efforts will continue within the Military Operational Medicine research area in FY 2016. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.			
Accomplishments/Planned Programs Subtotals	1.242	1.217	1.330

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240C / <i>Combat Casualty Care (USUHS)</i>
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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
240C: <i>Combat Casualty Care (USUHS)</i>	1.599	1.248	1.222	1.836	-	1.836	1.859	1.957	1.984	2.014	Continuing	Continuing

A. Mission Description and Budget Item Justification

Combat Casualty Care: Ischemia and reperfusion injury, traumatic brain and peripheral nerve injury, neural control of pain, endotoxic shock, cryotherapy, malignant hyperthermia, inflammation, soman induced neuropathology and wound healing, and the advancement of rehabilitative care for service members with combat related injuries, particularly those with orthopaedic trauma, limb loss and neurological complications.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Combat Casualty Care	1.248	1.222	1.836
<p>Description: Combat Casualty Care: Ischemia and reperfusion injury, traumatic brain and peripheral nerve injury, neural control of pain, endotoxic shock, cryotherapy, malignant hyperthermia, inflammation, and wound healing.</p> <p>FY 2014 Accomplishments: Representative projects will include: investigation of synaptic plasticity in temporal lobe epilepsy and possible development of novel therapies; determination whether BMP-2 is a effective therapy to promotes recapitulation of the meninges surrounding the spinal cord; understanding the contribution of inflammation to post-injury loss of function after traumatic brain and spinal cord injury; investigate the underlying mechanisms involved in heart failure and drug-induced arrhythmias; identifying how the formation of nerve cell circuits in the brain are affected by psychological stress and traumatic brain injury; analysis of the underlying mechanisms responsible for the development of tolerance following the chronic use of opiates for severe pain; development of psychological interventions to be used with military health care providers who experience post-traumatic stress symptoms to prevent burn-out; and development of accurate millisecond-level assessment tools and computer based analyses to assist in the evaluation and assessment of traumatic brain injury.</p> <p>These studies also support the essential military mission by further exploring the mechanism of pain control for an established treatment; providing the groundwork for effective treatments to limit nerve damage and encourage regeneration; and identifying a possible cause for life-threatening complications due to the combination of exertion and injury common under heavy battlefield conditions.</p> <p>FY 2015 Plans: Our efforts will concentrate on diagnosis and treatment for our wounded warriors to reduce mortality and morbidity resulting from injuries on the battlefield. We will study physical and biological determinants of brain injury and post-traumatic stress disorder. In</p>			

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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 0601101HP / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240C / <i>Combat Casualty Care (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>addition, we will also focus on rehabilitation for amputees and pain management. Our goal is to understand how to best care for soldiers who have suffered any type of physical or mental traumatic injury in the field.</p> <p>We will continue to foster the four research focuses in FY2015 that will support advances in clinical and rehabilitation strategies. New research studies will advance inter-service rehabilitation research that is relevant to the care of injured service members and to provide the necessary platform for transferring novel technologies into the clinical practice at the MTFs.</p> <p>Our proposed research for FY15 and beyond seeks to extend our current projects for the following three years as part of a broader effort to establish a post-injury monitoring project to follow patients with orthopedic and extremity trauma for succeeding years as they move through their life course.</p> <p>FY 2016 Plans: Efforts will continue within the Combat Casualty Care research area in FY 2016. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p> <p>We will continue to foster the four research focuses in FY2016 that will support advances in clinical and rehabilitation strategies. In particular, efforts in FY2016 have the potential to benefit all DoD sites with an instrumented gait analysis laboratory that care for patients with lower extremity injury. While the current focus of this program is to provide a long-term follow-up/outcome measure for evaluating patients with amputations and limb salvage, the Gait Quality Index (GQI) we are developing may be applied to any patient population with a lower extremity injury and/or gait deviation. The GQI provides a tool to evaluate patients across various DoD sites with a standardized three-component score, allowing for improved multi-site collaboration in research.</p>			
Accomplishments/Planned Programs Subtotals	1.248	1.222	1.836

C. Other Program Funding Summary (\$ in Millions) N/A
Remarks
D. Acquisition Strategy N/A
E. Performance Metrics N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0601117HP / <i>Basic Operational Medical Research Sciences</i>
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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	5.000	5.805	9.059	7.397	-	7.397	9.417	10.395	10.666	10.889	Continuing	Continuing
100A: <i>CSI - Congressional Special Interests</i>	2.237	-	1.578	-	-	-	-	-	-	-	Continuing	Continuing
371A: <i>GDF-Basic Operational Medical Research Sciences</i>	2.763	5.805	7.481	7.397	-	7.397	9.417	10.395	10.666	10.889	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Basic Operational Medical Research Sciences: This program element (PE) provides support for basic medical research directed toward greater knowledge and understanding of the fundamental principles of science and medicine that are relevant to the improvement of Force Health Protection. 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 sustainment of priority investments in science, technology, research, and development as stated in the Quadrennial Defense Review. Program development 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. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program Research, Development, Test and Evaluation (RDT&E) funding. Research supported by this PE includes coagulopathy of trauma (inability of blood to clot normally), polytrauma (multiple traumatic injuries) and blast injury, military infectious diseases, and operational medicine. Funds in this PE are for basic research that promises to provide important new approaches to complex military medical problems. As the research efforts mature, the most promising efforts will transition to applied research (PE 0602115HP) or technology development (PE 0603115HP) funding.

B. Program Change Summary (\$ in Millions)

	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>
Previous President's Budget	6.074	7.481	7.897	-	7.897
Current President's Budget	5.805	9.059	7.397	-	7.397
Total Adjustments	-0.269	1.578	-0.500	-	-0.500
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	1.578			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.269	-			
• Change Proposal Center for Rehabilitation Sciences (CRSR) - Project 371A	-	-	-0.500	-	-0.500

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0601117HP / <i>Basic Operational Medical Research Sciences</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 100A: *CSI - Congressional Special Interests*

Congressional Add: 461A – *Program Increase: Restore Core Research Funding Reduction (Army)*

Congressional Add Subtotals for Project: 100A

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	-	1.578
	-	1.578
	-	1.578

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$0.269 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.269 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0601101-Basic Operational Medical Research Sciences (+\$1.578 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$0.500 million) to DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (+\$0.500 million).

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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 0601117HP / <i>Basic Operational Medical Research Sciences</i>				Project (Number/Name) 100A / <i>CSI - Congressional Special Interests</i>			
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
100A: <i>CSI - Congressional Special Interests</i>	2.237	-	1.578	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY14 DHP Congressional Special Interest (CSI) funding is directed research for TBI/PH. Because of the CSI annual structure, out-year funding is not programmed.

The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0601117 - Basic Operational Medical Research Sciences. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
<i>Congressional Add:</i> 461A – Program Increase: Restore Core Research Funding Reduction (Army)	-	1.578
<i>FY 2014 Accomplishments:</i> No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.		
<i>FY 2015 Plans:</i> FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Products Support and Advanced Concept Development Program Element (PE) - 0604110.		
Congressional Adds Subtotals	-	1.578

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0601117HP / <i>Basic Operational Medical Research Sciences</i>				Project (Number/Name) 371A / <i>GDF-Basic Operational Medical Research Sciences</i>			
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
371A: <i>GDF-Basic Operational Medical Research Sciences</i>	2.763	5.805	7.481	7.397	-	7.397	9.417	10.395	10.666	10.889	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Basic Operational Medical Research Sciences: Basic research described here will be focused on enhancement of knowledge to support capabilities identified through the Joint Capabilities Integration and Development System (JCIDS) process and sustainment of priority investments in science, technology, research, and development as stated in the Quadrennial Defense Review. Within this Program Element, research will be conducted in the general categories of coagulopathy of trauma (inability of blood to clot normally), polytrauma (multiple traumatic injuries) and blast injury, military infectious diseases, and operational medicine. Polytrauma and blast injury efforts will focus on fundamental mechanisms to support devices and therapeutics for hemorrhage (bleeding) control, resuscitation and blood products, and blast injury models and performance standards for protections systems. Military infectious diseases research program is conducting basic research to identify biomarkers for detecting bacterial wound infections. Operational medicine is focusing on fundamental mechanisms to support research on prevention of training and operational injury, nutrition and dietary supplements, psychological health and resilience, operational exposure standards for cumulative mild traumatic brain injury, fatigue mechanisms, biomarkers (indicators) of inhalational exposure to toxic substances, and military operational computational modeling.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Project 371 GDF – Basic Operational Medical Research Sciences	5.805	7.481	7.397	-	7.397
Description: Provide support for basic medical research directed toward attaining greater knowledge and understanding of fundamental principles of science and medicine relevant to the improvement of medical care in operationally relevant environments.					
FY 2014 Accomplishments: The military operational medicine research program conducted studies to understand fundamental mechanisms of injury following exposure to blast, which will inform the development of exposure guidelines. Other research efforts included the identification of biomarkers (biological indicators of disease) for inhalation exposure to toxic substances such as burn pit emissions and sand from Afghanistan, and biomarkers indicative of neurological effects due to jet fuel exposure.					
The combat casualty care research program conducted studies on coagulopathy of trauma through a consortium of five universities.					
FY 2015 Plans:					

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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 0601117HP / <i>Basic Operational Medical Research Sciences</i>	Project (Number/Name) 371A / <i>GDF-Basic Operational Medical Research Sciences</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Military infectious diseases research is supporting antimicrobial countermeasures to discover antibacterial agents for biofilms (a group of microorganisms in which cells stick to each other on a surface), detect multidrug-resistant organisms (MDROs), identify MDRO biomarkers, and develop new targets. These laboratory studies provide an understanding of the mechanisms that make organisms infectious and mechanisms that render the human body response effective to prevent diseases caused by infectious agents.</p> <p>Military operational medicine research is continuing studies to understand the mechanisms of multiple low level blast exposures in animal models of repeated blast and blunt impact injuries, and identify potential biomarkers of pulmonary exposure to toxic substances from burn pit emissions, natural dust from Afghanistan and the interactions between pollutants, which are associated with adverse health outcomes and lung disease. Studies in nutrition and dietary supplements are assessing dietary status of different Service member populations. Additional studies include the identification of novel pharmacological interventions to promote sleep quality, and refine algorithms that predict the effects of fatigue countermeasures, such as caffeine and naps, to optimize warfighter physical and cognitive performance.</p> <p>Combat casualty care basic research is identifying underlying pathophysiologic (functional changes associated with injury) mechanisms associated with coagulopathy (inability of blood to clot normally) of trauma, and identifying potential diagnostic and therapeutic targets of coagulopathy of trauma.</p> <p>FY 2016 Base Plans: Military infectious diseases research will support basic research laboratory studies in wound infection prevention, treatment, and management to develop antibacterial agents targeting biofilms and MDROs, and host and microbial biomarkers for early detection of infection. Outcomes from FY15-16 laboratory studies will identify bacterial targets for prevention/treatment of diseases caused by bacterial agents.</p> <p>Military operational medicine research will identify mechanisms of blast injury that will guide the development of interventions for mitigating blast-induced brain injury. Will start studies to identify and assess anger, risky behaviors, grief, guilt, cognitive difficulties, substance abuse, and misuse of prescription medications in the military. Will start studies to identify gender-specific factors that impact military task performance, will define minimal physical requirements for entry into physically demanding military occupations, will investigate novel interventions to evaluate effectiveness in treating PTSD symptoms, will conduct basic studies to define medical standards for noise injury criteria, and will identify novel interventions to promote sleep quality and non-pharmacological approaches to reduce the need for sleep in order to sustain warfighter readiness.</p>					

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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 0601117HP / <i>Basic Operational Medical Research Sciences</i>	Project (Number/Name) 371A / <i>GDF-Basic Operational Medical Research Sciences</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Combat casualty care basic research will define the cellular mechanisms involved in the abnormal bleeding that occurs following severe trauma. The results from these studies will be included in the design of the next generation of hemostatic (process to stop bleeding) products.</p> <p>FY 2016 OCO Plans: N/A</p>					
Accomplishments/Planned Programs Subtotals	5.805	7.481	7.397	-	7.397

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review & analysis meetings, quarterly and annual status reports, and progress reviews to ensure that milestones are being met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with basic science funding is the attainment of a maturity level that is typical of Technology Readiness Level 2 or the equivalent for knowledge products.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0602115HP / <i>Applied Biomedical Technology</i>							
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	118.565	59.968	73.201	58.251	-	58.251	68.797	80.447	83.982	89.223	Continuing	Continuing
200A: <i>Congressional Special Interests</i>	55.883	15.000	25.303	-	-	-	-	-	-	-	-	-
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	-	-	-	3.150	-	3.150	3.157	2.552	1.949	1.949	Continuing	Continuing
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	3.377	3.535	2.968	-	-	-	-	-	-	-	Continuing	Continuing
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	-	-	-	1.728	-	1.728	1.757	1.987	2.025	2.066	Continuing	Continuing
306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>	-	-	-	1.728	-	1.728	1.758	1.988	2.026	2.066	Continuing	Continuing
372A: <i>GDF Applied Biomedical Technology</i>	59.305	33.023	37.755	43.579	-	43.579	53.913	64.631	68.517	73.488	Continuing	Continuing
447A: <i>Military HIV Research Program (Army)</i>	0.000	8.410	7.175	8.066	-	8.066	8.212	9.289	9.465	9.654	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Guidance for Development of the Force - Applied Biomedical Technology: This applied research funding is to refine concepts and ideas into potential solutions to military health and performance problems, with a view towards evaluating technical feasibility. Included are studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. Research in this Program Element (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 sustainment of priority investments in science, technology, research, and development as stated the strategy and initiatives described in the Quadrennial Defense Review. Program development is peer-reviewed and fully coordinated with all 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. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) funding. Research supported by this PE includes hemorrhage (bleeding) and resuscitation, diagnosis and treatment of brain injury,

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0602115HP / <i>Applied Biomedical Technology</i>
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treatments for extremity trauma (injury to tissue, head, face, jaw, and mouth, lungs, and burns), forward surgical intensive critical care, and en route care. Operational medicine efforts focus on injury prevention and reduction, psychological health and resilience, physiological health, and environmental health. Rehabilitation applied research focuses on neuromusculoskeletal injuries, pain management, regenerative medicine and sensory systems. Applied research efforts are also developing radiation medical countermeasures. And, within the area of military infectious diseases, applied researchers focus on wound infection prevention and antimicrobial countermeasures. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115HP) or advanced concept development (PE 0604110HP) funding.

For the Army Medical Command, beginning in FY14, the military HIV research program funding is transferred from the Army to the Defense Health Program. Work in this area includes refining improved identification methods to determine genetic diversity of the virus, preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and evaluating and preparing overseas sites for clinical trials with these vaccine candidates.

For the Army Medical Command, beginning in FY15, funding is provided to develop strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds through the Combating Antimicrobial Resistant Bacteria - WRAIR Discovery and Wound Program.

The Army Medical Command also received DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury and Psychological Health Research. Because of the CSI annual structure, out-year funding is not programmed.

For the Air Force, this PE funds applied research which seeks to promote 'omic'-informed personalized medicine, advanced diagnostic technologies and occupational toxicology with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve health in Warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This applied research supports multiple focus areas, each of which represents an identified barrier/gap which must be addressed for successful implementation of 'omic'-informed personalized medicine. Focus areas for applied research include knowledge generation research; ethical legal and social issues/policy research; bioinformatics research; educational research; research for development of advanced genomic diagnostic system. For efforts supported by this program element, research will be pursued with the intent to support solutions that answer Air Force specific needs. During this process, the efforts of other government agencies in those areas will be assessed to avoid redundancy.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0602115HP / <i>Applied Biomedical Technology</i>
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B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	46.761	47.898	55.101	-	55.101
Current President's Budget	59.968	73.201	58.251	-	58.251
Total Adjustments	13.207	25.303	3.150	-	3.150
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	15.000	25.303			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.793	-			
• Realignment in Support of the Global Health Security Agenda (GHSA) Initiative - Project 246A	-	-	3.150	-	3.150

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 200A: *Congressional Special Interests*

Congressional Add: 426A – *Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)*

Congressional Add: 469A – *CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)*

Congressional Add: 469B – *CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)*

Congressional Add: 462A – *CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)*

Congressional Add Subtotals for Project: 200A

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	15.000	-
	-	4.941
	-	0.742
	-	19.620
Congressional Add Subtotals for Project: 200A	15.000	25.303
Congressional Add Totals for all Projects	15.000	25.303

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-\$1.793 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$1.793 million).

FY 2014: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+\$15.000 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+\$25.303 million).

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: <i>Defense Health Program I BA 2: RDT&E</i>	PE 0602115HP / <i>Applied Biomedical Technology</i>

FY2016: Realignment Global Health Security Agenda (GHS) adjustment to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+\$3.150 million).

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 200A / <i>Congressional Special Interests</i>
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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
200A: <i>Congressional Special Interests</i>	55.883	15.000	25.303	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

For FY14, DHP Congressional Special Interest (CSI) funding is directed to stimulate innovative research through a competitive, peer-reviewed research program focused on peer-reviewed traumatic brain injury and psychological health research. Because of the CSI annual structure, out-year funding is not programmed.

The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0602115 - Applied Biomedical Technology. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)	15.000	-
FY 2014 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program aimed to execute studies that inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, veterans, family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing DoD efforts to ensure the health and readiness of our military forces by promoting a better standard of care for psychological health disorders and TBI in the areas of prevention, detection, diagnosis (identification of the nature and cause of an illness), treatment, and rehabilitation. Program announcements, programmatic reviews, Service-requested nominations, and ongoing studies that would benefit from program acceleration have been incorporated to address these priorities and gather proposals. In the area of TBI, researchers performed investigations to find a universally-agreed upon concussion grading system, and continued experiments into the effects of penetrating injuries on the brain and experiments on the effects of blasts on the brain. Proposals were solicited in the areas of blast-induced hyper-acceleration upon the generation of TBI and the role of inflammation in spreading TBI damage. Multiple awards relevant to combat casualty care were made including development of a large animal model of penetrating ballistic brain injury and development of metrics to define concussion and grade TBI. In the area of psychological health, researchers performed investigations to diagnose, prevent, and reduce symptoms of PTSD, and understand predictors of violence among workers in military settings.		
Congressional Add: 469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)	-	4.941

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 200A / <i>Congressional Special Interests</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<p>FY 2014 Accomplishments: No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.</p> <p>FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Applied Biomedical Technology Program Element (PE) - 0602115.</p>		
<p>Congressional Add: 469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)</p> <p>FY 2014 Accomplishments: No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.</p> <p>FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Applied Biomedical Technology Program Element (PE) - 0602115.</p>	-	0.742
<p>Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)</p> <p>FY 2014 Accomplishments: No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.</p> <p>FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Applied Biomedical Technology Program Element (PE) - 0602115.</p>	-	19.620
Congressional Adds Subtotals	15.000	25.303

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Individual efforts are monitored through a quarterly project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives), key performance parameters, and resolution of Force Health Protection gaps. Variances, deviations, and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of Science and Technology (S&T) governance. Annual reviews are also conducted in person for all of the projects within a specific program area.

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 246A / <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>
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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
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	-	-	-	3.150	-	3.150	3.157	2.552	1.949	1.949	Continuing	Continuing

A. Mission Description and Budget Item Justification

At the President's direction in late 2013, a National Strategy was created to address the critical issue of antimicrobial resistance. This strategy was devised using an interagency approach and ultimately approved at the executive level (2014). Inherent in this work are DoD sponsored efforts to support the DOD's beneficiaries, but that simultaneously complement national efforts to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria. One critical need identified is for new therapeutics, to include antibiotics. This effort's focus is on the development of new/novel antibiotics, especially one targeting the most resistant and worrisome Gram negative bacterial pathogens, using existing expertise at the Walter Reed Army Institute of Research (WRAIR), and leveraging other WRAIR capabilities to identify viable candidate targets for advanced discovery. This project supports (both directly and indirectly) Global Health Security Agenda priorities to respond rapidly and effectively to biological threats of international concern.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	-	-	3.150
Description: Initiate an antibacterial (AB) drug discovery program directed toward military relevant drug-resistant bacteria that (a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, (b) opens active intramural-based discovery efforts of new potential products/candidates/leads for development, and (c) initiates partnerships with external collaborators to develop/co-develop new potential AB treatment therapeutics.			
FY 2014 Accomplishments: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2015 Plans: Funding will be made available in the year of execution (FY2015). First year of funding establishes the research program and initiates assessment of antibacterial programs from companies that have exited the commercial antibacterial drug discovery (direct contact and literature publications) market for potential leads; identifies and hire staff; develops desired therapeutic product profile criteria and DoD-focused Target Product Profiles to meet military requirements; identifies chemical hits/leads with development potential; performs assays to assess potential lead candidates; synthesizes key chemical compounds and newly designed lead optimization chemical compounds; begins to establish in vivo (living organism) model standards; identifies late stage potential			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 246A / <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
external programs that could potentially treat military relevant resistant bacteria; establishes agreements if intellectual property is involved; acquires 2-4 compounds and assesses for effectiveness in laboratory and/or animal models. FY 2016 Plans: Applied research efforts will continue to identify chemical compounds for assessment in the laboratory and testing in animals, and complete market analysis of external antibiotic programs to identify small molecules that are in early drug discovery (pre-clinical, 1-4 years away from advanced development) that may be expanded or elaborated. Will obtain rights if intellectual property is owned by existing companies or complete partner agreements in order to explore and co-develop new antibiotics leads, then conduct screening against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) to select compounds for continued development.			
Accomplishments/Planned Programs Subtotals	-	-	3.150

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

An Acquisition Strategy will be developed to support future Milestone B when a clinical development candidate is identified and reaches TRL-6.

E. Performance Metrics

Performance metrics of the CARB drug discovery program will be provided through semi-annual status reports, periodic reviews by the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR) conducted by USAMRMC Decision Gate process. The performance metric benchmark is progression of research projects to Technology Readiness Level (TRL) 5 and their schedule to transition.

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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 0602115HP / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>			
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
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	3.377	3.535	2.968	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Advanced Diagnostics & Therapeutics Clinical Translational Applied Research (Air Force): This project provides applied research funding needed to increase efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Modernization Thrust Areas to improve and enhance clinical Diagnosis, Identification, Quantification and Mitigation (DIQM) methods, techniques protocols, guidelines and practices for all DoD wounded, ill and/or injured beneficiaries.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	3.535	2.968	-
Description: This project provides applied research funding needed to perform research in the area of diagnostic assay development/refinement for diseases of operational significance. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and support research of evidence based therapeutics.			
FY 2014 Accomplishments: Continued to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Perform AF Surgeon General directed deep dive on Health as a National Strategic Imperative/Lifestyle Medicine. Continued review of nanotechnology research projects at the Massachusetts Institute of Technology as they relate to En-Route Care and Expeditionary Medicine missions. Transfer the leadership of the continuing forum to educate leaders on futures based thinking from AFMS/SG to OSD/HA. Continued support and development of Personalized Medicine/Genomic Medicine through specific outcome-based milestones for upcoming PC2 task assignment. Continue to leverage joint diagnostic efforts to meet AF mission requirements. Continue to analyze findings / outcomes of intramural project to identify and characterize epigenetic biomarkers of stress caused by high altitude conditions in a collaborative clinical translational research project in collaboration with the Uniformed Services University of the Healthcare Sciences (USUHS) to clinical practice / practice guidelines. Continue to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Perform AF Surgeon General directed deep dive on Health as a National Strategic Imperative/Lifestyle Medicine. Continued review of nanotechnology research projects at the Massachusetts Institute of Technology as they relate to En-Route Care and Expeditionary Medicine missions. Transfer the leadership of the continuing forum to educate leaders on futures based thinking from AFMS/SG to OSD/HA. Continued support and development of Personalized Medicine/Genomic Medicine through specific outcome-based milestones for upcoming PC2 task assignment. Continue to leverage joint diagnostic efforts to meet AF mission requirements. Continue to analyze findings /			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>outcomes of intramural project to identify and characterize epigenetic biomarkers of stress caused by high altitude conditions in a collaborative translational research project in collaboration with the Uniformed Services University of the Healthcare Sciences (USUHS) to clinical practice / practice guidelines. Began project evaluating Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) and Influenza A/H7N9 on the Biomeme smart-device based pathogen identification system to meet USAF requirements for infectious disease characterization. Initiated project to reduce the time to detection of the etiological agent(s) responsible for sepsis infection. Obtained IRB approval for analysis of the Chagas disease threat within high-risk military and civilian populations. Completed allelic discrimination of single nucleotide polymorphisms associated with metformin response in MHS patients with Type II Diabetes.</p> <p>FY 2015 Plans: Continue to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Develop a process to effectively evaluate potential therapies/diagnostics/solutions to improve practices across the AFMS Complete AFMS Innovations nanotechnology research projects in collaboration with the Massachusetts Institute of Technology to address gaps in Hemorrhage control/hydration status, Pain management portable ultrasonography, and Compartment syndrome. Complete genomics clinical utility study.</p> <p>FY 2016 Plans: No Funding Programmed.</p>			
Accomplishments/Planned Programs Subtotals	3.535	2.968	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc).

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306C / <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>
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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
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	-	-	-	1.728	-	1.728	1.757	1.987	2.025	2.066	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project provides applied research funding needed to perform research in the area of assay development/refinement for diseases of operational significance/ conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Adv Diagnostics & Epigenomics Applied Research (AF)	-	-	1.728
Description: This project provides applied research funding needed to perform research in the area of assay development/refinement for diseases of operational significance/conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: In support of personalized treatment for type 2 diabetes and cardiovascular disease, provide a predictive genetic therapeutic strategy based on pharmacogenetic therapies at the onset of diagnosis and aimed at delaying disease progression. Perform intramural project for the rapid identification of etiological pathogens of sepsis in support of same-day treatment-specific modalities. Leverage joint personalized medicine efforts to identify biomarkers of physiological response to opioid use. Transition smartphone-based pathogen identification system to meet Air Force requirements for personalized medicine and infectious disease characterization. Provide an analysis of the Chagas disease threat within high-risk military populations to determine if force health protection measures should be implemented to decrease exposure risk.			
Accomplishments/Planned Programs Subtotals	-	-	1.728

C. Other Program Funding Summary (\$ in Millions)

N/A

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306C / <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>

C. Other Program Funding Summary (\$ in Millions)

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306D / <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>
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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
306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>	-	-	-	1.728	-	1.728	1.758	1.988	2.026	2.066	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	-	-	1.728
Description: This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Begin to develop advanced diagnostics for brain effects from hypobarica in USAF high altitude ops. Develop mitigation approaches and therapeutics to counter effects from air transport and low-dose hypobaric exposures to the brain and traumatized organ systems. Develop passive dosimeters to support 24/7 exposure monitoring.			
Accomplishments/Planned Programs Subtotals	-	-	1.728

C. Other Program Funding Summary (\$ in Millions)

N/A

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306D / <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>

C. Other Program Funding Summary (\$ in Millions)

Remarks

D. Acquisition Strategy

ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.***

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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 0602115HP / <i>Applied Biomedical Technology</i>				Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>			
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
372A: <i>GDF Applied Biomedical Technology</i>	59.305	33.023	37.755	43.579	-	43.579	53.913	64.631	68.517	73.488	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: Applied biomedical technology research will focus on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research will be conducted in the general categories of trauma, polytrauma (multiple traumatic injuries) and blast injury, rehabilitation, diagnosis and treatment of brain injury, radiation countermeasures, operational health and performance, physiological health, and psychological health and well-being for military personnel and families. Trauma, polytrauma and blast injury applied research focuses on control of bleeding, tissue viability (survival potential of a tissue or organ), diagnosis and life support, cranio-maxillofacial (head, neck, face, and jaw) injury, evacuation applications and practices, forward surgical applications, blast injury models and performance standards for protection systems, blast induced brain injury models, diagnostics and metrics for hearing loss and protection, blast exposure and breaching (process used to force open closed and/or locked doors), scar contracture (tightening of muscle, tendons, ligaments or skin that prevents normal movement), treatment of ocular and visual system traumatic injury, wound infection prevention and management, rapid screening of fresh whole blood, and antimicrobial (a substance that kills or inhibits the growth of microorganisms) countermeasures. Applied research in traumatic brain injury (TBI) focuses on diagnosis and treatment, disentanglement of combat stress injuries, and TBI in evaluations and clinical management. Operational medicine applied researchers also focus on injury prevention strategies for training and operational environments, sustainment of operational performance, early assessment and interventions to support Service member psychological and cognitive health, nutrition and dietary supplements, military, family and community psychological health and resilience, biomarkers of inhalation and other exposure to toxic substances, and military operational computational modeling. Applied research in radiation countermeasures includes activities to demonstrate capabilities to treat and mitigate the effects of acute radiation syndrome following radiation exposure.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: GDF Applied Biomedical Technology	33.023	37.755	43.579
Description: Applied Biomedical Technology Research focuses on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development.			
FY 2014 Accomplishments:			
Military infectious disease research supported the development of the rapid Nucleic Acid Test screening of donor derived fresh whole blood in emergency settings for infectious diseases. Down selection of the Nucleic Acid Testing platform was moved to the right one year due to technical issues with industry partners and will be done in Q1FY15. Five projects were funded with the aim to develop antimicrobial countermeasures to combat multiple-drug resistant bacterial infections, and to identify and validate host and pathogen biomarkers to detect bacterial infections in wounds. Under acute respiratory diseases, continued support to maintain core competency (subject matter experts).			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>Military operational medicine is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction conducted applied research studies on blast injury models and performance standards for protections systems, blast exposure during breaching (process used to force open closed and/or locked doors), and diagnostics and metrics for hearing loss and protection. Psychological health and resilience focused on providing solutions that build service members, family and community resilience to sustain and restore psychological health and readiness, diagnosis of deployment-related psychological health problems, diagnosis of post-traumatic stress disorder (PTSD), military family and warfighter resilience, and suicide prevention. Physiological health conducted research on nutrition and dietary supplements, and the environmental health portfolio focused on pulmonary (pertaining to the lungs) health in the deployed environment, the incidence of pulmonary disease in returned warfighters, and warfighter performance and sustainment in extreme environments (such as extreme heat, cold, or altitude).</p> <p>Combat casualty care research supported multi-year studies, initiated in FY12 and FY13 with applied research being divided into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, and joint enroute care. Within the hemorrhage and resuscitation portfolio, a consortium of universities took a systems biology approach to studying the coagulopathy of trauma. Others efforts studied techniques for modulating inflammation. The neurotrauma research efforts studied mechanisms and treatments for TBI, distinguished between primary and tertiary blast injury, evaluated neurophysiologic and systematic changes during aero-medical evacuation and enroute care, investigated TBI in animals using advanced magnetic resonance imaging (MRI) and histopathology (microscopic examination of tissue) techniques, conducted a military relevant model of closed concussive head injury in longitudinal studies characterizing and validating single and repetitive mild TBI, and developed biomarkers in animals for progressive tau (human brain protein) pathology after TBI. The traumatic tissue injury research portfolio is starting pre-clinical trials in face restoration. Forward surgical/intensive critical care research started research to address pre-hospital care, emergency care, surgical care, intensive care, nursing care, advanced monitoring and battlefield medical equipment. Joint enroute care conducted studies to automate comprehensive clinical practice guidelines to improve enroute care of combat casualties, to access blood vessels in hemorrhagic (profuse bleeding) cases, and characterize human blood vessels in normal and low blood pressure trauma patients. Promising candidate products were evaluated for transition from applied research into technology development.</p> <p>Radiation health effects research pursued strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conducted animal studies in mice and non-human primates to characterize several compounds with the potential to mitigate or prevent Acute Radiation Syndrome resulting from lethal doses of radiation. Additional efforts identified targets for safe, effective, and FDA-approved prevention, mitigation or treatment of radiation injury, and increased understanding of the molecular mechanisms by which radiation injuries are initiated and cell cycling pathways triggered leading to multi-organ system dysfunction and death.</p>			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Clinical and rehabilitative medicine conducted studies in neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury that identified and evaluated candidate approaches for incorporation into restoration and rehabilitation strategies and medical products. Specific focus areas included: neuromusculoskeletal injury rehabilitation strategies and devices, prosthetics & orthotics (device/support that corrects/relieves an orthopedic problem), neural interfaces (invasive and non-invasive methods of using the brain for device control), the prevention of heterotopic ossification (growth of bone in abnormal places like soft tissue), and treatment of training injuries to the musculoskeletal system; novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb (extremities) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury); and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. Clinical and rehabilitative medicine supported studies that started in FY13 and focused on evaluating and down-selecting novel diagnostic and treatment strategies in the areas of pain management and sensory system (vision, hearing, and balance) restoration and rehabilitation.</p> <p>FY 2015 Plans: Military infectious disease research is supporting multi-year studies in wound infection prevention and management and antimicrobial countermeasures; development of four novel FDA-approved therapeutics (e.g., drugs) to mitigate wound infection & biofilm processes, developing tools and practices for the detection/prevention of microbial infections in wounds and/or guide clinical wound management, performing confirmatory laboratory studies and initial animal studies to demonstrate drug potency and demonstrate biomarker accuracy and degree of confidence in identifying pathogens. Efforts to maintain core competency (subject matter expertise) in acute respiratory diseases and diagnostic systems for infectious diseases are continuing.</p> <p>Military operational medicine is grouped into four portfolios of injury prevention and reduction, psychological health, physiological health, and environmental health and performance. Injury prevention and reduction is establishing risk factors for heat injury susceptibility, establishing blast injury animal models for low-level repetitive blast exposure standards, and developing models of inner ear function to establish hearing injury criteria. Psychological health portfolio research is performing retrospective analysis of military workplace violence, examining reintegration difficulties following deployment, establishing an animal model for dependency and withdrawal associated with substance abuse, and establishing associations between deployment and psychological and physiological health problems. Physiological health is developing a reporting system for adverse events associated with dietary supplement use, and developing computational models that can predict bone and muscle health status. Environmental health and performance is studying select candidate biomarkers (biological indicators of health outcomes and disease) for inhalation exposure to toxic substances, and conducting dehydration studies to select stress biomarkers of hydration status.</p>			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Combat casualty care applied research is grouped into portfolios for hemorrhage (bleeding) and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, and joint enroute care. The hemorrhage and resuscitation research portfolio is supporting studies assessing the effectiveness of Valproic Acid, a FDA-approved anti-seizure drug, and ethinyl estradiol to increase survival of severe hemorrhage, establishing effects of modulating the inflammatory immune response associated with hemorrhagic shock and trauma. Neurotrauma research is developing traumatic brain injury (TBI) biomarkers (indicator of biological state or the past or present existence of a particular type of organism or molecule) and screening tools. The Traumatic tissue injury research portfolio is supporting treatments to address acute lung injury and to enhance healing of complex injuries of the face, extremities, groin and pelvis. Forward surgical intensive critical care is researching resuscitative interventions through seamless critical care. Enroute care, research aims to improve field management and safe air transport of patients with head and spine injuries.</p> <p>Radiation health effects research pursues strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conduct animal studies in mice and non-human primates to address research data gaps and to characterize several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. The research aims to identify mechanisms of action, effectiveness, and safety in animal models in the development of therapeutics for ARS hematopoietic (bone marrow) sub-syndrome.</p> <p>Clinical and rehabilitative medicine research is conducting applied research in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury. The neuromusculoskeletal injury portfolio is examining the impact of biopsychosocial effects on rehabilitation, improving the current technology available for residual limb-device interface, and developing objective metrics for device prescription and training. In pain management, research is studying enhanced chronic pain management using receptor antagonists (agents that block biochemical responses). Regenerative medicine research is studying novel tissue-engineered nerve grafts for currently unrepairable nerve injury, and treatment for re-innervated (restored nerve function) muscle. Sensory systems research is studying pre-clinical testing of sustained release drugs to prevent blinding complications following eye injury, and developing therapeutic drugs for hearing restoration after noise induced hearing loss.</p> <p>FY 2016 Plans: Military infectious diseases research will support multi-year studies in wound infection prevention and management and antimicrobial countermeasures, and will continue development efforts of four antibacterial projects and two projects for the detection of microbial infections in wounds. Studies will be aimed at development of novel therapeutics (drugs), biomarkers and clinical practice guidelines to mitigate wound infection and biofilm processes. Molecule(s) showing efficacy in laboratory studies</p>			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>and initial animal studies, and/or biomarkers demonstrating accuracy in identifying pathogens will be further developed. Efforts to maintain core competency (subject matter expertise) in acute respiratory diseases will be continued.</p> <p>Military operational medicine is grouped into four portfolios of injury prevention and reduction, psychological health, physiological health, and environmental health and performance. Injury prevention and reduction will perform validation studies of risk factors for heat injury susceptibility, will validate blast injury animal models for low-level repetitive blast exposure standards, and will improve models of inner ear function to establish hearing injury criteria. Psychological health will conduct research to establish predictors of military workplace violence, will develop strategies for effective reintegration following deployment, and will continue establishing associations between deployment and psychological and physiological health problems to inform development of policies and guidelines. Physiological health will develop interventions for sustainable weight loss in military families, and will continue the development of computational models that can predict bone and muscle health status. Environmental health and protection portfolio research will refine candidate biomarkers (biological indicators of health outcomes and disease) for inhalation exposure to toxic substances and for stress response to mild and moderate dehydration in clinical populations.</p> <p>Combat casualty care applied research is divided into portfolios for hemorrhage (bleeding) and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, and joint enroute care. Hemorrhage and resuscitation will identify new diagnostic tools and continue the development of treatments for abnormal hemorrhage following injury. Neurotrauma research will further develop traumatic brain injury (TBI) biomarkers and screening tools for far-forward medical evaluation of warriors. Forward surgical intensive critical care will study the effectiveness of acute lifesaving interventions in the pre-hospital/hospital setting. Traumatic tissue injury researchers will study the mechanisms of acute lung injury, and research the use of lasers to prevent scar tissue formation. Enroute care will study the physiology of patient transport (effects of altitude, temperature on patients), and develop new non-invasive monitoring technologies.</p> <p>Radiation health effects research will continue strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Will conduct animal studies in mice and non-human primates to address research data gaps and to characterize several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. Mitigators and therapeutics of ARS will focus primarily on bone marrow (hematopoietic), and to a lesser degree on gastrointestinal and pulmonary sub-syndromes. Based on research accomplishments, compounds will be evaluated as potential candidates for transition toward advanced development. Will identify mechanisms of action and demonstrate proof of principle for radioprotectants (prophylactics). Additional efforts will identify targets for safe, effective, and FDA-approved prevention, mitigation or treatment of radiation injury, and will increase understanding of the molecular mechanisms by which radiation injuries are initiated and cell cycling pathways triggered leading to multi-organ system dysfunction and death.</p>			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Clinical and rehabilitative medicine research will pursue down-selection of candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing, sight and balance) system traumatic injury. Will conduct applied research in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation after service-related injuries. Will study the effectiveness of leading solutions to alleviate acute and chronic battlefield pain, investigate solutions to replace or regenerate human cells, tissues, or organs to restore or establish normal tissue function, and conduct applied research to identify therapeutic targets to restore visual, auditory, and vestibular dysfunction associated with traumatic injury.			
Accomplishments/Planned Programs Subtotals	33.023	37.755	43.579

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Evaluate technical feasibility of potential solutions to military health issues. Implement models into data or knowledge and test in a laboratory environment. Milestone A packages will be developed to transition promising products to technology development funding.

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports to include information on publications, intellectual property, additional funding support, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with applied research funding is the attainment of a maturity level that is at least Technology Readiness Level (TRL) 4, and typically TRL 5, or the equivalent for knowledge products. Products nearing attainment of TRL 5 will be considered for transition.

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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 0602115HP / <i>Applied Biomedical Technology</i>				Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>			
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
447A: <i>Military HIV Research Program (Army)</i>	-	8.410	7.175	8.066	-	8.066	8.212	9.289	9.465	9.654	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project conducts research on the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS). Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for clinical trials with global vaccine candidates. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals. This project is jointly managed through an Interagency Agreement between US Army Medical Research Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). This project contains no duplication of effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas, and supports the principal area of Military Relevant Infectious Diseases to include HIV.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Military HIV Research Program	8.410	7.175	8.066
Description: This project conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
FY 2014 Accomplishments: Program transitioned from the Army to DHP. Identified and characterized new populations who are at high risk of being infected with HIV for clinical evaluation of potential new vaccine candidates. Identified and develop new clinical trial sites at overseas locations to test and down-select best candidates for HIV vaccine. Initiated production of additional vaccines for various world-wide HIV subtypes and initiated pre-clinical evaluation in non-human primates. Identify and characterize new populations who are at high risk of being infected with HIV for clinical evaluation of potential new vaccine candidates. Identify and develop new clinical trial sites at overseas locations to test and down-select best candidates for HIV vaccine. Initiate production of additional vaccines for various world-wide HIV subtypes and initiate pre-clinical evaluation in non-human primates.			
FY 2015 Plans: Complete production of additional vaccine candidates for various world-wide subtypes. Develop improved methods to evaluate immune responses to selected HIV vaccine candidates in non-human primates. Analyze host genetic factors related to HIV			

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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 0602115HP / <i>Applied Biomedical Technology</i>	Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
acquisition and disease progression in acute HIV infection to inform vaccine development. Complete down-selection of best candidates for use in Phase 1 safety studies in human volunteers. FY 2016 Plans: Will continue to produce additional vaccine candidates for various world-wide subtypes. Will characterize these new sub-types and evaluate their capability to induce protective immune responses in non-human primates. Will down-select one or more vaccine candidates for use in safety studies in human volunteers.				
Accomplishments/Planned Programs Subtotals		8.410	7.175	8.066
C. Other Program Funding Summary (\$ in Millions) N/A				
Remarks The program receives periodic funding from Division of AIDS of NIAID ranging from \$10-20 M/year through an Interagency Agreement with USAMRMC.				
D. Acquisition Strategy N/A				
E. Performance Metrics Performance of the HIV research program is monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR) conducted via the USAMRMC Decision Gate process to include Defense Health Agency representation.				

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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 0602787HP I *Medical Technology (AFRRI)*

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	4.718	1.139	1.241	1.222	-	1.222	1.242	1.331	1.356	1.383	Continuing	Continuing
020: <i>CSI - Congressional Special Interests</i>	0.000	-	0.124	-	-	-	-	-	-	-	Continuing	Continuing
241A: <i>Biodosimetry (USUHS)</i>	0.963	0.232	0.228	0.249	-	0.249	0.254	0.272	0.277	0.283	Continuing	Continuing
241B: <i>Internal Contamination (USUHS)</i>	0.500	0.121	0.119	0.131	-	0.131	0.133	0.143	0.146	0.149	Continuing	Continuing
241C: <i>Radiation Countermeasures (USUHS)</i>	3.255	0.786	0.770	0.842	-	0.842	0.855	0.916	0.933	0.951	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), Armed Forces Radiobiology Research Institute (AFRRI), this program supports developmental research to investigate new approaches that will lead to advancements in biomedical strategies for preventing, treating, assessing and predicting the health effects of human exposure to ionizing radiation. Program objectives focus on preventing or mitigating the health consequences from exposures to ionizing radiation that represent the highest probable threat to U.S. forces in current tactical, humanitarian and counterterrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both short-and long-term risks of adverse health consequences. Advances in assessment, prognostication, and therapy in case of actual or suspected radiation exposures will enhance triage, treatment decisions and risk assessment in operational settings.

B. Program Change Summary (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	1.216	1.117	1.222	-	1.222
Current President's Budget	1.139	1.241	1.222	-	1.222
Total Adjustments	-0.077	0.124	-	-	-
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	0.124			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.077	-			

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 020: *CSI - Congressional Special Interests*

Congressional Add: 472A – Program Increase: Restore Core Research Funding Reduction (USUHS)

FY 2014	FY 2015
-	0.124

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0602787HP I <i>Medical Technology (AFRRI)</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2014	FY 2015
Congressional Add Subtotals for Project: 020	-	0.124
Congressional Add Totals for all Projects	-	0.124

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0602787-Medical Technology (AFRRI) (-\$0.077 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.077 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (+\$0.124 million).

FY 2016: No Change.

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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 0602787HP / Medical Technology (AFRRI)				Project (Number/Name) 020 / 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
020: CSI - Congressional Special Interests	-	-	0.124	-	-	-	-	-	-	-	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) 0602787 - Medical Technology (AFRRI). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 472A – Program Increase: Restore Core Research Funding Reduction (USUHS)	-	0.124
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 Technology (AFRRI) Program Element (PE) - 0602787.		
Congressional Adds Subtotals	-	0.124

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0602787HP / <i>Medical Technology (AFRRI)</i>				Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>			
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
241A: <i>Biodosimetry (USUHS)</i>	0.963	0.232	0.228	0.249	-	0.249	0.254	0.272	0.277	0.283	Continuing	Continuing

A. Mission Description and Budget Item Justification

Biodosimetry (USUHS): For the Uniformed Services University of the Health Sciences (USUHS), the mission and research objectives for biodosimetry are to assess radiation exposure by developing and providing biological and biophysical dosimetry capabilities for acute, protracted, and prior radiation exposures.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Biodosimetry (USUHS)	0.232	0.228	0.249
FY 2014 Accomplishments:			
<ul style="list-style-type: none"> -Established the dosimetry map for protracted (Low-Dose-Rate or LDR) 60Co irradiation for murine model; initiated comparison studies between LDR and prompt radiation on selected biomarkers in murine models. -Completed study evaluating effects of 2 different dose rates on hematology and select proteomic biomarkers. -Began to evaluate protein biomarkers, hematological parameters, and clinical signs ranging 1d – 2d in partial-body irradiated mice. -Continued to evaluate whether epigenetic markers can be used to discriminate low-dose from high-dose radiation. -Determined if there is a chromosomal aberration difference between external radiation and internalized depleted uranium. -Evaluated whether the profile of chromosomal aberrations in human samples are able to discriminate uranium exposure from other toxic exposures. -Determined histological effects of radiation on intestinal organoid cultures. -Sent conditioned media samples from irradiated intestinal organoid cultures for proteomic analysis by liquid chromatography-tandem mass spectrometry to identify biomarkers. -Investigated impact of improving chromosome condensation on the ability to automate detection and counting of interphase chromosome aberrations. 			

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>-Developed and integrated a spooler for automatic gene expression data inclusion from experiments and literature for indexing into the automated analysis system.</p> <p>-Evaluated applicability of new hardware, imaging tools, and suitability for use of mobile platforms and tablets in the automated chromosome aberration scoring system.</p> <p>-Sustained efforts to provide necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable).</p> <p>-Reported on evaluation of both radiation induced hematological and plasma protein biomarkers in the early-phase after irradiation partial-body exposure model using x-ray source with lead shielding and mice restrained by holders.</p> <p>FY 2015 Plans:</p> <p>-Sustain studies evaluating new radiation-responsive biomarkers in animal models for early-phase and organ-specific bioindicators.</p> <p>-Begin a pilot study using samples from the mouse and NHP total-body irradiation models to permit testing of the measurement of novel tissue- and organ-specific biomarkers in peripheral blood using commercially available antibodies and assays developed at AFRRI.</p> <p>-Begin to analyze blood chemistry data collected in the NHP dose-response study with limited supportive care and in the high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs.</p> <p>-Begin to analyze results of necropsies performed on NHPs (limited and full supportive care) to determine the radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers. -</p> <p>-Initiate studies to evaluate effects of even lower dose rates on hematology and select radiation biomarkers.</p> <p>-Determine whether epigenetic markers can discriminate between chronic low dose and repeated low dose exposures.</p> <p>-Determine whether epigenetic markers can discriminate between external radiation and internalized depleted uranium.</p> <p>FY 2016 Plans:</p> <p>-Establish a partial-body radiation model using mice involving exposure of the abdomen with AFRRI's small animal irradiator to support studies identifying and validating organ (i.e., small intestine, kidney) injury biomarkers.</p> <p>-Establish murine model system to measure low dose epigenetic markers.</p> <p>-Examine radiation-induced mitochondrial DNA (mtDNA) deletion in animal samples from low and high doses of radiation exposure using a nested real-time PCR method, and evaluate the sensitivity and specificity of mtDNA deletion in response to gamma-radiation.</p> <p>-Develop a circulating micro-RNA profile in γ-irradiated animal model. Select the radiation-sensitive micro-RNAs that are stable and easy to calibrate in serum as radiation biomarkers to monitor radiation injury and efficacy of radiation countermeasures.</p> <p>-Evaluate proinflammatory cytokines as biomarkers to monitor ionizing radiation-induced acute and chronic injury and evaluate the efficacy of radiation countermeasures.</p>			

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
-Determine the mechanisms of circulating micro-RNA and proinflammatory cytokine release after radiation exposure.			
Accomplishments/Planned Programs Subtotals	0.232	0.228	0.249

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY14

- Identify radiation biomarkers that are dependent on exposure dose-rate and specific for various ARS subsyndromes.
- Demonstrate accurate radiological detection of radiation biomarkers from biological samples into quartiles of doses 0-1 Gy, 1-3 Gy, 3-6 Gy, 6-10 Gy, and greater than 10Gy.
- Characterize partial-body radiation murine models over a protracted time period and compare results with prompt irradiation on selected biomarkers.
- Provide preliminary analysis of the enhanced utility of combined hematological and protein biomarkers for biodosimetry applications following photon and mixed fieldneutron total-body irradiations in a total-body irradiation murine model.
- Identify subset of biomarkers useful for radiation dose assessment when confounded with thermal burns.
- Complete report of select radiation biomarkers that are dependent upon dose-rate.
- Report on gender and age effects as well as partial-body irradiation effects on the evaluated panel of protein biomarkers in mouse model.
- Submit samples from radiation-exposed intestinal epithelial cell organoid cultures for Liquid Chromatography-Tandem Mass Spectrometry analysis for novel radiationbiomarker discovery.
- Score histological injury to intestinal organoid cultures after irradiation.
- Measure specific methylation and histone changes using RT-PCR in low dose and high dose bronchial cells.
- Measure chromosomal aberrations in lymphocytes from gamma ray and depleted uranium exposed mice (spleen tissues).
- Measure intra-chromosomal aberrations using mBAND technology in human samples from individuals potentially exposed to toxic materials during deployment.
- Improve condensation of interphase chromatin into discrete chromosomes capable to be read through high-throughput image capture tools.
- Establish and incorporate Absorption Color Pigment (ACP) method for automated image extractors within CLASP.
- Provide report to validate specificity and sensitivity statistical models for the automated image system and analyses thereby testing CLASP efficiency.
- Evaluate the applicability and efficiency of developed SOPs after inclusion of multi-parametric approaches within CLASP.

By FY15

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>
<p>-Characterize partial-body radiation murine models over a protracted time period and compare results with prompt irradiation on selected biomarkers.</p> <p>-Perform a pilot study using samples from the mouse and NHP total-body irradiation models to permit testing of the measurement of novel tissue- and organ-specific biomarkers in peripheral blood using commercially available antibodies and assays developed at AFRRI.</p> <p>-Complete analysis of blood chemistry data collected in the NHP dose-response study with limited supportive care and in the high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs.</p> <p>-Complete analysis of results of necropsies performed on NHPs (limited and full supportive care) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers.</p> <p>-Begin to evaluate the identified tissue- and organ-specific biomarkers in partial-body irradiation models.</p> <p>-Provide necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable) and obtain the necessary FDA approval. Prepare preliminary report for FDA on combined utility of hematological and protein biomarkers for biodosimetry applications in two FDA-required animal models.</p> <p>-Identify other radiation biomarkers that are dependent on exposure dose-rate.</p> <p>-Validate dosimetric response of 3 biomarkers from IEC organoids exposed to 0-16 Gy gamma-ray radiation.</p> <p>-Measure specific methylation and histone changes using RT-PCR in low dose and high dose murine spleen samples.</p> <p>-Identify proteomic markers from irradiated organoid cultures for validation by enzyme linked immunosorbent assay.</p> <p>-Characterize dose profile for partial-body exposures using AFRRI's small animal irradiator (SAARP).</p> <p>-Establish assays for candidate radiation biomarkers for assessment of injury to specific radiation-sensitive organs.</p> <p>-Initiate studies to evaluate radiation-induced chromosomal damage in murine radiation model.</p> <p>By FY16</p> <p>-Initiate partial-body exposure study to characterize organ specific injury biomarkers using abdomen exposures of mice.</p> <p>-Report on measurements of miRNA levels to identify organ-specific injury biomarkers.</p> <p>-Measure the incidence of leukemia development in vivo after chronic or repeated exposure to low dose radiation in a murine model.</p> <p>-Continue to refine the combination of radiation biomarkers in blood with the best balance of discrimination of sensitivity and specificity.</p>		

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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 0602787HP / <i>Medical Technology (AFRRI)</i>				Project (Number/Name) 241B / <i>Internal Contamination (USUHS)</i>			
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
241B: <i>Internal Contamination (USUHS)</i>	0.500	0.121	0.119	0.131	-	0.131	0.133	0.143	0.146	0.149	Continuing	Continuing

A. Mission Description and Budget Item Justification

Internal Contamination (USUHS): For the Uniformed Services University of the Health Sciences (USUHS), the mission and research objective for Internal Contamination is to determine whether the short-term and long-term radiological and toxicological risks of embedded metals warrant changes in the current combat and post-combat fragment removal policies for military personnel. Additionally, the biological effects of internalization of radioactive elements from Radiological Dispersal Devices (RDDs) and depleted uranium weapons, as well as therapeutic approaches to enhance the elimination of radionuclides from the body are being investigated.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Internal Contamination (USUHS)	0.121	0.119	0.131
FY 2014 Accomplishments: -Determined the efficacy of molecularly imprinted polymers on reducing the body burden of internalized radionuclides using a rodent model system. -Validated combinatorial approach of depleted uranium-induced damage to cellular epigenetic machinery using an in vivo model.			
FY 2015 Plans: -Test novel leukemia countermeasures to determine if chemoprevention mechanism involves modification of chromatin regulation in depleted uranium-induced leukemia in vivo. -Design feasibility study to determine if non-radioactive metals can substitute as template molecules for high-specific activity radionuclides in the synthesis of molecularly imprinted polymers.			
FY 2016 Plans: -Initiate study to assess the applicability of molecularly imprinted polymers in the decontamination of skin exposed to radionuclides. -Begin development and validation of a polytrauma model to assess the combined effects of mild traumatic brain injury and low-level radiation exposure, from external or internalized sources, in a rodent model system. -Test novel countermeasure to low dose radiation and determine if chromatin remodeling is involved.			
Accomplishments/Planned Programs Subtotals	0.121	0.119	0.131

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241B / <i>Internal Contamination (USUHS)</i>

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY14

- Complete assessment of combinatorial approach for assessing depleted uranium-induced damage.
- Conclude evaluation of molecularly imprinted polymers as decorporation agents.

By FY15

- Initiate study to assess feasibility of using non-radioactive templates in the synthesis of molecularly imprinted polymers to radioactive metals.
- Complete in vivo study on the mechanism of depleted uranium-induced leukemia.

By FY16

- Conclude feasibility assessment studies on the possibility of using non-radioactive templates for the synthesis of molecularly imprinted polymers designed to bind radioactive metals.
- Initiate in vitro/in vivo model system study to assess novel countermeasure to low dose radiation leukemia that targets specific chromatin remodeling.

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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 0602787HP / Medical Technology (AFRRI)				Project (Number/Name) 241C / Radiation Countermeasures (USUHS)			
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
241C: Radiation Countermeasures (USUHS)	3.255	0.786	0.770	0.842	-	0.842	0.855	0.916	0.933	0.951	Continuing	Continuing

A. Mission Description and Budget Item Justification

Radiation Countermeasures (USUHS): For the Uniformed Services University of the Health Sciences (USUHS), this program supports developmental, mission directed research to investigate new concepts and approaches that will lead to advancements in biomedical strategies for preventing and treating the health effects of human exposure to ionizing radiation as well as radiation combined with injuries (burns, wounds, hemorrhage). Research ranges from exploration of biological processes likely to form the basis of technological solutions, to initial feasibility studies of promising solutions. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation, in the context of probable threats to U.S. forces in current tactical, humanitarian and counterterrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both short- and long-term risks of adverse health consequences.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Radiation Countermeasures (USUHS)	0.786	0.770	0.842
FY 2014 Accomplishments:			
<ul style="list-style-type: none"> - Evaluated the radioprotective and mitigative/therapeutic effects of nano-gamma-tocotrienol (GT3) in mouse model - Determined acute and late effects of radiation-induced bone damage and prevention by GT3 after whole body radiation. - Analyzed global protein profiling after radiation in mouse spleen and kidney with varying doses and times after radiation. - Evaluated radiation-induced micro-RNA changes in mouse jejunum after GT3 treatment. - Evaluated the efficacy of a combined pharmaceutical regimen against radiation combined injury (irradiation followed immediately by skin wound trauma). -Determined effectiveness of combined therapy of G-CSF and ALXN4100TPO, a thrombopoietin receptor agonist, to prevent, mitigate, or inhibit the long-term deleterious responses to radiation combined injury. -Evaluated the micro-RNA profile in mouse serum after radiation alone and combination with wound trauma. -Evaluated the efficacy of IL-10 as a countermeasure to radiation and combined injury-associated effects on bone microarchitecture, strength, tissue-level cellular mechanisms, biomarkers of bone metabolism and immune effects. -Explored the role of the immune system in bone's response to radiation and combined injury (i.e. osteoimmunology). -Investigated the molecular mechanisms involved in radiation, wounding, hemorrhage, and/or combined injury. -Investigated the effects of mixed neutron/gamma radiation on secondary immune organs (liver, spleen). -Determined the efficacy of CDX-301 as a radiation mitigator after mixed neutron/gamma radiation. -Investigated the effect(s) of CDX-301 on hematopoietic cells in the lung, spleen, bone marrow when administered after mixed neutron/gamma radiation. 			

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> -Explored the role that sclerostin, an inhibitor of osteoblastogenesis, has on radiation and/or combined injury-associated reductions in bone mass and its effects on Wnt/β-catenin signaling. -Determined whether protection of bone marrow environment epigenetic changes following radiation can prevent radiation leukemia. -Continued study of the mitigation of radiation injury using apoptotic pathway markers in mice receiving TS-mobilized progenitors. -Performed genome-wide transcriptomic and proteomic profiling to elucidate coordinate pathway activation markers associated with tocopherol-mediated bioactivity. -Performed RNA-sequence profiling of small RNA, as well as mRNA transcriptomes, antibody microarray and 2D gel electrophoresis profiling of low and high abundance proteomes with samples obtained after tocopherol succinate (TS) treatment. -Small molecule inhibitors for candidate signaling pathways associated with TS activity were utilized to determine their requirements for CSF family member production, most notably, G-CSF production. -Screened several human primary organ-specific cell types (epithelial, fibroblast, endothelial, etc.) for CSF transcript up-regulation in response to alpha-tocopherol. -Determined radioprotection (drug administered before irradiation) with 10 new compounds. -Tested radioprotection by BB-001 and ODSH. -Determined the efficacy of filgrastim (administered after irradiation) and ALXN4100TPO (administered prior to radiation) on radiation lethality and how the combination influences hematopoietic end points as measured by circulating blood elements. -Tested efficacy of ALXN4100TPO in different mouse strains. -Evaluated microRNAs and inflammatory factors as radiation biomarkers. -Evaluated the radioprotective and mitigative/therapeutic effects of tilorone hydrochloride in in vivo animal model. -Studied the role of inflammatory pathways in ionizing radiation-induced bone marrow failure. -Established 3 dimensional coculture in vitro model to evaluate the effects of bone marrow endothelial cells (BMEC) on hematopoietic stem and progenitor cells (HSPC) in a 3D environment. -Initiated ex vivo culture of murine BMEC for in vivo studies. -Tested hypothesis that EC improve animal survival after gamma irradiation. -Tested functional roles of EC in hematopoietic support after irradiation. -Tested hypothesis that Ang/Tie2 pathway is involved in animal survival after irradiation. -Tested functional roles of Ang/Tie2 pathway in hematopoietic support after irradiation. -Initiated analysis of gene array data from irradiated human marrow endothelial cells and hematopoietic progenitor cells. -Completed establishing the combined injury model with radiation followed by hemorrhage. -Completed evaluation of peg-G-CSF and Alxn4100TPO co-therapy after irradiation and wound combined injury. <p>FY 2015 Plans:</p> <ul style="list-style-type: none"> -Evaluate RANKL-mediated signaling pathways in skeletal tissues after radiation and their modulation by gamma-tocotrienol. 			

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> -Examine radiation-induced neuronal damage and mitigation by GT3 using cell culture and mouse brain. -Evaluate the role of nrf2 pathway after radiation in microglial cells and its modulation by GT3. -Evaluate intracellular signaling pathways in mechanisms of efficacy of GT3 in different mouse tissues after radiation. -Determine the role of hedgehog signaling in hematopoietic recovery following sub-lethal dose of radiation (in vitro and in vivo study). -Determine the role of HIF-1a and HIF-2a in the regulation of erythropoiesis after radiation, and effect of GT3. -Continue to evaluate micro-RNA profiles in mouse serum after both radiation alone and combination with wound trauma with treatment with countermeasures. -Determine the potential efficacy of a sclerostin antibody, which inhibits radiation-induced reductions in bone formation. -Continue to explore the role of the immune system in bone's response to radiation and combined injury. -Determine whether phenylbutyrate-induced suppression of neoplastic transformation of bronchial tissue is radiation dose dependent (low versus high) and whether epigenetic or genetic processes are predominant. -Study transcriptomics in various subsets of TS-mobilized progenitors. -Continue to evaluate changes in hematopoietic cell populations in multiple organs (spleen, lung, liver, bone marrow) in irradiated mice treated with bone marrow endothelial cells. -Evaluate alterations in signaling pathways and cytokine profiles in response to bone marrow endothelial cell induced responses to gamma radiation. -Complete analysis of gene array data from irradiated human marrow endothelial cells and hematopoietic progenitor cells. -Characterize mTOR-AKT and MAPK signal mediation of radiation-hemorrhage combined injury. -Identify dynamic changes in circulatory blood cell counts, bone marrow cellularity and ileum structure morphology after radiation-wound combined injury. -Evaluate systemic bacterial infection after radiation-wound combined injury. -Screen 10-15 drugs in a mouse model for their radiation countermeasure potential. <p>FY 2016 Plans:</p> <ul style="list-style-type: none"> -Continue to correlate mTOR-AKT and MAPK signaling network and ATP production after radiation-hemorrhage combined injury. -Continue to elucidate mechanisms underlying ghrelin efficacy on survival improvement after radiation-wound combined injury by profiling cytokine/chemokine, signal transduction pathway activation, and miRNA regulation. -Improve low dose risk assessment knowledge base by determining whether chronic or repeated low dose exposure in a murine model induces leukemia in comparison to a high dose radiation exposure. -Study efficacy biomarkers for Ex-RAD using in vitro and in vivo systems. -Study whether elevated levels of pAkt are associated with survival. -Investigate various signaling pathways for Ex-RAD biomarkers. 			
Accomplishments/Planned Programs Subtotals	0.786	0.770	0.842

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY14

- Complete evaluation of the therapeutic effects of G-CSF and ALXN4100TPO on survival after radiation combined injury.
- Complete evaluation of the micro-RNA profile in mouse serum after radiation alone and combination with wound trauma.
- Complete evaluation of IL-10 as a countermeasure to radiation combined injury-induced bone loss and effects on immune system.
- Complete evaluation of molecular mechanisms involved in radiation, wounding, hemorrhage, and/or combined injury.
- Complete determination of the role that sclerostin has on radiation and/or combined injury-associated reductions in bone mass and its effects on Wnt/ β -catenin signaling in bone.
- Measure methylation and histone changes in radiation-leukemogenic mice.
- Begin analysis of underlying mechanisms of therapeutic effects of G-CSF, TS-mobilized progenitors, and ALXN4100TPO after radiation combined injury.
- Complete studies on CDX-301 mechanism(s) of action.
- Complete DRF studies with filgrastim using our optimized schedule.
- Repeat strain survival studies to determine LD50 in four mouse strains.
- Establish supportive care in rhesus macaque model to include antibiotic treatment, blood transfusions and thereby establish LD50 in primates.
- Complete establishing the combined injury model with radiation followed by hemorrhage.
- Complete evaluation of peg-G-CSF and Alxn4100TPO co-therapy after irradiation-wound combined injury.

By FY15

- Begin determining the potential efficacy of a sclerostin antibody to inhibit combined injury-induced bone loss.
- Evaluate effect of chronic or repeated low dose radiation on neoplastic transformation of bronchial tissue.
- Initiate investigations into mechanisms of mitigation/protection by BB-001. Determine optimum dose and time schedules, followed by DRF studies.
- Characterize mTOR-AKT and MAPK signal mediation of radiation-hemorrhage combined injury.
- Identify dynamic changes in circulatory blood cell counts, bone marrow cellularity and ileum structure morphology after radiation-wound combined injury.
- Determine systemic bacterial infection after radiation-wound combined injury.
- Complete low dose study on bronchial tissues measuring low dose responses in vitro.
- Evaluate effect of chronic or repeated low dose radiation on neoplastic transformation of bronchial tissue.
- Screen 10-15 drugs in a mouse model for their radiation countermeasure potential.

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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 0602787HP / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>
By FY16 -Correlate mTOR-AKT and MAPK signaling network and ATP production after radiation-hemorrhage combined injury. -Characterize dynamic changes in cytokine/chemokine concentrations, signal transduction pathways, and miRNA regulation after radiation-wound combined injury. -Measure the incidence of leukemia development in vivo after chronic or repeated exposure to low dose radiation in a murine model. -Evaluate effects of Ex-RAD on phosphorylated Akt. -Elucidate cell survival role of pAkt. -Study apoptotic pathway targets for identification of biomarkers for Ex-RAD.		

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>
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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	0.989	0.284	0.310	0.305	-	0.305	0.310	0.332	0.338	0.345	Continuing	Continuing
030A: <i>CSI - Congressional Special Interests</i>	0.000	-	0.031	-	-	-	-	-	-	-	Continuing	Continuing
242A: <i>Biodosimetry (USUHS)</i>	0.594	0.171	0.167	0.183	-	0.183	0.186	0.199	0.202	0.206	Continuing	Continuing
242B: <i>Radiation Countermeasures (USUHS)</i>	0.395	0.113	0.112	0.122	-	0.122	0.124	0.133	0.136	0.139	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences/ Armed Forces Radiobiology Research Institute (USUHS/AFRRI), this program supports applied research for advanced development of biomedical strategies to prevent, treat and assess health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel medical countermeasures into and through pre-clinical studies toward newly licensed products. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation (alone or in combination with other injuries) that represent the highest probable threat to US forces in current tactical, humanitarian and counterterrorism mission environments. Findings from basic and developmental research are integrated into focused advanced technology development studies to produce the following: (1) protective and therapeutic strategies; (2) novel biological markers and delivery platforms for rapid, field-based individual medical assessment; and (3) experimental data needed to build accurate models for predicting casualties from complex injuries involving radiation and other battlefield insults. The AFRRI, because of its multidisciplinary staff and exceptional laboratory and radiation facilities, is uniquely positioned to execute the program as prescribed by its mission.

B. Program Change Summary (\$ in Millions)

	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>
Previous President's Budget	0.304	0.279	0.305	-	0.305
Current President's Budget	0.284	0.310	0.305	-	0.305
Total Adjustments	-0.020	0.031	-	-	-
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	0.031			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.020	-			

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 030A: *CSI - Congressional Special Interests*

Congressional Add: 473A – *Program Increase: Restore Core Research Funding Reduction (USUHS)*

FY 2014	FY 2015
-	0.031

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

	FY 2014	FY 2015
Congressional Add Subtotals for Project: 030A	-	0.031
Congressional Add Totals for all Projects	-	0.031

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603002-Advanced Technology (AFRRI) (-\$0.020 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.020 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (+\$0.031 million).

FY 2016: No Change.

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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 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>				Project (Number/Name) 030A / <i>CSI - Congressional Special Interests</i>			
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
030A: <i>CSI - Congressional Special Interests</i>	-	-	0.031	-	-	-	-	-	-	-	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) 0603002 - Medical Advanced Technology (AFRRI). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 473A – Program Increase: Restore Core Research Funding Reduction (USUHS)	-	0.031
FY 2014 Accomplishments: No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.		
FY 2015 Plans: The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0603002 - Medical Advanced Technology (AFRRI). Because of the CSI annual structure, out-year funding is not programmed.		
Congressional Adds Subtotals	-	0.031

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>				Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>			
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
242A: <i>Biodosimetry (USUHS)</i>	0.594	0.171	0.167	0.183	-	0.183	0.186	0.199	0.202	0.206	Continuing	Continuing

A. Mission Description and Budget Item Justification

Biodosimetry (USUHS): For the Uniformed Services University of the Health Sciences (USUHS), this program supports applied research for advanced development of biomedical and biophysical strategies to assess health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel biological markers and delivery platforms for rapid, field-based individual dose assessment and experimental data needed to build accurate models for predicting casualties from complex injuries involving radiation and other battlefield insults.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Biodosimetry (USUHS)	0.171	0.167	0.183
FY 2014 Accomplishments:			
<ul style="list-style-type: none"> -Continued the evaluation and validation of new radiation-responsive biomarkers in higher order animal (NHP) and human models for biodosimetric diagnostic applications. -Sustained efforts to establish a quality control and assurance plan for measurement of dose by cytogenetic chromosome aberration assay. -Optimized an interphase cytogenetic assay for high-dose and partial-body dose assessment. -Participated in two cytogenetic biodosimetry exercises that demonstrated the ability to successfully ship from military operations in CONUS and the laboratory's accuracy for dose assessment of unknown samples in an inter-laboratory comparison study. -Determined the feasibility of developing an early phase (<7 days) radiation dose assessment model and algorithm using predictive biomarkers from AFRRI archived minipig hematology and serum chemistry data for estimating a 1.6-2 Gy radiation dose. -Established baseline levels of body weight, body width, body temperature, hematology, blood chemistry, proteomic biomarkers, and ARS severity scores in the nonhuman primate total body irradiation model prior to irradiation. -Reported on study using samples from the NHP total-body dose-response irradiation model, to permit testing of the measurement of organ specific biomarkers in isolated peripheral blood using commercially available antibodies. -A full dose-response algorithm dose assessment (6 h – 7 d) was developed for combinations of selected protein and hematological biomarkers in the NHP total-body irradiation model. -Determined the feasibility of developing an early phase (<7 days) radiation dose assessment model and algorithm for estimating radiation doses between 1-8.5 Gy using archived NHP urine metabolite data. -Developed and validated a radiation dose algorithm using NHP hematology and plasma proteomic biomarker results using independent ("blinded") samples. 			

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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 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>-Establish LIMS (Laboratory Information Management Systems) modules and controls for remote access. Tested, validated and released the developed BETA version of the automated chromosome aberration scoring system to end user using a virtual protocol network.</p> <p>-Developed specificity and sensitivity models as well as multi-parametric approaches for internal automated self-validation of data before end-user reporting for the automated chromosome aberration analysis system.</p> <p>-Developed and established ultra-high-throughput miRNA based triage models.</p> <p>-Contributed to the preparation of a summary report for FDA use on the diagnostic utility of combined hematological and proteomic approach for triage biodosimetry applications based on the combination of hematological and proteomic biomarker results using the minipigs and nonhuman primate model systems.</p> <p>-Continued to provide necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable) for necessary FDA approval.</p> <p>-Began to develop the protocol on evaluated and newly developed protein biomarkers for use in human radiation accident cases.</p> <p>FY 2015 Plans:</p> <p>-Contribute to the further evaluation of discovered new radiation-responsive biomarkers in higher order animal and human models for diagnostic biodosimetry applications.</p> <p>-Begin a pilot study using samples from the mouse and NHP total-body irradiation models to permit testing of the measurement of novel tissue- and organ-specific biomarkers in peripheral blood using commercially available antibodies and assays developed at AFRRI.</p> <p>-Begin to analyze blood chemistry data collected in the NHP dose-response study with limited supportive care and in the high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs.</p> <p>-Begin to analyze results of necropsies performed on NHPs (limited and full supportive care) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers.</p> <p>-Complete NHP-specific ARS category score system based on multiple biodosimetric endpoints (i.e., clinical signs, peripheral blood cell counts, and radiation-responsive protein expression profile).</p> <p>-Sustain efforts to provide necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable) and obtain necessary FDA approval.</p> <p>-Complete report for FDA on combined utility of hematological and protein biomarkers for biodosimetry applications in two FDA required animal models.</p> <p>-Continue preparation of report for FDA on combined utility of hematological and protein biomarkers for biodosimetry applications using GLP study results.</p> <p>-Begin to develop the protocol for evaluating newly discovered protein biomarkers for use in human radiation accident cases.</p> <p>FY 2016 Plans:</p> <p>-Report a dose response algorithm using amylase activity 1 day after exposure.</p>			

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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 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> -Extend dose response radiation calibration curves to include low doses (10 cGy) and low-dose rates (10 cGy/min) for the lymphocyte metaphase spread dicentric assay. -Initiate efforts to adopt centromeric straining using the interphase chromosome aberration assay to permit scoring of dicentric aberrations 				
Accomplishments/Planned Programs Subtotals		0.171	0.167	0.183
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				
E. Performance Metrics				
By FY 2014				
<ul style="list-style-type: none"> -Evaluate proof of concept of two NHP radiation injury algorithms for estimating METREPOL Response Category (RC) 3, by comparing their differences, such as in the blood-based biomarkers selected, the derived beta (weighted-interaction) coefficients, amount of co-linearity between the independent variables, data collection time-points and the RC estimation efficiency percentages as indicated by multiple-R values. -Begin to develop the protocol on evaluated and newly developed protein biomarkers for use in human radiation accident cases. -Establish and evaluate hardware and automated machinery architecture within CLASP for its implementation, throughput and efficiency after inclusion of new multiparametric approaches with end user reporting. -Integration of new imaging and analysis methods within CLASP to develop Boolean operations based on machine learning for automated close to human prediction, using Artificial Intelligence. -Establish and develop filter-assays for quick distinction of Very Low Priority (VLP) cohorts to develop an effective triage dose model for miRNA based gene expression profiles. -Integrate and cross-link the existing CLASP platform to incorporate pathway and genomic data from established search engines to provide a better user annotation. 				
By FY 2015				
<ul style="list-style-type: none"> -Perform a pilot study using samples from the mouse and NHP total-body irradiation models to permit testing of the measurement of novel tissue- and organ-specific biomarkers in peripheral blood using commercially available antibodies and assays developed at AFRRI. -Complete analysis of blood chemistry data collected in the NHP dose-response study with limited supportive care and in the high-dose study with full supportive care (G-CSF, antibiotics, blood transfusions, etc.) to evaluate radiation damage to specific organs. 				

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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 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>
<p>-Complete analysis of results of necropsies performed on NHPs (limited and full supportive care) to determine radiation dose-dependent damage to different organs/tissues and correlate those results with levels of tissue/organ-specific protein biomarkers.</p> <p>-Begin to evaluate the identified tissue- and organ-specific biomarkers in partial-body irradiation models.</p> <p>-Exercise protocols for evaluation of newly developed proteomic biomarkers for use in radiation accident cases.</p> <p>-Provide necessary proof-of-concept dose-response data to transition combined proteomic and hematological concept for further development of diagnostic devices (i.e., hand-held, field deployable) to obtain the necessary FDA approval.</p> <p>-Report on natural history of ARS in NHP using total body irradiation radiation dose response model.</p> <p>-Establish a gamma-ray dose response calibration curve for high-dose and partial-body cytogenetic assay.</p> <p>By FY2016</p> <p>-Initiate efforts to expand AFRRI's dose assessment tools to include plasma protein biomarkers.</p> <p>-Provide an updated report on AFRRI's radiation calibration curves expanded to include low dose (10 cGy) and low-dose rates (10 cGy/min) for the metaphase spread dicentric chromosome aberration assay.</p> <p>-Demonstrate the utility of a multiple parameter biodosimetry diagnostic system.</p>		

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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 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242B / <i>Radiation Countermeasures (USUHS)</i>
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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
242B: <i>Radiation Countermeasures (USUHS)</i>	0.395	0.113	0.112	0.122	-	0.122	0.124	0.133	0.136	0.139	Continuing	Continuing

A. Mission Description and Budget Item Justification

Radiation Countermeasures (USUHS): For the Uniformed Services University of the Health Sciences (USUHS), this program supports applied research for advanced development of biomedical strategies to prevent, treat and assess health consequences from exposure to ionizing radiation. It capitalizes on findings under PE 0602787HP, Medical Technology, and from industry and academia to advance novel medical countermeasures into and through pre-clinical studies toward newly licensed products. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation alone or in combination with other injuries, in the context of probable threats to US forces in current tactical, humanitarian and counterterrorism mission environments. Findings from basic and developmental research are integrated into highly focused advanced technology development studies yielding protective and therapeutic strategies.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Radiation Countermeasures (USUHS)	0.113	0.112	0.122
FY 2014 Accomplishments:			
-Complete study examining effects of genistein in combination with G-CSF as a radiation countermeasure regimen.			
-Complete study evaluating effects of the role of the estrogen receptor on genistein-induced radioprotection.			
-Complete PK/PD analysis of NHP study samples for GT3.			
-Complete pilot NHP study for GT3 and analyze various biomarkers.			
-Investigate the radiomitigation potential of TS-mobilized progenitors in large animals (minipig or NHP).			
-Compare efficacy of CDX-301 as a radiation countermeasure when administered after pure gamma-rays or mixed neutron/gamma fields.			
-Complete study evaluating bone marrow endothelial cells as a radiation mitigator.			
FY 2015 Plans:			
-Evaluate radioprotective effects of genistein as a function of radiation dose rate.			
-Study GT3 biomarkers for efficacy in nonhuman primates.			
FY 2016 Plans:			
-Assess the effects of reduced doses of the radiation protector genistein in combination with other radioprotectors to increase both the therapeutic index and radioprotective efficacy.			
-Study radioprotective efficacy of two drug combination acting through two different mechanisms of action such as gamma-tocotrienol (GT3) and amifostine.			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002HP / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242B / <i>Radiation Countermeasures (USUHS)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
-Study radioprotective efficacy of Ex-RAD in different strains of mice.			
Accomplishments/Planned Programs Subtotals	0.113	0.112	0.122

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY 2014

- Complete study evaluating radioprotective effects when genistein is combined with a leucocyte growth factor.
- Complete study evaluating effects of the role of the estrogen receptor on genistein-induced radioprotection.
- Study the radioprotective efficacy of GT3 in at least six nonhuman primates.
- Survival, hematopoietic measures, and cytokine measurements in mice administered CDX-301 after pure gamma rays or mixed neutron/gamma fields.

By FY 2015

- Evaluate radioprotective effect of genistein as a function of radiation dose rate.
- Study efficacy biomarkers for GT3 efficacy in NHP.
- Study efficacy of TS-mobilized progenitors in large animals (mini pig or NHP).

By FY 2016

- Assess the effects of reduced doses of the radiation protector genistein in combination with other radioprotectors to increase both the therapeutic index and radioprotective efficacy.
- Evaluate effects of GT3 and amifostine combination.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>
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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	1,370.321	1,109.743	1,201.188	231.051	-	231.051	250.488	267.321	265.167	267.228	Continuing	Continuing
300A: <i>CSI - Congressional Special Interests</i>	1,061.685	802.400	975.057	-	-	-	-	-	-	-	-	-
238C: <i>Enroute Care Research & Development (Budgeted) (AF)</i>	3.685	4.666	3.394	1.340	-	1.340	-	-	-	-	Continuing	Continuing
238D: <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i>	0.000	-	-	0.997	-	0.997	2.045	2.240	2.282	2.328	Continuing	Continuing
238E: <i>Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)</i>	0.000	-	-	0.997	-	0.997	2.045	2.239	2.282	2.327	Continuing	Continuing
243A: <i>Medical Development (Lab Support) (Navy)</i>	61.968	35.074	34.378	37.580	-	37.580	38.211	40.942	41.720	42.554	Continuing	Continuing
247A: <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>	0.000	0.200	-	2.060	-	2.060	2.064	1.548	-	-	Continuing	Continuing
247B: <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>	0.000	0.425	-	1.040	-	1.040	1.135	1.238	-	-	Continuing	Continuing
284B: <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i>	2.646	3.694	2.280	1.700	-	1.700	-	-	-	-	Continuing	Continuing
284C: <i>Core Human Performance R&D - Clinical Translational Focus (AF)</i>	0.000	-	-	1.003	-	1.003	2.349	2.664	2.762	2.817	Continuing	Continuing
284D: <i>Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)</i>	0.000	-	-	1.002	-	1.002	2.348	2.663	2.761	2.816	Continuing	Continuing
285A: <i>Operational Medicine Research & Development (Budgeted) (AF)</i>	8.146	6.851	1.983	-	-	-	-	-	-	-	Continuing	Continuing

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program										Date: February 2015		
Appropriation/Budget Activity					R-1 Program Element (Number/Name)							
0130: Defense Health Program I BA 2: RDT&E					PE 0603115HP I Medical Technology Development							
285B: Core Operational Medicine R&D - Clinical Translational Focus (AF)	0.000	-	-	0.929	-	0.929	1.147	1.350	1.360	1.387	Continuing	Continuing
285C: Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)	0.000	-	-	0.928	-	0.928	1.147	1.349	1.360	1.387	Continuing	Continuing
307B: Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)	14.728	14.508	12.558	8.173	-	8.173	10.653	10.833	10.950	11.169	Continuing	Continuing
307C: Core Force Health Protection R&D - Clinical Translational Focus (AF)	0.000	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	Continuing	Continuing
307D: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	0.000	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	Continuing	Continuing
308B: Expeditionary Medicine Research & Development (Budgeted) (AF)	2.847	4.769	4.699	1.180	-	1.180	1.160	1.560	1.640	1.673	Continuing	Continuing
308C: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	0.000	-	-	1.503	-	1.503	1.500	1.497	1.501	1.531	Continuing	Continuing
308D: Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)	0.000	-	-	1.502	-	1.502	1.499	1.497	1.500	1.530	Continuing	Continuing
309A: Regenerative Medicine (USUHS)	6.877	7.031	9.190	9.489	-	9.489	9.646	9.823	10.009	10.209	Continuing	Continuing
373A: GDF - Medical Technology Development	128.139	168.541	113.048	116.775	-	116.775	134.178	149.012	150.022	149.701	Continuing	Continuing
378A: CoE-Breast Cancer Center of Excellence (Army)	13.077	11.965	8.664	7.299	-	7.299	5.709	4.068	3.553	3.624	Continuing	Continuing

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity					R-1 Program Element (Number/Name)								
0130: <i>Defense Health Program I BA 2: RDT&E</i>					PE 0603115HP <i>I Medical Technology Development</i>								
379A: <i>CoE-Gynecological Cancer Center of Excellence (Army)</i>	11.425	10.707	7.570	6.377	-	6.377	4.989	3.555	3.105	3.167	Continuing	Continuing	
381A: <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>	4.822	3.674	3.594	3.520	-	3.520	3.368	3.214	3.057	3.118	Continuing	Continuing	
382A: <i>CoE-Pain Center of Excellence (Army)</i>	3.652	2.784	-	-	-	-	-	-	-	-	Continuing	Continuing	
382B: <i>CoE-Pain Center of Excellence (USUHS)</i>	0.000	-	2.722	2.823	-	2.823	2.871	3.247	3.310	3.376	Continuing	Continuing	
383A: <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	13.516	7.771	6.907	6.260	-	6.260	5.456	4.628	3.300	3.366	Continuing	Continuing	
398A: <i>CoE-Neuroscience Center of Excellence (USUHS)</i>	1.822	1.857	-	-	-	-	-	-	-	-	-	-	
429A: <i>Hard Body Armor Testing (Army)</i>	1.356	-	-	-	-	-	-	-	-	-	-	-	
431A: <i>Underbody Blast Testing (Army)</i>	20.929	10.938	4.818	2.679	-	2.679	1.869	-	-	-	-	-	
448A: <i>Military HIV Research Program (Army)</i>	0.000	6.663	5.773	6.589	-	6.589	6.702	7.579	7.722	7.877	Continuing	Continuing	
830A: <i>Deployed Warfighter Protection (Army)</i>	9.001	5.225	4.553	5.306	-	5.306	5.397	6.105	6.221	6.345	Continuing	Continuing	

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this program element (PE) is designed to address areas of interest to the Secretary of Defense related to Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of priority investments in science, technology, research, and development as stated 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 the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) funding. Research supported by this PE includes JPC-1: medical simulation, health informatics, JPC-2: wound infection prevention and management, antimicrobial countermeasures, diagnostic systems for infectious diseases, JPC-5: injury prevention and reduction, psychological health and resilience, physiological health, environmental health and protection, JPC-6: hemorrhage (bleeding) and resuscitation, neurotrauma (diagnosis

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>
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and treatment of brain injury), traumatic tissue injury, forward surgical intensive critical care, joint en route care, military medical photonics, and JPC-8: rehabilitation of neuro-musculoskeletal injuries, pain management, regenerative medicine, and sensory system traumatic injury, restoration and rehabilitation. As research efforts mature, the most promising will transition to advanced concept development funding, PE 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

For the Army Medical Command, the Underbody Blast (UBB) Testing medical research project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle UBB events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human response and tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events. This enhanced understanding will support the establishment of an improved capability to conduct Title 10 Live Fire Test and Evaluation and to make acquisition decisions.

For the Army Medical Command, beginning in FY14, Military Human Immunodeficiency Virus (HIV) Research Program funding was transferred from the Army to the DHP. This project funds research to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect military personnel from risks associated with HIV infection.

For the Army Medical Command, the Armed Forces Pest Management Board (AFPMB) Deployed Warfighter Protection project provides for the development of new or improved protection of ground forces from disease-carrying insects.

For the Army Medical Command, four Centers of Excellence (CoE) receive medical technology development funds. The Breast Cancer CoE (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. The Gynecologic CoE (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and biologic therapeutics (a medicinal preparation created by a biological process used to treat diseases) for the management of gynecologic disease. The Cardiac Health CoE (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac (pertaining to the heart) event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular (CV) (pertaining to the heart and blood vessels) disease at an early stage to ultimately discover a signature for CV health, to find new genes that significantly increase risk for heart attack in Service members and other beneficiaries, and identify molecular markers of obesity and weight loss. The Pain CoE (Army) examines the relationship between acute (rapid onset and/or short course) and chronic (persistent or long-lasting, usually longer than 3 months) pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration. In FY15, the Pain CoE funding line is transferred from Army to the Uniformed Services University of the Health Sciences (USUHS).

In FY14, DHP funded the following Congressional Special Interest (CSI) peer-reviewed directed research programs: Amyotrophic Lateral Sclerosis (ALS) (degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis (MS) (disease that affects the brain and the spinal cord and causes severe physical and mental complications), Cancer, Lung Cancer, Orthopedics Research, Spinal Cord Research, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer's Research, Reconstructive Transplant, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs), Duchenne Muscular Dystrophy (gene mutation in boys that causes muscle degeneration

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program Date: February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>
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and eventual death). CSIs also included the following programs: Joint Warfighter Medical Research, Trauma Clinical Research Repository, Orthotics and Prosthetics Outcomes, and HIV/AIDS Program Increase. Because of the CSI annual structure, out-year funding is not programmed.

For the Navy Bureau of Medicine and Surgery, this program element includes funds for research management support costs. The Outside Continental US (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

For the Air Force Medical Service (AFMS), medical research and development programs are divided into five primary thrust areas: Enroute care, Expeditionary Medicine, Operational Medicine (in-garrison care), Force Health Protection (FHP) (detect, prevent, threats), and Human Performance. Expeditionary Medicine is focused on care on the battlefield and in field hospitals prior to transporting patients out of theater to CONUS, and studies trauma resuscitation, hemorrhage control, and other life-saving interventions to keep critically wounded patients alive in the golden hour and to the next level of care. The AFMS is the only service transporting patients on long aeromedical evacuation missions from theater to Landstuhl and from Landstuhl to CONUS. Therefore, the Enroute Care thrust area studies include optimal time for patient transport, cabin altitude, noise, vibration, and environmental issues affecting patient physiology on the aircraft, and the Human Performance thrust area compliments Enroute Care through its studies on medic and aircrew performance on long missions, as well as special operations forces performance. Medical development and biomedical technology investments in FHP seek to deliver an improved FHP capability across the full spectrum of operations with research that prevents injury/illness through improved identification and control of health risks. Under FHP, sub-project areas include: Directed Energy, Occupational and Environmental Health, and Advanced Diagnostics/Therapeutics. Operational medicine is focused on in garrison care – our next most critical issue post OIF/OEF – and how to care for the whole patient and consideration of comorbidities in treatment of wounded warriors and dependents.

For the Uniformed Services University of the Health Sciences (USUHS), medical development programs include the Prostate Cancer Center of Excellence (CoE), the Center for Neuroscience and Regenerative Medicine, and the Pain CoE. The Prostate CoE, formerly a CSI, was chartered in 1992 to conduct basic, clinical, and translational research programs to combat diseases of the prostate. The Center's mission is fulfilled primarily through its three principal programs -- the Clinical Translational Research Center, the Basic Science Research Program, and the Tri-Service Multicenter Prostate Cancer Database, which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients who participate in clinical trials. The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM research programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. Beginning in FY15, the Pain CoE funding line is transferred from Army to USUHS.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>
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B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	290.852	226.131	231.951	-	231.951
Current President's Budget	1,109.743	1,201.188	231.051	-	231.051
Total Adjustments	818.891	975.057	-0.900	-	-0.900
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	802.400	975.057			
• Congressional Directed Transfers	-	-			
• Reprogrammings	34.452	-			
• SBIR/STTR Transfer	-17.961	-			
• Program Increase in Support of the Global Health Security Agenda (GHSA) - Project 247	-	-	3.100	-	3.100
• Realignment - Project 307B	-	-	-4.000	-	-4.000

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 300A: *CSI - Congressional Special Interests*

Congressional Add: 245A - *Amyotrophic Lateral Sclerosis (ALS) Research*

Congressional Add: 293A - *Autism Research*

Congressional Add: 296A - *Bone Marrow Failure Disease Research*

Congressional Add: 310A - *Ovarian Cancer Research*

Congressional Add: 328A - *Multiple Sclerosis Research*

Congressional Add: 335A - *Peer-Reviewed Cancer Research*

Congressional Add: 336A - *Peer-Reviewed Lung Cancer Research*

Congressional Add: 337A - *Peer-Reviewed Orthopedic Research*

Congressional Add: 338A - *Peer-Reviewed Spinal Cord Research*

Congressional Add: 339A - *Peer-Reviewed Vision Research*

Congressional Add: 352A - *Traumatic Brain Injury/ Psychological Health Research*

Congressional Add: 380A - *Peer-Reviewed Breast Cancer Research*

Congressional Add: 390A - *Peer-Reviewed Prostate Cancer Research*

Congressional Add: 392A - *Gulf War Illness Peer-Reviewed Research*

Congressional Add: 396A - *Research in Alcohol and Substance Use Disorders*

	FY 2014	FY 2015
	7.500	7.500
	6.000	6.000
	3.200	3.200
	20.000	20.000
	5.000	5.000
	25.000	50.000
	10.500	10.500
	30.000	30.000
	30.000	30.000
	10.000	10.000
	100.000	105.000
	120.000	120.000
	80.000	80.000
	20.000	20.000
	4.000	4.000

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

	FY 2014	FY 2015
Congressional Add: 400A - <i>Peer-Reviewed Medical Research</i>	200.000	247.500
Congressional Add: 417A - <i>Peer-Reviewed Alzheimer Research</i>	12.000	12.000
Congressional Add: 439A - <i>Joint Warfighter Medical Research</i>	65.000	30.000
Congressional Add: 452A - <i>Peer-Reviewed Reconstructive Transplant Research</i>	15.000	15.000
Congressional Add: 453A - <i>Trauma Clinical Research Repository</i>	5.000	-
Congressional Add: 454A - <i>Orthotics and Prosthetics Outcomes Research</i>	10.000	10.000
Congressional Add: 456A - <i>HIV/AIDS Program</i>	7.000	12.900
Congressional Add: 540A - <i>Global HIV/AIDS Prevention (Navy)</i>	8.000	8.000
Congressional Add: 660A - <i>Tuberous Sclerosis Complex (TSC)</i>	6.000	6.000
Congressional Add: 790A - <i>Duchenne Muscular Dystrophy</i>	3.200	3.200
Congressional Add: 459A - <i>Peer-Reviewed Epilepsy Research</i>	-	7.500
Congressional Add: 474A – <i>Program Increase: Restore Core Research Funding Reduction (Army)</i>	-	7.575
Congressional Add: 474B – <i>Program Increase: Restore Core Research Funding Reduction (Navy)</i>	-	6.856
Congressional Add: 474C – <i>Program Increase: Restore Core Research Funding Reduction (Air Force)</i>	-	10.228
Congressional Add: 474D – <i>Program Increase: Restore Core Research Funding Reduction (USUHS)</i>	-	2.514
Congressional Add: 463A – <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i>	-	94.584
Congressional Add Subtotals for Project: 300A	802.400	975.057
Congressional Add Totals for all Projects	802.400	975.057

Change Summary Explanation

FY2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-\$17.961 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$17.961 million).

FY 2014: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+\$802.400 million).

FY 2015: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0603115-Medical Technology Development (+\$975.057 million).

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>
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FY2015: Transfer of Pain Center of Excellence (CoE) from Army DHP RDT&E, PE 0603115-Medical Development Technology Development (-\$2.722 million) to USUHS DHP RDT&E, PE 0603115-Medical Development Technology Development (+\$2.722 million).

FY 2015: Change Proposal to merge USUHS DHP RDT&E, PE 0603115-Medical Development Technology Development (+\$1.533 million) Center of Excellence for Neuroscience with Regenerative Medicine.

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-\$4.000 million) to DHP RDT&E PE 0604110-Medical Products Support and Advanced Concept Development (+\$4.000 million).

FY2016: Realignment Global Health Security Agenda (GHSA) adjustment to DHP RDT&E, PE 0603115-Medical Technology Development (+\$3.100 million).

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>			
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
300A: <i>CSI - Congressional Special Interests</i>	1,061.685	802.400	975.057	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

In FY14, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY14 Congressionally-directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific peer-reviewed research efforts include the following: Amyotrophic Lateral Sclerosis (ALS) (degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic Research, Spinal Cord Research, Vision, Traumatic Brain Injury and Psychological Health (TBI/PH), Breast Cancer, Prostate Cancer, Gulf War Illness, Alcohol and Substance Use Disorders, Medical Research, Alzheimer Research, Joint Warfighter Medical Research, Reconstructive Transplant, Trauma Clinical Research Repository, Orthotics and Prosthetics Outcomes, HIV/AIDS, Global HIV/AIDS Prevention, Tuberous Sclerosis Complex (rare multi-system genetic disease that causes growth of non-malignant tumors in the brain and other vital organs), and Duchenne Muscular Dystrophy (gene mutation affecting boys that causes muscle degeneration and eventual death). Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	7.500	7.500
FY 2014 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS) (a degenerative neuronal disorder that causes muscle weakness and atrophy throughout the body). The ALS Research Program is a broadly-competed, peer-reviewed research program with the goal to contribute to a cure for ALS by funding innovative preclinical research to develop new treatments for ALS. Two award mechanisms were offered in FY14, the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2014 followed by scientific peer review in October 2014. Funding recommendations will be made at programmatic review in December 2014. Awards will be made by September 2015.		
FY 2015 Plans: This Congressional Special Interest research initiative is for Amyotrophic Lateral Sclerosis (ALS) Research.		
Congressional Add: 293A - Autism Research	6.000	6.000
FY 2014 Accomplishments: This Congressional Special Interest initiative provided funds for research in Autism Research, to improve treatment outcomes of Autism Spectrum Disorder (ASD), lead to a better understanding of ASD, and integrate basic science and clinical observations by promoting innovative research. The Autism Research Program has funded research at universities, hospitals, nonprofit and for-profit institutions,		

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
as well as private industry. Two award mechanisms were offered in FY14, the Clinical Trial Award and the Idea Development Award. Applications were received in October 2014 followed by scientific peer review in December 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Autism Research.		
Congressional Add: 296A - Bone Marrow Failure Disease Research FY 2014 Accomplishments: This Congressional Special Interest initiative funded research for bone marrow failure diseases. The mission of the program is to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases, and improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. In FY14, applications were accepted through one funding opportunity, the Idea Development Award, released in March 2014. Applications were received in August 2014 followed by scientific peer review in October 2014. Funding recommendations will be made at programmatic review in January 2015. Award(s) will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Bone Marrow Failure Disease Research.	3.200	3.200
Congressional Add: 310A - Ovarian Cancer Research FY 2014 Accomplishments: This Congressional Special Interest initiative funded research in Ovarian Cancer. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) is challenging the research community to address high impact, innovative research. The FY14 OCRP supported innovative ideas that provide new paradigms, leverages critical resources, facilitates synergistic, multidisciplinary partnerships, and cultivates the next generation of investigators in ovarian cancer. Six award mechanisms were offered: Pilot Award, Clinical Translational Leverage Award, Investigator-Initiated Award, the Ovarian Cancer Academy Awards recruiting the Academy Leadership and Early-Career Investigators, and the Ovarian Cancer Academy Collaborative Award. Application submission deadlines were in August 2014 and in January 2015 followed by scientific peer reviews in October 2014 and March 2015. Funding recommendations will be made at the programmatic reviews in December 2014 and April 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Ovarian Cancer Research.	20.000	20.000
Congressional Add: 328A - Multiple Sclerosis Research	5.000	5.000

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<p>FY 2014 Accomplishments: This Congressional Special Interest initiative funded research in Multiple Sclerosis (MS). The mission of the program is to support pioneering concepts and high-impact research relevant to the prevention, etiology (causes or origins of), pathogenesis (the mechanism(s) that cause(s) MS or the development of MS), assessment, and treatment of MS. This year specific areas of MS research focus were not stipulated. A new mechanism, the Investigator Initiated Partnership Award was offered to encourage synergistic partnerships between clinicians and research scientists inside and outside the MS field that will accelerate the movement of promising ideas in MS into clinical applications. Applications were received in September 2014 followed by scientific peer review in November 2014. Funding recommendations will be made at programmatic review in January 2015. Awards will be made by September 2015.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Multiple Sclerosis Research.</p>		
<p>Congressional Add: 335A - Peer-Reviewed Cancer Research</p> <p>FY 2014 Accomplishments: This Congressional Special Interest research initiative was for the study of cancers designated by Congress. The goal of the Peer-Reviewed Cancer Research Program is to improve the quality of life by significantly decreasing the impact of cancer on Service members, their families, and the American public. The funds appropriated by Congress were directed for research in the following areas: blood cancers, cancers related to exposures to radiation (ionizing), colorectal cancer, genetic cancer research, kidney cancer, Listeria vaccine (bacterial-based vaccine) for cancer, melanoma and other skin cancers, mesothelioma (rare form of cancer developed from the protective lining that cover many of the internal organs of the body caused by exposure to asbestos), myeloproliferative disorders (abnormal growth of blood cells in bone marrow), neuroblastoma (extracranial solid cancer), pancreatic cancer, and pediatric brain tumors. Two award mechanisms to support these topic areas were released in April 2014: the Career Development Award and the Idea Award with Special Focus. Applications were received in September 2014 followed by scientific peer review in November 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Cancer Research.</p>	25.000	50.000
<p>Congressional Add: 336A - Peer-Reviewed Lung Cancer Research</p> <p>FY 2014 Accomplishments: This Congressional Special Interest initiative funded research in Lung Cancer. The goal of the Peer-Reviewed Lung Cancer Research Program is to eradicate deaths from lung cancer to better the health and welfare of military Service members, Veterans, their families, and the American public. This research effort is offering four award mechanisms in FY14: the Career Development, the Clinical Exploration, the Concept, and the Idea Development Awards. Applications were received in August and September 2014</p>	10.500	10.500

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
followed by scientific peer review in October and November 2014. Funding recommendations will be made at programmatic review in January 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Lung Cancer Research.		
Congressional Add: 337A - Peer-Reviewed Orthopedic Research FY 2014 Accomplishments: This Congressional Special Interest research initiative supported orthopedic research to advance optimal treatment and rehabilitation from neuromusculoskeletal (bone, muscle, tendon, ligament, nerve, and cartilage) injuries sustained during combat or combat-related activities. The overall goal of the Peer Reviewed Orthopedic Research Program is to provide all Warriors affected by orthopedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function. Six award mechanisms are being offered in FY14: Clinical Trial Award, Clinical Trial Development Award, Idea Development Award, Outcomes Research Award, Translational Research Award, and Expansion Award. Applications were received in August and October 2014 followed by scientific peer review in December 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Orthopedic Research.	30.000	30.000
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research FY 2014 Accomplishments: This Congressional Special Interest research initiative supported Spinal Cord Injury (SCI) research. The FY14 SCIRP challenged the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of SCI-focused research. Applications from investigators within the military Services, and applications involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other federal Government agencies were highly encouraged. Though the SCIRP supports groundbreaking research, all projects must demonstrate solid scientific rationale. The SCIRP has identified three Areas of Encouragement for the FY14 program. Pre-hospital, en route care, and early hospital management of SCI, development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery and identification and validation of best practices in SCI. Projects focused on other research areas relevant to SCI were submitted for consideration, provided that sufficient justification is included in the application. In FY14 four award mechanisms were offered including: Clinical Trial, Investigator-Initiated Research, Qualitative Research and Translational Research Awards. Pre-applications were due in July 2014; invited full applications were due in	30.000	30.000

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
October 2014 followed by scientific peer review in December 2014. Funding recommendations will be made at programmatic review in February 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Spinal Cord Research.		
Congressional Add: 339A - Peer-Reviewed Vision Research FY 2014 Accomplishments: This Congressional Special Interest research effort for Peer-Reviewed Vision Research targeted the causes, effects and treatments of eye damage, visual deficits due to traumatic brain injury (TBI) and diseases that, despite their different pathogenesis (mechanisms that occur during disease development), all have a common end result -- degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are intended to be used for restoration and maintenance of visual function to ensure and sustain combat readiness. Basic, translational (conversion of findings in basic science to practical applications) and clinical research efforts were sought to ensure that results of scientific research will be used to directly benefit the lives of military, Veteran and civilian populations. Critical areas of research include advances and improvements in: vision rehabilitation strategies and quality of life measures, vision restoration following traumatic injury, mitigation and treatment of traumatic injuries, treatment for war-related injuries and diseases to ocular structures and the visual system, treatment of visual dysfunction (abnormal functioning pertaining to the eyes) associated with TBI, and modeling and simulation of traumatic ocular injury. To meet the goals of the program, two award mechanisms supported vision research, the Translational Research and the Hypothesis Development Awards. Pre-applications were reviewed in November 2013, applications submitted in February 2014, the scientific peer review occurred in March 2014, and programmatic review was held in May 2014. Ten applications were recommended for funding and are currently being negotiated. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Vision Research.	10.000	10.000
Congressional Add: 352A - Traumatic Brain Injury/ Psychological Health Research FY 2014 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest research program aims to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. Key priorities of the FY14 TBI/PH research program were to support projects aligned with the National Research Action Plan, address Congressional intent, enable significant research collaborations, and complement ongoing Department of Defense (DoD) efforts to ensure the mental health and readiness of our military forces by promoting a better	100.000	105.000

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<p>standard of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In addition to service-requested nominations, individual Broad Agency Announcement applications, and promising ongoing studies, four program announcements (PAs) were released to solicit applications that address these priorities. The Psychological Health Research Award PA is intended to support both applied (preclinical) research and clinical trials within specific topic areas addressing the prevention and treatment of military-relevant psychological health issues. The Neurosensory and Rehabilitation Research Award PA Supports both applied (preclinical) research and clinical trials addressing TBI within specific focus areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation associated with TBI. The Investigative Treatments for TBI and PTSD Clinical Trial Award PA responds to Section 704 of the National Defense Authorization Act for Fiscal Year 2014 and supports investigational treatments (including diagnostic testing) of TBI and PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities. The Community Partners in Mental Health Research Award PA responds to Section 706 of the National Defense Authorization Act for Fiscal Year 2013 by supporting research on the causes, development, and innovative treatment of mental health, substance use disorders, TBI, and suicide prevention in members of the National Guard and Reserves, their family members, and their caregivers. Application submission deadlines for the PAs are in November 2014, January 2015, and February 2015. Scientific peer reviews will be held in January and March 2015 followed by programmatic reviews in March and May 2015. Awards will be made by September 2015.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Traumatic Brain Injury/ Psychological Health Research.</p>		
<p>Congressional Add: 380A - Peer-Reviewed Breast Cancer Research</p> <p>FY 2014 Accomplishments: This Congressional Special Interest research initiative was for Breast Cancer research. The Breast Cancer Research Program challenged the scientific community to design research that addresses the urgency of ending breast cancer. Applications were required to address at least one of ten overarching challenges, which were focused on preventing breast cancer, identifying what makes the breast susceptible to cancer, determining why some women get breast cancer while others do not, distinguishing aggressive breast cancer from indolent cancers, conquering the problems of over-diagnosis and overtreatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become life-threatening metastases, determining how to prevent recurrence, revolutionizing treatment regimens with safe and effective interventions, and eliminating the mortality associated with metastasis. To support the program's vision of ending breast cancer, three award mechanisms were developed to support meritorious breast cancer research: Breakthrough Award, Era of Hope Scholar Award, and Innovator Award.</p>	120.000	120.000

UNCLASSIFIED

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<p>The Breakthrough Award accepts applications under four funding levels, depending on the scope of the research project, which could range from initial proof-of-concept to clinical trials. The Breakthrough Award was offered twice during this fiscal year. Program Announcements (PAs) were released in March and September 2014. Application submission deadlines were in May and August 2014 for the first PAs. Application submission deadlines for the second PAs will be in December 2014 and January 2015. Scientific peer review was held in July and October 2014 and will be held again in March 2015 followed by programmatic reviews in September 2014, December 2014, January 2015, May 2015, and June 2015. Awards will be made by September 2015.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Breast Cancer Research.</p>		
<p>Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research</p> <p>FY 2014 Accomplishments: This Congressional Special Interest research is for Prostate Cancer research. The vision for this effort is to conquer prostate cancer by funding research to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. To address the most critical current needs in prostate cancer research and clinical care, the Prostate Cancer Research Program (PCRP) developed four overarching challenges to be addressed by the research community: (1) develop better tools for early detection of clinically relevant disease, (2) distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer, (3) develop effective treatments and address mechanisms of resistance for men with high risk or metastatic prostate cancer, and (4) develop strategies to optimize the physical and mental health of men with prostate cancer. In addition, research projects are being solicited in the areas of biomarker development, genetics, imaging, mechanisms of resistance, survivorship and palliative care, therapy, and tumor and microenvironment biology. To meet these goals for FY14, the following twelve award mechanisms were developed: Biomarker Development Award, Clinical Exploration Award, Collaborative Undergraduate HBCU Student Summer Training Award, Exploration-Hypothesis Development Award, Health Disparity Research Award, Idea Development Award, Laboratory-Clinical Transition Award, Physician Research Training Award, Population Science Impact Award, Postdoctoral Research Training Award, Prostate Cancer Biospecimen Resource Site Award, and Synergistic Idea Development Award. All Program Announcements were released in May 2014. The applications for the Exploration-Hypothesis Development Award were received and scientifically peer reviewed in July 2014, and recommended for funding at programmatic review in October 2014. Applications for the remaining funding mechanisms were received in September 2014-October 2014, and will undergo scientific peer review in November 2014-December 2014. Funding recommendations for these</p>	80.000	80.000

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>	
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	
mechanisms will be made at programmatic reviews in January 2015-February 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Prostate Cancer Research.			
Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research FY 2014 Accomplishments: This Congressional Special Interest research initiative was for Gulf War Illness research. The program's vision of improving the health and lives of Veterans who have the complex symptoms known as Gulf War Illness was addressed through the funding of innovative research to identify effective treatments, to improve its definition and diagnosis, and to better understand its pathobiology (study of structural and functional manifestations of a disease with emphasis on the biological aspects) and symptoms. Applications were accepted for FY14 through five award mechanisms: the Clinical Trial Award, the Innovative Treatment Evaluation Award, the Investigator-Initiated Research Award (IIRA), the Investigator-Initiated Research Expansion Award and a New Investigator Award. The IIRA included an option that encourages research focused on developing a consensus case definition for Gulf War Illness. Application submission deadlines are in September 2014 and January 2015 followed by scientific peer review in November 2014 and March 2015. Funding recommendations will be made at programmatic review in January 2015 and May 2015. Awards will be made by September 2015 FY 2015 Plans: This Congressional Special Interest research initiative is for Gulf War Illness Peer-Reviewed Research.	20.000	20.000	
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders FY 2014 Accomplishments: This Congressional Special Interest research effort on Research in Alcohol and Substance Use Disorders was a competitive program to create translational research addressing alcohol and substance abuse issues. The goal of the program was to identify and develop new medications to improve treatment outcomes for alcohol and substance use disorders, especially related to traumatic brain injury and post-traumatic stress disorder(PTSD), through organizing multidisciplinary, team-based research efforts to translate contemporary basic knowledge into enhanced clinical protocols. The projects will study the hypothesis that prior traumatic stress experience will increase drug and alcohol seeking and that systemic administration of certain medications decrease the impact of stress-related stimuli on drug and alcohol seeking in preclinical and clinical studies of patients with both PTSD/ Substance Use Disorder. Other funded areas of research included studies on PTSD and protecting degeneration of the nervous system against alcohol toxicity on the nerves	4.000	4.000	

UNCLASSIFIED

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
in order to determine the pathophysiologic significance (functional changes associated with disease or injury) following traumatic stress. FY 2015 Plans: This Congressional Special Interest research initiative is for Research in Alcohol and Substance Use Disorders.		
Congressional Add: 400A - Peer-Reviewed Medical Research FY 2014 Accomplishments: This Congressional Special Interest initiative for the Peer Reviewed Medical Research Program continues to strive for its vision to improve the health and well-being of all military Service members, Veterans, and beneficiaries by supporting military health-related research of exceptional scientific merit. Applications are required to address at least one of the following 25 Congressionally-directed topics: acupuncture, arthritis, chronic migraine and post-traumatic headache, congenital heart disease, DNA vaccine technology for post-exposure prophylaxis, dystonia, epilepsy, food allergies, fragile X syndrome, hereditary angioedema, illnesses related to radiation exposure, inflammatory bowel disease, interstitial cystitis, lupus, malaria, metabolic disease, neuroprosthetics (artificial extensions to the body that restore or improve function of the nervous system lost due to disease or injury), pancreatitis, polycystic kidney disease, post-traumatic osteoarthritis, psychotropic medications, respiratory health, rheumatoid arthritis, segmental bone defects (injuries in which a section of bone is completely shattered or absent), and tinnitus (perception of sound, such as ringing, when no actual sound is present). Five award mechanisms are being offered in FY14: the Clinical Trial Award, the Discovery Award, the Focused Program Award, the Investigator-Initiated Research Award, and the Technology/ Therapeutic Development Award. For the Discovery Award, application receipt occurred in July 2014, scientific peer review was conducted in September 2014, and funding recommendations will be made during programmatic review in January 2015. For the remaining mechanisms, application receipt will occur in October and November 2014, peer review will be conducted in December 2014 and January 2015, and funding recommendations will be made during programmatic review in March 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Medical Research.	200.000	247.500
Congressional Add: 417A - Peer-Reviewed Alzheimer Research FY 2014 Accomplishments: This Congressional Special Interest research program was to study Alzheimer's disease. The mission of the Peer Reviewed Alzheimer Research Program continued to be two-fold. The program sought to 1) build an integrated program devoted to understanding the association between Traumatic Brain Injury (TBI) and Alzheimer's disease (AD), and 2) reduce the burden on caregivers and individuals affected by TBI-AD symptoms, especially in the military community. The program offered three funding mechanisms	12.000	12.000

UNCLASSIFIED

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<p>in order to meet the program's mission. These are the 1) Convergence Science Research Award (CSRA), 2) Quality of Life Research Award (QUAL), and 3) Military Risk Factors Research Award (MRFA). The focus areas for the FY14 CSRA mechanism were expanded to include research that examines the role of non-neuronal cells (cells of the brain other than neurons e.g., glia) in TBI/AD pathogenesis. The CSRA mechanism also continued to request for research applications on genomic and proteomic studies to investigate the linkages between TBI and AD. The FY14 QUAL mechanism is to fund research which explores technologies, tests, interventions, epidemiological studies, or devices with the potential to benefit individuals suffering from the symptoms of TBI or AD, while reducing caregiver burden. The MRFA mechanism is to facilitate high-impact, systematic, population-based research investigating the association between TBI and the subsequent development of AD. The FY14 Program Announcements were released in September of 2014, with pre-applications, full applications, peer review, and programmatic review thereafter. Awards will be made by September 2015.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Alzheimer Research.</p>		
<p>Congressional Add: 439A - Joint Warfighter Medical Research</p> <p>FY 2014 Accomplishments: The Joint Warfighter Medical Research Program (JWMP) was intended to provide continuing support for promising previously funded Congressional Special Interest (CSI) projects. The focus was to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives and yield a benefit to military medicine. The JWMP directly supported military medical research in medical training and health information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. For the FY14 JWMP, through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committees, and execution management agencies/activities. Those projects deemed by the Joint Program Committees to have the highest priority to fill critical research or materiel gaps and those projects close to developing a product were invited to submit a pre-application and full application for the next level of effort. The external scientific peer review was completed in June 2014. The programmatic review was completed in August 2014 and 32 projects were recommended for funding. Award negotiations will be complete by the end of the third quarter of FY15.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Joint Warfighter Medical Research.</p>	65.000	30.000
<p>Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research</p> <p>FY 2014 Accomplishments: This Congressional Special Interest research initiative for Reconstructive Transplant Research (RTR) is to accelerate the movement of promising ideas in restorative transplantation into</p>	15.000	15.000

UNCLASSIFIED

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
clinical application. The initiative is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to have a major impact on RTR. Proposals are due in October 2014, scientific peer review is planned for December 2014, and programmatic review will take place in February 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Reconstructive Transplant Research.		
Congressional Add: 453A - Trauma Clinical Research Repository FY 2014 Accomplishments: This Congressional Special Interest research initiative studied the development of a Trauma Clinical Research Repository. The purpose of the repository is to capture data in theater for review and research on patient care and outcomes.	5.000	-
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research FY 2014 Accomplishments: FY 2014 Accomplishments: This Congressional Special Interest research initiative was offered for the first time in FY14. It is intended to support research that evaluates the comparative effectiveness of and functional outcomes associated with prosthetic and orthotic clinical interventions, and/or other rehabilitation interventions, for Service members and Veterans who have undergone limb salvage or limb amputation. The results of this research are intended to improve our understanding of and ultimately the implementation of the most effective prosthetic prescription, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, other caregivers, and policymakers. Basic, translational (conversion of findings in basic science to practical applications) and clinical research efforts are sought to ensure that results of scientific research will be used to directly benefit the lives of military, Veteran and civilian populations. Studies will be sought that: compare different standard care approaches, include patient-centric outcome assessments, have the potential to lead to new knowledge that can be developed into new clinical practice guidelines and/or new prescription algorithms for prosthetic and orthotic devices, have the potential to lead to new technology developments that can lead to improved prosthetic devices, therefore improving patient outcomes, provide information on quality of life, reintegration, and/or return to duty as it pertains to those patients who use a prosthetic or orthotic device due to limb trauma. Studies may also be proposed that consider outcome factors related to health care delivery and clinical decision-making such as cost, accessibility, adoption of medical policy, and patient preferences. Studies should have a clinical focus, and may include methodologies and designs such as surveys, retrospective data analyses, simulation modeling, longitudinal observation, cross sectional observation, case control, or qualitative research study designs. Collaboration with military researchers and clinicians is encouraged. Joint DoD-VA studies, including longitudinal outcome studies, are particularly sought. A Program Announcement was released in October 2014. A total of 109 pre-	10.000	10.000

UNCLASSIFIED

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<p>applications were received as of the pre-application receipt deadline in November 2014. Invitations to submit a full application are scheduled to be released in December 2014, with an application submission deadline in January 2015. Peer review is currently scheduled for March 2015, with programmatic review set for April 2015. Awards will be made by September 2015.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for Orthotics and Prosthetics Outcomes Research.</p>		
<p>Congressional Add: 456A - HIV/AIDS Program</p> <p>FY 2014 Accomplishments: This Congressional Special Interest research initiative complements the funding for the HIV/AIDS research program. Several potential vaccine candidates were down-selected for further testing in human volunteers to study their ability to provoke an immune response that can protect against HIV either as a single vaccine or combination of various subtypes.</p> <p>FY 2015 Plans: This Congressional Special Interest research initiative is for HIV/AIDS Program.</p>	7.000	12.900
<p>Congressional Add: 540A - Global HIV/AIDS Prevention (Navy)</p> <p>FY 2014 Accomplishments: This Congressional Special Interest project supports Global HIV/AIDS Prevention research. Program emphasis is placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY 2014 Congressionally directed research identified above is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. Specific research efforts include HIV/AIDS. The HIV/AIDS Prevention program conducts on-site visits to determine eligible areas for technical assistance and resource support. The program provides support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other prevention materials, provision of educational materials such as brochures, posters, and booklets (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support, (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment, and (4) strategic information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs. The HIV/AIDS Prevention program provided technical assistance and resource support for 25 foreign defense</p>	8.000	8.000

UNCLASSIFIED

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
forces in FY 2013. Accomplishments included over 45,000 individuals that received testing and counseling services for HIV and received their test results; 29,752 military members and their dependents targeted with HIV prevention interventions; more than 1,100 health care workers successfully completed an in-service training program; and 2,893 pregnant women knew their HIV status based on testing and counseling services provided to them. Accomplishments for FY 2014 will be reported after the end of the 2014 fiscal year, once annual program result data is collected. Because of the CSI annual structure, out-year funding is not programmed. FY 2015 Plans: This Congressional Special Interest research initiative is for Global HIV/AIDS Prevention.		
Congressional Add: 660A - Tuberos Sclerosis Complex (TSC) FY 2014 Accomplishments: The Congressional Special Interest research initiative for Tuberos Sclerosis Complex (TSC) encouraged innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches. Within this context, the FY14 TSCRCP encouraged applications that address vital program focus areas of Clinical Aspects of TSC, Personalization of Care and/or Optimization of Treatments. This research effort offered three award mechanisms to support TSC research: Idea Development, Exploration-Hypothesis Development, and Pilot Clinical Trial Awards. Applications were due July 2014, followed by scientific peer review in September 2014, and funding recommendations made at programmatic review in November 2014. Awards will be will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Tuberos Sclerosis Complex (TSC).	6.000	6.000
Congressional Add: 790A - Duchenne Muscular Dystrophy FY 2014 Accomplishments: This Congressional Special Interest initiative was for research focused on Duchenne Muscular Dystrophy (DMD) (gene mutations in dystrophin affecting approximately 1 in 3600 boys causing muscle degeneration and eventual death). The goal for this research program is to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD by supporting research to better inform the development of drugs, devices, and other interventions and promote their effective clinical testing. Within this context, this program encourages applications that address a number of focus areas including: 1) discovery and qualification of pharmacodynamic (the biochemical and physiological effects of drugs on the body, their mechanisms of action, and the relationship between drug concentration and effect), prognostic, and predictive biomarkers (characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or biological responses to a therapeutic intervention); 2) assessment of clinical trial outcomes; 3) extension or expansion of preclinical translational data; and 4) novel interventions to improve clinical care and quality of life. A total of two award mechanisms were offered in 2014, the Investigator-	3.200	3.200

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
Initiated Research Award and the Therapeutic Idea Award. Applications were received in October 2014 with scientific peer review in January 2015 and programmatic review in March 2015. Awards will be made by September 2015. FY 2015 Plans: This Congressional Special Interest research initiative is for Duchenne Muscular Dystrophy.		
Congressional Add: 459A - Peer-Reviewed Epilepsy Research FY 2014 Accomplishments: No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. FY 2015 Plans: This Congressional Special Interest research initiative is for Peer-Reviewed Epilepsy Research.	-	7.500
Congressional Add: 474A – Program Increase: Restore Core Research Funding Reduction (Army) FY 2014 Accomplishments: No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	7.575
Congressional Add: 474B – Program Increase: Restore Core Research Funding Reduction (Navy) FY 2014 Accomplishments: No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	6.856
Congressional Add: 474C – Program Increase: Restore Core Research Funding Reduction (Air Force) FY 2014 Accomplishments: No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	10.228
Congressional Add: 474D – Program Increase: Restore Core Research Funding Reduction (USUHS) FY 2014 Accomplishments: No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item. FY 2015 Plans: FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.	-	2.514
Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF)	-	94.584

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<i>FY 2014 Accomplishments:</i> No funding programmed. FY15 DHP Congressional Special Interest (CSI) Item.		
<i>FY 2015 Plans:</i> FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Technology Development Program Element (PE) - 0603115.		
Congressional Adds Subtotals	802.400	975.057

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Research proposals will be solicited by program announcements resulting in grants, contracts, or other transactions.

E. Performance Metrics

N/A

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>			
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
238C: <i>Enroute Care Research & Development (Budgeted) (AF)</i>	3.685	4.666	3.394	1.340	-	1.340	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Enroute Care Research & Development (Budgeted) (AF)	4.666	3.394	1.340
<p>Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.</p> <p>FY 2014 Accomplishments: Continued research to enhance the care of acutely injured AE trauma patients through projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Continued research to improve AE trauma patient care through the development and assessment of continuous, real-time vital sign monitoring system. Continued research assessing the clinical effect of prolonged hypobaric during AE on TBI, how AE affects blood volume responsiveness, improve pain management during AE, and identify/mitigate factors impacting patient safety during AE. Continued study of optimal time to transport patients. Continued development of the multi-channel negative pressure wound treatment device and monitor FDA 510K process. Began swine study to investigate post AE effects on coagulation and inflammation. Began a retrospective study of the efficacy of cabin altitude restrictions on AE patients. Continued automation of CCATT patient record, perform operational test. Began development</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>of en route care retrospective research database. Began investigating new research and development requirements based on results of prior studies and warfighter gap analyses. Completed Air Worthiness certification for simulator mannequin and initiated use on Aeromedical Evacuation (AE) and Critical Care Transport Team (CCATT) training flights – transitioned to the CCATT Pilot Unit. Continued research to enhance the care of acutely injured AE trauma patients through projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Completed and archived miniaturized Extra Corporal Membrane Oxygenation (ECMO) device bovine study. Analyzed initial results of research assessing the clinical effect of prolonged hypobaria during AE on Traumatic Brain Injury (TBI), how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE. Began assessing how the transport of psychiatric patients impacts AE crew protocols. Continued research examining medical records of traumatically injured patients transported by Critical Care Air Transport Teams (CCATT). Conducted research prospectively characterizing the incidence and success of Life Saving Interventions (LSI) performed by combat medics during pre-hospital and en route care. Began research for identifying optimal time to transport patients to ensure best outcomes. Began investigations into advanced development options for AE material solutions: began testing for a portable electrical power source; began development of a negative pressure multi-channel negative pressure wound therapy device; awarded and initiated automation of the CCATT patient record (Form 3899L) onto a widely-accepted portable physiologic monitoring device; and supported Air Mobility Command (AMC) in prototype development for a replacement aircraft patient loading system. Spear-headed DoD Information Assurance Certification and Accreditation Program (DIACAP) for telemedicine capability of a physiologic monitoring device in support of AMC requirements, which will allow for transmission of aeromedical electronic medical information across DoD information platforms. Presented research findings in peer-reviewed journals and at national meetings. Completed study on the following: effects of AE on the injury response, including potential worsening of the systemic inflammatory response, increased susceptibility to infection, and secondary brain injury after traumatic brain injury; the effects of hypobaric hypoxia exposure on a crush muscle crush injury during air transport. Continue research to enhance the care of acutely injured AE trauma patients through projects assessing closed loop technology for autonomous control of oxygenation and ventilation. Continue research assessing the clinical effect of prolonged hypobaria during AE on TBI, how AE affects blood volume responsiveness, improve pain management during AE, and identify/mitigate factors impacting patient safety during AE. Continue to study optimal time to transport patients. Continue development of the multi-channel negative pressure wound treatment device and monitor FDA 510K process. Begin Began swine study to investigate post AE effects on coagulation and inflammation. Begin Began a retrospective study of the efficacy of cabin altitude restrictions on AE patients. Begin Began study to determine the effects of altitude on patients requiring ECMO system for respiratory support during transport. Continue automation of CCATT patient record, perform operational test. Begin Began development of en route care retrospective research database. Begin Began investigating new research and development requirements based on results of prior studies and warfighter gap analyses.</p> <p>FY 2015 Plans:</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Plan and test for transition of miniaturized Extra Corporal Membrane Oxygenation device to Air Mobility Command (AMC) for Aeromedical Evacuation (AE) and Combat Casualty Air Transport Team (CCATT) and lung team use on long flight missions. Monitor technology readiness level of closed loop ventilation and oxygenation. Analyze final results of research describing blood administration, analgesics used, and burn care provided during Critical Care Air Transport. Development of new clinical practice guidelines and validation of existing guidelines for CCATT. Evaluate and describe current en route care practices from point of injury to in-theatre military treatment facilities. Provide descriptive analysis of non-traumatically injured patients and the clinical care provided during transport out of theatre on CCATT. Analyze final results of research assessing the clinical effect of prolonged hypobarica during AE, how AE affects blood volume responsiveness, improving pain management during AE, and factors impacting patient safety during AE, and determine translational elements of completed research or need for further studies. Complete and transition automated CCATT patient record and multi-channel negative pressure wound therapy device to acquisition process. Analyze results of cabin altitude restriction retrospective study, which should lead to better evidence-based decision-making for when to fly low. Continue swine study to investigate post AE effects on coagulation and inflammation. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses.</p> <p>FY 2016 Plans: Analyze final results of swine study investigating post AE effects on coagulation and inflammation, which will lead to a knowledge platform to develop guidelines for evacuation strategies during transport of combat casualties. Pursuant system build and demonstration of the closed loop ventilation and oxygen delivery system, the data from the pre-hospital use of capnometry and the ventilator registry will be used to define the requirements of a system to perform closed loop ventilation. Continue pursuing the AFMS strategic goal A1 to “Transform the En-route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport.”</p>			
Accomplishments/Planned Programs Subtotals	4.666	3.394	1.340

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807714HP: <i>Other Consolidated Health Support</i>	13.049	13.441	13.844	-	13.844	14.259	14.655	-	-	Continuing	Continuing

Remarks

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 238D / <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i>			
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
238D: <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i>	-	-	-	0.997	-	0.997	2.045	2.240	2.282	2.328	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Enroute Care R&D - Clinical Translational Focus (AF)	-	-	0.997
Description: This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in the En-Route Patient Safety sub-project area examine human factors considerations in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Analyze final results of swine study investigating post AE effects on coagulation and inflammation, which will lead to a knowledge platform to develop guidelines for evacuation strategies during transport of combat casualties. Pursuant system build and demonstration of the closed loop ventilation and oxygen delivery system, the data from the pre-hospital use of capnometry and			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 238D / <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
the ventilator registry will be used to define the requirements of a system to perform closed loop ventilation. Continue pursuing the AFMS strategic goal A1 to “Transform the En-route Care System” based on war fighter identified gaps and validated requirements. Begin and/or continue work that will improve mission effectiveness in the A2AD environment such as closed loop technologies and enabling capabilities leading to autonomous patient transport.”			
Accomplishments/Planned Programs Subtotals	-	-	0.997

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 238E / <i>Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)</i>			
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
238E: <i>Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)</i>	-	-	-	0.997	-	0.997	2.045	2.239	2.282	2.327	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to advance aeromedical evacuation (AE), Critical Care Air Transport Team (CCATT), and Tactical Critical Care Evacuation Team (TC CET) capabilities through the research and development of rapid, more efficient, and safer patient transport from the pre-staging for strategic or intra-theater air evacuation to definitive care, and to understand the effects of transport on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into translatable practice and technology products. The sub-project areas include: Impact of Transport on patients and crew which includes the optimization of provider performance and patient care, En-Route Medical Technologies which includes technology advances and assessment, and En-Route Patient Safety which includes efforts to ensure the safe transport of patients through the AE system.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)	-	-	0.997
<p>Description: This project area seeks to advance aeromedical evacuation (AE), Critical Care Air Transport Team (CCATT), and Tactical Critical Care Evacuation Team (TC CET) capabilities through the research and development of rapid, more efficient, and safer patient transport from the pre-staging for strategic or intra-theater air evacuation to definitive care, and to understand the effects of transport on injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into translatable practice and technology products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew which includes the optimization of provider performance and patient care, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety which includes technology advances and assessment. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in this the En-Route Patient Safety sub-project area will examine human factors considerations in en-route patient safety in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.</p> <p>FY 2014 Accomplishments: No funding programmed.</p> <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Plans:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 238E / <i>Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Continue development of the en route care retrospective research database. Continue research to improve patient outcomes by providing advanced notification of resuscitation needs. Continue research to identify the effects of altitude preconditioning and also biomarkers as predictors of acute lung injury prior to AE. Begin simulation research program: validate skill / outcome measures, develop simulation improvements / technologies to achieve those outcomes, understand perishability of skills. Continue investigating new research and development requirements based on results of prior studies and warfighter gap analyses. Continue closed loop interventions research and development.			
Accomplishments/Planned Programs Subtotals	-	-	0.997

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 243A / <i>Medical Development (Lab Support) (Navy)</i>
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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
243A: <i>Medical Development (Lab Support) (Navy)</i>	61.968	35.074	34.378	37.580	-	37.580	38.211	40.942	41.720	42.554	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Navy Bureau of Medicine and Surgery, this program element (PE) includes costs related to laboratory management and support salaries of government employees that are not paid from science/research competitively awarded funding. The Outside Continental U.S. (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Medical Development (Lab Support) (Navy)	35.074	34.378	37.580
Description: RDT&E funds for operating and miscellaneous support costs at RDT&E laboratories, including facility, equipment and civilian personnel costs that are not directly chargeable to RDT&E projects. Excludes military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.			
FY 2014 Accomplishments: Provided operating and miscellaneous support costs at BUMED research laboratories. Continued to provide support for technologically advanced cutting edge research equipment for research and data acquisition, automated sampling and real time statistical analysis of biomedical research data utilizing data information systems integral with new equipment. Continued to provide replacement of obsolete general purpose research equipment.			
Additional Funding received will be used for 64 administrative civilian FTE's that had to be reprogrammed from the overhead account, due to new financial model. Funding will also be used for existing government inherent civilian vacancies that are not in the current manpower controls.			
FY 2015 Plans: Provide operating support for eight medical RDT&E labs across 15 product lines to develop products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter, and enable the labs to meet or exceed science performance metric objectives.			
FY 2016 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 243A / <i>Medical Development (Lab Support) (Navy)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Continue to provide operating support for eight medical RDT&E labs across 15 product lines to develop products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter, and enable the labs to meet or exceed science performance metric objectives.			
Accomplishments/Planned Programs Subtotals	35.074	34.378	37.580

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include timely and proportionate distribution of funds to labs and product lines to optimize resource utilization in the development and evaluation of products that protect, treat, rehabilitate and enhance the performance of the Warfighter.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 247A / <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>			
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
247A: <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>	-	0.200	-	2.060	-	2.060	2.064	1.548	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally, the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project, significantly improving the chances of success of this project. Successful completion of this project could significantly enhance force health protection and global engagement by providing a vetted approach to malaria control in the Southeast Asia region where multi-drug resistant malaria is a major infectious disease threat. This project supports (both directly and indirectly in a priority country - Vietnam) Global Health Security Agenda priorities: Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	0.200	-	2.060
Description: This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, operations research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project significantly improving the chances of success of this project.			
FY 2014 Accomplishments: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2015 Plans: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2016 Plans: The first objective of this project, which is to enhance the malaria surveillance in Vietnam, will be completed in FY14. The malaria surveillance system is being optimized to define exactly where transmission is occurring with novel mapping to support targeted			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 247A / <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
<p>interventions and the monitoring and evaluation of their impact. It will build upon existing funded projects, leveraging investments from the US Government, international partners and non-Government Agencies.</p> <p>In FY15, surveillance efforts started in 2014 will expand to include military personnel, a mobile group working in malaria endemic areas of Vietnam. This population has traditionally been excluded from global malaria control programs and comprehensive malaria burden data is not available. The Vietnamese People’s Army Military Medicine Department (MMD) has requested a cross-sectional study be conducted to determine the parasite carriage rate and proportion of drug-resistant parasites within the military. This study is critical to understanding the malaria burden in this segment of the Vietnamese population and is a pre-requisite for additional malaria elimination efforts planned for FY16 and leverage FY14 investments.</p> <p>In FY16, after establishing a baseline parasite carriage rate and drug resistant burden in FY15 for the military, research efforts will focus on improving the quality of detecting individuals carrying the malaria parasite, treatment (the drugs themselves and the adherence to them) and the implementation of rigorous investigation of each case to determine the origin of infection to prevent further infections.</p> <p>The impact of the malaria interventions under study will be evaluated (and re-evaluated) to determine which quality improvement practices should be scaled up or if additional interventions are needed. The most effective combinations of interventions for different epidemiological strata in Vietnam will be determined to select and then directly evaluate the impact of the selected interventions on malaria parasite carriage and disease rates in an on-going iterative fashion (operations research). Collected malaria surveillance and intervention data will be modelled to measure impact of previous interventions in Vietnam. The most promising intervention or combination of interventions will be recommended for deployment for eliminate malaria in the defined geographic region of study in Vietnam.</p>				
Accomplishments/Planned Programs Subtotals		0.200	-	2.060
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 247A / <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>

E. Performance Metrics

Successful execution of this project will be measured by significant reduction of malaria parasite incidence and prevalence in the geographic area of study. Study results and recommendations will be reported in refereed professional journals and policy recommendations submitted to the Vietnamese and US Governments.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 247B / <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>			
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
247B: <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>	-	0.425	-	1.040	-	1.040	1.135	1.238	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project seeks to demonstrate that the impact of sepsis (severe infections) in Egypt can be mitigated through the Austere Environment Consortium for Enhanced Sepsis Outcomes (ACESO) approach of discovering common, host-based pathogenic pathways for improved recognition and management of sepsis and point of care (POC) diagnostic and prognostic biomarker panels. Sepsis is the common path to end-organ damage and death for a large proportion of globally-important infectious diseases. This project will improve the understanding of disease pathogenesis and antimicrobial resistance mechanisms through network and biomarker analysis thus offering unique opportunities for improving sepsis diagnosis and management. Insight into the disease pathogenesis of sepsis, and host factors which predict susceptibility, and sepsis severity provides opportunity for targeted interventions to forestall morbidity and mortality. Furthermore, enhanced knowledge of emerging antimicrobial resistance in strategic regions informs ongoing surveillance and mitigation efforts of critical importance to deployed forces. Successful completion of this project will provide reliable antimicrobial resistance data for forces deploying to Egypt and the region and also document improved methods for the treatment and management of sepsis. ACESO is an international consortium of sepsis researchers led by NMRC that has established a network of sepsis research sites in SE Asia and Sub-Saharan Africa to improve clinical outcomes and advance our understanding of pathogenesis, biomarkers of sepsis and antimicrobial resistance trends. The proximity of NAMRU-3 to the largest infectious disease hospital in Egypt (Abbassia Fever Hospital) affords an unparalleled opportunity for ACESO expansion and will provide critical severe infection and antimicrobial resistance data from the important North African Theater. This project supports (both directly and indirectly) Global Health Security Agenda priorities: Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Mitigate the Global Impact of SepSis Through ACESO (CARB) (Navy)	0.425	-	1.040
Description: This project seeks to demonstrate that the impact of sepsis in Egypt can be mitigated through the Austere Environment Consortium for Enhanced Sepsis Outcomes (ACESO) approach of discovering common, host-based pathogenic pathways for improved recognition and management of sepsis. This project will improve understanding of pathogenesis and antimicrobial resistance mechanisms through network and biomarker analysis to offer unique opportunities for improving sepsis diagnosis and management. Most specifically, ACESO will execute biomarker discovery identifying diagnostic and prognostic biomarker panels which may improve sepsis management in all environments including resourced and austere.			
FY 2014 Accomplishments: No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.			
FY 2015 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 247B / <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
<p>No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.</p> <p>FY 2016 Plans: FY14 efforts will be directed towards the development and approval of research protocols by NAMRU-3 and Ministry of Health Scientific Review Board and Institutional Review Board, as well as, the development of agreements, securing required equipment and supplies, and the recruitment of necessary contract staff to initiate patient enrollment during first quarter of FY15.</p> <p>FY15 efforts will support the continuation of the observational study of patients with sepsis in Egypt admitted to the Abbassia Fever Hospital, adjacent to NAMRU-3, Cairo. The goals of this study are to 1) identify diagnostic and prognostic markers, 2) investigate common pathogenic pathways, 3) describe the spectrum of pathogens causing sepsis, 4) describe the treatment strategies currently in use, and 5) assess the long-term sequelae. Adult patients with suspected infection and evidence of systemic inflammation will be considered for enrollment. Laboratory testing will augment the testing routinely performed at the hospital microbiology laboratory, and will include diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics (e.g. microarray analysis, multiplex PCR, and sequencing), and assays measuring the host-response (biomarker assays and host transcriptome arrays). Sophisticated analytic and statistical approaches will be applied to this complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways.</p> <p>FY16 funding will support the continuation of the observational study at the Abbassia Fever Hospital and the sophisticated analytic and statistical approaches will be applied to this complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways.</p>				
Accomplishments/Planned Programs Subtotals		0.425	-	1.040
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				
E. Performance Metrics				
Successful execution of this project will be measured by significant reduction in the mortality rate from sepsis, reduced hospitalization days, and by the number and impact factor of publications in refereed professional journals.				

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 284B / <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i>
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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
284B: <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i>	2.646	3.694	2.280	1.700	-	1.700	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	3.694	2.280	1.700
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.			
FY 2014 Accomplishments: Completed high altitude/U-2 pilot imaging and comparison baseline studies. Completed mountain altitude acclimatization research. Completed the study on risk and protective factors and social-occupational impairment among AF Special Operations Forces personnel. Assessed fatigue management using non-visual light stimulation. Expanded ongoing studies on understanding hypoxia, focusing on previously unidentified latent effects. Began initial evaluations of potential technologies capable of providing in-flight assessment of pilot physiological measures. Kick-off new study looking at acute MRI changes and time course of development secondary to hypobaric exposure in select AF physiology and pilot populations			
FY 2015 Plans: Complete high altitude/U-2 pilot imaging and comparison baseline studies. Complete the study on risk and protective factors and social-occupational impairment among AF Special Operations Forces personnel and evaluate some of the measures instituted as a result of this effort. Pursue human systems integration studies. Assess novel fatigue and cognitive management modalities.			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 284B / <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Expand ongoing studies on understanding hypoxia, focusing on previously unidentified latent effects. Initiate Pilot Physiology and Cognitive Performance to determine physiological impacts during manned flight to determine mitigations needed to maintain / optimize performance. Perform development of fitness readiness algorithms to enhance AF personnel training and prevent injuries. FY 2016 Plans: Expand evaluations of promising fatigue and cognitive management modalities. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research to define what is a “safe” altitude and potentially spur operational changes. Implement plans to pursue human systems integration studies, focusing on identified gaps. Mature a comprehensive program working to define and mitigate the extreme physiological demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
Accomplishments/Planned Programs Subtotals	3.694	2.280	1.700

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

SEE OTHER PROGRAM FUNDING SUMMARY FOR PROJECT CODE 238C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc).

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 284C / <i>Core Human Performance R&D - Clinical Translational Focus (AF)</i>
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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
284C: <i>Core Human Performance R&D - Clinical Translational Focus (AF)</i>	-	-	-	1.003	-	1.003	2.349	2.664	2.762	2.817	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Human Performance R&D - Clinical Translational Focus (AF)	-	-	1.003
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Mature a comprehensive program working to define and mitigate the extreme physiological demands of higher altitudes to include decompression sickness and hypoxia. Expand on previous studies to understand and mitigate fatigue, cognitive overload and how these conditions magnify each other. Advance understanding of appropriate selection as it pertains to new accessions, job placement, injury reduction, and retention.			
Accomplishments/Planned Programs Subtotals	-	-	1.003

C. Other Program Funding Summary (\$ in Millions)

N/A

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 284C / <i>Core Human Performance R&D - Clinical Translational Focus (AF)</i>

C. Other Program Funding Summary (\$ in Millions)

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 284D / <i>Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)</i>
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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
284D: <i>Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)</i>	-	-	-	1.002	-	1.002	2.348	2.663	2.761	2.816	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in piloted aircraft, as well as remote piloted aircraft operations, aviation performance and injury prevention, and personalized optimization of performance of AF personnel. The sub-project areas include: AF Aircrew Physiology and Cognition Performance which includes pilot performance monitoring and interventions, fatigue management, AF unique Physiological Performance and Targeted Conditioning Mitigation which includes personalized performance and training techniques for optimal performance, Aviator Injury Prevention and Performance Optimization, Select training and simulation to optimize performance of AF operators and personnel, and identification of solutions related to Operational and Environmental Challenges to Performance.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)	-	-	1.002
Description: This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in piloted aircraft, as well as remote piloted aircraft operations, aviation performance and injury prevention, and personalized optimization of performance. The sub-project areas include: AF Aircrew Physiology and Cognition Performance which includes pilot performance monitoring and interventions, fatigue management, AF unique Physiological Performance and Targeted Conditioning Mitigation which includes personalized performance and training techniques for optimal performance, Aviator Injury Prevention and Performance Optimization, Select training and simulation to optimize performance of AF operators and personnel, and identification of solutions related to Operational and Environmental Challenges to Performance.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 284D / <i>Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Continue assessment of in-flight pilot performance monitoring. Begin assessment of potential physiological measures capable of capturing physiological and cognitive state of AF pilot and operator personnel. Evaluate current / planned technologies employed in current generation aircraft against human performance limitations to address changes needed to technology or identify performance optimization techniques. Conclude efforts identifying the effects of combining over-the-counter stimulants with Modafinil, which may stimulate the need for further research. Apply results from high altitude and hypoxia studies to refine this line of research and potentially spur operational and training changes, and identify areas needed for further research. Implement plans to pursue human systems integration studies, focusing on identified gaps. Conduct operational based vision research.			
Accomplishments/Planned Programs Subtotals	-	-	1.002

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.***

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 285A / <i>Operational Medicine Research & Development (Budgeted) (AF)</i>			
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
285A: <i>Operational Medicine Research & Development (Budgeted) (AF)</i>	8.146	6.851	1.983	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Operational Medicine Research & Development (Air Force)	6.851	1.983	-
Description: The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.			
FY 2014 Accomplishments: Continued patient centered/personalized medicine research efforts related to autism and obesity. Aligned resources with academia and other health agencies to evaluate outcomes of standardized diabetes prevention initiatives, including online resources. Determined if medication therapy management program for patients with chronic pain at a large Military Treatment Facility reduced costs and improved outcomes. Evaluate personalized prevention and treatment efforts related to Patient-Centered Precision Care. Building on previous work, identified opportunities for advanced development of mobile health application technologies within the MHS for personalized disease prevention and management. Began evaluation of utilization and effectiveness of current AF mental health/family support programs for the purposes of identifying gaps and possible solutions to areas such as marital discord, family maltreatment, binge drinking, and suicide.			
FY 2015 Plans: Continue patient centered/personalized medicine research efforts related to autism and obesity. Align resources with academia and other health agencies to evaluate outcomes of standardized diabetes prevention initiatives, including online resources. Through intramural efforts, determine if a medication therapy management program for patients with chronic pain at a large Military Treatment Facility will reduce costs and improve outcomes. Evaluate personalized prevention and treatment efforts related			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 285A / <i>Operational Medicine Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>to Patient-Centered Precision Care. Building on previous work, identify opportunities for advanced development of mobile health application technologies within the MHS for personalized disease prevention and management. Begin evaluation of utilization and effectiveness of current AF mental health/family support programs for the purposes of identifying gaps and possible solutions to areas such as marital discord, family maltreatment, binge drinking, and suicide. Building on previous work, concentrate on the use of mobile health technologies to integrate evidenced-based solutions into clinical practice and the EHR to positively influence behavior and promote health. Further the work related to AF mental health/family support by pilot testing proposed solutions to specified issues in an effort to translate solutions into AFMS wide practice. Determine the timeliness of communication (information exchange) of clinical information and the effectiveness of communication processes to identify gaps or potential patient safety issues that may impact outcomes to include morbidity and mortality. Begin regenerative/reconstructive research to validate technologies for surgical reconstruction of service members with previously non-reconstructable injuries, and investigate devices for advanced wound healing. Continue evaluate personalized prevention and treatment efforts related to Patient-Centered Precision Care in the areas of chronic pain following traumatic brain injury, post-traumatic stress disorder, and substance abuse.</p> <p>FY 2016 Plans: No funding programmed.</p>			
Accomplishments/Planned Programs Subtotals	6.851	1.983	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc).

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 285B / <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i>			
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
285B: <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i>	-	-	-	0.929	-	0.929	1.147	1.350	1.360	1.387	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Operational Medicine R&D - Clinical Translational Focus (AF)	-	-	0.929
Description: The Operational Medicine Thrust Area develops validated solutions for the delivery of preventative care, intervention and treatment to Active Duty members and DoD beneficiaries. The primary focus areas include: physiologic and psychological health; sub-topics include resilience, personalized medicine, patient safety, and care coordination. Basic research initiatives are developed and translated into practice; advanced technology initiatives are focused on prevention and treatment of chronic disease such as obesity and diabetes. Personalized medicine focuses on genomic issues related to autism, asthma, and obesity.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Further identify practical health delivery platforms using health services research to adapt innovative, evidence-based health solutions to improve troop to beneficiary health. Pilot feasibility studies and expand to large scale, standardized implementation research to address current high diagnoses rates of musculoskeletal pain, anxiety/depressive disorders, autism, obesity and other chronic disease states. Research health priorities using data analytics to define and validate occupational and physical health performance measures to identify degrees of health needed to optimize, sustain and enhance health practices to improve troop reliability. Initiate research to enhance accession health and minimize/prevent training injury patterns. Assess the physical and psychological/cultural impact of Women in Combat. Research and incorporate health information technology to develop clinical communication networks to train providers and engage beneficiaries through integrated communities of care. Utilize patient genomic information to individualize population health services. Continue regenerative/reconstructive research to validate			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 285B / <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
technologies for surgical reconstruction of service members with previously non-reconstructable injuries. Continue development in the areas of chronic pain following traumatic brain injury, post-traumatic stress disorder, and substance abuse.				
Accomplishments/Planned Programs Subtotals		-	-	0.929
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)				
E. Performance Metrics				
Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.				

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 285C / <i>Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)</i>
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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
<i>285C: Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)</i>	-	-	-	0.928	-	0.928	1.147	1.349	1.360	1.387	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to provide research and development affecting AF beneficiary populations requiring specialized handling during routine medical care such as pilots, RPA operators, special tactics operators and personnel reliability program members. Research will evaluate and determine if special approaches to personal health and performance are required for these beneficiaries. It will also ascertain if conditions not found in the general patient population are applicable to those in this area of interest and conversely if there are conditions or trends in this population requiring attention that are not normally found in the general AF / DoD beneficiary pool. Overall research in this project will support optimization of health care delivery services to all AF / DoD beneficiaries but will focus on high-value asset personnel.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)	-	-	0.928
Description: This project area seeks to provide research and development affecting AF beneficiary populations requiring specialized handling during routine medical care such as pilots, RPA operators, special tactics operators and personnel reliability program members. Research will evaluate and determine if special approaches to personal health and performance are required for these beneficiaries. It will also ascertain if conditions not found in the general patient population are applicable to those in this area of interest and conversely if there are conditions or trends in this population requiring attention that are not normally found in the general AF / DoD beneficiary pool. Overall research in this project will support optimization of health care delivery services to all AF / DoD beneficiaries but will focus on high-value asset personnel.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Conduct research into select AF Flight Medicine enrollees identifying health and performance preventative and intervention needs. Evaluate human performance practice on general AF populations identifying success and areas of improvement required. Perform evaluation of aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families.			
Accomplishments/Planned Programs Subtotals	-	-	0.928

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 285C / <i>Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)</i>

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i>			
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
307B: <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i>	14.728	14.508	12.558	8.173	-	8.173	10.653	10.833	10.950	11.169	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	14.508	12.558	8.173
Description: This project area seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.</p> <p>FY 2014 Accomplishments: Tested miniaturized sensors to identify toxic breathing air and hypoxic aircrew. Initiated research and development for the integration and demonstration of advanced medical, physiological status sensors and exposure sensors in a laboratory environment to prepare them for aircraft integration. Developed a compact, insulated, leak-proof, laboratory-approved transport system for shipping food samples from remote locations to the laboratory. Developed prototype devices to detect and quantify lasers used to illuminate aircraft and qualify the health threat to aircrew. Analyzed methodologies and challenges associated with the establishment of a genome data repository for future implementation of genomic medicine. Continued to develop a high-content, rapid throughput toxicological capability with pluripotent stem-cells allowing for a rapid screening of possible threats in the aerospace environment. Developed extremely light weight and easy to use methodologies enabling Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Performed a comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed.</p> <p>FY 2015 Plans: Continue to engage with the Precision Care Advisory Panel (PCAP), a joint service committee to provide service-specific operational and policy guidance for the implementation of personalized medicine within the DoD. Initiated study to perform high-content, rapid throughput toxicology with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment.</p> <p>FY 2016 Plans: Continue evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Continue the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials.			
Accomplishments/Planned Programs Subtotals	14.508	12.558	8.173

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 307C / <i>Core Force Health Protection R&D - Clinical Translational Focus (AF)</i>			
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
307C: <i>Core Force Health Protection R&D - Clinical Translational Focus (AF)</i>	-	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Force Health Protection R&D - Clinical Translational Focus (AF)	-	-	1.000
Description: This project seeks to deliver improved capabilities across the full spectrum of operations in the areas of Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that enable effective surveillance, detection, identification, and mitigation of hazardous chemical, biological, and physical hazards that present a health risk to our forces and threaten to degrade and disrupt the missions they execute. Air Force FHP efforts focus on health protection across the spectrum of AF air and ground operations. These include hazards presented to high performance and high flyer aircraft crews facing extreme environments within their flight envelopes that are potentially more sensitive to physiologic and cognitive stressors and rely on aircraft systems to provide life support for protection. Because Air Force installations are typically very strategically important in combat execution, they are more often tied to performing ops at fixed locations; therefore, they drive the need			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307C / <i>Core Force Health Protection R&D - Clinical Translational Focus (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>to detect and identify the USAF- and environment-specific risks posed by chemical, biological, directed energy, and other radiological and physical hazards immediately and on-site so that operations can be resumed as quickly as possible. This requires enhanced monitoring capability, such as man-portable gold-standard hazard detection. Research is needed to improve these capabilities and to account for emerging threats. The mission needs driving the ability to detect also drives the need to rapidly reduce or mitigate threats once discovered. State of the art detection and monitoring equipment, therefore, is also an important FHP research need.</p> <p>FY 2014 Accomplishments: No funding programmed.</p> <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Plans: Continue evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Continue the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Start transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory; also, explore technology transfer potential to the civilian public health sector. Continue research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Complete studies to further improve HAPSITE capabilities to detect other classes of chemicals. Complete the Problem Definition Study (PDS) to develop a Portfolio Management Tool to define a research strategy that identifies critical and specific phased research studies and technology developments that are required to detect and characterize airborne pollution hazards in the deployed environment with specific relevance to the AF. Perform field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials. Proposed expansion of Genomic Studies to include analysis of conditions with operational and clinical importance, based on an assessment of AFMS needs. Continue AFMS Innovation initiatives including demonstration projects for process improvements, leadings practices, disruptive and transformative technologies. Analysis of genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Utilization of patient modeling algorithms to identify pharmacogenomic interventions that can improve patient health and reduce healthcare costs across the</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307C / <i>Core Force Health Protection R&D - Clinical Translational Focus (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>AFMS. Provide further analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressants and pain medication within the AFMS. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine. To augment capabilities for genomic research within the AFMS, the USAF will continue participation in National Human Genome Institute pharmacogenomic research projects. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment. Develop methodologies that are extremely light weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform a comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Complete evaluating foreign made, clinical lasers to validate that the devices meet U.S. safety and health standards. Complete the investigation of biomarkers associated with laser lesions, which is exploring the biophysical interactions between directed energy and biological tissue at optical frequencies. Continue developing a retinal injury atlas database for use by clinicians and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Continue studying high-powered microwave exposures to establish dose-response relationships. Continue developing and testing prototype devices to detect and quantify lasers used to illuminate aircraft and characterize the health threat to exposed aircrew and pilots. Complete the transition to the AF public health community a recently developed compact, insulated, leak-proof, laboratory-approved transport system for shipping contaminated food samples from remote locations to an analytical laboratory. Complete the technology transfer to the civilian public health sector. Complete research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Continue research to perform high-content, rapid throughput screening with pluripotent cells allowing for rapid determination of possible toxic threats in the aerospace environment. Develop new and innovative technologies to detect and assess hazardous chemical, biological, and physical agents relevant to AF deployment and garrison operations. Initiate studies identified the Problem Definition Study (PDS) and research strategy to detect and characterize airborne pollution hazards (to include burn pits) in the deployed environment. Continue field testing of smaller/more capable sensors for monitoring remote environmental health hazards and physiological parameters. Continue identifying and characterizing health effects associated with exposure to AF-relevant nanomaterials. Continue AFMS Innovation demonstration initiatives, including process improvements, leadings practices, disruptive and transformative technologies. Continued support for the AFMS Clinical Utility Study to include initial analysis of impact of genomic risk data on study participants. Analysis of recruited AF cohorts for diseases and conditions of operational importance. Continued support for research into educational interventions for the proper use of genetic testing within the AFMS and pharmacogenomics research regarding the use of anti-depressants and pain medication within the AFMS. Implementation of genomic education program at USAF testing facility to measure impact of education on genetic test utilization, clinical care, and patient outcomes. Pharmacogenomic demonstration projects at AFMS sites and AF MTFs to test the impact on patient health and healthcare costs. Investigation of methodologies and requirements for Air Force Medical System bioinformatics tools and processes, including the development of the AFMS digital Biobank and the integration of genomic data into clinical workflow through the development of predictive modeling clinical decision support tools that integrate with Electronic Medical</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307C / <i>Core Force Health Protection R&D - Clinical Translational Focus (AF)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Records. Continue to develop a high-content, rapid throughput toxicological capability with pluripotent cells allowing for a rapid screening of possible threats in the aerospace environment.			
Accomplishments/Planned Programs Subtotals	-	-	1.000

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307D / <i>Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)</i>
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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
307D: <i>Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)</i>	-	-	-	1.000	-	1.000	1.500	2.235	2.375	2.463	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area conducts research to Identify, evaluate and control occupational hazards in the workplace-including all settings such as deployed, in the aircraft, in the industrial (in garrison) environment or during emergency response. Information gained means risks are more fully understood with respect to potential mission impact or long-term health effect (Go vs. No Go above some pre-defined hazard level). Key focus areas include a better understanding of dosing, rates of dosing, and mechanistic effects of chemical, biological, radiological, directed energy, and other occupational exposure threats. This includes subtle cognitive effects where there is potential mission impact. Technological opportunities towards non-invasive sensing of the human and the environment are growing and can be exploited to enhance understanding of the risks and enable development of appropriate mitigation and treatment options

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	-	-	1.000
Description: This project area conducts research to Identify, evaluate and control occupational hazards in the workplace-including all settings such as deployed, in the aircraft, in the industrial (in garrison) environment or during emergency response. Information gained means risks are more fully understood with respect to potential mission impact or long-term health effect (Go vs. No Go above some pre-defined hazard level). Key focus areas include a better understanding of dosing, rates of dosing, and mechanistic effects of chemical, biological, radiological, directed energy, and other occupational exposure threats. This includes subtle cognitive effects where there is potential mission impact. Technological opportunities towards non-invasive sensing of the human and the environment are growing and can be exploited to enhance understanding of the risks and enable development of appropriate mitigation and treatment options			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Continue to develop a high-content, rapid throughput toxicological capability with pluripotent stem-cells allowing for a rapid screening of possible threats in the aerospace environment. Develop and validate devices or methods that are extremely light			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 307D / <i>Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
weight and easy to use for Air Force Special Operators to diagnose pathogens with almost no medical support in the field. Perform comprehensive study of aircraft breathing air quality across the Air Force fleet to ensure risks are understood and mitigated if needed. Develop capabilities for remote sensing. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference.			
Accomplishments/Planned Programs Subtotals	-	-	1.000

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>			
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
308B: <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>	2.847	4.769	4.699	1.180	-	1.180	1.160	1.560	1.640	1.673	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Expeditionary Medicine Research & Development (Air Force)	4.769	4.699	1.180
Description: This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.			
FY 2014 Accomplishments: Transition the Trauma Specific Vascular Injury Shunt device, and proceed to fielding and procurement. Initiate research on therapeutic drugs given by first responders to slow body functions providing more time to transfer of seriously wounded to definitive care. Continue research on a novel technique for infection control of traumatic wounds, predicting blood needs using pre-hospital vital signs, and hemorrhagic shock resuscitation. Pursue additional research to mature the multi-channel negative pressure wound treatment system and continue to address advanced development issues. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Completed the FDA approval process for the Trauma Specific Vascular Injury Shunt (TS-VIS). Completed follow on studies evaluating applied predictive algorithms for the continuous non-invasive monitoring of patient status in order to predict actionable interventions. Evaluated clinical utility of prototype laser device			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>for hemorrhage control and tissue cutting and archived results for future inquiries. Transitioned Virtual Medical Trainer (09) software platform for preparing leaders and decision makers to hone communication and planning skills for interagency disaster response efforts. Completed testing of predictive algorithms in field-deployable burn diagnostic tool to ultimately improve long-term prognosis. Completed research on predicting oxygen needs based on clinical variables and testing novel techniques for infection control of traumatic wounds to include a bioelectric dressing and topical agent for antibiotic resistant bacteria. Continued studies for predicting blood needs using pre-hospital vital signs, development of portable sterilization technology for surgical instruments in remote setting.</p> <p><i>FY 2015 Plans:</i> Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, rhabdomyolysis and ischemia-reperfusion injury. Complete research on coagulopathy, hemorrhagic shock resuscitation and other life-saving interventions (LSIs), and development of portable sterilization technology for surgical instruments in remote settings. Build on ongoing work with concentration on therapeutic interventions to sustain life through transfer to definitive care. Continue development of multi-channel negative pressure wound treatment system. Complete transitioning and fielding of TS-VIS via commercial or advanced development partners. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics.</p> <p><i>FY 2016 Plans:</i> Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics.</p>			
Accomplishments/Planned Programs Subtotals	4.769	4.699	1.180

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc).

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 308C / <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i>			
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
308C: <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i>	-	-	-	1.503	-	1.503	1.500	1.497	1.501	1.531	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	-	-	1.503
Description: This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: Continue research and development of therapeutic interventions to sustain life through transfer to definitive care to include research on blood sparing drugs for hemorrhagic shock resuscitation and treatment for neuroprotection, rhabdomyolysis and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development.			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 308C / <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
Support advanced development of TS-VIS if necessary. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics.				
Accomplishments/Planned Programs Subtotals		-	-	1.503
C. Other Program Funding Summary (\$ in Millions) N/A				
Remarks				
D. Acquisition Strategy Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)				
E. Performance Metrics Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.				

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 308D / <i>Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)</i>			
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
308D: <i>Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)</i>	-	-	-	1.502	-	1.502	1.499	1.497	1.500	1.530	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project area seeks to standardize training in use of deployed equipment and supplies because of the increasing number of missions that find teams from different countries working together. Evaluation of skills required in an environment with a lack of air dominance and vast geographic distances in future theaters that increases the tactical field care required and tactical evacuation care phases of casualty care in Role II care that may be unavailable for up to 48 hrs after injury and casualties will be maintained by field providers. Determination of what is required to train peacetime military care providers military medical providers with minimal experience in pre-hospital or acute trauma/critical care yet expert delivery of this care is absolutely required in an austere, isolated environment

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)	-	-	1.502
Description: : This project area seeks to standardize training in use of deployed equipment and supplies because of the increasing number of missions that find teams from different countries working together. Evaluation of skills required in an environment with a lack of air dominance and vast geographic distances in future theaters that increases the tactical field care required and tactical evacuation care phases of casualty care in Role II care that may be unavailable for up to 48 hrs after injury and casualties will be maintained by field providers. Determination of what is required to train peacetime military care providers military medical providers with minimal experience in pre-hospital or acute trauma/critical care yet expert delivery of this care is absolutely required in an austere, isolated environment			
FY 2014 Accomplishments: No Funding Programmed.			
FY 2015 Plans: No Funding Programmed.			
FY 2016 Plans: Establish the optimal timing to establish a capability when and where needed as expected to meet the “golden hour” requirement and hold patients until movement is available, stabilize and treat during transport, and provide effective, integrated HSS across service lines. Assess what resuscitation goals (e.g. evidence-based markers) are required during various phases of patient movement and different patient conditions to improve outcomes.			
Accomplishments/Planned Programs Subtotals	-	-	1.502

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 308D / <i>Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)</i>

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>
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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
309A: <i>Regenerative Medicine (USUHS)</i>	6.877	7.031	9.190	9.489	-	9.489	9.646	9.823	10.009	10.209	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Regenerative Medicine (USUHS)	7.031	9.190	9.489
<p>Description: The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center. The CNRM has established 11 research cores and funded over 104 research projects.</p> <p>FY 2014 Accomplishments:</p> <ul style="list-style-type: none"> -Natural history studies are identifying relevant outcome measures across the spectrum of TBI and co-morbid psychological health issues. Military and civilian cohort studies are addressing the post-injury progression from hyper-acute through chronic stages. This hyper-acute imaging is revealing changes that occur within the first hours and days after injury, demonstrating the importance of early MRI to better diagnose brain injury. -Under the Acute Studies Core, established productive clinical research program to address acute TBI injuries at Virginia Commonwealth University, Suburban Hospital and Washington Hospital Center that has resulted in recruitment of more than 300 participants into acute TBI studies with imaging. These early clinical interactions are also directly connected to longitudinal follow up at the NIH CC with potential for recruitment into other CNRM studies. -Across the spectrum of TBI severity and times post-injury, 2,719 patients have enrolled in CNRM clinical research protocols through 2014. -TBI clinical database has been implemented with policies for submission and sharing across CNRM investigators and institutions at USU, WRNMMC, and NIH, Importantly, the CNRM database is aligned with the Federal Interagency TBI Research (FITBIR) database. -State-of-the-art neuropathological center established under Dr. Dan Perl with infrastructure for brain specimen acquisition, evaluation, storage, and distribution. This brain repository is the first dedicated to military service members. -Advanced neuroimaging capabilities, including: acquisition of simultaneous human MRI and PET, improving diffusion imaging for clinical requirements, testing novel PET ligands for inflammation and neurodegeneration. The CNRM Siemens Biograph mMR 			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>System was the second installed in a U.S. clinical setting and the first to scan a human patient using simultaneous MRI and PET. 771 subjects have been scanned through July 31,2014.</p> <p>-The Translational Imaging core continues to develop novel scanning protocols for rodent microPET, microCT, and 7T MR, especially as relevant to specialized needs for TBI pathologies and with consideration of comparison with the human scanning applications.</p> <p>-The Image Processing Core has implemented a database platform for managing the CNRM Imaging Repository with integration of the database with the Informatics database addressed following initial deployment.</p> <p>-CNRM researchers are detecting molecular biomarkers of inflammation and neurodegeneration, including auto-antibodies that persist in blood and allow identification of transient responses to central nervous system damage. The center is collaborating in the biomarkers component of the Chronic Effects of Neurotrauma Consortium, a multi-site Veterans Affairs and Defense Department effort.</p> <p>-Pre-clinical studies across multiple TBI models are identifying mechanisms of CNS damage and repair, including molecular and cellular substrates of neuroregeneration and neuroplasticity. The range of TBI models is particularly designed to address the spectrum of injury experienced by military service members. A state-of-the-art Advanced Blast Simulator is being used for pathological, imaging, and behavioral analyses.</p> <p>-Hosted the annual National Capital Area TBI Research Symposium with no registration fees. The symposium has brought together scientists from local institutions and organizations to network, exchange data and ideas, and advance TBI research and treatment.</p> <p>-CNRM research project information was uploaded into the Federal RePORTER database in spring 2014. This contribution now allows project information to be publicly available and easily searchable, thus paving the way for other Defense Department funding agencies to follow suit.</p> <p>-Through summer-2014, CNRM has published over 140 peer-reviewed publications. In addition, CNRM researchers have presented at numerous national and international conferences.</p> <p>FY 2015 Plans: CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund start-up research of one new USU Radiology faculty member to maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY15-16 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research; (11) Merge the research work of the Neuroscience Center of Excellence (MCNCoE)through development of research fellowship program.</p> <p>FY 2016 Plans: CNRM objectives include: (1) Continue interdisciplinary, collaborative studies that bring together expertise across USU, WRNMMC, and intramural NIH to address the highest priority TBI research in diagnosis through treatment and recovery as relevant to military service members; (2) Continue operational capability of all Cores to provide efficient research infrastructure with high quality resources and technical expertise; (3)Fund start-up research of one new USU Radiology faculty member to maintain translational neuroimaging capability; (4) Define focus areas of next research stage and best funding format for those directions, optimize research teams, and support new research projects pending availability of FY16-17funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host internal CNRM data discussions to foster cross-fertilization of expertise and innovative development across basic, translational, and clinical research; (7) Host annual research symposium to foster interaction between CNRM investigators and other local research organizations; (8) Support open data access to completed clinical studies to qualified federal and academic investigators; (9) Provide human brain and biofluids specimens for use in approved research protocols within CNRM and to other qualified federal and academic investigators; (10) Partner with other funding agencies and commercial entities to advance translation of CNRM research;(11) Support fellowship program to facilitate neuroscience and regenerative medicine research capabilities at DoD sites in NCA.</p>			
Accomplishments/Planned Programs Subtotals	7.031	9.190	9.489

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, 0806721HP: <i>Uniformed Services University of the Health Sciences</i>	8.755	8.912	9.090	-	9.090	9.272	9.458	9.647	9.840	Continuing	Continuing

Remarks
 Provides funding to conduct Natural History study; Infrastructure to support the CNRM program; and salaries of neuroscience faculty and technical and administrative support personnel.

D. Acquisition Strategy
 N/A

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>

E. Performance Metrics

Center for Neuroscience and Regenerative Medicine: In FY14 through FY16, identify, design protocols, perform scientific and program reviews, and conduct research in Clinical Core activities such as Phenotyping, Imaging and Imaging Analysis, to aid in patient diagnosis and evaluation.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>			
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
373A: <i>GDF - Medical Technology Development</i>	128.139	168.541	113.048	116.775	-	116.775	134.178	149.012	150.022	149.701	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small-scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. 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 sustainment of priority investments in science, technology, research and development as stated 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 the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research Development Test and Evaluation (RDT&E) funding. Research supported by this PE includes(JPC-1): medical simulation, health informatics, (JPC-2): wound infection prevention and management, antimicrobial countermeasures, diagnostic systems for infectious diseases, (JPC-5): injury prevention and reduction, psychological health and resilience, physiological health, environmental health and protection, (JPC-6): hemorrhage (bleeding) and resuscitation, neurotrauma (diagnosis and treatment of brain injury), traumatic tissue injury, forward surgical intensive critical care, joint en route care, military medical photonics, and (JPC-8): rehabilitation of neuro-musculoskeletal injuries, pain management, regenerative medicine, and sensory system traumatic injury, restoration and rehabilitation. As research efforts mature, the most promising will transition to advanced concept development funding, PE 0604110. For knowledge products, successful findings will transition into clinical practice guidelines.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: GDF – Medical Technology Development	168.541	113.048	116.775
Description: Funds provide for the development of medical technology candidate solutions and components of early prototype systems for test and evaluation. Promising drug and vaccine candidates, knowledge products, and medical devices and technologies are selected for initial safety and effectiveness testing in small scale human clinical trials.			
FY 2014 Accomplishments:			
The medical simulation and information sciences research program conducted research in two primary research portfolios: Medical Simulation and Training, and Health Informatics and Information Technology. Medical simulation and training focused on research to support combat medic training and inform decisions regarding the reduction and refinement of live-tissue training. Began development of open-source virtual tissue advancement program to better understand the tissue characteristics needed to integrate into medical models for future simulations. Additional emphasis was placed on the technologies to teach and train effective team performance. Health informatics and information technology progressed in evaluating algorithms to provide nurses			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>with appropriate medical information to inform better decisions. Progress was also made in developing a test environment for electronic health records, allowing developers a robust environment to optimize products before launch to live systems.</p> <p>The military infectious diseases research program funded a multi-year, clinical study for development of an antibacterial drug against multiple drug resistant bacteria to mitigate hard to treat wound infections. A study in humans evaluated safety and effectiveness of a bacteriophage (viruses in bacteria) cocktail against <i>Staphylococcus aureus</i> (a drug-resistant bacteria) with the aim to develop novel skin and soft tissue infection treatment options. An additional study was initiated to reduce surgical site infection rates during complex combat-related wounds, which will help reduce the need for an extended course of systemic antibiotics, irrigation, and surgical debridement. Evaluated effectiveness to detect bacterial infections in wounds aimed to reduce excess empiric antibiotic use while awaiting conventional culture and susceptibility results. Research was initiated on the Next Generation Diagnostic Systems to detect malaria, dengue, and chikungunya.</p> <p>Military operational medicine research is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction developed standards for low level, repetitive blast exposures during breaching (process used to force open closed and/or locked doors), developed performance and musculoskeletal health metrics (pertaining to muscle and bone health) for Warfighters in military training environments, and developed blast and auditory injury models to provide medical injury criteria. Psychological health and resilience evaluated behavioral interventions to treat alcohol and substance abuse, determined the feasibility of cognitive behavioral interventions (a type of therapy that focuses on examining the relationships among thoughts, feelings and behaviors) for the treatment of PTSD, evaluated interventions to build resiliency in military families and Warfighters, and initiated efforts to improve accurate suicide prevention screening and delivery of innovative peer leader-led suicide prevention interventions. Physiological health developed guidelines for nutritional supplementation to minimize injuries during initial military training and developed interventions for dietary and weight loss in Warfighters. Environmental health and performance measured health effects of chemical exposures (e.g., permethrin, an insecticide used to treat uniforms), measured biomarkers of pulmonary health (pertaining to the lungs) from exposures to toxic substances in the deployed environment to assess health and disease outcomes, and developed decision aids for managing thermal physiological strain.</p> <p>Combat casualty care is grouped into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, joint enroute care, and military medical photonics. Hemorrhage and resuscitation developed platelet-derived agents to stop bleeding and modulate immune inflammatory responses, foams to stop internal bleeding, enhanced storage of red blood cells, and low blood volume resuscitation techniques, conducted a clinical trial on using plasma first during resuscitation of traumatic hemorrhages, developed techniques to reduce pathogens in whole blood. Neurotrauma developed biomarkers (substance, such as a protein, indicating the presence of a condition) for TBI, developed a prehospital drug for TBI, conducted a clinical trial on Eye-Trac technology to diagnose and assess TBI, conducted a pivotal clinical trial</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>on a preconditioning oral nutritional supplement as a possible treatment for TBI, and developed neuroassessment protocols to standardize treatment practice. Traumatic tissue injury conducted research on face restoration, orthopedic advances, and compartment syndrome (a life-threatening condition resulting from injury wherein increased pressure occurs within legs or arms). The traumatic tissue injury program also conducted outcomes-related research on genitourinary injury (a follow-up to the basic epidemiology study done earlier, looking at long-term outcomes). Forward surgical intensive critical care conducted a clinical study on a technique using an endovascular (minimally invasive surgery to access regions of the body via major blood vessels) balloon to open occlusions of the aorta in severe pelvic fracture and hemorrhagic shock cases, started research on intensive care interventions with the Joint Trauma System in the US Army Institute of Surgical Research. Joint enroute care conducted research on real-time, physiologic monitoring across the battle space, supported a patient immobilization effort, developed improved field management and safe air transport of patients with head and spine injuries, developed a joint-force aeromedical transport litter immobilization and stabilization platform, and developed an enroute care registry to better track best practices. Military medical photonics developed optical technology for military medical applications with a focus on the use of lasers, spectroscopy, and imaging.</p> <p>Clinical and rehabilitative medicine advanced studies in neuromusculoskeletal injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Extended studies started in FY13 to support development and preclinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. In pain management, a pain outcome registry tracked treatment results and created evidence-based clinical guidelines for care, studied the effects of a treatment drug on burn pain, and evaluated methadone and opioid related adverse events. Regenerative medicine initiated clinical studies for craniomaxillofacial intraoral defects (defects within the mouth), immunomodulation strategies for composite tissue allotransplantation (hand and face transplantation), and skin coverage following burn injury. Sensory systems research started studies to verify the prevalence of central auditory processing disorders in blast-exposed Warfighters, evaluated computerized oculomotor (eye motion) vision screening to expedite the diagnosis of TBI-related oculomotor dysfunctions in a military population, studied the effects of blast exposure on the hearing of deployed Navy and Marine Corps personnel, and evaluated cochlear implants to improve hearing for active duty Service members.</p> <p>FY 2015 Plans: Medical simulation and information sciences research program is focusing in two primary research portfolios: Medical simulation and training and health informatics and information technology. Medical simulation and training research is continuing development of an open source virtual tissue advancement model that will be open to developers and end-users, allowing them to focus on content creation into a variety of simulation system tools and for end-users to better validate simulation systems. Medical simulation is supporting research to improve the realism of virtual standardized patients (avatars) used for high volume scenario rehearsal as well as for those hard-to-come-by cases, through improved artificial intelligence and realistic body language within a medical context. Medical simulation is releasing a program announcement focused on effective ways to interface with technology</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>through gestures or facial expressions that are military medically relevant. Medical simulation is also requesting proposals via a program announcement to improve en route care methods for wounded Service members. This effort is focusing on the hand-offs and transfer of patients between providers.</p> <p>Military infectious diseases research is focusing on Next Generation Diagnostic Systems, where we are developing the capability to detect malaria, dengue, and chikungunya, achieving TRL-6, and preparing for transition to Medical Countermeasure Systems for advanced development. Evaluating the results of the bacteriophage (a group of viruses that infect and replicate in bacteria) study to determine a path forward. The wound infection prevention and management host/pathogen biomarker project, for detection of bacterial infection in wounds, is completing laboratory and initial animal studies to confirm its effectiveness and accuracy. Under antimicrobial countermeasures, clinical studies continue for the development of an antibacterial drug against multiple drug resistant bacteria and to reduce surgical site infection rates that often occur with complex combat-related wounds. Several studies are also being initiated for the development of antibacterial or other wound infection prevention strategies.</p> <p>Military operational medicine research is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction is validating blast and auditory injury models to deliver guidelines for medical injury criteria, validating medical criteria standards for low level, repetitive blast exposures during breaching (process used to force open closed or locked doors), and verifying performance and musculoskeletal health metrics of Service members in military training environments. Psychological health is determining the effectiveness of behavioral interventions to treat alcohol and substance abuse, evaluating cognitive behavioral interventions (a type of therapy that focuses on examining the relationships among thoughts, feelings and behaviors) for the treatment of PTSD, improving interventions to build resiliency in military families and Warfighters, and improving accuracy of suicide prevention screening. Physiological health is evaluating interventions to promote and sustain weight loss in Warfighters and military families, and validating a policy for vitamin supplementation to reduce injuries during operational and training scenarios. Environmental health and performance is validating decision aids for managing thermal physiological work strain (ability to perform work tasks safely in hot environments), determining health outcomes of chemical exposures (e.g., permethrin, an insecticide used to treat uniforms), determining specific biomarkers of pulmonary health (pertaining to the lungs) from exposures to toxic substances in the deployed environment and specific stress response biomarkers of mild and moderate dehydration for assessing hydration status of Warfighters.</p> <p>Combat casualty care is grouped into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, joint enroute care, and military medical photonics. Hemorrhage and resuscitation is conducting clinical assessments of new agents that control severe internal bleeding and can be administered by first responders at or near the point of injury, developing multiple new TBI diagnostic approaches that when used together provide a more comprehensive diagnosis than what is currently available, evaluate ability to control the immune inflammatory response in hemorrhage.</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Neurotrauma is pursuing successful efforts from FY14 in developing biomarkers (substance, such as a protein, indicating the presence of a condition) for TBI, validating results of a clinical trial on Eye-Trac technology to diagnose and assess TBI, and finalizing neuroassessment protocols to standardize treatment practice. Traumatic tissue injury is continuing work on cellular and extracorporeal therapies for acute lung injury and fracture putty for improved bone fracture repairs. In addition the portfolio is developing strategies for maxillofacial (mouth, jaw, and neck) stabilization techniques for initial wound coverage and potential treatments and conducting studies to understand the impact of both the injuries and certain treatments on long term outcomes. Forward surgical intensive critical care is supporting development of a virtual intensive care unit linking patient movement and medical support providers at all levels within the theater of operations, developing guidelines for resuscitative interventions, including comprehensive resuscitation and rewarming of casualties after severe blood loss, continuing a FY14 clinical study using an endovascular (minimally invasive surgery to access regions of the body via major blood vessels) balloon to open occlusions (blocked blood vessels) of the aorta in severe pelvic fracture and hemorrhagic shock cases, and conducting a pilot clinical study of bioengineered blood vessels for vascular trauma. Joint enroute care is continuing the evaluation of the joint-force aeromedical air transport litter immobilization and stabilization platform, with emphasis on patient safety, impact of transport, and medical technology. Military medical photonics is developing technologies that focus on the use of advanced optical technologies, including lasers, spectroscopy, and imaging.</p> <p>Clinical and rehabilitative medicine is continuing efforts and down-selecting products for advanced development for neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Neuromusculoskeletal injury rehabilitation is evaluating the safety and effectiveness of candidate technologies for restoration and rehabilitation medical products. Pain management is tracking methadone and opioid related adverse events; developing novel treatments to control pain, to include battlefield pain, burn pain, neuropathic (nervous system) pain, and chronic pain after amputation; studying modulation of inflammatory cells as an approach to mitigate spinal cord injury neuropathic pain; studying effects of peripherally administered opioids, and developing nerve blocks for knee and hip arthroplasty (joint replacement) in Veterans. Regenerative medicine is focusing on novel approaches to engineer regeneration and repair of damaged muscle tissue, to repair nerve gap injuries, to repair blood vascular injury, and evaluating methods to prevent tissue rejection of allografts (a tissue graft from a donor). Sensory systems is conducting research to verify central auditory processing disorders in blast-exposed Warfighters, evaluating computerized oculomotor vision screening to expedite the diagnosis of TBI-related oculomotor dysfunctions in a military population, testing cochlear implants for active-duty Service members, clinically assessing pharmacotherapy of hidden noise injury toward a molecular understanding of noise-induced hearing loss, developing a portable mild TBI screening device based on evaluation of a patient's gait, preventing noise damage to cochlear synapses, and developing a silica-collagen composite for corneal replacement.</p> <p>FY 2016 Plans:</p>			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Medical simulation and information sciences research will focus on the medical simulation and training portfolio. Medical simulation will complete the virtual tissue advancement research which should provide open source resources to enable developers to create more appropriate virtual tissue simulations. En route training research will continue addressing several issues with providing care to wounded Service members during transport and transfer between providers. Research evaluating the effectiveness of gaming in virtual environments with combat medics will be investigated. Will evaluate training metrics that can best be translated into optimal patient outcomes. This will provide educators the building blocks to create better trainers in the future and begin the long process of linking evidenced-based training to actual patient outcomes.</p> <p>Military infectious diseases research will support a clinical trial to develop therapies for antibiotic-resistant bacteria. Positive results in this clinical trial will be used to support further clinical testing. Skin and soft tissue infections in military trainees will be studied under wound infection prevention and management. The information gained will be used to develop prevention and treatment solutions that will protect the military training force from Staphylococcal skin infection. Progression from FY15 diagnostic assays for selected bacteria that are commonly found in wound infections will be developed for use on an already FDA-approved diagnostic system. These assays will result in quicker diagnosis and appropriate treatment.</p> <p>Military operational medicine research is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction will develop low level blast exposure guidelines and auditory injury standards for health hazard assessments, and will develop predictive models of military performance and the likelihood of musculoskeletal (muscle and bone tissues) injury in military training and applicable to operational environments. Psychological health will incorporate behavioral intervention regimens into clinical practice guidelines for the treatment of alcohol and substance abuse, will compare cognitive behavioral interventions(a type of therapy that focuses on examining the relationships among thoughts, feelings and behaviors)for the treatment of PTSD to current standards of care, and will deliver validated interventions for enhanced resiliency in military families and Warfighters, as well as, more accurate suicide prevention screening tools. Physiological health will develop dietary supplement interventions to promote resiliency to brain injuries and sustain cognitive performance in Warfighters, and will transition policy and guidelines to the Services for improved nutrition during training and operations that will sustain Warfighter performance, health and readiness. Environmental health will incorporate decision aids for managing thermal physiological work strain into physiological health status monitoring for Warfighters to provide extended health, performance and safety assessments, will develop strategies to mitigate adverse health and disease outcomes of chemical exposures (e.g., permethrin, an insecticide used to treat uniforms), and will validate the appropriate stress response biomarkers of pulmonary health (pertaining to the lungs) from exposures to toxic substances in the deployed environment and specific stress response biomarkers of mild and moderate dehydration for assessing hydration status of Warfighters.</p>			

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Combat casualty care research is grouped into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, joint enroute care, and military medical photonics. Hemorrhage and resuscitation will test immune system modulating drugs to treat hemorrhagic shock, and evaluate drugs to control the immune inflammatory response in hemorrhage. Neurotrauma will continue validating a multi-site collaborative TBI endpoints study to improve clinical trial design to inform/accelerate FDA approval of TBI diagnostic tools and therapeutic agents. Traumatic tissue injury will continue the development of a putty to repair fractures, address treatments for acute lung injury, enhance limb and craniofacial salvage, and improve wound healing in the acute setting. Forward surgical intensive critical care will transition to advanced development the vascular occlusion (blocked blood vessels) devices for the treatment of acute hemorrhage and technology to detect cardiovascular collapse. Joint enroute care research will develop new patient immobilization technology, and study the physiologic impact of patient transport. Military medical photonics will develop technologies that focus on the use of advanced optical technologies, including lasers, spectroscopy, and imaging.</p> <p>Clinical and rehabilitative medicine will transfer current efforts and down-select products to advanced development for neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury rehabilitation, pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Clinical and rehabilitative medicine will support development of preclinical and pilot/early-phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas will include: neuromusculoskeletal injury rehabilitation strategies and devices; prosthetics; (artificial device that replaces a missing body part); orthotics (devices used to support or supplement a weakened joint or limb); neural interfaces (invasive and non-invasive methods of using the brain and/or nerves in the arms and legs for device control and the prevention and treatment of heterotopic ossification (bone formation in soft tissue following injury)); novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb and digit salvage; craniomaxillofacial (skull, face and jaw) reconstruction; scarless wound healing; repair of skin injury resulting from burns; composite tissue allotransplantation (tissue/organ transplantation between genetically different individuals) and associated immune system modulation technologies; genitourinary (genital and urinary organs) restoration; and advancing diagnosis, restoration and rehabilitation of injured and dysfunctional sensory systems, including vision (total orbit, cornea, retina, ocular nerve), hearing (hair cells, tympanic membrane, cochlea, auditory nerve) and balance (vestibular complex).</p>			
Accomplishments/Planned Programs Subtotals	168.541	113.048	116.775

C. Other Program Funding Summary (\$ in Millions)

N/A
Remarks

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

D. Acquisition Strategy

Mature and demonstrate safety and effectiveness of medical procedures, medical devices, and drug and vaccine candidates intended to prevent or minimize effects from battlefield injuries, diseases, and extreme or hazardous environments. Milestone B packages will be developed to transition promising products into advanced development.

E. Performance Metrics

Research is evaluated through In-Progress Reviews, quarterly and annual status reports, and Program Office and/or progress reviews to ensure that milestones are being met and deliverables will be transitioned on schedule. The benchmark performance metric for transition of research conducted with medical technology development funding will be the attainment of maturity level that is typical of Technology Readiness Level 6 or the equivalent for knowledge products.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 378A / <i>CoE-Breast Cancer Center of Excellence (Army)</i>			
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
378A: <i>CoE-Breast Cancer Center of Excellence (Army)</i>	13.077	11.965	8.664	7.299	-	7.299	5.709	4.068	3.553	3.624	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Breast Cancer CoE (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. This approach integrates prevention, screening, diagnosis, treatment and continuing care, incorporation of advances in risk reduction, biomedical informatics, tissue banking and translational research. The project is based on a discovery science paradigm, leveraging high-throughput molecular biology technology and our unique clinically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of breast diseases and breast cancer among all military beneficiaries.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Breast Cancer Center of Excellence	11.965	8.664	7.299
Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2014 Accomplishments: In FY14, the Breast Cancer CoE (Army), also referred to as the Clinical Breast Care Project (CBCP), at Walter Reed National Military Medical Center (WRNMMC) Bethesda continued to accrue subjects annually to the core CBCP protocols. The CBCP continued to acquire, through consented protocol, specimens (normal and abnormal breast tissues and tumors, lymph nodes, metastatic (spread of a cancer from one organ or part to another non-adjacent organ or part) deposits, blood and its components, bone marrow) annually from subjects with all types of breast diseases and cancer. The repository continued to be utilized as the basis for all molecular analyses in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA, and protein features and as the basis for intramural and extramural collaborations for secondary usage research. CBCP performed whole-genome DNA sequencing on DNA from 60 cases of breast cancer; continued the development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective database to support translational research and ultimately support physician decision making; continued development of an analytical system for integrative data analysis and mining, and further refined a breast knowledge base to support research activities in CBCP; utilized Clinical Laboratory Workflow System as the data analysis tool and integrated Armed Forces Health Longitudinal Technology Application (AHLTA) data from the military's main electronic medical record; identified research subjects at high-risk for development of breast cancer, and employed risk reduction strategies; completed genomic and proteomic analysis of samples collected at various developmental stages of breast cancer; and presented findings in peer-reviewed publications and at national meetings.			
FY 2015 Plans:			

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 378A / <i>CoE-Breast Cancer Center of Excellence (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>The Clinical Breast Care Project will continue performing whole genome DNA sequencing on DNA from cases of breast cancer; continue development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective, database to support translational research and ultimately support physician decision making; continue development of an analytical system for integrative data analysis and mining, and further refine a breast knowledge base to support clinical and research activities in the Breast Cancer CoE; utilize Clinical Laboratory Workflow System as the data analysis tool and integrated Armed Forces Health Longitudinal Technology Application data from the military's main electronic medical record; identify and counsel patients at high risk for development of breast cancer, and employ risk reduction strategies; perform targeted research by conducting DNA and protein analysis of Stages I, II, and III breast cancer, cancer found in the breast ducts and lobules, and pre-malignant breast lesions; and will present findings in peer-reviewed publications and at national meetings.</p> <p>FY 2016 Plans: The Clinical Breast Care Project will conduct clinical studies to relate genomic and functional heterogeneity and metastasis with breast cancer patient outcomes. The program will continue to collect and catalog breast cancer tumors and blood from DoD beneficiaries and include donor consented samples in the Tissue and Blood libraries for analysis; conduct studies to determine if there is a correlation between environmental chemical burden and molecular aberrations with breast cancer patient outcomes; conduct human epidermal growth factor receptor 2 (HER2) targeted therapy optimization studies to gain a better understanding of the molecular changes associated with alterations in HER2 expression. Results are expected to lead to a more precise diagnosis and customized treatment plans of patients diagnosed with HER2+ breast cancer.</p>			
Accomplishments/Planned Programs Subtotals	11.965	8.664	7.299

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 379A / <i>CoE-Gynecological Cancer Center of Excellence (Army)</i>			
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
379A: <i>CoE-Gynecological Cancer Center of Excellence (Army)</i>	11.425	10.707	7.570	6.377	-	6.377	4.989	3.555	3.105	3.167	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Gynecologic Cancer Center of Excellence (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of gynecologic diseases among all military beneficiaries.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Gynecologic Cancer Center of Excellence (Army)	10.707	7.570	6.377
Description: The Gynecologic Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease.			
FY 2014 Accomplishments: The Gynecologic Cancer Center of Excellence conducted retrospective longitudinal (observations over long periods of historical time) and prospective (observations during a current or future study period) validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations rely on collected specimens as well as external biospecimen (materials taken from the human body, such as blood, plasma, urine, etc., that can be used for diagnosis and analysis) collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in our preclinical models are being evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies were evaluated using models of ovarian and endometrial (pertaining to the lining of the uterus) cancer. These novel hypotheses establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates are being incorporated into a newly established ensemble of safety and efficacy gynecologic cancer clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open			

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 379A / <i>CoE-Gynecological Cancer Center of Excellence (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids (biological fluids like blood, urine, breast milk, and cerebrospinal fluid).</p> <p>FY 2015 Plans: The Gynecologic Cancer Center of Excellence conducts retrospective longitudinal and prospective validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations will rely on collected specimens as well as external biospecimen (materials taken from the human body such as blood, plasma, urine, etc that can be used for diagnosis and analysis) collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in preclinical models will be evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems-level integration of molecular studies will be evaluated using models of ovarian and endometrial cancer. These novel hypotheses establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates will be incorporated into a newly established ensemble of safety and efficacy gynecologic cancer clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids.</p> <p>FY 2016 Plans: The Gynecologic Cancer Center of Excellence will continue validation efforts of identified molecular targets for the treatment of ovarian and endometrial cancers, evaluate the effect of stress intervention on the recurrence of ovarian cancer, work with the Walter Reed National Military Medical Center Cancer Risk and Prevention Clinic to develop a Clinical Practice Guideline for cancer screening and prevention in patients with hereditary cancer risk syndromes, and develop strategies to overcome Taxol(a chemotherapy drug)-resistance in gynecologic cancer cells.</p>			
Accomplishments/Planned Programs Subtotals	10.707	7.570	6.377

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 379A / <i>CoE-Gynecological Cancer Center of Excellence (Army)</i>

E. Performance Metrics

Performance of the Gynecological Cancer Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 381A / <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>			
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
381A: <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>	4.822	3.674	3.594	3.520	-	3.520	3.368	3.214	3.057	3.118	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), the focus is the investigation of cutting-edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular (pertaining to organic molecules occurring in living organisms) research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members. Using a systems biology outcomes research approach, ICHP characterizes relationships between CVD, other cardio-metabolic disease states and maladaptive lifestyle behavior patterns unique to Service members such as pre-diabetes, stress, obesity and sleep disorders with the aim of targeting these disorders in their pre-clinical phase and achieving ideal/optimal cardiovascular health goals outlined by the American Heart Association. ICHP's ultimate goal is to translate the evidence-based research findings for application into clinical practice in an effort to achieve the following research aims: (1) improve Force Health by better understanding the CVD risk susceptibility of military-specific populations such as Wounded Warriors through leading-edge research using novel tools and technologies, (2) investigate and create transformational models of healthcare delivery through personalized CVD prevention tracks as an adjunct to traditional care, and (3) refine individualized prevention strategies through statistical data modeling to define the most cost-effective and sustainable approaches in promoting cardiovascular health throughout the military lifecycle.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Cardiac Health Center of Excellence (Army)	3.674	3.594	3.520
Description: The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members.			
FY 2014 Accomplishments: The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), continued research studies initiated in FY12-13. Data collection from approved FY12-13 protocols is continuing and being analyzed and synthesized. ICHP is translating and communicating best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, ICHP are incorporating findings from studies for new hypothesis generation and development of new protocols for FY14-18 to expand the use of point-of-care technology in the ICHP model, whole genome sequencing for early CVD detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors.			
FY 2015 Plans:			

UNCLASSIFIED

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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 381A / <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
<p>The Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), continues conducting research studies initiated in FY13-14. Data collection from approved FY13-14 protocols is analyzed and synthesized. ICHP continues translating and communicating best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, ICHP continues incorporating findings from our studies for new hypothesis generation and development of new protocols for FY15-19 to expand the use of point-of-care technology in the ICHP model, whole-genome sequencing for early CVD detection, and investigating the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors.</p> <p>FY 2016 Plans: The Cardiac Health Center of Excellence (Army) will develop clinical practice guidelines or tools for cardiovascular health and internal medicine, conduct clinical studies to investigate the effectiveness of lifestyle change interventions and the effects on preclinical atherosclerosis (plaque deposits in artery) measures, continue molecular studies to understand the cardiovascular risk in wounded warriors, explore predictive biomarkers (biological indicators of disease) over time, conduct clinical study to examine effectiveness of point-of-care technology in pre-diabetic patients at risk for cardiovascular disease, and explore predictive patterns for the development of diabetes, a cardiovascular disease equivalent.</p>				
Accomplishments/Planned Programs Subtotals		3.674	3.594	3.520
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
Disseminate medical knowledge products resulting from research and development through articles in peer reviewed journals, revised clinical practice guidelines, and training of residents and fellows in the Military Health System				
E. Performance Metrics				
Integrative Cardiac Health Care Center of Excellence performance is judged on high impact discoveries, development of new diagnostic and treatment strategies, identification of emerging issues of disease feature and patterns, the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of medical students, residents and post-doctoral fellows in the Military Health System.				

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i>			
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
382A: <i>CoE-Pain Center of Excellence (Army)</i>	3.652	2.784	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY15, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Pain Center of Excellence (Army)	2.784	-	-
Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration.			
FY 2014 Accomplishments: The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) continues to validate major lines of effort including the Defense and Veterans Pain Rating Scale (DVPRS), Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS), and Extension for Community Healthcare Outcomes (ECHO) programs. DVCIPM continues to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program focuses on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities including yoga and acupuncture, and exploration of the pathophysiology (study of functional changes associated with disease or injury) and molecular mechanisms of pain with established and new academic partners. DVCIPM continues to provide subject matter expertise, coordination, and guidance to all services and Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.			
FY 2015 Plans: No funding programmed. Program transferred to USUHS starting in FY 2015.			
FY 2016 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	2.784	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 382B / <i>CoE-Pain Center of Excellence (USUHS)</i>			
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
382B: <i>CoE-Pain Center of Excellence (USUHS)</i>	-	-	2.722	2.823	-	2.823	2.871	3.247	3.310	3.376	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world-class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board-approved clinical research and Institutional Animal Care and Use Committee-approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System. In FY15, the Pain CoE funding line is transferred from Army to USUHS.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Pain Center of Excellence (USUHS)	-	2.722	2.823
Description: The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect pain has throughout the continuum of care to rehabilitation and reintegration.			
FY 2014 Accomplishments: No funding programmed.			
FY 2015 Plans: The Uniformed Services University of the Health Sciences (USUHS) will assume the research oversight of the DVCIPM beginning in FY 2015. The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) will focus primarily on further developing the Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS); to include data collection, report generation, and the study of biomarkers in pain. DVCIPM will continue to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program will focus on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities such as battlefield acupuncture, and the exploration of the pathophysiology (functional change) and molecular mechanisms of pain with established, and new academic partners. DVCIPM will provide subject matter expertise, coordination, and guidance to all the armed services and the Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.			
FY 2016 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 382B / <i>CoE-Pain Center of Excellence (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
The Uniformed Services University of the Health Sciences (USUHS) will assume the research oversight of the DVCIPM beginning in FY 2015. The Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) will focus primarily on further developing the Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS); to include data collection, report generation, and the study of biomarkers in pain. DVCIPM will continue to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program will focus on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities such as battlefield acupuncture, and the exploration of the pathophysiology (functional change) and molecular mechanisms of pain with established, and new academic partners. DVCIPM will provide subject matter expertise, coordination, and guidance to all the armed services and the Veterans Health Administration regarding pain-related issues in support of the Pain Task Force.			
Accomplishments/Planned Programs Subtotals	-	2.722	2.823

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate medical knowledge products resulting from research and development through articles in peer-reviewed journals, revised clinical practice guidelines, incorporation into training curriculum throughout the Military Health System, and other applicable means.

E. Performance Metrics

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>			
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
383A: <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	13.516	7.771	6.907	6.260	-	6.260	5.456	4.628	3.300	3.366	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Prostate Cancer Center of Excellence (CoE), formerly a Congressional Special Interest program, the Center for Prostate Disease Research (CPDR), was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The CPDR studies prostate cancer and prostate diseases in the military health care system. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research, the Basic Science Research and the Tri-Service Multicenter Database which includes five participating military medical centers. The CPDR has been conducting patient centric cutting-edge translational research to improve the management of all stages of prostate cancer for over 22 yrs as recognized by nearly 400 scientific publications. CPDR has also been committed to the research training of the next generation of DoD doctors and scientists (USU medical and graduate students and Walter Reed residents). Many of the trainees are now service chiefs and program directors in prestigious military and civilian medical centers.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	7.771	6.907	6.260
<p>Description: The CPDR is at the forefront of cutting-edge clinical research improving diagnosis and treatment of prostate cancer involving new modalities such as, MRI guided biopsy, and evaluation of new drugs and vaccines for advanced prostate cancer. The CPDR Database continues to highlight emerging issues in prostate cancer management such as, treatment outcomes, ethnic differences and quality of life. In light of current treatment challenges with early detected prostate cancers in PSA testing era and poorly understood biology of prostate cancer, CPDR's high-impact research is focusing on cancer causing genes that will lead to better diagnostic and prognostic markers in the management of the disease. New gene discoveries are also unraveling ethnic differences of prostate cancer biology that has potential to enhance personalized medicine.</p> <p>FY 2014 Accomplishments:</p> <ul style="list-style-type: none"> • Evaluate the efficacy of the newly developed MRI guided biopsy technology in the diagnosis of clinically significant prostate cancer. • Assess new FDA approved drugs and vaccines for the treatment of the metastatic disease. • Investigate minimally invasive modalities for the treatment of early detected prostate cancer. • Analyze the features of onset and progression of prostate cancer among DoD prostate disease patients in relation to ethnicity and obesity. • Complete a new collaborative study with Genomic Health towards the evaluation of early prognostic gene expression markers for differentiating indolent versus aggressive disease. 			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> • Using the CPDR ERG-MAb, continue to enhance the ERG-based stratification of prostate cancer world-wide in collaboration with Biocare Medical Inc. • Complete the evaluation of ERG oncoprotein frequency in patient populations of China, Germany, Hungary, Japan, India, Malaysia, Philippines and Switzerland. • Develop and enhance strategies to inhibit ERG-mediated oncogenesis using small molecule inhibitors, ERG-MAb and ERG vaccine. • Complete the integrated comparative evaluations of genomics and transcriptomics (expression level of RNA molecules in a given cell population) datasets of African American and Caucasian American patients. • Accelerate prostate cancer-related genome queries by acquiring high-throughput technologies to support advanced bioinformatics capabilities. • Provide solution for the unmet need of prognostic biomarkers that will differentiate between indolent and aggressive disease. Evaluate the NanoString platform towards this goal. • Enhance the CPDR discovery of male hormone signaling-based stratification of prostate cancer, conceptually similar to breast cancer. • Define new mechanisms of male hormone receptor regulation towards developing innovative therapeutic strategies. • Improve non-invasive approaches for the detection of prostate cancer in urine or blood specimens by evaluating prostate cancer antigens, as well as auto-antibodies. • Continue to enhance and transform Prostate Cancer COE database and biospecimen banks to a national center for academic and industrial collaborations to accelerate translational research <p>FY 2015 Plans:</p> <ul style="list-style-type: none"> • Continue to conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for prostate cancer to include robot assisted radical prostatectomy, external beam radiotherapy, brachytherapy, high intensity focused ultrasound, and active surveillance. Assess the impact of these treatments with or without neoadjuvant and adjuvant hormonal or other novel therapies. • Compare the features of disease onset and progression between DoD and civilian prostate cancer patient populations. • Continue focus on long-term studies of the epidemiology to include clinical progression of the disease defined by metastasis, ethnicity, obesity, quality-of-life-adjusted survival and prostate cancer specific death. • Evaluate traditional and emerging molecular marker panels for differentiating indolent versus aggressive disease for guiding treatment decisions. • Leverage the CPDR discovery of the ETS-related gene (ERG), the first major prostate cancer-causing gene identified, which is present in over half of prostate cancers in Western countries, and can be used for precision diagnosis and therapy. • Develop new molecular strategies for improving prostate cancer diagnosis and prognosis, specifically to find replacement for PSA test. 			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> • Establish the molecular bases of ethnic differences in prostate cancer biology by employing integrated comparative genomics and transcriptomics. • Develop new paradigms for the identification and treatment of highly aggressive prostate cancers based on hormone signaling defects. • Continue to evaluate cancer biology of prostate cancer relevant genes and/or proteins using transgenic and knockout mice models. • Identify molecular determinants of prostate cancer susceptibility in high-risk groups such as African Americans. • Continue to develop and maintain long-term molecular specimen resources for translational investigations at CPDR and collaborations with other institutions. • Maintain the state-of-the-art CPDR translational research infrastructure and expertise to train the next generation of DoD physicians and scientists. <p>FY 2016 Plans: Clinical Research Focusing on Precise Diagnosis and Therapy:</p> <ul style="list-style-type: none"> •Assess new FDA approved therapies; e.g., Enzalutamide, Abiraterone Acetate, Provenge and Radium-223, and vaccine therapy therapies. •Evaluate the newest aspects for prostate biopsy procedure using MRI-ultrasound fusion image technology for improving diagnosis of clinically significant cancer. •Leverage the vision of long-term biospecimens and database for timely collaborative studies, complete the collaborative validation study of the Oncotype DX-Prostate Cancer prognostic panel to differentiate indolent prostate cancers from the aggressive disease. •Develop more accurate prognostic models to predict organ-confined (curable) and outcome (survival) after the above-noted treatments. •Conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for early stage prostate cancer. •Conduct a long-term study of the epidemiology of prostate cancer, to include the tracking of changing stage, age at diagnosis, racial makeup, long-term survival, and quality-of-life-adjusted survival. <p>CPDR Tri-Service National Database Operations:</p> <ul style="list-style-type: none"> •Build clinical models for predicting probability of prostate cancer detection in the diagnosis phase, optimal treatment decision in the treatment phase, and outcome based treatment in the follow-up phase. •Integrate clinical and molecular biomarker prognostic variables for evaluating patient diagnosis, progression, and treatment outcomes. •Facilitate collaborations between basic science research and clinical research at the CPDR and other institutions. 			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> •Support translational research at WRNMMC where clinical data are linked to tissue and serum data banks to support molecular genetic studies. •Provide a resource for education/training of urology, radiation oncology, medical oncology and other residents, fellows, and students. <p>Biospecimen Banking Effort:</p> <ul style="list-style-type: none"> •Leverage the unique whole mounted prostate specimen bank with long post-treatment follow up for the identification of early prognostic markers of indolent or progressive disease. •Complete validation of Oncotype DX® Prostate Cancer prognostic assay with Genomic Health, Inc. to distinguish between indolent and aggressive prostate cancer utilizing diagnostic biopsy specimens. •Support our major new initiative of CaP genome analysis in African American patients by NextGen sequencing technologies. •Complete the translation of the new post-DRE urine assay developed at CPDR for the detection of prostate cancer by immunocytochemistry based platform. •Enhance DOD, Government and other academic collaborations assessing the association of BRCA1&2 mutations in aggressive CaP and defining the genetic determinants of African American prostate cancer. •Maintain Bio-Medical Informatics Core to support the current information systems requirements of the CPDR programs. <p>New Biomarker and Therapeutic Target Discoveries:</p> <ul style="list-style-type: none"> •Continue to build on new molecular strategies at the CPDR for improving prostate cancer diagnosis and prognosis. •Leverage new promising data on molecular differences of cancer gene defects between African American and Caucasian American prostate cancer patients towards enhancing personalized medicine in diverse population represented in DOD equal access healthcare system. •Continue to enhance the clinical utility of the CPDR-ERG monoclonal antibody (100% specific for prostate cancer detection) based new strategies of biological stratification and treatment of prostate cancer with in DoD and civilian setting. •Develop and evaluate novel molecular therapeutic agents for early detected cancer targeting the most common ERG positive prostate cancer with potential in leading to paradigm shift in new generation of prostate cancer therapeutics. •Continue to define genetic and molecular determinants of prostate cancer in high-risk groups focusing on African-American men. •Evaluate cancer biology of prostate cancer relevant genes or proteins using established and new experimental models. •Continue to enhance hormonal mechanisms for more precise and effective therapeutic stratification of prostate cancers treated by androgen ablation therapies. •Leverage the CPDR discovery platforms for frequent and potentially causal prostate cancer gene alterations using cutting edge technologies and well annotated and precisely processed bio-specimens. <p>Education and Training Program:</p> <ul style="list-style-type: none"> •Foster education and training in prostate cancer basic science and translational research and provide opportunities for post-doctoral fellows, residents, visiting scientists, medical and graduate students and summer interns. •Utilize the CPDR developed structured molecular oncology training program in prostate cancer for physician and scientists. 			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> •Invite leading experts in prostate cancer field to give state-of-the-art lectures as a part of education and training of post-doctoral fellows, residents, graduate students and research staff. •Sponsor research investigator programs for DOD physicians and scientists on prostate cancer research diagnosis, treatment and therapeutic advances. •Collaborate with other DOD, government, and private agencies in promoting and sponsoring prostate disease research education. <p>Material and Knowledge Products - Continue to:</p> <ul style="list-style-type: none"> •Support new knowledge products through in-house initiatives and collaborative efforts with leading medical institutions and biotechnology companies. •Leverage the largest (27,500+ subjects) and long term (22+ years) multi-center CPDR database within the DOD for developing more precise diagnostic and prognostic biomarkers and nomograms towards enhancing personalized medicine with special focus on ethnically diverse patient population within the DOD. •Enhance CPDR Biospecimen Bank which is considered to be a national treasure for new discoveries of prostate cancer biomarkers and therapy targets. •Leverage the growing intellectual property portfolio of USU-CPDR for developing innovative diagnostic and therapeutic products and technologies to enhance the care of prostate cancer patients within the MHS. 			
Accomplishments/Planned Programs Subtotals	7.771	6.907	6.260

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Prostate Cancer Center of Excellence: Performance is judged on high impact discoveries, development of new diagnostic and treatment strategies, identification of emerging issues of disease feature and patterns, the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of medical students, residents and post-doctoral fellows in the Military Health System.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i>			
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
398A: <i>CoE-Neuroscience Center of Excellence (USUHS)</i>	1.822	1.857	-	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USUHS), the Military Clinical Neuroscience Center of Excellence (MCNCoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical, and translational research studies of militarily relevant neurological disorders affecting U.S. service members and military beneficiaries. The Center's mission is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE goals include supporting neuroscience education and research endeavors at military treatment facilities across the DOD healthcare system and facilitating a network of collaborations between investigators across these facilities.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: CoE-Neuroscience Center of Excellence (USUHS)	1.857	-	-
Description: The Military Clinical Neuroscience Center of Excellence (MCNCoE) is to improve prevention, diagnosis, and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The MCNCoE's approach to its goals includes supporting the research potential of military treatment facilities across the DOD system as well as the national capital area, and facilitating a network of collaborations between investigators across these facilities.			
FY 2014 Accomplishments: The MCNCoE will complete restructuring of its vision and mission. This restructuring began in 2013 and continues into 2014, and includes re-codifying of the governance of MCNCoE, establishing a permanent external scientific advisory board (SAB). The MCNCoE will fund new clinical research projects through a call for proposals reviewed by SAB, and enhance the capability of MCNCoE to involve clinical neuroscientists across the DoD and at affiliated civilian academic centers in collaborative work with MCNCoE. Plans include involvement of national and international research leaders in the field of neurology from national capital area as well as across military healthcare system. Mission will also refocus on promoting education and training of military medical students, residents, fellows and staff in clinical neuroscience standards of care, outcome measures, and research initiatives with a focus on military-specific neurological conditions. With three ACGME accredited joint (tri-service) Military Neurology training programs in the DoD affiliated with USUHS Neurology, restructuring will include evaluating and augmenting clinical residency research opportunities in neurological disorders seen in military beneficiaries to include co-occurring conditions of special interest such as traumatic brain injury, neurodegenerative conditions, post-traumatic headaches, depression, chronic pain, epilepsy, nerve injury, post-traumatic stress disorders, and other clinical conditions that impact on full recovery. In sync with the President's call for Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, MCNCoE is poised			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
to leverage military neuroscience clinicians at USUHS, in the national capital area, across the DoD Military Treatment Facilities, and with MTF academic affiliates to augment the understanding of human brain function which the President has established as an "enormous mystery waiting to be unlocked" (April 2013). FY 2015 Plans: None, MCNCoE research has been merged into the CNRM beginning in FY 2015. FY 2016 Plans: No Funding Programmed.				
Accomplishments/Planned Programs Subtotals		1.857	-	-
C. Other Program Funding Summary (\$ in Millions) N/A				
Remarks				
D. Acquisition Strategy N/A				
E. Performance Metrics Performance of individual PIs will be judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the amount of extramural funding received. Performance of the overall program will be also measured on the effective achievement of better communication and research collaborations between neurology researchers across the DOD system, and on the ability of the Program to affect improvements to the academic curriculum at USUHS.				

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 429A / <i>Hard Body Armor Testing (Army)</i>
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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
429A: <i>Hard Body Armor Testing (Army)</i>	1.356	-	-	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

The Hard Body Armor project plans to develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. This research develops and validates a method for assessing body armor performance against blunt trauma and will be fully compatible with the current testing method. The adoption of armor and helmet design standards that estimate injury type and severity based on biomechanics will allow designers to rationally create armor and helmets that protect each body region and allow the development of standards based on true protection outcomes.

B. Accomplishments/Planned Programs (\$ in Millions)

Title: Hard Body Armor			
Description: Develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head.	FY 2014	FY 2015	FY 2016
FY 2014 Accomplishments: No funding programmed.	-	-	-
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: No funding programmed.			
Accomplishments/Planned Programs Subtotals	-	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Disseminate to the DoD testing community an improved biofidelic blast test manikin (model with characteristics that mimic pertinent human physical ones such as size, shape, mass) that includes the capability to measure and predict skeletal occupant injury during under body blast events in combat and transport vehicles involving a landmine or improvised explosive device.

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 429A / <i>Hard Body Armor Testing (Army)</i>

E. Performance Metrics

Principal investigators will participate in In-Progress Reviews, DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and/or are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 431A / <i>Underbody Blast Testing (Army)</i>			
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
431A: <i>Underbody Blast Testing (Army)</i>	20.929	10.938	4.818	2.679	-	2.679	1.869	-	-	-	-	-

A. Mission Description and Budget Item Justification

To better protect mounted warriors from the effects of underbody blast (UBB) caused by landmines or Improvised Explosive Devices (IEDs), the Underbody Blast (UBB) Testing medical research project will provide new data on the biomechanics of human skeletal response that occurs in an attack on a ground combat vehicle. The data will provide a biomedical basis for the development of a Warrior-representative blast test manikin (the Warrior Injury Assessment Manikin or WIAMan project) and the required biomedically-valid injury criteria that can be used in Title 10 Live Fire Test and Evaluation to characterize dynamic events, the risk of injury to mounted warriors, and to support acquisition decisions. This new data will also benefit the overall DoD effort in vehicle and protection technology for the UBB threat. This work is needed to overcome the limitations of the current test manikin and injury criteria which were designed for the civilian automotive industry for frontal crash testing and as such are not adequate in the combat environment. The current manikins do not represent the modern Soldier and were not designed for the vertical acceleration environment associated with UBB events. Consequently, current LFT&E crew survivability assessment methodologies are limited in their ability to predict the types and severity of injuries seen in these events. Due to this technology gap, military ground vehicles are being fielded without fully defined levels of injury risk and crew survivability for UBB events. The data produced by this project will be used to satisfy a critical need for a scientifically valid capability for analyzing the risk of injury caused by UBB.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Underbody Blast Testing	10.938	4.818	2.679
Description: Will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and will provide the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for live-fire test and evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.			
FY 2014 Accomplishments: The Underbody Blast Testing project focused on generating and providing medical research data needed to support the development of the WIAMan anthropomorphic (resembling a human) test device concept and the first generation prototype. The emphasis was on non-injurious testing conditions and biofidelity data but also included injurious testing. All body regions were addressed including whole-body testing and also prioritized testing of the following body regions, foot and ankle, leg, pelvis, lumbar spine, thoracic spine, cervical spine, torso, head and neck. Validation studies were conducted to contrast injuries observed in theater with those created in the testing program to prioritize research. Emerging medical research data was used to support the protection technology development and the modeling and simulation initiatives.			
FY 2015 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 431A / <i>Underbody Blast Testing (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

<p>The Underbody Blast Testing project is continuing medical research in the areas initiated in FY14 but with the emphasis shifting during the year from non-injurious conditions to those which cause injuries. This will enable the development of initial human injury probability curves that account for influences unique to the military and to the underbody blast environment. All data are transitioning into the WIAMan project to enable the fabrication of the first and second generation prototype anthropometric test devices (ATDs; manikins or crash test dummies). Validation studies are contrasting injuries observed in theater with those created in the testing program to prioritize further research. Emerging medical research data are supporting the protection technology development and the modeling and simulation initiatives.</p> <p>FY 2016 Plans: The Underbody Blast Testing project will continue medical research in the areas initiated in FY15 but with the emphasis shifting to perform matched pair testing of the first generation WIAMan prototype. This will enable a pairwise comparison between the human injury probability curves and the responsiveness of the WIAMan first generation prototype in the military and underbody blast environments. This work will inform the development of whole-body injury criteria and the protective technology for use in the underbody blast environment.</p>	FY 2014	FY 2015	FY 2016
	Accomplishments/Planned Programs Subtotals	10.938	4.818

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Produce biofidelity response corridors (BRC) and human injury probability curves (HIPC) for human skeletal response and tolerance in the military UBB environment and transition them for use in the development of the WIAMan UBB test manikin and for general use in the RDT&E community. Develop injury assessment reference curves for use with WIAMan manikin to support vehicle and protection technology acquisition decisions.

E. Performance Metrics

Performance metrics include the timely transition of actionable medical research from principal investigators for use in the development of the WIAMan UBB test manikin and to benefit the RDT&E protection technology and acquisition community. Actionable medical research includes biofidelity response corridors (BRCs), human injury probability curves (HIPC), and injury assessment reference curves (IARCs). Principal investigators (PI's) will participate in In-Progress Reviews, technical interchange meetings, and theater injury analysis reviews. PIs will publish emerging results in the proceedings of injury biomechanics symposia and in relevant journals. As required, PIs will participate in DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule. An external peer review of the medical research will be conducted to ensure the medical research is scientifically valid and suitable for accreditation for use in supporting acquisition decisions.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 448A / <i>Military HIV Research Program (Army)</i>			
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
448A: <i>Military HIV Research Program (Army)</i>	-	6.663	5.773	6.589	-	6.589	6.702	7.579	7.722	7.877	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project funds research to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. All HIV technology development is conducted in compliance with US Food and Drug Administration (FDA) regulations. Evaluations in human subjects are conducted to demonstrate safety and effectiveness of candidate vaccines, as required by FDA regulation. Studies are conducted stepwise: first, to prove safety; second, to demonstrate the desired effectiveness of the drug, vaccine, or device for the targeted disease or condition in a small study; and third, to demonstrate effectiveness in large, diverse human population trials. All results are submitted to the FDA for evaluation to ultimately obtain approval (licensure) for medical use. This project supports studies for effectiveness testing on small study groups after which they transition to the next phase of development for completion of effectiveness testing in larger populations. This program is jointly managed through an Interagency Agreement between USAMRMC and the National Institute of Allergy and Infectious Diseases (NIAID). This project contains no duplication with any effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Military HIV Research Program	6.663	5.773	6.589
Description: The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection.			
FY 2014 Accomplishments: The Military HIV Research Program conducted safety and effectiveness studies with a combination vaccine in human volunteers at clinical trial sites world-wide and down-selected best candidates. Clinical trial results informed the need for further testing in human volunteers to study the ability of HIV vaccine candidates to provoke an immune response that can protect against HIV.			
FY 2015 Plans: Conducting initial testing in humans for safety and effectiveness at CONUS and OCONUS sites with down-selected HIV-1 multivalent vaccine candidates, either a single vaccine or a combination of several sub-types. Preparing for large scale production of vaccine candidates from various world-wide subtypes. These candidates will be used in future large scale clinical studies.			
FY 2016 Plans:			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 448A / <i>Military HIV Research Program (Army)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
The Military HIV Research Program will complete large scale production and characterization of selected vaccine candidates. Will initiate large scale safety and effectiveness trials with one or more vaccine candidates either as single vaccine or combination of several sub-types representing major world-wide distribution.			
Accomplishments/Planned Programs Subtotals	6.663	5.773	6.589

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Mature and demonstrate candidate HIV vaccines, prepare and conduct human clinical studies to assess safety and effectiveness of candidate HIV vaccines. All HIV technology development activities are conducted in compliance with FDA regulations. Best selected candidates will be transitioned to advanced development through Milestone B.

E. Performance Metrics

Performance of the HIV research program will be monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR) conducted by USAMRMC Decision Gate process to include Defense Health Agency representation.

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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 0603115HP / <i>Medical Technology Development</i>				Project (Number/Name) 830A / <i>Deployed Warfighter Protection (Army)</i>			
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
830A: <i>Deployed Warfighter Protection (Army)</i>	9.001	5.225	4.553	5.306	-	5.306	5.397	6.105	6.221	6.345	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Armed Forces Pest Management Board (AFPMB), the Deployed Warfighter Protection project plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that carry disease under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe, and effective applications.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Deployed Warfighter Protection	5.225	4.553	5.306
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.			
FY 2014 Accomplishments: The Deployed Warfighter Protection (DWFP) research project focused on three major areas to develop products to control biting insects, primarily mosquitoes and sand flies, that transmit force degrading diseases: personal protection systems, new insecticides, and vector control/insecticide application technologies. The personal protection system for today's warfighter relies upon permethrin treated uniforms, applying topical repellents to all exposed skin daily, and sleeping under an insecticide treated net. These countermeasures are often ineffective for several reasons including low user acceptance and the logistical burden of supplying and carrying these products. New personal protection system tools – such as lower concentration repellent chemicals and spatial repellents - were in development by DWFP scientists and their partners. In the area of new insecticides, expanded regulatory requirements and development of insecticide resistance have resulted in a reduction in the number of public health pesticides available for controlling mosquitoes and sand flies. DWFP transitioned a patented Attractive Targeted Sugar Bait (ATSB) delivery technology to a commercial partner as a novel reduced risk pesticide. This new mosquito control product promises to revolutionize mosquito control. To improve the effectiveness and the sustainability of insect control operations in deployed settings, the DWFP focused on developing updated insect control methods, lighter weight insecticide sprayers, and new application technologies that take advantage of engineering advances such as smartphones and robotics.			
FY 2015 Plans:			

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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 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 830A / <i>Deployed Warfighter Protection (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>The Deployed Warfighter Protection (DWFP) research project is developing products that will enable deployed forces to better protect themselves and control biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. The DWFP is focusing research efforts on critical gaps identified by the Services and Combatant Commands to control insect disease vectors to provide solutions in three thrust areas: personal protection systems, new insecticides, and vector control/insecticide application technologies. Within the enhanced personal protection systems, DWFP is evaluating the feasibility of bite-proof fabrics, studying the durability of factory permethrin-treated uniforms, and searching for a replacement insecticide that safely outperforms the current treated uniforms. Regarding spatial repellents, the DWFP down-selected and is extensively evaluating a chemical to augment the use of personal topical repellents, such as DEET, which require frequent application, suffer from low levels of user acceptability, and are short lived (lasting only hours). Such a spatial repellent promises to protect personnel when not in uniform and when DEET or other skin repellents are not used. The DWFP is conducting early field tests of prototype micro-dispensers and textile-based area/spatial-repellent dispensers; and conducting a preregistration meeting with the parent commercial company and the EPA to determine steps required for regulatory approval of the repellent in the US. To counter the rising problem of mosquito resistance to existing insecticides and the issue of currently approved insecticides being removed due to more stringent regulatory requirements, the DWFP is focused on developing the next generation of insecticides which will be more effective at protecting deployed personnel while also being safer for humans and the environment. The DWFP is collaborating with multiple industry partners to develop such new insecticides for EPA registration. For vector control technologies, the DWFP is targeting pesticide delivery methods that are more effective, efficient, and sustainable in austere and tropical environments. In addition to materiel solutions/products, DWFP priorities include knowledge products that support vector control and disease risk reduction to include improving current practices used in the field.</p> <p>FY 2016 Plans: In FY16 the Deployed Warfighter Protection (DWFP) research project will develop and field tools that enable deployed forces to better protect themselves and control biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. This will be accomplished through research, testing and evaluation of products, patent submissions, licensing, and EPA registrations for new insecticides. The DWFP will maintain its focus within personal protection systems, new insecticides, and vector control/insecticide application technologies. For enhanced personal protection systems, protective clothing efforts will review pending positive results of the FY15 evaluations of prototype bite proof fabric for commercialization; the alternative to permethrin for treating combat uniforms will complete efficacy evaluations and, if effective, will be submitted to the Armed Forces Pest Management Board (AFPMB) and the EPA for approval and registration. Within this same focus area, under area/spatial repellents the DWFP will expand field tests focused on the best performing area/spatial-repellent dispensers evaluated in FY15 and will work with the EPA and associated industry partner to pursue EPA registration for military use. For new insecticides, the DWFP will down select top performing novel molecular pesticides-tested in FY15 for expanded field testing; will conduct faster, more efficient, lab based screening of potential plant-derived and synthetic insecticides to identify promising candidate compounds; and will execute field evaluations of insecticides identified in FY15. For vector control/insecticide application</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115HP / <i>Medical Technology Development</i>	Project (Number/Name) 830A / <i>Deployed Warfighter Protection (Army)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
technologies, lab and field testing of insecticide sprayer products identified as promising tools in FY15 will be conducted. Best performing products/sprayers and technologies tested in FY15 will transition to commercial partners for submission to the AFPMB for addition to the National Stock System.			
Accomplishments/Planned Programs Subtotals	5.225	4.553	5.306

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Develop, mature and field new or improved products and strategies that protect US forces from disease-carrying insects. Secure registered trademarks, patents, commercial partners, and/or EPA registration of new or improved insecticides, application technologies and repellent systems. Continue to partner with industry to field products and coordinate with the Services and relevant Program Executive Offices (PEOs) to transition efforts.

E. Performance Metrics

Performance for the Deployed Warfighter Protection Program is measured by the insecticides and other products given EPA registration and added to the military stock system, changes in pest management techniques or technologies used by the military to control biting/disease causing insects, patents, and peer-reviewed scientific manuscripts. The Program conducts an annual Research Review during which a panel of DoD subject matter experts provides input on programmatic alignment and strategic priorities.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>							
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	352.253	296.634	150.822	103.443	-	103.443	129.137	140.826	146.781	149.354	Continuing	Continuing
374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	280.424	244.621	97.614	99.443	-	99.443	125.137	136.826	142.781	145.354	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	67.933	49.000	53.208	-	-	-	-	-	-	-	Continuing	Continuing
434A: <i>Medical Products Support and Advanced Concept Development (AF)</i>	3.896	3.013	-	4.000	-	4.000	4.000	4.000	4.000	4.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF) - Medical Products Support and Advanced Concept Development: Funding supports (1) advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA), (2) clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user,(3) prototyping, (4) risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Office for possible integration into the Military Health System, and (5) medical simulation and training system technologies. This portfolio is designed to address areas of interest to the Secretary of Defense related to Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the sustainment of priority investments in science, technology, research, and development, as stated 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 such as 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 Defense Health Agency's Joint Program Committees (JPC), which were established to manage research, development, test and evaluation for Defense Health Program (DHP) sponsored research. Research within this program element encompasses Medical Simulation and Information Sciences (through JPC-1), Military Infectious Disease (through JPC-2), Military Operational Medicine (through JPC-5), Combat Casualty Care (through JPC-6), and Clinical and Rehabilitative Medicine (through JPC-8). As the research efforts mature, the most promising efforts will transition to medical products and support systems development funding, Program Element 0605145.

For the Air Force Medical Service, funding in this program element supports technology development for the rapid transition of medical products and capabilities from Air Force laboratories, and the ability to perform modifications /enhancements required to integrate commercial off-the-shelf (COTS) and near-COTS products into the military operating environment. Ability to enhance or modify existing COTS is a cost effective technique we should maximize where possible, ensuring warfighters have appropriate technology at hand to care for wounded at the point of injury through definitive care and on to rehabilitation and reintegration at the most efficient cost and schedule possible. Significant benefits can be obtained from rapid insertion of high value / impact technologies into healthcare operations to address capabilities that enter the acquisition life-cycle at high TRL levels that can readily be implemented with significant upside potential. Cannot ensure viability of S&T and translational research efforts with a materiel component without correctly programmed funding for logical progression and transition of those activities in the product development

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>
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lifecycle. Ensures viability of S&T and translational research efforts with a materiel component by providing programmed funding for logical progression and transition of those activities in the product development lifecycle.

The Army Medical Command received DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury/ Psychological Health, and Peer-Reviewed Joint Warfighter Medical Research. The Uniformed Services University received CSI funding for the Therapeutics Service Dog Training Program. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	132.430	97.787	95.815	-	95.815
Current President's Budget	296.634	150.822	103.443	-	103.443
Total Adjustments	164.204	53.035	7.628	-	7.628
• Congressional General Reductions	-0.124	-0.173			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	49.000	53.208			
• Congressional Directed Transfers	-	-			
• Reprogrammings	126.369	-			
• SBIR/STTR Transfer	-11.041	-			
• Program Realignment - Project 374A	-	-	3.628	-	3.628
• Program Realignment - Project 434A	-	-	4.000	-	4.000

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 400Z: *CSI - Congressional Special Interests*

Congressional Add: 427A - *Traumatic Brain Injury/ Psychological Health*

Congressional Add: 441A - *Joint Warfighter Medical Research Program*

Congressional Add: 455A - *Therapeutic Service Dog Training Program (USUHS)*

Congressional Add: 464A – *Program Increase: Restore Core Research Funding Reduction (GDF)*

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	10.000	20.000
	35.000	20.000
	4.000	3.000
	-	10.208
Congressional Add Subtotals for Project: 400Z	49.000	53.208
Congressional Add Totals for all Projects	49.000	53.208

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0604110-Medical Products Support and Advanced Concept Development (-\$11.041 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$11.041 million).

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program Date: February 2015

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: Defense Health Program I BA 2: RDT&E	PE 0604110HP I Medical Products Support and Advanced Concept Development

FY 2014: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ \$49.000 million).

FY 2014: Federally Funded Research and Development Center Reduction, PE 0604110-Medical Products Support and Advanced Concept Development (-\$0.124 million).

FY 2015: Federally Funded Research and Development Center Reduction, PE 0604110-Medical Products Support and Advanced Concept Development (-\$0.173 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ \$53.208 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-\$4.000 million) to DHP RDT&E PE 0604110-Medical Products Support and Advanced Concept Development (+\$4.000 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).

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>				Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>			
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
374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	280.424	244.621	97.614	99.443	-	99.443	125.137	136.826	142.781	145.354	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF)-Medical Products Support and Advanced Concept Development: This funding supports (1) clinical trials of promising technologies that may provide solutions for the most pressing medical needs of the Warfighter, (2) accelerated transition of promising technologies to the field, and (3) promulgation of new, evidence-based approaches to the practice of medicine as clinical practice guidelines. Research will be conducted in the following areas: (1) Medical Simulation and Information Sciences/JPC-1. This JPC seeks to promote long-term efficiencies by defining processes improving the electronic healthcare record/other medical related systems, and the implementation of new trends and advancements in technology to improve healthcare access, availability, continuity, cost effectiveness, and quality. Initial candidates will be selected from those funded by other medical research sponsors in the Department, and from external sources such as academia and industry, including efforts funded with prior year CSI funding; (2) Military Infectious Disease/JPC-2. This JPC supports the advanced development of systems to rapidly detect pathogens (infectious agents) in fresh whole blood, as well as efforts related to the prevention and management of wound infections and the development of antimicrobial countermeasures and infectious disease-related diagnostic systems; (3) Military Operational Medicine/JPC-5. This JPC supports clinical assessments related to interventions for post-traumatic stress disorder (PTSD), nutrition and dietary supplementation to promote health and resilience, the development of mitigation strategies to prevent hearing loss, the development of techniques to enhance military family and community health and resilience, validation trials for enhanced suicide prevention, and the accomplishment of related field studies with end users; (4) Combat Casualty Care/JPC-6. This JPC supports clinical trials such as those assessing biomarkers (biological indicators) for traumatic brain injury (TBI) and spinal cord injury, product development related to forward surgical/intensive critical care, enroute care, hemorrhage and resuscitation, and treatments for tissue injury; (5) Clinical and Rehabilitative Medicine/JPC-8. Advanced development efforts in this JPC involve clinical trials related to pain management and regenerative medicine.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: GDF – Medical Product Support and Advanced Concept Development	244.621	97.614	99.443
Description: Product support and advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); the accelerated transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications, and medical training systems technologies.			
FY 2014 Accomplishments:			
Medical Simulation and Information Sciences conducted research in two primary research portfolios -- Medical Simulation and Training, and Health Informatics and Information Technology. Under the Medical Simulation and Training portfolio, development began on the core (torso) portion (Phase 1) of the Advanced Modular Manikin. This platform will be used in the training of medical intervention procedures. Under the Health Informatics and Information Technology portfolio, coordination continued on electronic			

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>medical information technology research to support care for the Warfighter, and to mitigate program risk for the Military Health System. Identified options to reduce potential near- and long-term risks associated with information technology development and legacy systems, and prepared for the transition to the Department of Defense modernized Electronic Health Record. Research continued on closing gaps related to mobile health and personal health management, and advancing the ability to capture data from the point of injury to the point of definitive care. This effort involves data transmission initiatives, new clinical decision support algorithms, and patient identification issues incorporating patient consent, privacy, and security.</p> <p>Military Infectious Diseases completed down-selection on a Next Generation Diagnostic System for the Combat Support Hospital. Initiated advanced development on three polymerase chain reaction-based assays (malaria, dengue, and chikungunya) to be used on the Next Generation Diagnostic System (NGDS).</p> <p>Military Operational Medicine completed clinical trials on the use of improved psychotherapies (psychological treatment of mental disorders) for the treatment of PTSD in Operation Iraqi Freedom/Operation Enduring Freedom returnees. These studies provided evidence for the efficacy of delivering PTSD treatment in-home, and supported delivery of PTSD treatment in a shortened period of time. In collaboration with the Veterans Administration, clinical trials were initiated examining the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares). Clinical trials continued on alcohol and substance abuse and suicide prevention interventions. Development was completed on actionable algorithms for integration into physiological health status monitoring systems. Field studies were conducted with end users. Continued initiatives developing mitigation strategies for prevention of hearing loss, and on safety and efficacy studies related to clinical nutrition and dietary supplements.</p> <p>Combat Casualty Care conducted research in Hemorrhage and Resuscitation, Neurotrauma, Traumatic Tissue Injury, Forward Surgical Intensive Critical Care, and joint Enroute Care. Under Hemorrhage and Resuscitation: Initiated a Phase 2 clinical trial in humans on a spray dried plasma product in support of a FDA Biologic License Application. Initiated Phase 2 and Phase 3 clinical trials on a device to kill infectious organisms in fresh whole blood collected on the battlefield for transfusion. Conducted clinical trials on the pre-hospital use of plasma. Under Neurotrauma: Conducted a DoD-Veteran's Administration multi-site collaborative study assessing the effectiveness of commonly prescribed off-label treatments for combat-related PTSD. Continued study assessing the effectiveness of non-invasive diagnostic/assessment tools for Traumatic Brain Injury (TBI), and the assessment of TBI biomarkers in patients with concussive injuries. Conducted clinical trials on a drug to treat concussions. Continued validation studies on a smooth-pursuit eye tracking system to diagnose concussions. Under Forward Surgical Intensive Critical Care and joint Enroute Care: Initiated advanced development on a system bringing advanced intensive care capabilities to frontline medics and medical treatment facilities.</p>			

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
<p>Clinical and Rehabilitative Medicine sponsored advanced clinical studies within the areas of pain management, and regenerative and rehabilitative therapies after traumatic injury. Continued clinical research and clinical trials for regenerative medicine-based approaches for restoration of limb (arms and legs) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, and genitourinary system (reproductive and urinary organs). Continued composite tissue allotransplantation (hand and face transplantation) efforts and associated immune system modulation technologies. Initiated clinical research and new clinical trials for pain management.</p> <p>FY 2015 Plans: Medical Simulation and Information Sciences conduct research in two primary research portfolios -- Medical Simulation and Training, and Health Informatics and Information Technology. Under the Medical Simulation and Training portfolio, the Advanced Modular Manikin Phase 1 effort continues developing a core (torso) portion for use in the training of medical intervention procedures. Efforts are underway to assess the value of stress inoculation simulation training methodologies, technologies, and techniques in better protecting Warfighters from deployment related psychological stresses and trauma. Under the Health Informatics portfolio, efforts continue towards filling theater information technology research gaps such as the capturing and transmission of point of injury data, the incorporation of theater health information into DoD and Veteran's Administration health systems, and technology issues related to a theater environment.</p> <p>Military Infectious Disease continue advanced development on polymerase chain reaction-based assays for malaria, dengue, and chikungunya to be used on the Next Generation Diagnostic System (NGDS) for Combat Support Hospitals. Efforts begin on an antimicrobial countermeasures study supporting the development of an antibacterial drug effective against multiple drug resistant bacteria. A clinical study on wound infection prevention and management begins.</p> <p>Military Operational Medicine is applying the results of clinical trials to the development of clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for the treatment of PTSD. Continue Veterans Administration-DoD clinical trials studying the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares). Complete clinical trials on alcohol and substance abuse and suicide prevention interventions, and begin to apply results to the development of clinical practice guidelines. Continue integration of actionable algorithms into physiologic status monitoring systems based on end user feedback. Validate data from human studies on nutrition and dietary supplements.</p> <p>Combat Casualty Care conducts research in Hemorrhage and Resuscitation, Neurotrauma, Traumatic Tissue Injury, Forward Surgical Intensive Critical Care, and joint Enroute Care. Under Hemorrhage and Resuscitation: Continue Phase 2 and initiate Phase 3 clinical trials supporting FDA Biologic License Application for a spray-dried plasma product. Complete clinical trials on a device killing infectious organisms in fresh whole blood collected on the battlefield for transfusion. Under Neurotrauma: Continue</p>				

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>a DoD-Veteran’s Affairs multi-site collaborative study assessing the effectiveness of commonly prescribed off-label treatments for combat-related PTSD. Continue studying the effectiveness of non-invasive diagnostic tools for TBI and the assessment of TBI biomarkers in patients with concussive injuries. Evaluate and validate two TBI biomarker point-of-care devices in conjunction with a biomarker-specific diagnostic assay system. Continue to develop the Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System (BANDITS) diagnostic. Validate pivotal clinical trial results from the Portable Neuromodulation Stimulator (PONS) as a treatment for TBI balance disorders. Under Forward Surgical Intensive Care and joint Enroute Care: Continue the advanced development of a system to provide advanced intensive care capabilities to first responders and frontline Military Treatment Facilities.</p> <p>Clinical and Rehabilitative Medicine continues to maximize the opportunity to transition current efforts to fielding, private industry, or medical systems development. Continue clinical studies in the areas of pain management, and regenerative and rehabilitative therapies for traumatic injury. Continue clinical trials for regenerative medicine-based approaches for restoration of limb (arms and legs) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, repair of skin injury resulting from burns, and genitourinary system (reproductive and urinary organs). Continue composite tissue allotransplantation (hand and face transplantation) efforts and associated immune system modulation technologies. Transition product for battlefield pain management to late-phase FDA regulated clinical trials.</p> <p>For the tri-service translational research at Military Treatment Facilities, collaborative efforts are underway to solicit and make awards. Applications are to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and/or clinical and rehabilitative medicine. These include clinical trials for validation of improved psychotherapies (psychological treatment of mental disorders), improved pharmaceuticals (medications) and devices for the treatment of TBI/PH.</p> <p>FY 2016 Plans: Medical Simulation and Information Sciences will conduct research in two primary research portfolios -- Medical Simulation and Training, and Health Informatics and Information Technology. Under the Medical Simulation and Training portfolio, Phase 1 of the Advanced Modular Manikin project will end with platform downselect and one award for a standardized manikin core (torso) platform. Advanced Modular Manikin, Phase 2 will begin the development of task specific peripherals (i.e., arm, legs, and head) for integration onto the core platform selected from Phase 1. Advanced development efforts will continue on a stress inoculation simulation system to better protect Warfighters from the deployment related psychological stresses and trauma. Testing will continue on next generation mobile technologies for more effective advanced distributed learning applications, and on systems development for improved mobile health technologies, visualization of health related data, and medical provider decision support algorithms.</p>			

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Military Infectious Diseases will initiate advanced development on one infectious disease polymerase chain reaction-based assay to be used on the Next Generation Diagnostic System (NGDS). Clinical studies will continue on the development of an antibacterial drug effective against multiple drug resistant bacteria, and on wound infection prevention and management.</p> <p>Military Operational Medicine will continue the development of clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for PTSD, for the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares), and on alcohol and substance abuse and suicide prevention interventions. Continue validation studies on clinical nutrition and dietary supplement safety and efficacy. Develop gender-specific and gender-neutral standards that apply across garrison and combat operations to reduce injuries in the total force. Continue efforts within the area of environmental health and protection to refine algorithms to reliably predict core body temperature from non-invasive measurements (e.g., skin temperature and heart rate) for a physiological health status monitoring system. Initiate studies assessing the use of a physiological health monitoring system to determine the prevalence and severity of pulmonary disease in pre-deployed and returned service members.</p> <p>Combat Casualty Care conducted research in Hemorrhage and Resuscitation, Neurotrauma, Traumatic Tissue Injury, Forward Surgical Intensive Critical Care, and joint Enroute Care. Under Hemorrhage and Resuscitation: Complete Phase 2 and Phase 3 clinical trials supporting FDA Biologic License Application for a spray-dried plasma product. Complete clinical trials on a device that kills infectious organisms in fresh whole blood. Initiate clinical trials on an intracavitary hemostatic product and a low-volume resuscitation drug. Under Neurotrauma: Continue clinical trials on a point-of-care diagnostic tool for traumatic brain injury. Continue studies advancing the development of TBI biomarker devices. Validate results of a multi-site collaborative TBI endpoints study to improve clinical trial design. Continue the advanced development of novel diagnostics for traumatic brain injury. Under Traumatic Tissue Injury: Continue the development of technologies transitioned from the Peer Reviewed Orthopedic Research Program. Under Forward Surgical Intensive Critical Care and joint Enroute Care: Continue advanced development of a system to provide advanced intensive care capabilities to first responders, frontline Military Treatment Facilities, and data collection systems for battlefield point of injury</p> <p>Clinical and Rehabilitative medicine will continue to transition current efforts to fielding or private industry for products/solutions/guidelines. Complete late phase FDA regulated clinical trials for battlefield pain management products and submit a New Drug Application with the US FDA. Continue the development of regenerative and rehabilitative therapies for traumatic injury. Progress clinical trials for regenerative medicine-based approaches for restoration of limb (arms and legs) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, repair of skin injury resulting from burns, and genitourinary system (reproductive and urinary organs). Improve non-invasive clinical monitoring of composite tissue allotransplantation (hand and face transplantation) and continue support for associated immune system modulation technologies.</p>			

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Initiate clinical trials on methods to reconstruct facial features (such as lips and eyelids), test nerve allograft materials, and enhance muscle regeneration. The Tri-service translational research Military Treatment Facility-based studies recommended for funding in FY15 will recruit, screen, and enroll patients and will begin to collect data for advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and clinical and rehabilitative medicine. Examples of initiatives within this area include clinical trials to validate improved psychotherapies (psychological treatment of mental disorders), and efforts to improve pharmaceuticals (medications) and devices for the treatment of TBI/PH).			
Accomplishments/Planned Programs Subtotals	244.621	97.614	99.443

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Test and evaluate medical device prototypes, medical procedures, and drug and vaccine candidates in government-managed Phase 2 clinical trials to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval and Environmental Protection Agency registration.

E. Performance Metrics

Research will be evaluated through In-Progress Reviews, high-level DHP-sponsored review and analysis meetings, quarterly and annual status reports, and will be subject to Program Office or Program Sponsor Representatives progress reviews to ensure that Decision Gate milestones are being met and deliverables will be transitioned on schedule. In addition, 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 (TRL) 7.

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>				Project (Number/Name) 400Z / <i>CSI - Congressional Special Interests</i>			
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
400Z: <i>CSI - Congressional Special Interests</i>	67.933	49.000	53.208	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY14 DHP Congressional Special Interest (CSI) funding supported peer-reviewed directed research for Traumatic Brain Injury and Psychological Health, and Joint Warfighter Medical Research. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 427A - Traumatic Brain Injury/ Psychological Health	10.000	20.000
<p>FY 2014 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest research program aims to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. Key priorities of the FY14 TBI/PH research program were to support projects aligned with the National Research Action Plan, address Congressional intent, enable significant research collaborations, and complement ongoing Department of Defense (DoD) efforts to ensure the mental health and readiness of our military forces by promoting a better standard of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In addition to service-requested nominations, individual Broad Agency Announcement applications, and promising ongoing studies, four program announcements (PAs) were released to solicit applications that address these priorities. The Psychological Health Research Award PA is intended to support both applied (preclinical) research and clinical trials within specific topic areas addressing the prevention and treatment of military-relevant psychological health issues. The Neurosensory and Rehabilitation Research Award PA Supports both applied (preclinical) research and clinical trials addressing TBI within specific focus areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation associated with TBI. The Investigative Treatments for TBI and PTSD Clinical Trial Award PA responds to Section 704 of the National Defense Authorization Act for Fiscal Year 2014 and supports investigational treatments (including diagnostic testing) of TBI and PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities. The Community Partners in Mental Health Research Award PA responds to Section 706 of the National Defense Authorization Act for Fiscal Year 2013 by supporting research on the causes, development, and innovative treatment of mental health, substance use disorders, TBI, and suicide prevention in members of the National Guard and Reserves, their family members, and their caregivers. Application submission deadlines for the PAs are in November 2014, January 2015, and February 2015. Scientific peer</p>		

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 400Z / <i>CSI - Congressional Special Interests</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015
reviews will be held in January and March 2015 followed by programmatic reviews in March and May 2015. Awards will be made by September 2015.			
FY 2015 Plans: This Congressional Special Interest research initiative is for Traumatic Brain Injury/ Psychological Health.			
Congressional Add: 441A - Joint Warfighter Medical Research Program		35.000	20.000
FY 2014 Accomplishments: The Joint Warfighter Medical Research Program (JWMP) provides continuing support for promising research previously funded under Congressional Special Interest programs. The focus is to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives, and yielding a benefit to military medicine. Project funding is divided into technology development and engineering and manufacturing development efforts. The JWMP directly supports military medical research in military infectious diseases, combat casualty care, military operational medicine, medical training and health information sciences, and clinical and rehabilitative medicine. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committees, and Execution Management Agency activities. Those projects deemed by the Joint Program Committees to have the highest priority to fill critical research or materiel gaps, and those projects close to developing a product were invited to submit a full proposal for the next level of effort. The scientific peer review was completed in late June. The programmatic review was completed in August with the recommended funding list for 16 projects forwarded to the Director of Research and Development, Defense Health Agency for approval. Award negotiations will be complete by September 2015.			
FY 2015 Plans: This Congressional Special Interest research initiative is for Joint Warfighter Medical Research Program.			
Congressional Add: 455A - Therapeutic Service Dog Training Program (USUHS)		4.000	3.000
FY 2014 Accomplishments: This Congressional Special Interest project will support Therapeutics Service Dog Training research.			
FY 2015 Plans: This Congressional Special Interest research initiative is for Therapeutic Service Dog Training Program (USUHS).			
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF)		-	10.208

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 400Z / <i>CSI - Congressional Special Interests</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015
<i>FY 2014 Accomplishments:</i> No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.		
<i>FY 2015 Plans:</i> FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoration of core research initiatives in the Medical Products Support and Advanced Concept Development Program Element (PE) - 0604110.		
Congressional Adds Subtotals	49.000	53.208

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Prior year CSI funded research will be assessed for developmental maturity and qualification for initial or continued advanced development funding. If advanced development criteria are met, follow-on development will be solicited through a peer-reviewed process.

E. Performance Metrics

N/A

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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 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>				Project (Number/Name) 434A / <i>Medical Products Support and Advanced Concept Development (AF)</i>			
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
434A: <i>Medical Products Support and Advanced Concept Development (AF)</i>	3.896	3.013	-	4.000	-	4.000	4.000	4.000	4.000	4.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Air Force Medical Products Support and Advanced Concept Development & Prototyping efforts are focused on achieving rapid transition of promising, high TRL commercially-available off-the-shelf products through minor modifications and/or enhancements to address the most pressing medical needs of the Warfighter, accelerating of the transition of those technologies to the operators in the field. Development, Modification and Enhancement projects will emphasize technologies supporting Expeditionary Medicine, Enroute Care, Force Health Protection, Operational Medicine and Human Performance. Ensure Healthcare delivery remains current and relevant. Provide critical capability to make and act on material solution investment decisions in an annual cycle. Derive benefits from rapid insertion of high value / impact technologies into healthcare operations with programmed funding to address capabilities that enter the acquisition life-cycle at high TRL levels that can readily be implemented with significant upside potential. Ensure viability of S&T and translational research efforts with a materiel component without programmed funding for logical progression and transition of those activities in the product development lifecycle.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Medical Products Support and Advanced Concept Development (AF)	3.013	-	4.000
Description: Rapidly transition key COTS and near-COTS based technology solutions to the warfighter through assessment/ evaluation and minor modification or enhancement of solutions to address threshold operational requirements and associated key performance parameters. Provide core capability to rapidly transition key, high value and impact technologies to operational use. Provide core capability to logically progress initiatives and concepts in the S&T and translational/knowledge-focused programs (6.1-6.3) into material solutions and conduct the advanced development and transition activities needed to ensure those products are fielded in an effective, timely and efficient manner.			
FY 2014 Accomplishments: Completed transition of non-invasive Patient Warming & Cooling technology to Program of Record; expanded pathogen detection, identification and quantification (DIQ) technology to operational use on existing COTS gas chromatograph, mass spectrometer platforms to address harmful and potentially harmful microbial volatile organic compounds (MVOC) and improve Force Health Protection. Completed transition of expanded multi-lingual voice translation COTS capability to operational use in beyond line of site / comm-out settings requiring on-board hardware based rapid translation capability. Prepare and issue solicitation for award of an advanced technology development effort to refine and transition the Cardiovascular Sonospectrographic Analyzer (CSA) pursuant to the approved FY14 Omnibus Reprogramming action.			
FY 2015 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 434A / <i>Medical Products Support and Advanced Concept Development (AF)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>Award effort to refine and commercialize the Cardiovascular Sonospectrographic Analyzer (CSA). Conduct developmental engineering activities to ready the device for inclusion in advanced clinical trials and guiding it to the FDA regulatory approval pathway. Award effort to develop a next generation multi-channel infusion pump via a modified-COTS approach to rapidly and safely deliver drugs and therapeutics to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care.</p> <p>FY 2016 Plans: Evaluate the Cardiovascular Sonospectrographic Analyzer (CSA), technology through clinical trials by improving sensitivity and specificity and form factor enhancements to device that can process sound signatures of turbulent blood through partially occluded arteries - target level of sensitivity is CT angiography--include device in ongoing and planned clinical trials for submission of the 510K predicate device application to the FDA. Continue efforts to develop a next generation multi-channel and prepare for predicate device submission to the FDA for transition of the technology.</p>			
Accomplishments/Planned Programs Subtotals	3.013	-	4.000

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Partnership with the US Navy, AFRL and the Department of the Interior in inter-agency agreements and use (award of delivery orders and task assignments) to engineering and manufacturing development IDIQ vehicles awarded under SBIR phase III provisions. Utilization of Small Business Innovative Research program direct awards for Phase III transition efforts and a Cooperative Agreement structure through Foundations supporting military medical research and development programs.

E. Performance Metrics

Achievement of required TRL for each advanced concept development/product support project and fulfillment of established KPPs for same.

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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 0605013HP I Information Technology 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	219.540	44.451	21.696	19.312	-	19.312	19.679	23.582	21.386	21.813	Continuing	Continuing
239B: Health Services Data Warehouse (Air Force)	0.000	1.112	0.717	0.908	-	0.908	0.962	1.436	1.461	1.490	Continuing	Continuing
239F: IM/IT Test Bed (Air Force)	3.800	2.265	1.801	1.844	-	1.844	1.837	2.222	2.686	2.740	Continuing	Continuing
283C: Medical Operational Data System (MODS) (Army)	1.472	3.384	3.413	2.601	-	2.601	2.678	3.547	4.016	4.096	Continuing	Continuing
283D: Army Medicine CIO Management Operations	1.492	2.113	0.120	0.867	-	0.867	0.794	2.649	3.371	3.438	Continuing	Continuing
283F: Army Warrior Care and Transition System (AWCTS)	0.488	-	-	-	-	-	-	-	-	-	Continuing	Continuing
283H: Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)	0.000	-	-	0.080	-	0.080	0.080	0.080	0.080	0.082	Continuing	Continuing
283I: Workload Management System for Nursing-Internet	0.264	-	-	-	-	-	-	-	-	-	Continuing	Continuing
283J: Multi-Drug Resistant Surveillance Network (MRSN)	1.374	-	0.807	0.844	-	0.844	0.878	-	-	-	Continuing	Continuing
283K: Veterinary Services Systems Management (VSSM)	0.000	0.238	-	-	-	-	-	-	-	-	Continuing	Continuing
283L: Pharmacovigilance Defense Application System	0.000	-	0.300	0.275	-	0.275	0.400	0.350	0.350	0.357	Continuing	Continuing
283M: Business Intelligence Competency Center (BICC)	0.000	1.488	-	-	-	-	-	-	-	-	Continuing	Continuing
283N: Corporate Dental System (CDS)	0.000	0.709	-	-	-	-	-	-	-	-	Continuing	Continuing
283P: Mobile HealthCare Environment (MHCE)	0.000	0.273	-	0.362	-	0.362	0.300	0.417	0.331	0.338	Continuing	Continuing
385A: Integrated Electronic Health Record Inc 1 (Tri-Service)	130.693	-	-	-	-	-	-	-	-	-	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program											Date: February 2015		
Appropriation/Budget Activity					R-1 Program Element (Number/Name)								
0130: Defense Health Program I BA 2: RDT&E					PE 0605013HP I Information Technology Development								
386A: Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)	14.464	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
423A: Defense Center of Excellence (FHP&RP)	1.177	2.287	-	-	-	-	-	-	-	-	-	Continuing	Continuing
423B: Defense Center of Excellence (Army)	0.000	-	1.105	1.346	-	1.346	1.369	1.395	1.422	1.450	-	Continuing	Continuing
435A: NICOE Continuity Management Tool	2.855	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
446A: Disability Mediation Service (DMS)	0.000	0.539	0.382	0.433	-	0.433	0.445	0.588	0.666	0.679	-	Continuing	Continuing
480B: Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)	0.585	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
480C: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)	5.370	4.478	3.978	1.933	-	1.933	-	-	-	-	-	Continuing	Continuing
480D: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRs-IH) (Tri-Service)	3.372	4.680	-	-	-	-	3.633	3.694	2.803	2.859	-	Continuing	Continuing
480F: Executive Information/ Decision Support (EI/DS) (Tri-Service)	3.127	2.809	-	2.551	-	2.551	1.791	-	-	-	-	Continuing	Continuing
480G: Health Artifact and Image Management Solution (HAIMS) (Tri-Service)	0.000	5.828	0.304	-	-	-	-	-	-	-	-	Continuing	Continuing
480K: integrated Federal Health Registry Framework (Tri-Service)	0.000	2.591	1.093	0.450	-	0.450	-	-	-	-	-	Continuing	Continuing
480M: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	28.731	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity				R-1 Program Element (Number/Name)									
0130: <i>Defense Health Program I BA 2: RDT&E</i>				PE 0605013HP / <i>Information Technology Development</i>									
480P: <i>Other Related Technical Activities (Tri-Service)</i>	4.123	-	2.990	-	-	-	-	1.683	3.500	-	-	Continuing	Continuing
480R: <i>TMA E-Commerce (TMA)</i>	2.934	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
480Y: <i>Clinical Case Management (Tri-Service)</i>	2.925	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
480Z: <i>Centralized Credentials and Quality Assurance System (CCQAS) (Tri-Service)</i>	1.692	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
481A: <i>Theather Enterprise Wide Logistics System (TEWLS) Tri-Service)</i>	5.127	-	-	-	-	-	-	-	-	-	-	Continuing	Continuing
482A: <i>E-Commerce (DHA)</i>	0.000	5.526	2.494	2.766	-	2.766	2.829	3.704	4.200	4.284		Continuing	Continuing
490I: <i>Navy Medicine Chief Information Officer</i>	2.106	4.131	-	-	-	-	-	-	-	-	-	Continuing	Continuing
490J: <i>Navy Medicine Online</i>	1.369	-	2.192	2.052	-	2.052	-	-	-	-	-	Continuing	Continuing

MDAP/MAIS Code:
Other MDAP/MAIS Code(s): 465

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key technologies to overcome medical and military unique technology barriers. Programs include Army service level support for the Army Warrior Care and Transition System (AWCTS), the Medical Operational Data System (MODS), the Workload Management System for Nursing – Internet (WMSN_i), the Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM), the Multidrug-Resistant Organism Repository and Surveillance Network (MRSN), the Business Intelligence Competency Center (BICC), the Mobile HealthCare Environment (MHCE), the Corporate Dental System (CDS), and the Defense Center of Excellence (DCoE).

The Navy Medical Command RDT&E funding supports the development required for those systems which are integral to Navy Medicine (i.e., Navy Medicine Online (NMO)). Navy Medicine also funds, when appropriate, a number of small-scale, opportunistic business improvements when the technology makes a sudden advance. These projects are generally not in the scope of the TRICARE Management Activity (TMA) Central Programs such as the development/integration of Defense Optical Fabrication Enterprise Management System (DOFEMS) into a fully automated system to support workload distribution, performance metrics, staffing requirements, supply management, calculation of operating costs from the current independently or manually DOFEMS system. This effort will be a web based centralized management tool and provide a standalone standard set of Lab Management software for all 26 Navy labs. Additionally, the re-design of HIV Management System (HMS) will be more user friendly, less time to perform everyday tasks and prevents the need to maintain separate databases. The re-design will also automate and minimize functions that require manual assistance and assist in fulfilling new requirements.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>
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For the Air Force Medical Service (AFMS), this program element supports IM/IT development requirements within four AFMS Chief Information Officer defined core capabilities as essential to Air Force Medical Service IM/IT mission support. Data warehousing, reporting services, systems integration, and custom application development are featured in almost all IM/IT systems and application requests. The information needs of the AFMS are growing in volume, complexity, and delivery formats. In order to meet future requirements, aggregation of more and varied data sources require increasingly complex data warehousing capabilities. Demand for dynamic analytic capability will require investments in business intelligence, predictive analytic tools, open source research data models, and emerging personalized medicine analysis. Information is still largely produced in an ad hoc manner without standard methodologies, mapping of business requirements, transparent analytic models, and distributed by office productivity software. Centralized production of standard reports, balance sheets, and dynamic query tools would relieve many managers and action officer of routine work and increase leadership decision support. AFMS medical readiness reporting and tracking has set the standard in the DoD for over a decade but multiple applications now encompass what has merged into a common process of tracking unit capability and personal health assessments. Consolidation of medical readiness applications would streamline disability, medical readiness, deployment surveillance, and flying status tracking and reporting who currently must move between multiple applications.

For the Air Force, the funding in this program element provides for sustainment of the IM/IT Test Bed (IMIT-TB) capability, which is a dedicated OT location and staff encompassing the entire spectrum of healthcare services and products available in MTFs, to provide risk controlled testing of designated core and interim medical applications in a live environment.

Military Health System (MHS) Health Information Technology (HIT) [previously known as Tri-Service IM/IT] - HIT activities include: Innovation and Advanced Technology; Infrastructure & Operations; Solution Delivery; Information Delivery; Cyber Security; and Portfolio Management and Customer Relations. RDT&E program includes funding for development/integration, modernization, test and evaluation for the Defense Health Agency initiatives, and any special interest that are shared within all components of the Defense Health Program (DHP), excluding the Integrated Electronic Health Record, Defense Medical Information Exchange and the DoD Healthcare Management System Modernization Program (DHMSM).

The DHP RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System (E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce is composed of several major applications including: Contract Management (CM), utilizing Prism software to support contract action development and documentation; Resource Management (RM), employing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; Document Management, utilizing Document software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting, utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care and Contractor's Resource Center web sites that provide up-to-date financial information for both TMA and the Services concerning the military treatment facilities (MTFs), and expenditures for MTF enrollee purchased care and supplemental care. E-Commerce includes an infrastructure of over 60 servers supporting development, test, and production. E-Commerce is employed by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without influencing system performance or support to any individual user. Server configurations must remain current with respect to security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>
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Disability Mediation Service (DMS): The VTA (Veteran's Tracking Application) has been the primary system to track, record, and report data for the IDES (Integrated Disability Evaluation System) process. The VTA is scheduled to sun-set, by VA (Veterans Affairs), and the data is being moved to another application. Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA.

The DMS will facilitate the improvement of non-medical case management tracking and IDES data/information management. It will eliminate redundant data entry within DoD (Department of Defense), improving data quality by capturing more data for operational reporting from the Services and WCP, decrease backlog by eliminating data entry duplication, and minimize impact to DoD Services by allowing the Services to continue using their existing/planned systems without requiring retraining on a new applications.

The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts. Services will assume responsibility and POM costs for modifications, enhancements, and maintenance in the out years."

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	43.135	21.696	18.862	-	18.862
Current President's Budget	44.451	21.696	19.312	-	19.312
Total Adjustments	1.316	-	0.450	-	0.450
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	3.480	-			
• SBIR/STTR Transfer	-2.164	-			
• Program Realignment - Project 480K	-	-	0.450	-	0.450

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605013-Information Technology Development (-\$2.164 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$2.164 million).

FY 2015: Departmental Fiscal Guidance directed reductions to DHP RDT&E, PE 0605013-Information Technology Development (-\$7.466 million).

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>
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FY 2015: Transfer between DHP RDT&E Components of the Defense Center of Excellence (FHP&RP) Program, PE 0605013-Information Technology Development from the DHA (-\$1.225 million) to Army (+\$1.225 million).

FY 2016: Change Proposal adjustment to DHP RDT&E, PE 0605013-Information Technology Development (+0.450 million).

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 239B / <i>Health Services Data Warehouse (Air Force)</i>			
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
239B: <i>Health Services Data Warehouse (Air Force)</i>	-	1.112	0.717	0.908	-	0.908	0.962	1.436	1.461	1.490	Continuing	Continuing

A. Mission Description and Budget Item Justification

Previously known as Assessment Demonstration Center (ADC), Health Services Data Warehouse (HSDW) addresses and focuses on Air Force Medical Service (AFMS) Data Strategy under the DoD and AF Net Centric Enterprise Services. HSDW will develop an Enterprise Data Warehouse (EDW) and Data Marts consolidating databases and transition to a SOA architecture. Program will improve data collection, aggregation, analysis, and data visualization of medical information. New data models will allow rapid development of enterprise-wide reports utilizing Business Intelligence tools.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: 239B - Health Services Data Warehouse	1.112	0.717	0.908	-	0.908
Description: AFMS will purchase COTS software/licenses and build custom scripts for development of the data warehouse. The COTS software will expedite consolidation and cleansing of data, measure data quality, merge and organize data for reporting tools. These efforts will be used to complete the transition of CDM data into the HSDW.					
FY 2014 Accomplishments: For FY14 RDTE funding, the AFMS will purchase COTS software/licenses and build custom scripts for development of the data warehouse. The COTS software will expedite consolidation and cleansing of data, measure data quality, merge and organize data for reporting tools. These efforts will be used to complete the transition of CDM data into the HSDW.					
FY 2015 Plans: AFMS will continue to use COTS software to build custom scripts for development of the data warehouse. The COTS software will expedite consolidation and cleansing of data, measure data quality, merge and organize data for reporting tools. These efforts will be used to complete the transition of CDM data into the HSDW.					
FY 2016 Base Plans: AFMS will continue to use COTS software to build custom scripts for development of the data warehouse. The COTS software will expedite consolidation and cleansing of data, measure data quality, merge and organize data for reporting tools. These efforts will be used to complete the transition of CDM data into the HSDW.					
Accomplishments/Planned Programs Subtotals	1.112	0.717	0.908	-	0.908

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 239B / <i>Health Services Data Warehouse (Air Force)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	10.900	11.267	4.011	-	4.011	4.072	4.133	4.195	4.250	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 239F / <i>IM/IT Test Bed (Air Force)</i>			
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
239F: <i>IM/IT Test Bed (Air Force)</i>	3.800	2.265	1.801	1.844	-	1.844	1.837	2.222	2.686	2.740	Continuing	Continuing

A. Mission Description and Budget Item Justification

Dedicated operational test (OT) location and staff encompassing the entire spectrum of healthcare services and products available in Military Treatment Facilities (MTFs), to provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: 239F IM/IT Test Bed (Air Force)	2.265	1.801	1.844	-	1.844
Description: Provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.					
FY 2014 Accomplishments: Provided realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB offered complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical					

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 239F / <i>IM/IT Test Bed (Air Force)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
information systems. Led integration plans for all IMIT programs; developed conceptual systems test/integration requirements. Provided technical/management leadership on EHR program development with zero test mishaps. Evaluated 40 AF/Joint operational test programs; employed \$11M test assets/19K labor hours; no OT&E related delays. Catalyst for VPN linkage at premier DoD common development site; leveraged Joint platform to complement AFMS. Oversaw AFMS OT for 3 ACAT 1 programs/\$3B; OT schedule on target.					
<i>FY 2015 Plans:</i> Continue to provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.					
<i>FY 2016 Base Plans:</i> Continue to provide realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment. Critical component of ongoing capability development & fielding efforts, ensuring that each is supported by an independent, unbiased assessment of effectiveness, suitability, security, and survivability in a realistic operational environment as required by the FAR 46.103, DoD 5000, and AFI 99-103. The AFMISTB is a complementary service to existing MHS developmental, integration, interoperability, and security testing facilities, forming a logical test process continuum leading to effective deployment decisions. Outcomes include decreasing life-cycle costs of IM/IT products by catching errors early in the acquisition process where they are less costly to fix, and increasing patient safety by fielding operationally tested medical information systems.					
Accomplishments/Planned Programs Subtotals	2.265	1.801	1.844	-	1.844

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• N/A: N/A	-	-	-	-	-	-	-	-	-	Continuing	Continuing

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 239F / <i>IM/IT Test Bed (Air Force)</i>

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
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Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283C / <i>Medical Operational Data System (MODS) (Army)</i>
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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
283C: <i>Medical Operational Data System (MODS) (Army)</i>	1.472	3.384	3.413	2.601	-	2.601	2.678	3.547	4.016	4.096	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding for the Medical Operational Data System (MODS) to deploy modernized data visualization capabilities to enhance Army Unit and Individual Medical Readiness Reporting. MODS provides Army leadership with a responsive and reliable human resource and readiness information management data system for all categories of military and civilian medical and support personnel. MODS provide Tri-Service support through applications such as Electronic Profile, Behavioral Health, and Medical Education.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Medical Operational Data System (MODS)	3.384	3.413	2.601	-	2.601
Description: Information management system to provide responsive and reliable human resource and medical readiness data for all categories of military and civilian medical and support personnel.					
FY 2014 Accomplishments: FY14 certification/funding made it possible for the MODS program to propagate and strengthen its Three-Tiered Object-Oriented Architecture making the development of critical software solutions more cost effective, well-performing, predictable, extensible and uniformed. Products developed under this architecture include all Army Deployment Health Assessments, core Period Health Assessment modules, and modifications needed for the Tri-service mandated promotion of the Behavioral Health Data Portal. FY14 funding also allowed for the MODS data warehouse to be complemented with robust data visualization tools. A proof-of-concept using these new capabilities successfully produced a static instantiation of the complete physical data design of the entire medical readiness domain for super users to analyze.					
FY 2015 Plans: FY15 funds are being used to elicit the entire business requirement and developmental design of the Electronic Profile System using the Three-Tiered Object-Oriented Architecture. This is to be proceeded by the development of a completely refactored solution. In addition, all design processes and products will be verified and validated by a senior Federally-Funded Research and Development (FFRDC) Team – MITRE. The Human Resources suite of applications will use this model in parallel. Additionally, the full production increment of MODS Data Warehouse will be executed.					
FY 2016 Base Plans:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283C / <i>Medical Operational Data System (MODS) (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
FY16 funds will be used to respond to Milestone Decision Authority decisions to add new capabilities, significantly enhance, and technically upgrade existing capabilities, and use federally funded research and development center resources for system engineering and acquisition effectiveness services.					
Accomplishments/Planned Programs Subtotals	3.384	3.413	2.601	-	2.601

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	12.260	12.689	13.326	-	13.326	13.726	14.138	14.392	14.642	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernizaation</i>	0.360	0.420	0.120	-	0.120	0.620	0.300	0.400	0.200	Continuing	Continuing

Remarks

D. Acquisition Strategy

Select the business, technical, and contract actions that will minimize cost, reduce program risk, and remain within schedule while meeting program objectives.

E. Performance Metrics

- MEASURE: Data Warehouse reduces total number of database maintenance hours.
METRIC: % database maintenance hours = number of monthly database maintenance hours/total database maintenance hours of previous year average.
- MEASURE: Data Warehouse supports queries and reports with few data errors (information quality/accuracy).
METRIC: % of reports and queries that contain data errors = total number of reports and queries with data errors /total number of reports and queries.
- MEASURE: Data Warehouse provides the data needed by users and applications (information quality/completeness).
METRIC: % post-Data Warehouse = total number (post-Data Warehouse) queries and reports/total number (pre + post-Data Warehouse) queries and reports.
- MEASURE: Three-Tier Object Oriented Architectural Design (3TOOAD) benefits are reduced costs for implementation of new functionalities.
METRIC: % of labor cost = cost of MSR for functional implementation/average cost of similar MSR from previous year(s).
- MEASURE: Organizational and individual impact of Data Warehouse, 3TOOAD, and Robust Business Intelligence.

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283C / <i>Medical Operational Data System (MODS) (Army)</i>

METRIC: >= 8.5 avg. benchmark score (0 to 10 scale) on quarterly quality and impact surveys from users.

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 283D / <i>Army Medicine CIO Management Operations</i>			
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
283D: <i>Army Medicine CIO Management Operations</i>	1.492	2.113	0.120	0.867	-	0.867	0.794	2.649	3.371	3.438	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Army Medicine CIO Management Operations program includes development projects for Army service level support. Specifically, the Army Medicine CIO Management Operations encompasses the Army Medical CIO's Information Management/Information Technology (IM/IT) development activities to ensure compliance with Congressional, Office of Management and Budget, DoD, and Military Health System requirements.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: 283D - Army Medicine CIO Management Operations	2.113	0.120	0.867	-	0.867
Description: The Army Medicine CIO Management Operations will provide system development, engineering, and testing requirements of interim Army medical applications in an operationally realistic, risk controlled test environment to comply with Congressional, Office of Management and Budget, DoD, and Military Health System requirements.					
FY 2014 Accomplishments: FY14 funds were used to complete system development, engineering, and testing requirements of Army Medical applications, that provides realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment.					
FY 2015 Plans: For FY15, the Army Medicine CIO Management Operations is developing and enhancing a system that will provide system development, engineering, and testing requirements of Army Medical applications, which provides realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment.					
FY 2016 Base Plans: For FY16, the Army Medicine CIO Management Operations will be developing and enhancing a system that will provide system development, engineering, and testing requirements of Army Medical applications, which will					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283D / <i>Army Medicine CIO Management Operations</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
provides realistic, risk controlled testing of designated core and interim medical applications in an operationally realistic environment.					
Accomplishments/Planned Programs Subtotals	2.113	0.120	0.867	-	0.867

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	32.489	41.743	38.125	-	38.125	35.696	36.230	41.664	41.664	Continuing	Continuing
• BA-1, 0807721HP: <i>Replacement/Modernization</i>	2.773	1.665	0.387	-	0.387	1.099	3.975	4.051	-	Continuing	Continuing
• BA-1, 0807798HP: <i>Management Headquarters</i>	-	3.975	3.979	-	3.979	3.983	3.987	3.991	3.991	Continuing	Continuing
• BA-1, 0807796HP: <i>Base Operations</i>	-	2.805	2.853	-	2.853	2.901	2.950	3.001	3.001	Continuing	Continuing

Remarks

D. Acquisition Strategy
Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics
Periodic management evaluation based on ability to provide system development, engineering, and testing requirements of new Army medical applications.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283F / <i>Army Warrior Care and Transition System (AWCTS)</i>
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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
283F: <i>Army Warrior Care and Transition System (AWCTS)</i>	0.488	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Army Warrior Care and Transition System (AWCTS) program includes development projects for Army service level support. Specifically, the AWCTS is a family of systems that allows the integration of multiple business processes under the consolidated oversight of the Warrior Transition Command.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Army Warrior Care and Transition System (AWCTS)	-	-	-	-	-
Description: A family of systems that allows the integration of multiple business processes under the consolidated oversight of the Warrior Transition Command.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

Line Item	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
• BA-1, 0807714HP: <i>Other Health Activities</i>	1.587	1.691	1.776	-	1.776	1.865	1.958	1.995	1.995	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283F / <i>Army Warrior Care and Transition System (AWCTS)</i>

major decisions.

E. Performance Metrics

1. MEASURE: Increase Soldier's ability to access career and education, and communication with transition coordinators.
METRIC: Days from submitting request to an appointment or obtaining information
2. MEASURE: Provide the capability for staff to be able to gain visibility of a Soldier's transition status.
METRIC: Days from submitting request to receiving status of Soldier.
3. MEASURE: Provide the capability for staff to analyze metrics and business processes.
METRIC: Days from requesting metrics/BP reports until receipt of data.
4. MEASURE: Provide the capability for automated workflow processes to decrease manual and decentralized processes.
METRIC: Percentage of automated processes versus manual processes

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283H / <i>Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)</i>
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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
283H: <i>Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)</i>	-	-	-	0.080	-	0.080	0.080	0.080	0.080	0.082	Continuing	Continuing

A. Mission Description and Budget Item Justification

The US Army Medical Command (MEDCOM) and Defense Centers of Excellence (DCOE) have partnered to develop this information technology project for joint service level support. The PBH-TERM platform addresses two congressionally mandated initiatives including the behavioral health management within the Warrior Transition Command (GH risk Management module/BHRM and within primary care settings (FIRST-STEPS). Further development efforts allow expansion of capabilities to deliver ongoing user support and training via web-based modules within PBH-TERM and will provide costs casings in terms of staffing requirements, conferencing and reporting.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM)	-	-	0.080	-	0.080
Description: PBH-TERM is a web-based psychological and Behavioral Health (BH) information technology platform, which supports evidence-based, standardized and integrated BH risk and case management initiatives as well as program evaluation for the Warrior Transition Command and Patient/Soldier-Centered BH (PCBH) care in primary care settings.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: Adds self-service functionality with direct input by the eligible beneficiaries. Improves health system visibility; add “view” only feature, which allows enhanced visibility by authorized BH providers. Adds program management module for marriage and family therapy program.					
Accomplishments/Planned Programs Subtotals	-	-	0.080	-	0.080

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283H / <i>Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)</i>

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u>	<u>FY 2016</u>	<u>FY 2016</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u>	
			<u>Base</u>	<u>OCO</u>	<u>Total</u>					<u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	0.153	0.090	0.074	-	0.074	0.074	0.074	0.074	0.074	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting congressional mandates and program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

FY16

Measure: Improved user efficiencies through automation of support/training modules and guidelines.

Baseline: January 2014, 25% user efficiency rating.

Target: March 2018, 90% user efficiency rating.

Source: Audits and analysis performed by Defense Centers of Excellence, Patient-Centered Behavioral Health personnel.

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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 0605013HP / <i>Information Technology Development</i>			Project (Number/Name) 2831 / <i>Workload Management System for Nursing-Internet</i>			
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
2831: <i>Workload Management System for Nursing-Internet</i>	0.264	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Workload Management System for Nursing – Internet (WMSNi) program includes development projects for Army service level support. Specifically, the WMSNi supports clinical staff scheduling, based on known and projected patient care needs, for continuous 24x7 hospital operations.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Workload Management System for Nursing-Internet	-	-	-	-	-
Description: The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Workload Management System for Nursing – Internet (WMSNi) program includes development projects for Army service level support. Specifically, the WMSNi supports clinical staff scheduling, based on known and projected patient care needs, for continuous 24x7 hospital operations.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

Line Item	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
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	0.767	0.696	0.722	-	0.722	0.723	0.762	0.723	0.723	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 2831 / <i>Workload Management System for Nursing-Internet</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
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Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting congressional mandates and program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

1. MEASURE: All Tier 2 tickets were resolved as required.
METRIC: Maintain application including software components resolving 100% of all problems resolvable at the Tier 2 level

2. MEASURE: Hosted Environment up time maintained at 98%.
METRIC: Provide an operational readiness up time of 98% for the hosted environment, excluding scheduled maintenance windows

3. MEASURE: Execute required security patches to enterprise systems IAW Army directives.
METRIC: 95% of Security Patches and critical updates executed within required timeframe

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 283J / <i>Multi-Drug Resistant Surveillance Network (MRSN)</i>			
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
283J: <i>Multi-Drug Resistant Surveillance Network (MRSN)</i>	1.374	-	0.807	0.844	-	0.844	0.878	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Multi-Drug Resistant Surveillance Network (MRSN) program includes development projects for Army service level support. Specifically, the MRSN is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Multi-Drug Resistant Surveillance Network (MRSN)	-	0.807	0.844	-	0.844
Description: MRSN is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: Funding are being used to develop and Test Phase 2 Features of MRSN. Funding are also be used to develop and deploy the First System Update which places the new features into production; and Phase 3 Features.					
FY 2016 Base Plans: Funding will be used to develop and Test Phase 3 Features of MRSN. Funding are also be used to finalize the development and deployments of the System Updates which places the new features into production.					
Accomplishments/Planned Programs Subtotals	-	0.807	0.844	-	0.844

C. Other Program Funding Summary (\$ in Millions)

Line Item	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
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	0.450	-	0.565	-	0.565	0.544	0.757	0.775	0.790	Continuing	Continuing

Remarks

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283J / <i>Multi-Drug Resistant Surveillance Network (MRSN)</i>

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Business metrics:

1. Turn-around time from receipt of isolate shipment to initial test results being available on MRSN System.

Current Performance : 2 weeks

Target Performance: 4 days

Data Source: Comparison of isolate receipt date and test result date

2. Time to prepare monthly Antibiogram Report

Current Performance: 8 weeks

Target Performance: 2 weeks

Data Source: Number of days following the end of the month that the report is distributed/posted

3. Antibiogram (or other major product) Report Views

Current Performance: N/A (not currently implemented)

Target Performance: 30 per month

Data Source: Server logs

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283K / <i>Veterinary Services Systems Management (VSSM)</i>
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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
283K: <i>Veterinary Services Systems Management (VSSM)</i>	-	0.238	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Veterinary Services Systems Management (VSSM) program includes development projects for Army service level support. Specifically, the VSSM will capture veterinary health care treatment information to include laboratory findings from various medical institutions.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Title: Veterinary Services Systems Management (VSSM)</p> <p>Description: VSSM is a worldwide web access application capable of capturing veterinary health care treatment information to include laboratory findings of Military working dogs, all government owned animals, and dependent owned animals, and dependent owned animals.</p> <p>FY 2014 Accomplishments: FY14 Funding for Veterinary Services Systems Management (VSSM) program was used to provide the additional capability needed for a commercial laboratories interface to electronically exchange laboratory test results data between the VSSM application and all approved commercial laboratories. ANTECH Laboratory is the only commercial laboratory interface currently supports. FY14 Funds provides the solution scope allowing Veterinary Services the ability to achieve the business objects of providing a clinically integrated, secure web-based application to support the Veterinary Services mission.</p> <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Base Plans: No funding programmed.</p>	0.238	-	-	-	-
Accomplishments/Planned Programs Subtotals	0.238	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283K / <i>Veterinary Services Systems Management (VSSM)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	2.068	1.689	1.816	-	1.816	1.880	1.971	1.971	1.880	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	0.500	-	0.450	-	0.450	0.750	-	0.500	0.500	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

MEASURE: The success of Commercial Laboratories Interface will be the capability in VSSM to electronically request and receive laboratory test results from approved external commercial laboratories, resulting in minable data.

METRIC: The electronic laboratory test result data will be timely, accurate, and allow alerts for potential disease surveillances to be triggered in VSSM.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283L / <i>Pharmacovigilance Defense Application System</i>
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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
283L: <i>Pharmacovigilance Defense Application System</i>	-	-	0.300	0.275	-	0.275	0.400	0.350	0.350	0.357	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Pharmacovigilance Defense Application System (PVDAS) provides Military providers Defense Patient Safety reports from the Food and Drug Administration (FDA) after a drug's release to market.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Pharmacovigilance Defense Application System (PVDAS)	-	0.300	0.275	-	0.275
Description: The Pharmacovigilance Defense Application System (PVDAS) provides Military providers Defense Patient Safety reports from the Food and Drug Administration (FDA) after a drug's release to market.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: FY15 funding are being used to finalize the process improvements that provide improved information for making military health system formulary decisions, better visibility into medical practice enhancing patient safety, and greater access to drug risk/benefit information for military physicians.					
FY 2016 Base Plans: FY16 funding will be used to continue the process improvements that will provide improved information for making military health system formulary decisions. This process improvement will also provide better visibility into medical practice enhancing patient safety, and greater access to drug risk/benefit information for military physicians.					
Accomplishments/Planned Programs Subtotals	-	0.300	0.275	-	0.275

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283L / <i>Pharmacovigilance Defense Application System</i>
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C. Other Program Funding Summary (\$ in Millions)

Line Item	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
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	1.190	1.118	1.205	-	1.205	1.311	1.474	1.544	1.696	Continuing	Continuing
• BA-1, 0807714HP: <i>Other Health Activities</i>	1.677	0.035	-	-	-	-	-	-	-	Continuing	Continuing
• BA-1, 0807798HP: <i>Management Headquarters</i>	0.852	1.395	1.418	-	1.418	1.443	1.467	1.492	1.492	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	1.200	-	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

1. MEASURE: All Tier 2 tickets were resolved as required.

METRIC: Maintain application including software components resolving 100% of all problems resolvable at the Tier 2 level

2. MEASURE: Hosted Environment up time maintained at 98%.

METRIC: Provide an operational readiness up time of 98% for the hosted environment, where the application is never inoperable for longer than 3 business days

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 283M / <i>Business Intelligence Competency Center (BICC)</i>			
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
283M: <i>Business Intelligence Competency Center (BICC)</i>	-	1.488	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Business Intelligence Competency Center (BICC) is the business intelligence capability and management processes, focused on providing actionable data at the point of service that facilitates provisioning of actionable information for MTF Commanders, AMEDD Leadership and end users.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Business Intelligence Competency Center (BICC)	1.488	-	-	-	-
Description: The Business Intelligence Competency Center (BICC) is the business intelligence capability and management processes, focused on providing actionable data at the point of service that facilitates provisioning of actionable information for MTF Commanders, AMEDD Leadership and end users.					
FY 2014 Accomplishments: FY14 funds were used to continue the finalization of the baseline code for MEDCOM 360. MEDCOM 360 is a low complexity system utilizing pre-existing aggregated data sources to present de-identified data for performance and quality reviews at the headquarters level. FY14 Funds were used to aggregate data from several legacy systems into a single user friendly information source to meet patient care needs and chronic disease management for the care team and case management. The information was aggregated up to clinic and practice management personnel and was used for performance management, with the main focus at the patient/care team level in order to provide actionable information. Funds were used to optimize order entry reporting for pending and completed provider orders, and remaining bug fixes. Funds were used to integrate existing alerts and transitioning of care functions, providing an increased stability and performance. Funds provided user access management and security review for role based and CAC enabled access. Funds were used to coordinate CHCS Cache SQL review with MEDCOM and DHA concerning interface data exchange.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283M / <i>Business Intelligence Competency Center (BICC)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
No funding programmed.					
Accomplishments/Planned Programs Subtotals	1.488	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	1.320	1.097	1.163	-	1.163	1.155	1.398	0.947	0.947	Continuing	Continuing
• BA-3, 0807721HP: <i>replacement/Modernization</i>	-	0.900	-	-	-	-	0.050	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy
Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

N/A

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 283N / <i>Corporate Dental System (CDS)</i>			
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
283N: <i>Corporate Dental System (CDS)</i>	-	0.709	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Corporate Dental System (CDS) is the Dental digital web based DICOM image capture and viewing application.

B. Accomplishments/Planned Programs (\$ in Millions)

Title: Corporate Dental System (CDS)

Description: The Corporate Dental System (CDS) is the Dental digital web based DICOM image capture and viewing application.

FY 2014 Accomplishments:

FY14 funds were used to provide all required imaging capabilities at USA dental facilities to include DICOM image view, capture, store, and forward. Corporate Dental Imaging (CDI) 1.0 provides the capability to scan the patient's CAC which also verifies patient metadata within DEERS. CDI 1.0 can now capture images using the hardware vendor's Software Development Kit (SDK) for image enhancement and filtering rather than a TWAIN driver. This version of CDI uses the SDK from Planmeca and Carestream and supports the Panograph (PX), Cephalometric (DX), intra oral (IO), and Cone Beam CT modalities. FY14 funds were also used to create image progression capabilities which allow capturing various image combinations depending on the images required for care. CDI storage server can store, forward and verify that images taken at a dental facility are stored locally and in the global repository at FT Sam Houston, TX. At the completion of this development cycle CDI became a client-side capture and web-based viewing application that includes EDI identification in the DICOM image data; enables Web viewing of the original DICOM images stored at the enterprise level, enables image enhancements that are saved as layers on top of the original DICOM, and provides reporting for completed image studies, series, and all individual I/O DICOM images taken.

FY 2015 Plans:

No funding programmed.

FY 2016 Base Plans:

FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
0.709	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283N / <i>Corporate Dental System (CDS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
No funding programmed.					
Accomplishments/Planned Programs Subtotals	0.709	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	0.866	2.464	2.517	-	2.517	2.571	2.627	2.685	2.685	Continuing	Continuing
• BA-1, 0807715HP: <i>Dental Care Activities</i>	5.933	6.967	8.084	-	8.084	8.292	8.497	8.750	8.750	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	-	2.100	2.541	-	2.541	2.614	2.688	2.757	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

N/A

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 283P / <i>Mobile HealthCare Environment (MHCE)</i>			
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
283P: <i>Mobile HealthCare Environment (MHCE)</i>	-	0.273	-	0.362	-	0.362	0.300	0.417	0.331	0.338	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command received PE 0605013 funding to identify, explore, and demonstrate key information technologies to overcome medical and military unique technology barriers. The Mobile HealthCare Environment (MHCE) is the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Mobile HealthCare Environment (MHCE)	0.273	-	0.362	-	0.362
Description: The Mobile HealthCare Environment (MHCE) is the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device.					
FY 2014 Accomplishments: FY14 funds established an enterprise presence for the system, Mobile Health Care Environment (MHCE). This expansion provides the mobile health outreach used for patient care outside of clinical research protocols, which was a limitation prior to FY14. Additionally, the MHCE system was modernized for both the research and enterprise space to allow for the use of multimedia content, and end user tracking of interactions within the mobile app. Finally the MHCE system was enhanced to including synchronization with biosensor technologies, which will afford the DHA to provide at home monitoring of chronic conditions, such as diabetes in the future.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: FY16 certification/funding will be utilized to expand the MHCE functionality to include data exchange with other systems, specifically a patient's personal health record, and enterprise systems such as their electronic health record.					
Accomplishments/Planned Programs Subtotals	0.273	-	0.362	-	0.362

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 283P / <i>Mobile HealthCare Environment (MHCE)</i>

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u>			<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u>	
			<u>Base</u>	<u>OCO</u>	<u>Total</u>					<u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	1.268	1.226	1.285	-	1.285	1.350	1.416	1.489	1.564	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

N/A

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 385A / <i>Integrated Electronic Health Record Inc 1 (Tri-Service)</i>
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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
385A: <i>Integrated Electronic Health Record Inc 1 (Tri-Service)</i>	130.693	-	-	-	-	-	-	-	-	-	Continuing	Continuing

MDAP/MAIS Code: 465

A. Mission Description and Budget Item Justification

The integrated Electronic Health Record (iEHR) was approved to provide seamless integrated sharing of electronic health data between the DoD and Department of Veterans Affairs (VA).

Commensurate with the OSD AT&L Acquisition Decision Memoranda (ADM), dated July 21, 2013 and January 2, 2014, the former joint DoD and VA iEHR program has been restructured within the DoD to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a redefined iEHR program. These programs report through the PEO DoD Healthcare Management Systems (DHMS) to the USD (AT&L).

iEHR RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Integrated Electronic Health Record (iEHR) Inc 1 (Tri-Service)	-	-	-	-	-
Description: The iEHR primary role is health care delivery services. iEHR is a collaborative effort between the DoD and VA to share Health Care Resources to improve access to, and quality and cost effectiveness of, health care as mandated by law. This investment is deeply embedded in the MHS Enterprise Roadmap as both Departments have need for modernization/ replacement of existing legacy systems. This investment will use a combination of an open architecture approach, and the purchase (in some instances) of GOTS and COTS products.					
FY 2014 Accomplishments: No funding programmed in this program element.					
FY 2015 Plans: No funding programmed in this program element.					
FY 2016 Base Plans: No funding programmed in this program element.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 385A / <i>Integrated Electronic Health Record Inc 1 (Tri-Service)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements. Program cost, schedule and performance are measured periodically using a systematic approach.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 386A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)</i>			
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
386A: <i>Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)</i>	14.464	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The primary goal of the VLER Health initiative is to enable the secure sharing of health information (i.e., demographic and clinical data) between DoD and external Federal and private sector partners which meets Meaningful Use (MU) requirements to improve healthcare quality, safety, and efficiency. By electronically sharing health information using national standards, that information can support tracking key clinical conditions, communicating that information to better coordinate care, and engaging patients in their own care. The VLER Health initiative provides clinicians with the most up-to-date information, potentially reducing redundant diagnostic tests, medical errors, paperwork and handling, and overall healthcare costs. These benefits, in turn, align with the MHS quadruple aim by ensuring that the military force is medically ready to deploy; the military beneficiary population remains healthy through focused prevention; patient care is convenient, equitable, safe, and of the highest quality; and the total cost of healthcare is reduced through the reduction of waste and focus on quality.

VLER Health funding will be reflected in the Integrated Electronic Health Record Program Element 0605023 in FY 2014 and out.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)	-	-	-	-	-
Description: Work with Department of Veterans Affairs (VA), Department of Health & Human Services (HHS), and Private Sector to expand VLER.					
FY 2014 Accomplishments: No funding programmed in this program element.					
FY 2015 Plans: No funding programmed in this program element.					
FY 2016 Base Plans: No funding programmed in this program element.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 386A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	-	-	-	-	-	-	-	-	-	-	-

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 423A / <i>Defense Center of Excellence (FHP&RP)</i>			
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
423A: <i>Defense Center of Excellence (FHP&RP)</i>	1.177	2.287	-	-	-	-	-	-	-	-	Continuing	Continuing

Note
In FY15, transferred from FHP&R (Project Code 423A) to Army (Project Code 423B).

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE) is a United States Department of Defense (DoD) organization that provides guidance across DoD programs related to psychological health (PH) and traumatic brain injury (TBI) issues. The organization’s mission statement is: “DCoE assesses, validates, oversees and facilitates prevention, resilience, identification, treatment, outreach, rehabilitation, and reintegration programs for PH and TBI to ensure the Department of Defense meets the needs of the USA’s military communities, warriors and families.” DCoE focuses on education and training; clinical care; prevention; research; and service member, family and community outreach. In collaboration with the Department of Veterans Affairs, the organization supports the Department of Defense’s commitment of caring for service members from the time they enter service and throughout the completion of their service. DCoE also seeks to mitigate the stigma that still deters some from reaching out for help for problems such as post-traumatic stress disorder and TBI. The organization has a leadership role in collaborating with a national network of external entities[1] including non-profit organizations,[2] other DoD agencies, academia, Congress,[3] military services and other federal agencies.[4] Public health service and civil service workers, including personnel from the Department of Veterans Affairs and individuals from all the military services as well as contract personnel comprise the staff of DCoE. DCoE’s goals include providing the necessary resources to facilitate the care of service members who experience TBI or PH concerns and ensuring that appropriate standards of care exist and are maintained across the Department of Defense. DCoE seeks to create, identify and share best practices, conducting necessary pilot or demonstration projects to better inform quality standards when best practices or evidence based recommendations are not readily available. Other DCoE goals include ensuring that program standards are executed and quality is consistent and creating a system in which individuals across the United States expect and receive the same level and quality of service regardless of their service branch, component, rank or geographic location. DCoE comprises eight directorates and six component centers responsible for TBI/PH issues. These DCoE entities execute programs, provide clinical care, conduct research, identify and share best practices and provide strategic planning for PH and TBI across the DoD.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Defense Center Of Excellence (FHP&RP)	2.287	-	-	-	-
Description: DCoE programs and products are developed to drive innovation across the continuum of care by identifying treatment options and other clinical and research methods that deliver superior outcomes. Products range from tools customized for health care providers to electronic resources for service members and families.					
FY 2014 Accomplishments:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 423A / <i>Defense Center of Excellence (FHP&RP)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Funds will be utilized to finalize the multi-phased upgrade and redesign of the afterdeployment.org website. Afterdeployment.org will provide the latest in self-care tools that assist with a range of adjustment concerns (combat stress, sleep problems, anger management, etc.), with an emphasis on exercise-based interactivity, community support, and multimedia applications. For the T2 Toolkit (T2T), funding would be used for the final phase of development focusing on the new generation of PH Mobile Apps that will enhance many area of PH for DoD service members, family, and veterans.</p> <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Base Plans: No funding programmed.</p>					
Accomplishments/Planned Programs Subtotals	2.287	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 423B / <i>Defense Center of Excellence (Army)</i>			
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
423B: <i>Defense Center of Excellence (Army)</i>	-	-	1.105	1.346	-	1.346	1.369	1.395	1.422	1.450	Continuing	Continuing

Note
Transferred from FHP&R (Project Code 423A) to Army (Project Code 423B) in FY15.

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury is administratively managed under the United States Army Medical Command (MEDCOM) Organization that provides guidance across DoD program related to psychological health (PH) and traumatic brain injury (TBI) issues. The organizational mission statement is: "DCoE's mission is to improve the lives of our nation's Service Members, Families, and Veterans by advancing excellence in psychological health and traumatic brain injury prevention and care." DCoE focuses on education and training; clinical care; prevention; research, and Service Member, Family, and community outreach. In collaboration with the Department of Veterans Affairs, DCoE supports the DoD's commitment of caring for service members from the time they enter service and throughout the completion of their service. DCoE also seeks to mitigate the stigma that still deters some from reaching out for help for problems such as post-traumatic stress disorder and TBI. The organization has a leadership role in collaborating with a national network of external entities to include: 1. Non-profit organizations, 2. Other DoD agencies, academia, and Congress, 3. Military services and other federal agencies and, 4. Public Health Service and civil service workers, to include personnel from the Department of Veterans Affairs and individuals from all military services as well as contractor personnel assigned to DCoE. DCoE's goals include providing the necessary resources to facilitate the care of service members who experience TBI and/or PH concerns and ensuring that appropriate standards of care exist and are maintained across the DoD. DCoE seeks to create, identify, and share best practices; conducting necessary pilot or demonstration projects to better inform quality standards when best practices or evidence-based recommendations are not available. Additional goals include ensuring that program standards are executed and quality is consistent for all individuals throughout the United States so that they receive the same level and quality of service regardless of service branch, component, rank, or location. DCoE is comprised of a HQs element and three component centers responsible for PH/TBI issues. These DCoE directorates and centers execute programs, provide clinical care, conduct research, and identify and share best practices and provide strategic planning for all PH and TBI throughout the DoD.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Defense Center of Excellence (Army)	-	1.105	1.346	-	1.346
Description: DCoE programs and products are developed and implemented to drive innovation across the continuum of care by identifying treatment options and other clinical and research methods that deliver superior healthcare outcomes. Products range from tools customized for healthcare providers to electronic resources such as online games and mobile apps for Service Members and their Families.					
FY 2014 Accomplishments:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 423B / <i>Defense Center of Excellence (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Plans noted and funded under Project 423A.					
<i>FY 2015 Plans:</i> FY15 funds are being used to continue the development, modernization, sustainment, and release of mobile apps, PH games, websites, and longitudinal services in support of the T2 Toolkit portfolio, as listed in the FY2014 Accomplishments above. This new generation of PH mobile apps, games, and websites are improving the PH outcomes for DoD Service Members, their Families, and Veterans. Continued for 2015 is the use of RDT&E funds for the Deployment Health Clinical Center's (DHCC) development of a module (FIRST STEPS) in support of Psychological and Behavioral Health. This expansion effort is intended to further the focus of the behavioral healthcare of all adult primary care. The emphasis within 2015 is to develop automated user training in lieu of direct face-to-face training for Behavioral Health personnel.					
<i>FY 2016 Base Plans:</i> FY16 funds will be used to complete the development and transition to sustainment for the electronic capabilities listed above. The T2 toolkit and its sub-components will be more fully developed in order to allow for further collaboration and remote access to tools. RDT&E funding will be utilized to continue development of mobile applications, 3D games, websites, and other applications. In addition, the DHCC FIRST STEPS module will continue to evolve and develop capabilities to tailor reporting, track data by individual service, and monitor conditions such as smoking cessation and obesity/weight management. This program will also add healthcare facilitators in behavioral activation and motivational interviewing techniques with patients.					
Accomplishments/Planned Programs Subtotals	-	1.105	1.346	-	1.346

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	-	2.097	2.128	-	2.128	2.159	2.199	2.239	2.239	Continuing	Continuing
• BA-1, 0807724HP: <i>Military Unique - Other Medical</i>	-	1.396	1.478	-	1.478	1.549	1.588	1.685	1.685	Continuing	Continuing
Remarks											

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 423B / <i>Defense Center of Excellence (Army)</i>

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements. Program cost, schedule and performance are measured periodically using a systematic approach.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 435A / <i>NICoE Continuity Management Tool</i>			
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
435A: <i>NICoE Continuity Management Tool</i>	2.855	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The NICoE Continuity Management Tool (NCMT) is a business intelligence tool to perform healthcare modeling and analysis of NICoE activities.

Major capabilities defined by the NICoE in Jun 2009 and refined in Jun 2010 prior to the program procurement in Sep 2010, are subsystems that make up the NCMT end-to-end system, and were prioritized in the following order: Continuity Management Subsystem, Scheduling Subsystem, Clinical Subsystem, Research Subsystem, Training and Education Subsystem, Administration Subsystem.

Continuity Management Subsystem: Records every interaction with a particular Warrior and his or her Family as one entity to manage initial contact, referral, screening, intake, pre-admission, admission, discharge and follow-up processes.

Scheduling Subsystem: Captures, organizes, displays the complex schedules of the NICoE. Used to manage patient appointments, the utilization of facility resources including treatment rooms, modalities, provider staff and support staff.

Clinical Subsystem: A clinical application and clinical database that includes the functions that allow the user to store, classify, analyze, retrieve, interpret, present clinical data. Allows the visualization of all of the various components of the patient's health record: radiology, pathology, lab results, neurological assessments, etc.

Research Subsystem: Consists of the research database and the applications that allow the user to store, classify, analyze, retrieve, interpret, present data. Allows NICoE to aggregate data from disparate systems, both within the NICoE and from partner organizations, helping the research move faster, with more agility, and with purpose and direction supported by validated facts. Allows researchers to address many data challenges from a single system and transforms the way they do research.

Training and Education Subsystem: Provides the ability to share relevant research, diagnosis, treatment information with authorized users.

Administration Subsystem: Provides the ability to manage a portfolio of projects related to continuity of care, clinical operations, research, training and education functions in the NICoE.

The NCMT is supported by Three Contracts: Hosting (Provides Hardware, Software, Maintenance), System Integration (Implements NICoE Functional Requirements, Turns NICoE Ideas and Goals into Computer Screens, Templates, Applications – Capabilities) and Decision Support (Acquisition Management, Requirements Definition, Implementation Planning).

The NICoE's missions are to:

UNCLASSIFIED

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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 435A / <i>NICoE Continuity Management Tool</i>
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- 1) Explore novel, promising, and futuristic solutions to the complex spectrum of combat brain injury from TBI to posttraumatic stress disorder (PTSD) and other psychological injuries;
- 2) Ensure – through continuous outreach and high quality health care – that America embraces those who have served and sacrificed so much on its behalf; and
- 3) Train the next generation of providers in the most effective approaches to prevention, detection, and treatment options.

Currently the established AHLTA specification does not adequately support the specialized care and continuity management integration necessary to support NICoE clinical operations and research. Additionally, AHLTA does not support the data mining and pattern recognition requirements of the NICoE.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: NICoE Continuity Management Tool	-	-	-	-	-
Description: The NCMT is a tool designed to perform healthcare modeling and analysis of NICoE activities. Major capabilities include Continuity Management, Scheduling, Clinical Database, Research Database, Training and Education, and Administration.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

Line Item	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
• 4187 807783: <i>NCMT</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4187 807781: <i>NCMT</i>	3.819	3.961	4.107	-	4.107	4.259	4.332	-	-	Continuing	Continuing
• 1690 807781: <i>HEIS</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4859 807781: <i>JMED</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4940 807781: <i>JTFCMI</i>	39.170	40.792	41.610	-	41.610	42.395	43.267	-	-	Continuing	Continuing
• 4940 807720: <i>JTFCMI</i>	-	4.600	-	-	-	-	-	-	-	Continuing	Continuing

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 435A / <i>NICOE Continuity Management Tool</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• 4273 807781: <i>Engineering and Deployment</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4280 807721: <i>Engineering and Deployment</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4361 807781: <i>IA Operational Resiliency</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4126 807781: <i>Computer Network Defense</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4111 807781: <i>Computer Network Defense</i>	0.463	0.473	0.482	-	0.482	0.492	0.502	-	-	Continuing	Continuing
• 4165 807781: <i>Computer Network Defense</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4177 807781: <i>Computer Network Defense</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4364 807781: <i>Workforce Development</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

This requirement is currently contracted through the USA Medical Research Activity. The vendor is Evolvent Technologies Inc.

E. Performance Metrics

This performance metrics or milestones shall include, but is not limited to:

- Coordination with Government representatives
- Review, evaluation and transition of current support services
- Transition of historic data to new contractor system
- Government-approved training and certification process
- Transfer of hardware warranties and software licenses
- Transfer of all System/Tool documentation to include, at a minimum: user manuals, system administration manuals, training materials, disaster recovery manual, requirements traceability matrix, configuration control documents and all other documents required to operate, maintain and administer systems and tools

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 435A / <i>NICOE Continuity Management Tool</i>

If another contractor follows this contractor with work related to this work, this contractor will provide any developed source code (compiled and uncompiled, including all versions, maintenance updates and patches) with written instructions for the source code on which this contractor has worked, so that an experienced software engineer, previously not familiar with the source code can understand and efficiently work with the source code. In addition, this contractor will provide for 30 days, a software engineer (or person of comparable work level) with significant experience working with the source code, to assist the new contractor

Orientation phase and program to introduce Government personnel, programs, and users to the Contractor's team, tools, methodologies, and business processes

Disposition of Contractor purchased Government owned assets, including facilities, equipment, furniture, phone lines, computer equipment, etc.

Transfer of Government Furnished Equipment (GFE) and Government Furnished Information (GFI), and GFE inventory management assistance

Applicable TMA debriefing and personnel out-processing procedures

Turn-in of all government keys, ID/access cards, and security codes.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 446A / <i>Disability Mediation Service (DMS)</i>			
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
446A: <i>Disability Mediation Service (DMS)</i>	-	0.539	0.382	0.433	-	0.433	0.445	0.588	0.666	0.679	Continuing	Continuing

A. Mission Description and Budget Item Justification

"Disability Mediation Service (DMS):

The VTA (Veteran's Tracking Application) has been the primary system to track, record, and report data for the IDES (Integrated Disability Evaluation System) process. The VTA is scheduled to sun-set, by VA (Veterans Affairs), and the data is being moved to another application. Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA.

The DMS will facilitate the improvement of non-medical case management tracking and IDES data/information management. It will eliminate redundant data entry within DoD (Department of Defense), improving data quality by capturing more data for operational reporting from the Services and WCP, decrease backlog by eliminating data entry duplication, and minimize impact to DoD Services by allowing the Services to continue using their existing/planned systems without requiring retraining on a new applications.

The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts. Services will assume responsibility and POM costs for modifications, enhancements, and maintenance in the out years."

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Disability Mediation Service (DMS)	0.539	0.382	0.433	-	0.433
Description: The VTA (Veteran's Tracking Application) has been the primary system to track, record, and report data for the IDES (Integrated Disability Evaluation System) process. The VTA is scheduled to sun-set, by VA (Veterans Affairs), and the data is being moved to another application. Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA. The DMS will facilitate the improvement of non-medical case management tracking and IDES data/information management. It will eliminate redundant data entry within DoD (Department of Defense), improving data quality by capturing more data for operational reporting from the Services and WCP, decrease backlog by eliminating data entry duplication, and minimize impact to DoD Services by allowing the Services to continue using their existing/planned systems without requiring retraining on a new applications.					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 446A / <i>Disability Mediation Service (DMS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts. Services will assume responsibility and POM costs for modifications, enhancements, and maintenance in the out years."</p> <p>FY 2014 Accomplishments: The Warrior Care Program Office realigned manpower and program control during in FY 2014. Necessary project planning and requirement development have not progressed sufficiently to obtain DBT certification required to execute. Program responsibility has been assigned and project is proposed to be realigned to support the Joint Disability Evaluation System (JDES) project.</p> <p>FY 2015 Plans: Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA. The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts.</p> <p>FY 2016 Base Plans: Migration of VTA to another application creates the requirement to allow data exchange between Service non-medical case management and new VA DES (Disability Evaluation System) IT application. The BEC (Benefits Executive Council) is looking to create a DMS (Disability Mediation Service), which is an integrator between the Services and VA. The DMS will be created from existing technology. It will provide a mediation service to help isolate each system from changes and uniqueness in the other systems and allow the Services and WCP to report and drill down on data that we capture during the exchange. This IT solution will not replace current DoD systems, but will require some modifications and enhancements to those systems to support the date exchange. WCP will support development costs for these efforts.</p>					
Accomplishments/Planned Programs Subtotals	0.539	0.382	0.433	-	0.433

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 446A / <i>Disability Mediation Service (DMS)</i>

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

To be determined when an approach has been determined.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480B / <i>Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)</i>
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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
480B: <i>Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)</i>	0.585	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Medical Human Resources System – internet (DMHRSi) enables the Services to standardize and optimize the management of human resource assets across the Military Health System (MHS). DMHRSi is a Web-based system that enables improved decision making by facilitating the collection and analysis of critical human resource data. It standardizes medical human resource information and provides enterprise-wide visibility for all categories of human resources (Active Duty, Reserve, Guard, civilian, contractor, and volunteer medical personnel); improves reporting of medical personnel readiness and; streamlines business processes to improve data quality for management decision making and managing the business; provides Tri-Service visibility of associated labor costs and is source for personnel cost data.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Title: Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)</p> <p>Description: The Defense Medical Human Resources System – internet (DMHRSi) enables the Services to standardize and optimize the management of human resource assets across the Military Health System (MHS). DMHRSi is a Web-based system that enables improved decision making by facilitating the collection and analysis of critical human resource data. It standardizes medical human resource information and provides enterprise-wide visibility for all categories of human resources (Active Duty, Reserve, Guard, civilian, contractor, and volunteer medical personnel); improves reporting of medical personnel readiness and; streamlines business processes to improve data quality for management decision making and managing the business; provides Tri-Service visibility of associated labor costs and is source for personnel cost data.</p> <p>FY 2014 Accomplishments: No funding programmed.</p> <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Base Plans: No funding programmed.</p>	-	-	-	-	-
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480B / <i>Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480C / <i>Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)</i>			
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
480C: <i>Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)</i>	5.370	4.478	3.978	1.933	-	1.933	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

DMLSS provides the Military Medical Departments one standard Department of Defense (DoD) medical logistics system. The DMLSS suite of applications provides the healthcare driven capability to support the medical logistics needs of the DoD community for critical medical commodities - pharmaceuticals and medical/surgical supplies across the continuum of care from the battlefield to tertiary care at a major DoD military treatment facility (MTF). This capability is enabled by the partnership of the Defense Logistics Agency (DLA) Defense Supply Center Philadelphia and the Military Health System (MHS) providing an industry to practitioner supply chain for the medical commodity. The DMLSS Defense Logistics Agency Wholesale (DMLSS-W) applications are funded by Defense Logistics Agency while the garrison medical treatment facilities and theater applications are funded by the Defense Health Program. The current DMLSS system provides full spectrum capability for medical logistics management. Basic functionality includes stock control, Prime Vendor operations, preparation of procurement documents, research and price comparison for products, property accounting, biomedical maintenance operations, capital equipment, property management, inventory, and a facility management application that supports the operations of a fixed medical treatment facility physical plant and supports Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) accreditation requirements. DMLSS, in coordination with the Theater Medical Information Program – Joint (TMIP-J), is providing to the Services and the Combatant Commanders the functional logistics capabilities necessary to rapidly project and sustain joint medical capabilities for medical logistics management of theater medical materiel operations. Current products deployed to the theater include the DMLSS Customer Assistance Module (DCAM), a medical logistics ordering tool that allows users to view their supplier’s catalog and generate electronic orders. Primarily focused on the theater environment, DCAM automates the Class VIII supply process at the lower levels of care, and allows non-logisticians, who maintain their medical supplies as an additional duty, to electronically exchange catalog, order, and status information with their supply activity.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)	4.478	3.978	1.933	-	1.933
Description: Development, integration and modernization of DMLSS modules.					
FY 2014 Accomplishments: Develop additional logic in the Medical Master Catalog (MMC) to identify to the end user those products that have been standardized by the Medical Material Enterprise Standardization Office (MMESO) and those items that are sourced by a preferred distribution channel or at an available better price.					
FY 2015 Plans:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480C / <i>Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Support critical functional and technical changes in the Medical Logistics environment to include: implement additional pharmaceutical (Holding Orders, Wide Area Work Flow (WAWF), Real-time Price verification) ordering logic and catalog data for Pharmacy Global contract award. Implement additional business logic to support equipment maintenance planning and equipment lifecycle management. Expand the Master Ordering Facility functionality to support DoD support of Civil Authorities contingency operations. Provide foundational support for regionalization of DMLSS application, reducing the deployed footprint without compromise in performance and quality.					
<i>FY 2016 Base Plans:</i> Support DMLSS Regionalization and data consolidation, reducing the deployed footprint (Hardware and License) without compromise in performance and quality and increasing access to near real time information.					
Accomplishments/Planned Programs Subtotals	4.478	3.978	1.933	-	1.933

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	51.405	30.291	30.889	-	30.889	31.416	31.961	32.506	33.156	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480D / <i>Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)</i>
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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
480D: <i>Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)</i>	3.372	4.680	-	-	-	-	3.633	3.694	2.803	2.859	Continuing	Continuing

A. Mission Description and Budget Item Justification

Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) is a comprehensive, automated information system that provides a single point for assembling, comparing, using, evaluating, and storing occupational personnel exposure information, workplace environmental monitoring data, personnel protective equipment usage data, observation of work practices data, and employee health hazard educational data. DOEHRS-IH will provide for the definition, collection and analysis platform to generate and maintain a Service Member’s Longitudinal Exposure Record. DOEHRS-IH will describe the exposure assessment, identify similar exposure groups, establish a longitudinal exposure record baseline to facilitate post-deployment follow-up, and provide information to enable exposure-based medical surveillance and risk reduction.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Title: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)</p> <p>Description: Configure, enhance and interface DOEHRS-IH modules.</p> <p>FY 2014 Accomplishments: This funding will be used to support Critical User Enhancements of the DOEHRS-IH system, including the web application, the Mobile capability, and the Data Warehouse. Critical User Enhancements are Service-identified technical software changes required to enhance the usability of the system in three core areas:</p> <ul style="list-style-type: none"> • Data control: Facilitate the user’s ability to access and edit all data fields, delete/mark invalid/outdate data, move/migrate data and search for data criteria • Workflow: Facilitate a smoother workflow and minimize unnecessary steps and clicks within the application. 	4.680	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480D / <i>Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<ul style="list-style-type: none"> • System Management: Facilitate DOEHRS-IH program users ability to search for and gain access to Occupational and Environmental Health (OEH) data, extract records and generate reports and create data search criteria, generating information for analysis. <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Base Plans: No funding programmed.</p>					
Accomplishments/Planned Programs Subtotals	4.680	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	13.200	7.517	9.290	-	9.290	9.520	9.821	10.000	10.176	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	0.108	0.239	0.113	-	0.113	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480F / <i>Executive Information/Decision Support (EI/DS) (Tri-Service)</i>			
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
480F: <i>Executive Information/Decision Support (EI/DS) (Tri-Service)</i>	3.127	2.809	-	2.551	-	2.551	1.791	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

EI/DS is comprised of a central datamart Military Health System Data Repository (MDR) and several smaller datamarts: MHS Management Analysis and Reporting Tool (M2), Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE), and Purchased Care Operations Systems -TRICARE Encounter Data (TED) & Patient Encounter Processing and Reporting (PEPR). Many of these operate within a Business Objects XI (BOXI) environment. EI/DS manages receipt, processing, and storage of over 155 terabytes of data from both Military Treatment Facilities (MTF) and the TRICARE purchased care network systems. These data include inpatient dispositions, outpatient encounters, laboratory, radiology, and pharmacy workload, TRICARE network patient encounter records, TRICARE mail order pharmacy patient encounter records, beneficiary demographics, MTF workload and cost information, eligibility and enrollment, Pharmacy Data Transaction Service data, customer satisfaction surveys, and data associated with the Wounded Warrior care. EI/DS provides centralized collection, storage and availability of data, in various data marts, to managers, clinicians, and analysts for the management of the business of health care.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Executive Information/Decision Support (EI/DS) (Tri-Service)	2.809	-	2.551	-	2.551
Description: Development, modernization, upgrades and testing for various EI/DS modules.					
FY 2014 Accomplishments:					
<ul style="list-style-type: none"> • Completed testing for Central Billing Events Repository in the Military Health System Data Repository (MDR) to perform billing and collections activities. • Provided the capability to download the National Plan and Provider Enumeration System file and to match the National Provider Identifier (NPI) and Provider Record within TRICARE Encounter Data (TED). Modify Patient Encounter Processing and Reporting (PEPR) to report revenue codes and NPI. • Completed transition of International Classification of Diseases (ICD)-10 codes within TED. • Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) <ul style="list-style-type: none"> - Developed a Fused Detection and Dashboard capability that will reduce the number of “false positive” alerts. - Provided a user-defined customizable dashboard functionality; and, - Provided drilldown capabilities so users can see the raw data and specific patient details underlying the “fused alert.” 					
FY 2015 Plans:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480F / <i>Executive Information/Decision Support (EI/DS) (Tri-Service)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
No funding programmed.					
<i>FY 2016 Base Plans:</i> Develop the Enhanced Query capabilities which will substantially expand the scope of the current query functionality. The enhanced query functionality will allow user to include parameters from all current and future data sources to create specific disease case definitions. The query will also enable the user to define a specific population, e.g., one or more MTFs, age-groups, etc. This enhanced functionality will expand ESSENCE's scope beyond the existing broad syndromes and allow users to monitor specific diseases, e.g., influenza. Develop an enhanced reference table management capability. This will allow designated Service Authorized "Super Users" to update key reference tables thus unlocking a cost traditionally borne by the Tier III support vendor and allow greater agility and more accurate results within the ESSENCE Program					
Accomplishments/Planned Programs Subtotals	2.809	-	2.551	-	2.551

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	23.815	29.940	31.070	-	31.070	32.080	32.586	33.298	33.964	Continuing	Continuing
• BA-1, 0807752HP: <i>Miscellaneous Support Activities</i>	13.942	16.040	16.329	-	16.329	16.623	16.922	17.226	17.537	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480G / <i>Health Artifact and Image Management Solution (HAIMS) (Tri-Service)</i>			
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
480G: <i>Health Artifact and Image Management Solution (HAIMS) (Tri-Service)</i>	-	5.828	0.304	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Health Artifact and Image Management Solution (HAIMS) enables the DoD and the VA healthcare providers to have global access and awareness of artifacts and images (A&I) generated during the healthcare delivery process. HAIMS will provide the new capability for users throughout the MHS to be aware and have access to A&I that have been registered with the central “system”, currently on local workstations and Military Treatment Facility (MTF) Picture Archive and Communications Systems (PACs). As patients move through the continuum of care from Continental United States to Theater and then return to DoD sustaining bases facilities, healthcare A&I moves seamlessly and simultaneously with the patient. This advances several MHS strategy initiatives such as achievement of paperless record, global access of Wounded Warrior scanned documents, and an alternative to finding storage space for paper records of merging MTFs. HAIMS will supply access to VHA and other external A&I both inside and outside the Military Health System (MHS) Electronic Health Record (EHR). Funding has been provided within this program element in prior years for HAIMS before it was identified as its own system in the budget cycle. HAIMS will experience Incremental development as each new requirement is identified for FY 2014 and FY 2015.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Health Artifact and Image Management Solution (HAIMS) (Tri-Service)	5.828	0.304	-	-	-
Description: Integrate new functionality into HAIMS.					
FY 2014 Accomplishments:					
Develop Graphical User Interface (GUI) for asset preview capability.					
Provide full functionality with one account (w/o multiple logins)					
Provide functionality for Social Security Number (SSN) reduction and Data at Rest.					
Interface with Veterans Benefits Administration.					
Reduce Social Security Numbers in the application.					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480G / <i>Health Artifact and Image Management Solution (HAIMS) (Tri-Service)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Develop interfaces for Health Readiness Record, additional Picture Archiving and Communications System (PACS) based systems, additional non-PACS systems, and dental repositories. FY 2015 Plans: Complete interface activities began in FY14 RDT&E to include improved search capabilities and monitoring improvements. FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	5.828	0.304	-	-	-

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	17.205	20.075	17.575	-	17.575	18.884	20.300	21.358	21.783	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	5.828	1.991	9.500	-	9.500	12.500	12.604	13.732	14.007	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480K / <i>Integrated Federal Health Registry Framework (Tri-Service)</i>			
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
480K: <i>Integrated Federal Health Registry Framework (Tri-Service)</i>	-	2.591	1.093	0.450	-	0.450	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The purpose of an integrated Federal Health Registry capability is to provide a viable solution to fulfill a critical need for improved sharing and exchange of Service member and Veteran health information and data between the Department of Defense - Health Affairs and the Department of Veterans Affairs-Veterans Health Administration communities of interest (COIs) as mandated in Section 1635 of the 2008 National Defense Authorization Act (NDAA, 2008). This ability to share and exchange vital health care data between the respective specialties of care is essential to conduct longitudinal analyses necessary to improve patient care and quality of life outcomes. To maximize efficiencies and most effectively meet the needs of the functional communities, the Centers of Excellence (CoEs) have developed a consolidated framework solution for an integrated Federal Health Registry capability. This effort provides a comprehensive solution that meets the specialty care needs of each of the Services and Veteran Affairs that are represented by the Joint DoD and VA CoEs, (Army-Extremity Trauma and Amputation Center of Excellence; TMA-Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury; Navy-DoD/VA Vision Center of Excellence; Air Force-Hearing Center of Excellence; and JTFCAPMED-National Intrepid Center of Excellence).

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Federated Registry Framework (Tri-Service)	2.591	1.093	0.450	-	0.450
Description: Develop, integrate and test a common registry.					
FY 2014 Accomplishments: Funding to support a consolidated technical approach for the Centers of Excellence, which will provide a repeatable process that includes integration of their registry requirements into federated subspecialty clinical data elements that were determined by representative subject matter experts from the Tri-Services and Veteran's Affairs.					
FY 2015 Plans: Funding to support a consolidated technical approach for the Centers of Excellence, which will provide a repeatable process that includes integration of their registry requirements into federated subspecialty clinical data elements that were determined by representative subject matter experts from the Tri-Services and Veteran's Affairs.					
FY 2016 Base Plans:					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480K / <i>integrated Federal Health Registry Framework (Tri-Service)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Additional funding added in FY 2016 to finalize all development and testing necessary for a consolidated technical approach.					
Accomplishments/Planned Programs Subtotals	2.591	1.093	0.450	-	0.450

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, 0807793HP: <i>MHS Tri-Service Information</i>	0.258	2.433	2.838	-	2.838	2.865	2.913	2.962	3.018	Continuing	Continuing
• BA-3, 0807721HP: <i>Other Procurement, Replacement/Modernization</i>	-	-	0.015	-	0.015	0.094	0.066	0.040	0.041	Continuing	Continuing

Remarks

D. Acquisition Strategy
Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics
Program cost, schedule and performance are measured periodically using a systematic approach as required for Major Automated Information Systems (MAIS) per DoD Directives and Instructions.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480M / <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>			
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
480M: <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>	28.731	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Theater Medical Information Program - Joint (TMIP-J) integrates components of the Military Health System sustaining base systems and the Services' medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of all Theater and deployed forces in support of any mission. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and forges the theater links of the longitudinal health record to the sustaining base and the Department of Veterans Affairs. TMIP-J is the medical component of the Global Combat Support System. TMIP-J provides information at the point of care and to the Theater tactical and strategic decision makers through efficient, reliable data capture, and data transmission to a centralized Theater database. This delivers TMIP-J's four pillars of information support through the electronic health record, integrated medical logistics, patient movement and tracking, and medical command and control through data aggregation, reporting and analysis tools for trend analysis and situational awareness. TMIP-J fulfills the premise of "Train as you fight" through the integration of components which are identical or analogous to systems from the sustaining base. TMIP-J adapts and integrates these systems to specific Theater requirements and assures their availability in the no- and low- communications settings of the deployed environment through store and forward capture and transmission technology.

TMIP-J RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	-	-	-	-	-
Description: The Theater Medical Information Program - Joint (TMIP-J) integrates components of the Military Health System sustaining base systems and the Services' medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of all Theater and deployed forces in support of any mission. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and forges the theater links of the longitudinal health record to the sustaining base and the Department of Veterans Affairs. TMIP-J is the medical component of the Global Combat Support System. TMIP-J provides information at the point of care and to the Theater tactical and strategic decision makers through efficient, reliable data capture, and data transmission to a centralized Theater database. This delivers TMIP-J's four pillars of information support through the electronic health record, integrated medical logistics, patient movement and tracking, and medical command and control through data aggregation, reporting and analysis					

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480M / <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)

tools for trend analysis and situational awareness. TMIP-J fulfills the premise of "Train as you fight" through the integration of components which are identical or analogous to systems from the sustaining base. TMIP-J adapts and integrates these systems to specific Theater requirements and assures their availability in the no- and low-communications settings of the deployed environment through store and forward capture and transmission technology.

TMIP-J RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

FY 2014 Accomplishments:

No funding programmed.

FY 2015 Plans:

No funding programmed.

FY 2016 Base Plans:

No funding programmed.

FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Accomplishments/Planned Programs Subtotals				
-	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480P / <i>Other Related Technical Activities (Tri-Service)</i>			
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
480P: <i>Other Related Technical Activities (Tri-Service)</i>	4.123	-	2.990	-	-	-	1.683	3.500	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Other Related Technical Activities includes funding for Information Technology activities common to multiple or all Tri-Service systems/programs and can not be associated with any one individual Tri-Service initiative, which includes enterprise Messaging and other common IT services requirements. Funding is included in FY 2012 for International Classification of Diseases and Related Health Problems 10th edition (ICD-10). ICD-10 funding for FY 2013 and out is shown in the appropriate initiative's Accomplishments/Planned Program sections within this program element.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Other Related Technical Activities (Tri-Service)	-	2.990	-	-	-
Description: Develop, integrate, test of activities common to multiple or all Tri-Service IT activities.					
FY 2014 Accomplishments: No funding programmed/executed.					
FY 2015 Plans: Funding in support of Health Information Technology Shared Services investment.					
FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	-	2.990	-	-	-

C. Other Program Funding Summary (\$ in Millions)

Line Item	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
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	-	2.100	-	-	-	2.310	2.730	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480P / <i>Other Related Technical Activities (Tri-Service)</i>

E. Performance Metrics

Each activity establishes performance measurements. Program cost, schedule and performance are measured periodically using a systematic approach. Since this is an enterprise initiative which crosses multiple initiatives, performance metrics of the common activities are part of and/or contributing factors in the measurement of the performance metrics of the individual initiatives.

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 480R / <i>TMA E-Commerce (TMA)</i>			
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
480R: <i>TMA E-Commerce (TMA)</i>	2.934	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The DHP, RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System(E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce replaces multiple legacy systems. E-Commerce consists of several major subsystems including: CM subsystem utilizing Prism software to support contract action development and documentation; the RM subsystem utilizing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; the document management subsystem utilizing Documentum software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting subsystem utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care Web site that provides up-to-date financial information for both TMA and the Services concerning the military treatment facilities' (MTFs') expenditures for MTF enrollee purchased care and supplemental care. E-Commerce includes 5 major subsystems and over 60 servers supporting development, test, and production. The system will be utilized by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without impacting the system performance or support to any individual user. Server configurations must be kept current in terms of security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.

B. Accomplishments/Planned Programs (\$ in Millions)

Title: TMA E-Commerce (TMA)

Description: The DHP, RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System(E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce replaces multiple legacy systems. E-Commerce consists of several major subsystems including: CM subsystem utilizing Prism software to support contract action development and documentation; the RM subsystem utilizing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; the document management subsystem utilizing Documentum software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting subsystem utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care Web site that provides up-to-date financial information for both TMA and the Services concerning the military treatment facilities' (MTFs') expenditures for MTF enrollee purchased care and supplemental care. E-

FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
-	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480R / <i>TMA E-Commerce (TMA)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Commerce includes 5 major subsystems and over 60 servers supporting development, test, and production. The system will be utilized by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without impacting the system performance or support to any individual user. Server configurations must be kept current in terms of security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.</p> <p>FY 2014 Accomplishments: Implemented enhancement solutions to improve management of private sector care contracts, processing of private sector care healthcare claims, compliance with DoD policy and guidance, and private sector care operational efficiency. Completed healthcare claims and financial processing and reporting changes to enhance compliance with IPv6, SFIS, PDS, and SLOA direction. Modified contract management and healthcare claims processing to accommodate healthcare policy and contract changes. Improved private sector care efficiencies and productivity by enhancing contract performance assessment, deliverable processing, and refining operational and financial reporting. Continued receiving unqualified audit opinions through the upgrade of accounting, budgeting, and audit processing. Finished the first phase of the pharmacy management modernization activity to support the tracking of pharmaceutical manufacturer refunds and collections. Implemented a change in appropriation order at the beginning of the fiscal year.</p> <p>FY 2015 Plans: -Program transfer in FY 2015 to project 482A.</p> <p>FY 2016 Base Plans: No funding programmed.</p>					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>	
• BA-1, 0807752HP:	12.857	-	-	-	-	-	-	-	-	-	Continuing	Continuing
<i>Miscellaneous Support Activities</i>												
• BA-3, 0807721HP:	0.500	-	-	-	-	-	-	-	-	-	Continuing	Continuing
<i>Replacement/Modernization</i>												

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480R / <i>TMA E-Commerce (TMA)</i>

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
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Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of TRL8.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480Y / <i>Clinical Case Management (Tri-Service)</i>
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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
480Y: <i>Clinical Case Management (Tri-Service)</i>	2.925	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Provides a seamless view of the care and the health of the patient from the origin of injury or illness to the end of the need for that episode of care. It will capture relevant events, information, documents and other data to support the overall improvement of the patient's condition utilizing medical Case Management practices. It will provide the ability to collect clinical information in support of the medical Case Manager's mission and will provide information gathered to MTFs and MSCSs.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Clinical Case Management (Tri-Service)	-	-	-	-	-
Description: Provides a seamless view of the care and the health of the patient from the origin of injury or illness to the end of the need for that episode of care. It will capture relevant events, information, documents and other data to support the overall improvement of the patient's condition utilizing medical Case Management practices. It will provide the ability to collect clinical information in support of the medical Case Manager's mission and will provide information gathered to MTFs and MSCSs.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480Y / <i>Clinical Case Management (Tri-Service)</i>

<u>E. Performance Metrics</u> N/A

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480Z / <i>Centralized Credentials and Quality Assurance System (CCQAS) (Tri-Service)</i>
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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
480Z: <i>Centralized Credentials and Quality Assurance System (CCQAS) (Tri-Service)</i>	1.692	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Central Credentials Quality Assurance System (CCQAS) enables the military medical community to electronically manage the credentials, risk management, and adverse privileging actions of medical personnel and is hosted at secure Defense Information Systems Agency facility. It is deployed worldwide to over 1,350 professional affairs coordinators in 535 locations and contains nearly 60,000 credentials records for Active Duty, Reserve, Guard, Civil Service, contractors, and volunteers in the Military Health System. CCQAS tracks trends in medical malpractice claims in an effort to improve health care quality, ensure legal due process for clinicians undergoing adverse actions, and assist the Medical Treatment Facilities in meeting Joint Commission on Accreditation of Healthcare Organization’s accreditation standards.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Centralized Credentials and Quality Assurance System (CCQAS) (Tri-Service)	-	-	-	-	-
Description: The Central Credentials Quality Assurance System (CCQAS) enables the military medical community to electronically manage the credentials, risk management, and adverse privileging actions of medical personnel and is hosted at secure Defense Information Systems Agency facility. It is deployed worldwide to over 1,350 professional affairs coordinators in 535 locations and contains nearly 60,000 credentials records for Active Duty, Reserve, Guard, Civil Service, contractors, and volunteers in the Military Health System. CCQAS tracks trends in medical malpractice claims in an effort to improve health care quality, ensure legal due process for clinicians undergoing adverse actions, and assist the Medical Treatment Facilities in meeting Joint Commission on Accreditation of Healthcare Organization’s accreditation standards.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: No funding programmed.					
FY 2016 Base Plans: No funding programmed.					
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 480Z / <i>Centralized Credentials and Quality Assurance System (CCQAS) (Tri-Service)</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 481A / <i>Theater Enterprise Wide Logistics System (TEWLS) Tri-Service</i>
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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
481A: <i>Theater Enterprise Wide Logistics System (TEWLS) Tri-Service</i>	5.127	-	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification
 Theater Enterprise-Wide Logistics System (TEWLS) supports critical medical logistics warfighter requirements in a net-centric environment. It ties the national, regional, and deployed units into a single business environment. It creates the necessary links for planners, commercial partners, and AMEDD logisticians to accomplish essential care in the theater through a single customer facing portal. It removes disparate data and replaces it with a single instance of actionable data. TEWLS supports today's modern, non-contiguous battlefield at the regional, COCOM, and Service levels by leveraging emerging Medical Materiel Executive Agency and Theater Lead Agent infrastructure concepts to manage the entire medical supply chain from the industrial base to the end user.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Title: Theater Enterprise Wide Logistics System (TEWLS) Tri-Service)</p> <p>Description: Theater Enterprise-Wide Logistics System (TEWLS) supports critical medical logistics warfighter requirements in a net-centric environment. It ties the national, regional, and deployed units into a single business environment. It creates the necessary links for planners, commercial partners, and AMEDD logisticians to accomplish essential care in the theater through a single customer facing portal. It removes disparate data and replaces it with a single instance of actionable data. TEWLS supports today's modern, non-contiguous battlefield at the regional, COCOM, and Service levels by leveraging emerging Medical Materiel Executive Agency and Theater Lead Agent infrastructure concepts to manage the entire medical supply chain from the industrial base to the end user.</p> <p>FY 2014 Accomplishments: No funding programmed.</p> <p>FY 2015 Plans: No funding programmed.</p> <p>FY 2016 Base Plans: No funding programmed.</p>	-	-	-	-	-
Accomplishments/Planned Programs Subtotals	-	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 481A / <i>Theater Enterprise Wide Logistics System (TEWLS) Tri-Service</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 482A / <i>E-Commerce (DHA)</i>			
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
482A: <i>E-Commerce (DHA)</i>	-	5.526	2.494	2.766	-	2.766	2.829	3.704	4.200	4.284	Continuing	Continuing

A. Mission Description and Budget Item Justification

The DHP, RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System(E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce replaces multiple legacy systems. E-Commerce consists of several major subsystems including: CM subsystem utilizing Prism software to support contract action development and documentation; the RM subsystem utilizing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; the document management subsystem utilizing Documentum software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting subsystem utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care Web site that provides up-to-date financial information for both TMA and the Services concerning the military treatment facilities' (MTFs') expenditures for MTF enrollee purchased care and supplemental care. E-Commerce includes 5 major subsystems and over 60 servers supporting development, test, and production. The system will be utilized by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without impacting the system performance or support to any individual user. Server configurations must be kept current in terms of security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: E-Commerce (DHA)	5.526	2.494	2.766	-	2.766
Description: The DHP, RDT&E appropriation includes the following TMA initiatives: Electronic Commerce System(E-Commerce): This system was developed for centralized collection, integration, and reporting of accurate purchased care contracting and financial data. It provides an integrated set of data reports from multiple data sources to management, as well as tools to control the end-to-end program change management process. E-Commerce replaces multiple legacy systems. E-Commerce consists of several major subsystems including: CM subsystem utilizing Prism software to support contract action development and documentation; the RM subsystem utilizing Oracle Federal Financials and TED interface software to support the budgeting, accounting, case recoupment, and disbursement processes; the document management subsystem utilizing Documentum software to provide electronic storage, management, and retrieval of contract files; Management Tracking and Reporting subsystem utilizing custom software to provide reports to assist in the management and tracking of changes to the managed care contracts as well as current and out year liabilities; the Purchased Care Web site that provides up-to-date financial information for both TMA and the Services concerning the military treatment facilities' (MTFs') expenditures for MTF enrollee purchased care and supplemental care. E-					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 482A / <i>E-Commerce (DHA)</i>

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
<p>Commerce includes 5 major subsystems and over 60 servers supporting development, test, and production. The system will be utilized by several hundred users in more than 7 different organizations. Project oversight and coordination must be provided to ensure that the needs of the disparate organizations are met without impacting the system performance or support to any individual user. Server configurations must be kept current in terms of security policies, user authorizations, and interactions with other systems and functions. All of these activities must be managed and coordinated on a daily basis.</p> <p>FY 2014 Accomplishments: Plans noted and funded under Project Project 480R.</p> <p>FY 2015 Plans: - Continue compliance enhancements and modernization of financial processing and reporting. Enhance application functionality to respond to changes in health care policy and guidance, to improve operational efficiency, and to continue providing operational personnel with effective financial, contract management, and acquisition support capabilities. Enhance health care claims and financial processing to accommodate changes in health care requirements and to improve contractor performance assessment and deliverable processing. Implement accounting improvements to support user interface processing, audit support, financial and audit reporting, and enterprise budget management. Finally, implement software changes, mandated by Congress and the DoD, to accommodate financial application health care policy modifications, and BEA SFIS changes.</p> <p>FY 2016 Base Plans: Continue compliance enhancements and modernization of healthcare financial processing, contract operations, and financial reporting. Enhance application functionality to respond to changes in healthcare policy and guidance, to improve operational efficiency, and to continue providing DHA operational personnel with effective financial, contract management, and acquisition management capabilities. Enhance healthcare claims and financial processing to accommodate new healthcare contracts, to support processing changes in healthcare requirements, and to improve private sector care contractor performance assessment and deliverable processing. Enhance accounting and finance capabilities to improve the tracking of pharmaceutical manufacturer refunds, dispute handling, collections, and case management. Implement accounting improvements to support healthcare accounting operations, financial audit support, financial reporting, and private sector care budget management. Finally, implement software changes, mandated by Congress and</p>					

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 482A / <i>E-Commerce (DHA)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
the DoD, to accommodate financial application healthcare policy modifications, BEA SFIS changes, and PDS compliance. FY 2016 OCO Plans: No OCO					
Accomplishments/Planned Programs Subtotals	5.526	2.494	2.766	-	2.766

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807752HP:	-	14.443	14.615	-	14.615	14.933	14.438	14.286	14.543	Continuing	Continuing
<i>Miscellaneous Support Activities</i>											
• BA-3, 0807721HP:	-	-	-	-	-	-	-	0.549	0.560	Continuing	Continuing
<i>Replacement/Modernization</i>											

Remarks
Program transfer from project 480R.

D. Acquisition Strategy
N/A

E. Performance Metrics
The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of TRL8.

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 4901 / <i>Navy Medicine Chief Information Officer</i>
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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
4901: <i>Navy Medicine Chief Information Officer</i>	2.106	4.131	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Navy Medicine CIO Management Operations - IM/IT RDT&E requests will be vetted through the Bureau of Navy Medicine (BUMED) Governance Process. BUMED IM/IT CIO Governance will monitor progress and milestones every six months.

B. Accomplishments/Planned Programs (\$ in Millions)

Title: Navy Medicine Chief Information Officer (CIO) Management Operations

Description: Navy Medicine CIO Management Operations - IM/IT RDT&E requests will be vetted through the Bureau of Navy Medicine (BUMED) Governance Process. BUMED IM/IT CIO Governance will monitor progress and milestones every six months.

FY 2014 Accomplishments:

This is an ongoing activity recently enacted by the Navy Medicine IM/IT process which further defines/transforms future IM/IT Medical Program Enhancements and Medical Capabilities.

The development/integration of Defense Optical Fabrication Enterprise Management System (DOFEMS) into a fully automated system to support workload distribution, performance metrics, staffing requirements, supply management, calculation of operating costs from the current independently or manually DOFEMS system. This effort will be a web based centralized management tool and provide a standalone standard set of Lab Management software for all 26 Navy labs.

The re-design of HIV Management System (HMS) so that it is user friendly, minimizes the amount of time required to perform everyday tasks and prevents the need to maintain separate databases, automate and minimize functions that require manual assistance and assist in fulfilling new requirements.

The development/integration of the Corporate Dental System (CDS) will replace the current Navy Dental system, Dental Common Access System (DENCAS). The CDS is the Military Health System Enterprise solution providing for the accurate collection, processing, and presentation of dental workload, readiness, scheduling,

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Navy Medicine Chief Information Officer (CIO) Management Operations	4.131	-	-	-	-

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 490I / <i>Navy Medicine Chief Information Officer</i>
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B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
and digital radiographic information for both treatment operations and the oversight of management activities at all levels of the dental enterprise.					
<i>FY 2015 Plans:</i> No funding programmed.					
<i>FY 2016 Base Plans:</i> No funding programmed.					
Accomplishments/Planned Programs Subtotals	4.131	-	-	-	-

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	163.298	161.049	163.730	-	163.730	164.098	167.023	157.459	160.293	Continuing	Continuing
• BA-1, PE 0807795HP: <i>Base Communications - CONUS</i>	16.502	16.796	17.108	-	17.108	17.414	17.709	18.039	18.364	Continuing	Continuing
• BA-1, PE 0807995HP: <i>Base Communications - OCONUS</i>	2.416	2.458	2.505	-	2.505	2.549	2.595	2.640	2.688	Continuing	Continuing
• BA-3, PE 0807720HP: <i>Initial Outfitting</i>	-	-	-	-	-	-	-	-	-	Continuing	Continuing
• BA-3, PE 0807721HP: <i>Replacement/Modernization</i>	2.782	1.107	1.305	-	1.305	2.737	2.907	3.041	3.096	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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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 0605013HP / <i>Information Technology Development</i>				Project (Number/Name) 490J / <i>Navy Medicine Online</i>			
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
490J: <i>Navy Medicine Online</i>	1.369	-	2.192	2.052	-	2.052	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Navy Medicine Online System (NMO) is the designated data broker for Navy Medicine. NMO collects individual readiness information from legacy Navy Medicine data systems (i.e SAMS,DENCAS, MEDBOLTT, etc.). NMO transmits select information to MRRS to support DoD IMR reporting, DHIMS Force Health Protection, Master CMS, and other Navy systems. NMO also provides the programs used to manage the medical waiver process and to track USNA midshipmen medical issues. The goal of this RDT&E effort is to merge NMKMS into Navy Medicine Online (NMO) as a data broker, to establish a single operational data warehouse for Navy Medicine operational data, as well as to support programs for managing medical staffing planning and operational workload reports.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Title: Navy Medicine Online (NMO)	-	2.192	2.052	-	2.052
Description: The Navy Medicine Online System (NMO) is the designated data broker for Navy Medicine. NMO collects individual readiness information from legacy Navy Medicine data systems (i.e SAMS,DENCAS, MEDBOLTT, etc.). NMO transmits select information to MRRS to support DoD IMR reporting, DHIMS Force Health Protection, Master CMS, and other Navy systems. NMO also provides the programs used to manage the medical waiver process and to track USNA midshipmen medical issues. The goal of this RDT&E effort is to merge NMKMS into Navy Medicine Online (NMO) as a data broker, to establish a single operational data warehouse for Navy Medicine operational data, as well as to support programs for managing medical staffing planning and operational workload reports.					
FY 2014 Accomplishments: No funding programmed.					
FY 2015 Plans: This is an ongoing activity recently enacted by the Navy Medicine IM/IT process which further defines/transforms future IM/IT Medical Program Enhancements and Medical Capabilities.					
FY 2016 Base Plans: This is an ongoing activity recently enacted by the Navy Medicine IM/IT process which further defines/transforms future IM/IT Medical Program Enhancements and Medical Capabilities.					
Accomplishments/Planned Programs Subtotals	-	2.192	2.052	-	2.052

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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 0605013HP / <i>Information Technology Development</i>	Project (Number/Name) 490J / <i>Navy Medicine Online</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>
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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	0.000	19.912	68.267	9.216	-	9.216	8.125	-	-	-	Continuing	Continuing
444A: <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>	0.000	12.634	45.915	9.216	-	9.216	8.125	-	-	-	Continuing	Continuing
444B: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>	0.000	4.720	-	-	-	-	-	-	-	-	Continuing	Continuing
449A: <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>	0.000	2.558	22.352	-	-	-	-	-	-	-	Continuing	Continuing

MDAP/MAIS Code:
Other MDAP/MAIS Code(s): 465

A. Mission Description and Budget Item Justification

In March 2008, the MHS embarked upon Electronic Health Record (EHR) modernization planning, establishing the initial Electronic Health Records Way Ahead (EHRWA).

In March 2011, the Program was expanded to include the VA in a joint initiative to implement a new, integrated electronic health record for both Departments, called the Integrated Electronic Health Record (iEHR) program.

Secretary Hagel’s Memorandum titled “Integrated Electronic Health Records,” dated May 2013, provided additional direction to the program:

- DoD shall continue near-term coordinated efforts with VA to develop data federation, presentation, and interoperability. This near-term goal shall be pursued as a first priority separately from the longer-term goal of health record information technology (IT) modernization.
- DoD shall pursue a full and open competition for a core set of capabilities for EHR modernization.

To fulfill Secretary Hagel’s directive, parallel programs have been defined, splitting the original iEHR program into two distinct areas. In the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) Acquisition Decision Memoranda (ADM), dated June 21, 2013 and January 2, 2014, the former joint DoD and VA Integrated Electronic Health Record (iEHR) program was restructured to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a newly defined iEHR focused on providing seamless integrated sharing of electronic health

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>
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data between the DoD and VA to be called Defense Medical Information Exchange (DMIX). The remaining iEHR Increment 1 (iEHR Inc 1) was significantly de-scoped to only the Medical Single Sign-on/Context management (MSSO/CM) implemented at James A. Lovell Federal Health Care Center (JAL FHCC).

iEHR RDT&E is reported under the program element (PE) 0605013 through FY 2013 inclusive, but iEHR, VLER Health and DHMSM will be reported under new program element 0605023 for FY 2014.

In FY 2015, PE 0605023 will report only iEHR and VLER Health since DHMSM will have its own PE starting in FY 2015.

In FY 2016 and out, only iEHR Increment 1 will be reported in PE 0605023. DHMSM will continue to be only initiative reported in PE 0605026. However, new PE 06050039 is established for DMIX for FY 2016 and out. DMIX will incorporate the previous VLER Health and JEHRI initiatives.

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	64.100	68.267	34.560	-	34.560
Current President's Budget	19.912	68.267	9.216	-	9.216
Total Adjustments	-44.188	-	-25.344	-	-25.344
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-43.614	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.574	-			
• Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)	-	-	-25.344	-	-25.344

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record (iEHR) (-\$0.574 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.574 million).

FY 2014: Congressional Rescissions to DHP RDT&E, PE 0605013-Information Technology Development (-\$43.614 million)

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605023-Integrated Electronic Health Record Inc 1 / Defense Medical Information Exchange (DMIX) (-\$25.344 million).

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 444A / <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>
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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
444A: <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>	-	12.634	45.915	9.216	-	9.216	8.125	-	-	-	Continuing	Continuing

MDAP/MAIS Code: 465

A. Mission Description and Budget Item Justification

In March 2008, the MHS embarked upon Electronic Health Record (EHR) modernization planning, establishing the initial Electronic Health Records Way Ahead (EHRWA).

In March 2011, the Program was expanded to include the VA in a joint initiative to implement a new, integrated electronic health record for both Departments, called the Integrated Electronic Health Record (iEHR) program.

Secretary Hagel’s Memorandum titled “Integrated Electronic Health Records,” dated May 2013, provided additional direction to the program:

- DoD shall continue near-term coordinated efforts with VA to develop data federation, presentation, and interoperability. This near-term goal shall be pursued as a first priority separately from the longer-term goal of health record information technology (IT) modernization.
- DoD shall pursue a full and open competition for a core set of capabilities for EHR modernization.

To fulfill Secretary Hagel’s directive, parallel programs have been defined, splitting the original iEHR program into two distinct areas. In the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) Acquisition Decision Memoranda (ADM), dated June 21, 2013 and January 2, 2014, the former joint DoD and VA Integrated Electronic Health Record (iEHR) program was restructured to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a newly defined iEHR focused on providing seamless integrated sharing of electronic health data between the DoD and VA to be called Defense Medical Information Exchange (DMIX). The remaining iEHR Increment 1 (iEHR Inc 1) was significantly de-scoped to only the Medical Single Sign-on/Context management (MSSO/CM) implemented at James A. Lovell Federal Health Care Center (JAL FHCC).

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX) (Tri-Service)	12.634	45.915	9.216
Description: The iEHR Increment 1 initiative achieved Full Deployment Decision November 2014 and is targeted to reach Full Deployment milestone by May 2016. Sustainment efforts for iEHR Increment 1 include the DoD sustainment of the James A			

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 444A / <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>Lovell Federal Health Care Center (JAL FHCC) health care information technology that includes medical single sign-on/context management (MSSO/CM). Program funding is also included to maintain DoD operations at the Interagency Program Office (IPO).</p> <ul style="list-style-type: none"> The DoD/VA Interagency Program Office (IPO) was re-chartered on December 5, 2013. The mission focus is addressing and coordinating the establishment of a clinical and technical standards profile and processes for data interoperability to create seamless integration of health data for DoD and VA. The IPO will leverage national and international standards and open architecture design principles to preserve flexibility, and foster data interoperability with each other and appropriate commercial entities. The IPO will enhance existing DoD and VA efforts with The Office of the National Coordinator (ONC) for Health Information Technology within the Health and Human Services (HHS) and other national and international standards organizations and coordinate and monitor the common components required for health data sharing and interoperability. The primary deliverables include technical data interoperability architecture requirements, interface control documentation, terminology standards identification and data exchange guidance. <p>FY 2014 Accomplishments:</p> <ul style="list-style-type: none"> Achieved a Milestone C July, 2014 Achieved a Fielding Deployment Decision on November, 2014 <p>FY 2015 Plans: Funding for testing as needed.</p> <p>FY 2016 Plans: Funding for testing as needed.</p>			
Accomplishments/Planned Programs Subtotals	12.634	45.915	9.216

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, PE 0807784HP: <i>Information Technology Development -</i>	81.342	40.699	19.500	-	19.500	22.212	34.247	40.533	41.349	Continuing	Continuing
• BA-3, 0807784HP: <i>Replacement/Modernization</i>	-	8.243	7.897	-	7.897	1.043	0.075	0.076	0.079	Continuing	Continuing
Remarks											

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 444A / <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>

D. Acquisition Strategy
Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

iEHR/DMIX is a collaborative effort between the DoD and VA to share Health Care Resources to improve access to, and quality and cost effectiveness of, health care as mandated by law. This investment is deeply embedded in the MHS Enterprise Roadmap as both Departments have need for modernization/ replacement of existing legacy systems. This investment will use a combination of an open architecture approach, and the purchase (in some instances) of GOTS and COTS products.

E. Performance Metrics
Program cost, schedule and performance are measured periodically using a systematic approach as required for Major Automated Information Systems (MAIS) per DoD Directives and Instructions.

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>				Project (Number/Name) 444B / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>			
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
444B: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>	-	4.720	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

DHMSM will acquire and support deployment, and implementation of an electronic health record (EHR) system that replaces the DoD legacy MHS inpatient and outpatient EHR systems. Overarching goal of the program is to enable healthcare teams to deliver high-quality, safe care and preventive services to patients through the use of easily accessible standards-based computerized patient records resulting in: improved accuracy of diagnoses and medication; improved impact on health outcomes; increased patient participation in the healthcare process; improved patient-centered care coordination; and increased practice efficiencies in all settings, including operational environments.

DHMSM replaces DoD legacy healthcare systems with a commercial solution in use in other medical systems that is open, rendered as a modular architecture, using standards-based/non-proprietary interfaces. DHMSM will support the Department's goals of net centrality by providing a framework for full human and technical connectivity and interoperability that allows DoD users and mission partners to share the information they need, when they need it, in a form they can understand and act on with confidence, and protects information from those who should not have it. Once fielded, the EHR will support the following healthcare activities for DoD's 44,000 practitioners and 9.5 million beneficiaries.

1. Clinical workflow and provider clinical decision support;
2. Capture, maintain, use, protect, preserve and share health data and information;
3. Retrieval and presentation of health data and information that is meaningful for EHR users regardless of where the patient's records are physically maintained; and
4. Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: DoD Healthcare Management System Modernization (DHMSM)	4.720	-	-
Description: DHMSM will be executed to deliver uniform information management options across both garrison and theater environments. DHMSM will focus on replacement of inpatient and outpatient systems, and will encompass deployment of the enterprise EHR to fixed facilities as well as expeditionary components.			
FY 2014 Accomplishments: Program Planning Activities including: • Finalized requirements.			

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 444B / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<ul style="list-style-type: none"> Conducted multiple Industry days. Prepared supporting Acquisition Documentation to include Acquisition Strategy, Business Case, Engineering Master Plan, Cost Benefit Analysis, Test Strategy, and Deployment and Supportability Plan. Developed and vetted multiple drafts of the Request for Proposal (RFP) Packages to insure completeness of the package to capture the finalized requirements. Developed and staffed Acquisition artifacts to support Authority to Process (ATP) for RFP release. Received ATP for RFP release and released final RFP for full and open competition. <p>FY 2015 Plans: Funding not programmed in this program element.</p> <p>FY 2016 Plans: Funding not programmed in this program element.</p>			
Accomplishments/Planned Programs Subtotals	4.720	-	-

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807784HP: <i>Information Technology Development - Integrated Electronic Health Record</i>	24.882	-	-	-	-	-	-	-	-	-	Continuing Continuing
Remarks											

D. Acquisition Strategy
Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics
Program cost, schedule and performance are measured periodically using a systematic approach per DoD directives and instructions.

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>				Project (Number/Name) 449A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>			
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
449A: <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>	-	2.558	22.352	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The primary goal of the VLER Health initiative is to enable the secure sharing of health information (i.e., demographic and clinical data) between DoD and external Federal and private sector partners which meets Meaningful Use (MU) requirements to improve healthcare quality, safety, and efficiency. By electronically sharing health information using national standards, that information can support tracking key clinical conditions, communicating that information to better coordinate care, and engaging patients in their own care. The VLER Health initiative provides clinicians with the most up-to-date information, potentially reducing redundant diagnostic tests, medical errors, paperwork and handling, and overall healthcare costs. These benefits, in turn, align with the MHS quadruple aim by ensuring that the military force is medically ready to deploy; the military beneficiary population remains healthy through focused prevention; patient care is convenient, equitable, safe, and of the highest quality; and the total cost of healthcare is reduced through the reduction of waste and focus on quality

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Virtual Lifetime Electronic Record (VLER) HEALTH	2.558	22.352	-
Description: Pursue the primary goal of the VLER Health initiative is to enable the secure sharing of health information (i.e., demographic and clinical data) between DoD and external Federal and private sector partners which meets Meaningful Use (MU) requirements to improve healthcare quality, safety, and efficiency.			
FY 2014 Accomplishments:			
• Completed development and test of VLER Health 2.1.0.0 in support of expanding the VLER Health Exchange			
FY 2015 Plans:			
• Included in DMIX Data Exchange Initial Release			
• Included in DMIX Data Exchange for DHMSM Integration testing			
• Begin collapse of the BHIE DoD Adaptor and VLER DoD Adaptor to a single DoD Adaptor			
• Begin upgrade of VLER DoD functionality limited to eHealth Exchange Gateway, GUI, C32/C62 generation			
FY 2016 Plans:			
No funding programmed for this initiative in this program element.			
Accomplishments/Planned Programs Subtotals	2.558	22.352	-

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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 0605023HP / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 449A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807784: <i>Integrated Electronic Health Record (iEHR)</i>	3.900	6.299	-	-	-	-	-	-	-	Continuing	Continuing
• BA-3, PE 0807784: <i>Replacement/ Modernization, Integrated Electronic Health Record</i>	-	0.938	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605025HP / <i>Theater Medical Information Program - Joint (TMIP-J)</i>
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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	0.000	23.783	22.042	22.100	-	22.100	22.140	22.180	22.619	23.071	Continuing	Continuing
445A: <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>	0.000	23.783	22.042	-	-	-	-	-	-	-	Continuing	Continuing
445B: <i>Operational Medicine Support</i>	0.000	-	-	22.100	-	22.100	22.140	22.180	22.619	23.071	Continuing	Continuing

MDAP/MAIS Code:
Other MDAP/MAIS Code(s): M07

A. Mission Description and Budget Item Justification

The Theater Medical Information Program - Joint (TMIP-J) integrates components of the Military Health System sustaining base systems and the Services medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of all Theater and deployed forces in support of any mission. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and forges the theater links of the longitudinal health record to the sustaining base and the Department of Veterans Affairs. TMIP-J is the medical component of the Global Combat Support System. TMIP-J provides information at the point of care and to the Theater tactical and strategic decision makers through efficient, reliable data capture, and data transmission to a centralized Theater database. This delivers TMIP-J's four pillars of information support through the electronic health record, integrated medical logistics, patient movement and tracking, and medical command and control through data aggregation, reporting and analysis tools for trend analysis and situational awareness. TMIP-J fulfills the premise of "Train as you fight" through the integration of components which are identical or analogous to systems from the sustaining base. TMIP-J adapts and integrates these systems to specific Theater requirements and assures their availability in the no- and low- communications settings of the deployed environment through store and forward capture and transmission technology.

Operational Medicine Support (OpMedSpt): Due to the unique nature of the operational environment, the Military Health System must modernize the following capabilities: medical command and control (MC2); medical situational awareness (MSA) (aggregation of operational medical data at a classified level, denying the enemy access to data which could reveal operational plans); Defense blood management; assemblage management; and data interoperability with the pending EHR solution and operational allies. The clinical needs of the operational community are to be met by the pending EHR solution, but there are functional needs, outside the capture of clinical data, to inform decision making regarding the ability of the MHS to meet the needs of the medically ready force, to support the joint warfighter and share data with line systems. It will support mission delivery and execution through the maximization of information technologies, driving standards compliance to ensure non-EHR capabilities will effectively consume the data created through the use of the pending EHR solution in the operational environment, and to allow the solution to share data with these other capabilities, eliminating the need for one to one interfaces, their limitations and cost. Along with the need to modernize those non-clinical capabilities, this enterprise's risk mitigation strategy also supports ongoing missions and clinical needs in the operational environment until sufficient testing of pending solutions can be accomplished in environments indicative of the operational environments, tactical, mobile and dismounted. TMIP-J (MSAT, TMDS, DCAM, TRAC2ES,

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605025HP / <i>Theater Medical Information Program - Joint (TMIP-J)</i>
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AHLTA-T, MCC (formerly AHLTA-Mobile), Single Sign On, MMM, SAMS, and TC2) is the “umbrella” system for these solutions and the functional capabilities they support and achieves Full Operational Capability (FOC) in FY15. While the modernization of the operational environment clinical solutions (AHLTA-T, MCC (AHLTA-Mobile) and TC2) is planned to take place under the auspices of the pending EHR solution, there is currently no such plan for the non-EHR capability modernization activities. The Operational Medicine project was created to ensure the MHS is able to meet the needs of the joint warfighter, line and higher level headquarters for MC2, MSA, Defense blood management and assemblage management.

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	35.463	22.042	22.100	-	22.100
Current President's Budget	23.783	22.042	22.100	-	22.100
Total Adjustments	-11.680	-	-	-	-
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-7.791	-			
• SBIR/STTR Transfer	-3.889	-			

Change Summary Explanation

FY 2014: Realignment from DHP RDT&E, PE 0605013-Information Technology Development (-\$35.463 million) to DHP RDT&E, PE 0605025-Theater Medical Information Program – Joint (TMIP-J) (+\$35.463 million) for Theater Medical Information Program – Joint (TMIP-J).

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605025-Theater Medical Information Program – Joint (TMIP-J) (-\$3.889 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$3.889 million).

FY 2014: OMNIBUS Prior Approval Reprogramming (FY 14-11 PA) from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605025-Theater Medical Information Program – Joint (TMIP-J) (-\$7.791 million) to DHP Procurement, PE 0807721/R&M CoPath Plus (+\$7.791 million).

FY 2016: No Change.

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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 0605025HP / Theater Medical Information Program - Joint (TMIP-J)				Project (Number/Name) 445A / Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)			
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
445A: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	-	23.783	22.042	-	-	-	-	-	-	-	Continuing	Continuing

MDAP/MAIS Code: M07

A. Mission Description and Budget Item Justification

The Theater Medical Information Program - Joint (TMIP-J) integrates components of the Military Health System sustaining base systems and the Services' medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of all Theater and deployed forces in support of any mission. TMIP-J enhances the clinical care and information capture at all levels of care in Theater, transmits critical information to the Theater Commander, the evacuation chain for combat and non-combat casualties, and forges the theater links of the longitudinal health record to the sustaining base and the Department of Veterans Affairs. TMIP-J is the medical component of the Global Combat Support System. TMIP-J provides information at the point of care and to the Theater tactical and strategic decision makers through efficient, reliable data capture, and data transmission to a centralized Theater database. This delivers TMIP-J's four pillars of information support through the electronic health record, integrated medical logistics, patient movement and tracking, and medical command and control through data aggregation, reporting and analysis tools for trend analysis and situational awareness. TMIP-J fulfills the premise of "Train as you fight" through the integration of components which are identical or analogous to systems from the sustaining base. TMIP-J adapts and integrates these systems to specific Theater requirements and assures their availability in the no- and low- communications settings of the deployed environment through store and forward capture and transmission technology.

TMIP-J RDT&E is reported under the program element 0605013 through FY 2013 inclusive, but will be reported under new program element 0605023 for FY 2014 and out.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	23.783	22.042	-
Description: Complete Increment 2 Release 2 (I2 R2) and Increment 2 Release 3 (I2 R3) development/integration and conduct operational testing/operational assessment.			
FY 2014 Accomplishments: Completed Increment 2 Release 2 (I2 R2) and Increment 2 Release 3 (I2 R3) development/integration and conduct operational testing/operational assessment.			
Completed testing and release to the Service Infrastructure Program Offices I2 R2 Service Packs that will include AHLTA-Theater first release of the Aeromedical Evacuation capability, TMIP Composite Health Care System Cache (TC2) updates.			

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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 0605025HP / Theater Medical Information Program - Joint (TMIP-J)	Project (Number/Name) 445A / Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Completed development and integration of I2 R3 that will include International Classification of Diseases (ICD-10) for TMIP-J, a modernization of the TMIP Framework, Mobile Computing Capability (MCC) and enhancements to the TC2 graphical user interface released in I2 R2. FY 2015 Plans: Completed system integration and testing for Increment 2 Release 3 (I2R3) and held a successful I2R3 Test Readiness Review in First Quarter of FY 2015. FY 2016 Plans: No funding programmed.			
Accomplishments/Planned Programs Subtotals	23.783	22.042	-

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807793HP: MHS Tri-Service Information	44.581	54.496	55.731	-	55.731	57.530	59.316	60.442	61.651	Continuing	Continuing
• BA-3, 0807721HP: Replacement/Modernization	4.838	-	-	-	-	-	-	-	-	Continuing	Continuing
• BA-3, 0807744HP: Theater Medical Information Program - Joint (TMIP-J)	-	3.145	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources. Performance metrics for specific projects may be viewed at the OMB Federal IT Dashboard website.

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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 0605025HP / Theater Medical Information Program - Joint (TMIP-J)				Project (Number/Name) 445B / Operational Medicine Support			
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
445B: Operational Medicine Support	-	-	-	22.100	-	22.100	22.140	22.180	22.619	23.071	Continuing	Continuing

A. Mission Description and Budget Item Justification

This initiative supports executive directives and legal mandates to ensure "...every Soldier, Sailor, Airman and Marine will have a comprehensive, life-long medical record..."(Source: Special report of the Presidential Advisory Committee on Gulf War Veterans' Illness, 1997) and "The Secretary of Defense shall establish a system to assess the medical condition of members of the Armed Forces...who are deployed" (Source: Title 10; Section 1074f (1997): Medical tracking system for members deployed overseas). It also supports the June 21, 2013 acquisition decision memorandum from the Undersecretary of Defense for Acquisition, Technology and Logistics to "...focus on the goal of acquiring a replacement for the DoD legacy Military Health System (MHS) clinical systems including but not limited to...the EHR component of the Theater Medical Information Program with the objective of fielding a modernized replacement by 2017."

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Operational Medicine Support	-	-	22.100
<p>Description: It will support mission delivery and execution through the maximization of information technologies, driving standards compliance to ensure non-EHR capabilities will effectively consume the data created through the use of the pending EHR solution in the operational environment, and to allow the solution to share data with these other capabilities, eliminating the need for one to one interfaces, their limitations and cost.</p> <p>Along with the need to modernize those non-clinical capabilities, this enterprise's risk mitigation strategy also supports ongoing missions and clinical needs in the operational environment until sufficient testing of pending solutions can be accomplished in environments indicative of the operational environments, tactical, mobile and dismounted. TMIP-J (MSAT, TMDS, DCAM, TRAC2ES, AHLTA-T, MCC (formerly AHLTA-Mobile), Single Sign On, MMM, SAMS, and TC2) is the "umbrella" system for these solutions and the functional capabilities they support and achieves Full Operational Capability (FOC) in FY15. While the modernization of the operational environment clinical solutions (AHLTA-T, MCC (AHLTA-Mobile) and TC2) is planned to take place under the auspices of the pending EHR solution, there is currently no such plan for the non-EHR capability modernization activities. The Operational Medicine project was created to ensure the MHS is able to meet the needs of the joint warfighter, line and higher level headquarters for MC2, MSA, Defense blood management and assemblage management.</p> <p>FY 2014 Accomplishments: Not applicable. This initiative was previously reported under TMIP-J funding profile but is being pulled out separately for the FY 2016 budget submission for transparency. Funding for this initiative begins in FY 2016.</p> <p>FY 2015 Plans:</p>			

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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 0605025HP / Theater Medical Information Program - Joint (TMIP-J)	Project (Number/Name) 445B / Operational Medicine Support

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Not applicable. This initiative was previously reported under TMIP-J funding profile but is being pulled out separately for the FY 2016 budget submission for transparency. Funding for this initiative begins in FY 2016. FY 2016 Plans: Modernize the following capabilities: medical command and control (MC2); medical situational awareness (MSA) (aggregation of operational medical data at a classified level, denying the enemy access to data which could reveal operational plans); Defense blood management; assemblage management; and data interoperability with the pending EHR solution and operational allies. While the clinical needs of the operational community are to be met by the future EHR solution, there are functional needs, outside the capture of clinical data, to inform decision making regarding the ability of the MHS to meet the needs of the medically ready force, to support the joint warfighter and share data with line systems.			
Accomplishments/Planned Programs Subtotals	-	-	22.100

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-3, 0807744HP: <i>Theater Medical Information Program - Joint (TMIP-J)</i>	-	-	1.494	-	1.494	2.413	2.689	2.850	2.907	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605026HP / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>
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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	0.000	-	91.394	438.376	-	438.376	260.501	-	-	-	Continuing	Continuing
483A: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>	0.000	-	91.394	438.376	-	438.376	260.501	-	-	-	Continuing	Continuing

MDAP/MAIS Code:
Other MDAP/MAIS Code(s): 496

A. Mission Description and Budget Item Justification

DHMSM will acquire and support deployment, and implementation of an electronic health record (EHR) system that replaces the DoD legacy MHS inpatient and outpatient EHR systems. Overarching goal of the program is to enable healthcare teams to deliver high-quality, safe care and preventive services to patients through the use of easily accessible standards-based computerized patient records resulting in: improved accuracy of diagnoses and medication; improved impact on health outcomes; increased patient participation in the healthcare process; improved patient-centered care coordination; and increased practice efficiencies in all settings, including operational environments.

iEHR RDT&E is reported under the program element (PE) 0605013 through FY 2013 inclusive, but iEHR, VLER Health and DHMSM will be reported under new program element 0605023 for FY 2014.

In FY 2015, PE 0605023 will report only iEHR and VLER Health since DHMSM will have its own PE starting in FY 2015.

In FY 2016 and out, only iEHR Increment 1 will be reported in PE 0605023. DHMSM will continue to be only initiative reported in PE 0605026.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605026HP / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>
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B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	-	91.394	499.209	-	499.209
Current President's Budget	-	91.394	438.376	-	438.376
Total Adjustments	-	-	-60.833	-	-60.833
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA	-	-	-60.833	-	-60.833

Change Summary Explanation

FY 2014: No Change.

FY 2015: No Change

FY 2016: Departmental Fiscal Guidance adjustment to DHP RDT&E, PE 0605026-Information Technology Development - DoD Healthcare Management System Modernization DHMSM) (-\$60.833 million).

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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 0605026HP / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>				Project (Number/Name) 483A / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>			
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
483A: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>	-	-	91.394	438.376	-	438.376	260.501	-	-	-	Continuing	Continuing

MDAP/MAIS Code: 496

A. Mission Description and Budget Item Justification

DHMSM will acquire and support deployment, and implementation of an electronic health record (EHR) system that replaces the DoD legacy MHS inpatient and outpatient EHR systems. Overarching goal of the program is to enable healthcare teams to deliver high-quality, safe care and preventive services to patients through the use of easily accessible standards-based computerized patient records resulting in: improved accuracy of diagnoses and medication; improved impact on health outcomes; increased patient participation in the healthcare process; improved patient-centered care coordination; and increased practice efficiencies in all settings, including operational environments.

DHMSM replaces DoD legacy healthcare systems with a commercial solution in use in other medical systems that is open, rendered as a modular architecture, using standards-based/non-proprietary interfaces. DHMSM will support the Department's goals of net centrality by providing a framework for full human and technical connectivity and interoperability that allows DoD users and mission partners to share the information they need, when they need it, in a form they can understand and act on with confidence, and protects information from those who should not have it. Once fielded, the EHR will support the following healthcare activities for DoD's 44,000 practitioners and 9.5 million beneficiaries.

1. Clinical workflow and provider clinical decision support;
2. Capture, maintain, use, protect, preserve and share health data and information;
3. Retrieval and presentation of health data and information that is meaningful for EHR users regardless of where the patient's records are physically maintained; and
4. Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

iEHR RDT&E is reported under the program element (PE) 0605013 through FY 2013 inclusive, but iEHR, VLER Health and DHMSM will be reported under new program element 0605023 for FY 2014.

In FY 2015, PE 0605023 will report only iEHR and VLER Health since DHMSM will have its own PE starting in FY 2015.

In FY 2016 and out, only iEHR Increment 1 will be reported in PE 0605023. DHMSM will continue to be only initiative reported in PE 0605026.

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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 0605026HP / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>	Project (Number/Name) 483A / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>Title: DoD Healthcare Mgmt System Modernization (DHMSM) Program</p> <p>Description: DHMSM will be executed to deliver uniform information management options across both garrison and theater environments. DHMSM will focus on replacement of inpatient and outpatient systems, and will encompass deployment of the enterprise EHR to fixed facilities as well as expeditionary components.</p> <p>FY 2014 Accomplishments: No funding programmed in this program element in this fiscal year.</p> <p>FY 2015 Plans:</p> <ul style="list-style-type: none"> • Update Acquisition Documentation (Acquisition Strategy, Business Case, Engineering Master Plan, Cost and Benefit Analysis, Test Strategy, and Deployment and Supportability Plan) to support Authority to Proceed for contract award. • Inauguration of Government Approved Laboratories for Fixed Facility and Operational testing of the DHMSM EHR. • Conduct Source Selection Process. • Achieve Authority to Proceed (ATP) for contract awards. • Contract Award activities. • Configuration and Integration of solution in test environment. • Independent Verification and Validation (IV&V). • Initiate inclusive of contracts integration testing, development, testing, and operation testing. <p>FY 2016 Plans:</p> <ul style="list-style-type: none"> • Initial Design Review/Final Requirements Review. • Formal (or Final) Design Review/Test Readiness Review. • System Verification Review/Operational Test Readiness Review. • Configuration & Integration Test. • Developmental Test & Evaluation. • Training for Subject Matter Experts. • Limited Fielding Training. • Installed at Initial Operational Capability Sites. • Continue Configuration and Integration of solution in testing environment. • Continue Independent Verification and Validation (IV&V). 	-	91.394	438.376
Accomplishments/Planned Programs Subtotals	-	91.394	438.376

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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 0605026HP / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>	Project (Number/Name) 483A / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u> <u>Base</u>	<u>FY 2016</u> <u>OCO</u>	<u>FY 2016</u> <u>Total</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807787: <i>DoD Healthcare Management Systems</i>	-	57.554	89.188	-	89.188	134.427	225.825	301.427	380.402	Continuing	Continuing
• BA-3, PE 0807787: <i>Information Technology Development and Sustainment - DoD Healthcare Management System Modernization</i>	-	-	-	-	-	181.458	663.956	684.084	699.014	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

E. Performance Metrics

Each program establishes performance measurements which are usually included in the MHS IT Annual Performance Plan. Program cost, schedule and performance are measured periodically using a systematic approach. The results of these measurements are presented to management on a regular basis in various as part of the Integrated Product and Process Development (IPPD) process, In Process Reviews (IPRs), or other reviews to determine program effectiveness and provide new direction as needed to ensure the efficient use of resources are also used.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605039HP / PE 0605039HP / <i>DoD Medical Information Exchange and Interoperability</i>
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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	0.000	-	-	11.000	-	11.000	-	-	-	-	Continuing	Continuing
458A: <i>DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)</i>	0.000	-	-	11.000	-	11.000	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

In March 2008, the MHS embarked upon Electronic Health Record (EHR) modernization planning, establishing the initial Electronic Health Records Way Ahead (EHRWA).

In March 2011, the Program was expanded to include the VA in a joint initiative to implement a new, integrated electronic health record for both Departments, called the Integrated Electronic Health Record (iEHR) program.

Secretary Hagel’s Memorandum titled “Integrated Electronic Health Records,” dated May 2013, provided additional direction to the program:

- DoD shall continue near-term coordinated efforts with VA to develop data federation, presentation, and interoperability. This near-term goal shall be pursued as a first priority separately from the longer-term goal of health record information technology (IT) modernization.
- DoD shall pursue a full and open competition for a core set of capabilities for EHR modernization.

To fulfill Secretary Hagel’s directive, parallel programs have been defined, splitting the original iEHR program into two distinct areas. In the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) Acquisition Decision Memoranda (ADM), dated June 21, 2013 and January 2, 2014, the former joint DoD and VA Integrated Electronic Health Record (iEHR) program was restructured to pursue two separate but related healthcare information technology efforts, the DoD Healthcare Management System Modernization (DHMSM) program and a newly defined iEHR focused on providing seamless integrated sharing of electronic health data between the DoD and VA to be called Defense Medical Information Exchange (DMIX). The remaining iEHR Increment 1 (iEHR Inc 1) was significantly de-scoped to only the Medical Single Sign-on/Context management (MSSO/CM) implemented at James A. Lovell Federal Health Care Center (JAL FHCC).

iEHR RDT&E is reported under the program element (PE) 0605013 through FY 2013 inclusive, but iEHR, VLER Health and DHMSM will be reported under new program element 0605023 for FY 2014.

In FY 2015, PE 0605023 will report only iEHR and VLER Health since DHMSM will have its own PE starting in FY 2015.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605039HP / PE 0605039HP / DoD Medical Information Exchange and Interoperability
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In FY 2016 and out, only iEHR Increment 1 will be reported in PE 0605023. DHMSM will continue to be only initiative reported in PE 0605026. However, new PE 06050039 is established for DMIX for FY 2016 and out. DMIX will incorporate the previous VLER Health and JEHRI initiatives.

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	-	-	-	-	-
Current President's Budget	-	-	11.000	-	11.000
Total Adjustments	-	-	11.000	-	11.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• DoD Medical Information Exchange and Interoperability (DMIX) Realignment	-	-	11.000	-	11.000

Change Summary Explanation

FY 2016: Realignment to DHP RDT&E, PE 0605039-Information Technology Development - DoD Medical Information Exchange and Interoperability (DMIX) (+ \$11.000 million).

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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 0605039HP / PE 0605039HP / DoD Medical Information Exchange and Interoperability				Project (Number/Name) 458A / DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)			
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
458A: DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)	-	-	-	11.000	-	11.000	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

DMIX program will acquire the capabilities necessary to securely and reliably exchange standardized, normalized, and correlated health data with all partners through standard data/information exchange mechanisms. This allows users in different places and different organizations to access, use, and supplement health data (technical interoperability) that has a shared meaning so users (assisted by computers) are able to make care decisions (Semantic Interoperability – Level 4). DMIX manages the data exchange capability from legacy data stores in order to prepare for the transition to the modernized Electronic Health Record platform being acquired by DoD Healthcare Management System Modernization (DHMSM). DMIX consists of a family of capability initiatives supporting the seamless exchange of standardized health data among DoD, VA, other Federal agencies, and private providers as well as benefits administrators. The DMIX program provides the capability for health care providers to access and view complete and accurate patient health records from a variety of data sources thereby allowing healthcare providers to make faster and higher quality care decisions. DMIX was established in accordance with the joint memo from USD(C) and USD(AT&L) titled "Joint Memorandum on Major Defense Acquisition Program and Major Automated Information System Program Resource Transparency in Department of Defense Budget Systems" dated June 27, 2013.

In addition, Joint Electronic Health Record Interoperability (JEHRI) and Virtual Lifetime Electronic Record (VLER) Health (to include Exchange (Query and retrieve "Pull" methodology), and Direct (Point to Point "Push") transport mechanisms), are part of the DMIX program as a direct result of the Acquisition Decision Memorandum (ADM) signed January 2, 2014 by the Under Secretary of Defense for Acquisition, Technology and Logistic (USD AT&L). Use of the health data may be done via legacy systems, clinical mobile applications and system agnostic viewers such as the Joint Legacy Viewer (JLV). Customers include the MHS, VA, other federal agencies and over 200,000 medical care practitioners.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Defense Medical Information Exchange (DMIX) Program	-	-	11.000
Description: Comprised of the infrastructure and services needed to provide seamless integrated sharing of electronic health data between the DoD, VA, other Federal agencies, and private sector partners that is viewable to DoD and VA providers through a joint viewer.			
FY 2014 Accomplishments: No programmed funding under this initiative.			
FY 2015 Plans:			

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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 0605039HP / PE 0605039HP / DoD Medical Information Exchange and Interoperability	Project (Number/Name) 458A / DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
No programmed funding under this initiative.			
FY 2016 Plans: DMIX: <ul style="list-style-type: none"> • DMIX Data Exchange Initial Release • DMIX Data Exchange for DHMSM Integration testing • Collapse multiple viewers into a single agnostic viewer for displaying integrated data • Collapse multiple data sharing services (adaptors) into a single data sharing service/capability for the exchange of healthcare data within DoD, with VA and other Federal Agencies, and with private health information exchange partners. • Sunset VLER Health and Joint Electronic Health Record Interoperability (JEHRI) legacy data sharing capabilities and transitions all data sharing exchange to the “new” DMIX Data Exchange Service. • DMIX will sustain existing health data domains, and continue to monitor updated data standards for implementation. Also as national standards evolve for additional data domains, update health data domains to ensure data exchange is standards based. • Collapse of the BHIE DoD Adaptor and VLER DoD Adaptor to a single DoD Adaptor • Upgrade of VLER DoD functionality limited to eHealth Exchange Gateway, GUI, C32/C62 generation • Sunset VLER Health to the “new” DMIX Data Exchange Service. 			
Accomplishments/Planned Programs Subtotals	-	-	11.000

C. Other Program Funding Summary (\$ in Millions)											
Line Item	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
• BA-1, 0807788HP: DoD Medical Information Exchange and Interoperability	-	-	59.743	-	59.743	57.894	51.423	47.376	48.242	Continuing	Continuing

Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting program objectives. Strategy is revised as required as a result of periodic program reviews or major decisions.

DMIX is a collaborative effort between the DoD and VA to share Health Care Resources to improve access to, and quality and cost effectiveness of, health care as mandated by law. This investment is deeply embedded in the MHS Enterprise Roadmap as both Departments have need for modernization/ replacement of existing legacy systems. This investment will use a combination of an open architecture approach, and the purchase (in some instances) of GOTS and COTS products.

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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 0605039HP / PE 0605039HP / DoD Medical Information Exchange and Interoperability	Project (Number/Name) 458A / DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)

E. Performance Metrics

Program cost, schedule and performance are measured periodically using a systematic approach as required for Major Automated Information Systems (MAIS) per DoD Directives and Instructions.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0605145HP / <i>Medical Products and Support Systems Development</i>							
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: <i>GDF-Medical Products and Support System Development</i>	23.780	9.262	12.694	15.051	-	15.051	19.239	20.905	21.319	21.750	Continuing	Continuing
399A: <i>Hyperbaric Oxygen Therapy Clinical Trial (Army)</i>	18.533	5.153	1.805	0.855	-	0.855	0.855	0.900	0.917	0.935	Continuing	Continuing
500A: <i>CSI - Congressional Special Interests</i>	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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605145HP / <i>Medical Products and Support Systems Development</i>
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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)

Project: 500A: *CSI - Congressional Special Interests*

Congressional Add: 465A – *Program Increase: Restore Core Research Funding Reduction (GDF)*

Congressional Add: 475A – *Program Increase: Restore Core Research Funding Reduction (Army)*

Congressional Add Subtotals for Project: 500A

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	-	5.000
	-	7.150
	-	12.150
	-	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).

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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 / <i>Medical Products and Support Systems Development</i>				Project (Number/Name) 375A / <i>GDF-Medical Products and Support System Development</i>			
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: <i>GDF-Medical Products and Support System Development</i>	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
<p>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.</p> <p>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.</p> <p>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).</p> <p>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.</p>			

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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 / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 375A / <i>GDF-Medical Products and Support System Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>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.</p> <p>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.</p> <p>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.</p>			
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.

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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)
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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:			

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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 / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 399A / <i>Hyperbaric Oxygen Therapy Clinical Trial (Army)</i>

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.

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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 / <i>Medical Products and Support Systems Development</i>				Project (Number/Name) 500A / <i>CSI - Congressional Special Interests</i>			
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: <i>CSI - Congressional Special Interests</i>	-	-	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)	-	5.000
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.		
Congressional Add: 475A – Program Increase: Restore Core Research Funding Reduction (Army)	-	7.150
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.		
Congressional Adds Subtotals	-	12.150

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

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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 / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 500A / <i>CSI - Congressional Special Interests</i>

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0605502HP / <i>Small Business Innovation Research (SBIR) Program</i>							
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	63.347	47.882	-	-	-	-	-	-	-	-	Continuing	Continuing
470A: <i>Small Business Innovation Research (SBIR) (Army)</i>	63.347	47.882	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Small Business Innovation Research (SBIR) program was established in the Defense Health Program (DHP), Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2001, and is funded in the year of execution. The objective of the DHP SBIR Program includes stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The program funds small business proposals chosen to enhance military medical research and information technology research.

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	-	-	-	-	-
Current President's Budget	47.882	-	-	-	-
Total Adjustments	47.882	-	-	-	-
• Congressional General Reductions	-	-	-	-	-
• Congressional Directed Reductions	-	-	-	-	-
• Congressional Rescissions	-	-	-	-	-
• Congressional Adds	-	-	-	-	-
• Congressional Directed Transfers	-	-	-	-	-
• Reprogrammings	-	-	-	-	-
• SBIR/STTR Transfer	47.882	-	-	-	-

Change Summary Explanation

FY 2014: Realignment to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+\$19.205 million) from the following DHP PEs:
 DHP RDT&E, PE 0601101-In-House Laboratory Independent Research (-\$0.194 million);
 DHP RDT&E, PE 0601117-Basic Operational Medical Research Sciences (-\$0.269 million);
 DHP RDT&E, PE 0602115-Applied Biomedical Technology (-\$1.793 million);
 DHP RDT&E, PE 0602787-Medical Technology (AFRRI) (-\$0.077 million);
 DHP RDT&E, PE 0603002-Advanced Technology (AFRRI) (-\$0.020 million);
 DHP RDT&E, PE 0603115-Medical Technology Development (-\$17.961 million);
 DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$11.165 million);
 DHP RDT&E, PE 0605013-Information Technology Development (-\$2.164 million);
 DHP RDT&E, PE 0605023-Integrated Electronic Record (iEHR) (-\$0.574 million);

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program Date: February 2015

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: Defense Health Program I BA 2: RDT&E	PE 0605502HP I Small Business Innovation Research (SBIR) Program

DHP RDT&E, PE 0605025-Theater Medical Information Program - Joint (TMIP-J) (-\$3.889 million);
DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-\$4.561 million);
DHP RDT&E, PE 0606105-Medical Program-Wide Activities (-\$4.291 million);
DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.924 million).

FY 2015: No Change.

FY 2016: No Change.

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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 0605502HP / <i>Small Business Innovation Research (SBIR) Program</i>				Project (Number/Name) 470A / <i>Small Business Innovation Research (SBIR) (Army)</i>			
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
470A: <i>Small Business Innovation Research (SBIR) (Army)</i>	63.347	47.882	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Small Business Innovation Research (SBIR): The SBIR program was established in the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2001, and is funded in the year of execution. The program funds small business proposals chosen to enhance military medical research and information technology research.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: Small Business Innovation Research (SBIR) Program	47.882	-	-
Description: The program funds small business proposals chosen to enhance military medical research and information technology research. The following reflects the FY14 research area topics sought for proposals.			
FY 2014 Accomplishments:			
For FY14 (DHP SBIR 15.1), sixteen topics were developed for solicitation of biomedical technology SBIR proposals. Funding for each topic was based on the merits of responses to solicitations. Topics include:			
(1) a simulation-based system to provide psychomotor (cognitive functions causing physical movement) skills training to advanced health care providers in the performance of a Lateral Canthotomy and Cantholysis (LCC) procedure (a surgical technique at corner of the eyes where upper and lower eyelids meet);			
(2) develop and demonstrate video overlay capability of virtual augmented reality technology, also known as VIPAAR, on a mobile Android Smart device (also known as an End User Device (EUD)) over a military tactical network;			
(3) demonstrate a prototype medical concierge application that will improve patient, employee, and visitor engagement with Military Health System Military Treatment Facilities (MTFs);			
(4) develop a toolset for analyzing the security properties of interconnected medical devices in an Integrated Clinical Environment (ICE) architecture;			
(5) develop new controls for securing in an integrated clinical environment from malicious threats, which minimizes impacts on clinical workflows and usability, and promotes patient safety using a model-based approach;			
(6) develop a sensitive, specific, rapid, portable, field friendly assay to determine whether a tick or pool of ticks is infected with the <i>Borrelia burgdorferi</i> bacterium, the causative agent for Lyme disease;			
(7) develop a small molecule to target at least one of the, but preferably multiple, multidrug-resistant bacteria that pose the greatest threat to military populations, specifically methicillin-resistant <i>Staphylococcus aureus</i> (MRSA), <i>Acinetobacter baumannii</i> , <i>Enterobacter</i> species (<i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i>), and <i>Pseudomonas aeruginosa</i> ;			
(8) demonstrate a prototype system that will successfully predict the incidence of human infectious disease;			

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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 0605502HP / <i>Small Business Innovation Research (SBIR) Program</i>	Project (Number/Name) 470A / <i>Small Business Innovation Research (SBIR) (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>(9) develop a non-invasive, wearable passive dosimeter that can be stored indefinitely until analysis is required;</p> <p>(10) develop and demonstrate new techniques to separate/enrich oxygen from air using minimal power to provide supplemental oxygen for injured soldiers under field conditions;</p> <p>(11) demonstrate that a kinetic pathway model of blood platelet physiology and biochemistry can be used to simulate the deleterious effects of storage upon isolated platelets within 5-7 days, and to develop a prototype program or a commercially viable software product for improved blood product storage;</p> <p>(12) develop a biosensor technology capable of measuring specific analytes in blood, continuously, in real-time;</p> <p>(13) develop novel cryoprotectants (a substance that prevents damage to cells during freezing), cryotherapeutics (therapy using cold), and cryopreservation (process where cells susceptible to damage caused by chemical reactivity or time are preserved by cooling to sub-zero temperatures) protocols that will permit clinically effective banking of large complex vascularized composite tissues such as vital organs and limbs;</p> <p>(14) develop a capability to solve one of the remaining barriers towards true banking of organs and vascularized composite tissues – optimal rewarming methods of large cryopreserved tissues;</p> <p>(15) develop objective measurement tool for the detection of noise-induced hearing loss and a smart algorithm for monitoring; and</p> <p>(16) develop a novel intraocular visualization tool to improve surgical outcomes following complex ocular trauma.</p> <p>FY 2015 Plans: No funding programmed. The DHP SBIR program is funded in the year of execution.</p> <p>FY 2016 Plans: No funding programmed. The DHP SBIR program is funded in the year of execution.</p>			
Accomplishments/Planned Programs Subtotals	47.882	-	-

C. Other Program Funding Summary (\$ in Millions)
N/A

Remarks

D. Acquisition Strategy
Test and evaluate commercially developed prototypes funded by the SBIR program to ensure military and regulatory requirements are met prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.

E. Performance Metrics
The number of Phase I awards supporting innovative technology development. The number of Phase II and III awards leading to technology transition.

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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 0606105HP / *Medical Program-Wide Activities*

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	87.087	68.277	44.042	41.567	-	41.567	25.156	23.731	24.182	24.665	Continuing	Continuing
305T: <i>USAMRIID IO&T (Army)</i>	29.063	37.513	8.029	20.027	-	20.027	3.245	-	-	-	Continuing	Continuing
368A: <i>Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)</i>	10.987	7.882	4.748	-	-	-	-	-	-	-	Continuing	Continuing
397T: <i>USAMRICD IO&T (Army)</i>	22.795	8.236	5.003	0.103	-	0.103	-	-	-	-	Continuing	Continuing
401A: <i>CONUS Laboratory Support Clinical Infrastructure (Army)</i>	11.966	2.811	4.886	4.975	-	4.975	5.064	5.155	5.253	5.358	Continuing	Continuing
432A: <i>OCONUS Laboratory Infrastructure Support (Army)</i>	9.298	7.572	11.823	12.487	-	12.487	12.699	13.608	13.867	14.144	Continuing	Continuing
433A: <i>NMRC Biological Defense Research Directorate (BDRD) (Navy)</i>	2.978	4.077	3.586	3.975	-	3.975	4.148	4.968	5.062	5.163	Continuing	Continuing
442A: <i>USARIEM Pike's Peak IO&T (Army)</i>	0.000	0.186	-	-	-	-	-	-	-	-	Continuing	Continuing
600A: <i>CSI - Congressional Special Interests</i>	0.000	-	5.967	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Army Medical Command receives funding for research infrastructure management support at select continental United States (CONUS) and outside the continental US (OCONUS) laboratories and clinical trial sites; work is done in collaboration with DoD Military Treatment Facilities (MTFs). This funding does not fund research. It funds the infrastructure support enabling research scientists at these laboratories to conduct bio-surveillance and early-to-late-stage clinical investigations into biologics, drugs, protectants, device technologies, and knowledge products. Areas of research interest include the treatment/prevention/diagnosis of polytrauma (multiple traumatic injuries), infectious diseases, psychological health, traumatic brain injury, and military training injuries. The funding provides for the sustainment of technical subject matter expertise, independent of the number of assigned projects, and the costs related to the initial outfitting and transition (IO&T) of research, development, test and evaluation (RDT&E) medical laboratories funded under multi-year military construction (MILCON) projects. These IO&T funds are designated as appropriations other than MILCON.

The Office of the Assistant Secretary of Defense for Health Affairs (Force Health Protection & Readiness) receives funds to provide management support for research projects at Pacific Joint Information Technology Center (P-JITC).

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0606105HP / <i>Medical Program-Wide Activities</i>
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For the Navy Bureau of Medicine and Surgery, this program element includes facility operational funding for the Medical Biological Defense research sub-function of the Naval Medical Research Center (NMRC) Biological Defense Research Directorate (BDRD). The program mission is mandated by the Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND) baseline capabilities assessment of chemical and biological passive defense. The primary function is research on countermeasures to biological threat agents, development of assays to detect biological threat agents, and bioforensic analysis of biological threat agents.

B. Program Change Summary (\$ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	72.568	38.075	44.043	-	44.043
Current President's Budget	68.277	44.042	41.567	-	41.567
Total Adjustments	-4.291	5.967	-2.476	-	-2.476
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	5.967			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-4.291	-			
• Program Enhancement - Project 305T	-	-	2.698	-	2.698
• Realignment - Project 305T	-	-	-5.174	-	-5.174

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 600A: *CSI - Congressional Special Interests*

Congressional Add: 476A – *Program Increase: Restore Core Research Funding Reduction (Army)*

Congressional Add: 476B – *Program Increase: Restore Core Research Funding Reduction (Army)*

Congressional Add: 476C – *Program Increase: Restore Core Research Funding Reduction (Navy)*

Congressional Add Subtotals for Project: 600A

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	-	3.757
	-	1.314
	-	0.896
Congressional Add Subtotals for Project: 600A	-	5.967
Congressional Add Totals for all Projects	-	5.967

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0606105-Medical Program-Wide Activities (-\$4.291 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$4.291 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+\$5.967 million).

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0606105HP / <i>Medical Program-Wide Activities</i>
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FY 2016: Transfer between DHP Budget Activities of the Pacific-Based Joint Information Technology Center-Maui (JITC-Maui) (-\$5.174 million).

FY 2016: Realignment adjustment to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+\$2.698 million).

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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 0606105HP / Medical Program-Wide Activities	Project (Number/Name) 305T / USAMRIID IO&T (Army)
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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
305T: USAMRIID IO&T (Army)	29.063	37.513	8.029	20.027	-	20.027	3.245	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) costs associated with military construction (MILCON) for the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
<p>Title: USAMRIID IO&T (Army)</p> <p>Description: US Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland, initial outfitting and transition (IO&T) costs associated with military construction.</p> <p>FY 2014 Accomplishments: The FY14 USAMRIID IO&T (Initial Outfitting and Transition) program reflected the phase requirements based on construction progress. Construction of the building, however, has been delayed due to a fire that caused extensive damage to the new BSL4 laboratory. IO requirement execution was impacted and will shift the procurement of equipment towards the next fiscal year. FY14 transition costs were the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds provided for personnel, travel, planning and acquisition support, movement support for materiel from the old to new or intermediate facility sites, old site equipment turn-in support, post-move old site cleaning support, phased dual occupancy costs of old and new sites, commissioning and transition support, and decommissioning planning and management support.</p> <p>FY 2015 Plans: The FY15 USAMRIID IO&T program reflects the phased requirements based on construction progress as the building is turned over in two Beneficial Occupancy Date (BOD) phases. IO equipment to be purchased for FY15 is from fiscal year equipment listings based on delivery lead time, building placement, installation, and bona-fide need criteria. FY15 transition costs are the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds are to provide for personnel, travel, planning and acquisition support, any remaining movement support for materiel from the old to new or intermediate facility sites, and increased phased dual occupancy costs.</p> <p>FY 2016 Plans: The FY16 USAMRIID IO&T program reflects the phased requirements based on construction progress as the building reaches Phase 1 BOD for safety and Center for Disease Control certifications. Remaining IO equipment will be purchased from equipment listings based on delivery lead time, building placement, installation, and bona-fide need criteria. FY16 transition costs will be the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds will be used to provide for personnel, travel, planning and acquisition support, any remaining movement support for materiel from the old to new or</p>	37.513	8.029	20.027

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 305T / <i>USAMRIID IO&T (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
intermediate facility sites, increased phased dual occupancy costs of old and new sites, hazardous material movement, medical cleaning, etc.			
Accomplishments/Planned Programs Subtotals	37.513	8.029	20.027

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.

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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 0606105HP / Medical Program-Wide Activities	Project (Number/Name) 368A / Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)
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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
368A: Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)	10.987	7.882	4.748	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification
 Pacific Joint Information Technology Center (Pacific JITC) (DHA HIT Directorate) was established to rapidly research, test and develop Warfighter medical solutions and products, through pilot projects or prototypes that provide mission critical value and actionable information to the DoD, including Services, combatant commanders, and the Department of Veterans Affairs.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>Title: Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)</p> <p>Description: Management support for research projects at Pacific Joint Information Technology Center (JITC).</p> <p>FY 2014 Accomplishments: The Pacific JITC managers work with the functional end users and Defense Health Agency sponsors to map proposals and initiatives critical to the Warfighter, address Joint Service capability gaps, and Department requirements.</p> <p>FY 2015 Plans: Pacific JITC will maintain, utilize, and promote use of the Pacific JITC Integrated Test and Evaluation Center (ITEC) (IV & V) by government entities including the testing and integration of Department Warfighter projects within the SCIF laboratory. The Pacific JITC will continue to work with functional end users and Defense Health Agency sponsors to map proposals and initiatives critical to the Warfighter, address Joint Service capability gaps, and Department requirements.</p> <p>Future funding for operations and support will be Operations & Maintenance as a result of re-organization within Defense Health Agency.</p> <p>FY 2016 Plans: No funding programmed.</p>	7.882	4.748	-
Accomplishments/Planned Programs Subtotals	7.882	4.748	-

C. Other Program Funding Summary (\$ in Millions)
 N/A

Remarks

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 368A / <i>Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)</i>

D. Acquisition Strategy

N/A

E. Performance Metrics

Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.

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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 0606105HP / <i>Medical Program-Wide Activities</i>				Project (Number/Name) 397T / <i>USAMRICD IO&T (Army)</i>			
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
397T: <i>USAMRICD IO&T (Army)</i>	22.795	8.236	5.003	0.103	-	0.103	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the IO&T costs associated with MILCON for the US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, MD.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: USAMRICD IO&T (Army)	8.236	5.003	0.103
Description: The US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, Maryland, initial outfitting and transition costs associated with military construction.			
FY 2014 Accomplishments: The FY14 USAMRICD IO&T program reflects the phased requirements based on construction progress as the building nears completion. Any remaining IO equipment was purchased for FY14 was from fiscal year equipment listings based on delivery lead time, building placement, installation, and bona-fide need criteria. FY14 transition costs were incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds provided for personnel, planning and acquisition support, movement support for materiel from the old to new or intermediate facility sites, old site equipment turn-in support, medical cleaning of old site, relocation of laboratory chemical agents, decommissioning support to include chemical and radiological survey and decontamination, phased dual occupancy costs of old and new sites, commissioning and transition support.			
FY 2015 Plans: The FY15 USAMRICD IO&T program reflects the phased requirements based on construction progress as the building nears completion. FY15 transition costs are the incremental fiscal year requirements for operations that support this multi-year MILCON project. Funds provide for personnel, relocation of laboratory chemical agents, continued decommissioning support for chemical and radiological decontamination, phased dual occupancy costs of old and new sites, and any remaining commissioning and transition support.			
FY 2016 Plans: For FY16 the USAMRICD IO&T program reflects the final phased requirements based on construction progress as the building completes. FY16 transition costs reflect the incremental requirements for operations that will support this multi-year MILCON project. Funds will be used to provide for the phased dual occupancy costs of old and new sites, and any remaining commissioning and transition costs.			
Accomplishments/Planned Programs Subtotals	8.236	5.003	0.103

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 397T / <i>USAMRICD IO&T (Army)</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.		

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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 0606105HP / Medical Program-Wide Activities				Project (Number/Name) 401A / CONUS Laboratory Support Clinical Infrastructure (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
401A: CONUS Laboratory Support Clinical Infrastructure (Army)	11.966	2.811	4.886	4.975	-	4.975	5.064	5.155	5.253	5.358	Continuing	Continuing

A. Mission Description and Budget Item Justification

CONUS Laboratory Infrastructure Support funding provides infrastructure and management support for selected laboratories and research sites, enabling basic to late-stage clinical investigations on medical products through collaborative efforts with the Military Health System's (MHS) Military Treatment Facilities (MTFs). MTFs provide access to the patient populations who will benefit the most from the medical products and capabilities being developed. The funds support the retention of technical subject matter expertise, independent of the number of assigned projects. The infrastructure funds also support Institutional Review Board and Institutional Animal Care and Use Committee functions, research technical support, statistical support, grant writing assistance, and other essential functions for maintaining research in MTFs. The funds do not support research, but provide the infrastructure support enabling MTF investigators to compete for RDT&E research funds.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: CONUS Laboratory Support Clinical Infrastructure (Army)	2.811	4.886	4.975
Description: Management support for research infrastructure at select laboratories and research sites that conduct basic to late-stage clinical research and evaluation of investigational products, such as biologics, drugs, and devices to treat/prevent polytrauma (multiple traumatic injuries), through collaborative efforts with the MHS MTFs.			
FY 2014 Accomplishments: In FY14, provided infrastructure support for Air Force, Army, and Navy MTFs, the Uniformed Services University of the Health Sciences, the Defense Health Agency National Capital Region Medical Directorate, and the National Intrepid Center of Excellence. These facilities competed for FY14 RDT&E funding based on their clinical research capabilities and applicable patient population. The MTFs in this program submitted 22 research applications in response to a Program Announcement entitled: Clinical Research Initiative Intramural Research Award-Military Training Injuries. It is anticipated that a minimum of four (4) of these applications will be funded. Infrastructure research personnel that were hired to support clinical trials include Clinical Research Coordinators, FDA Regulatory Experts, Human Research Subject Protection Experts, Animal Research Coordinators, and Surgical Vet Technologists. Staff duties include: protocol writing, submitting input from Central Institutional Review Board Network, recruitment/enrollment of human research/subjects volunteers, obtaining/preparing clinical specimens for analysis, data analysis, and preparation of manuscripts for scientific journals.			
FY 2015 Plans: Initiate the projects funded under the Program Announcement entitled: Clinical Research Initiative Intramural Research Award-Military Training Injuries. RDT&E Continue the infrastructure support for DoD facility-based RDT&E research across the three			

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 401A / <i>CONUS Laboratory Support Clinical Infrastructure (Army)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015	FY 2016
<p>Services, the Uniformed Services University of Health Sciences, and the Defense Health Agency National Capital Region Medical Directorate. Continue to monitor the program for successful implementation. Release a RDT&E Program Announcement to fund additional research projects at these facilities.</p> <p>FY 2016 Plans: Continue to support Military Treatment Facility research infrastructure and offer Clinical Research Award Program Announcements. Expand clinical research infrastructure support and improve monitoring by increasing the specificity of the metrics that are collected. Improvements will include a requirement for each facility to submit a budget request with detailed justification, and a statement of work when requesting infrastructure funds. Initiate use of the Electronic Data Management System to facilitate data collection, communication, record keeping and tracking of performance metrics and funding.</p>				
Accomplishments/Planned Programs Subtotals		2.811	4.886	4.975
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				
E. Performance Metrics				
Metrics include completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing. Successful establishment of a sufficient infrastructure will result in close coordination and cooperation between the RDT&E community, Clinical Investigation Program, Military Treatment Facilities, and Defense Centers of Excellence communities with the initiation of new collaborative clinical studies and trials.				

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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 0606105HP / Medical Program-Wide Activities				Project (Number/Name) 432A / OCONUS Laboratory Infrastructure Support (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
432A: OCONUS Laboratory Infrastructure Support (Army)	9.298	7.572	11.823	12.487	-	12.487	12.699	13.608	13.867	14.144	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Outside of the Continental United States (OCONUS) Laboratory Infrastructure Support provides management support for research infrastructure at selected overseas laboratories and research sites that conduct biosurveillance and basic to late-stage clinical research and evaluation of investigational products, such as biologics, drugs, protectants, technologies, and knowledge products to treat/prevent infectious diseases for the purpose of protecting the Warfighter; this is accomplished through collaborative efforts with the respective host nation governments. These sites are the US Army Medical Research Unit-Kenya (USAMRU-K) in Nairobi, Kenya, the US Army Medical Research Unit-Georgia (USAMRU-G) in Tbilisi, Georgia, and the US Army Medical Component-Armed Forces Research Institute of Medical Sciences (USAMC-AFRIMS) in Bangkok, Thailand. USAMRU-G is the newest laboratory, and is being established to provide support in the Caucasus region, similar to that provided by the laboratories in Kenya and Thailand to East Africa and Southeast Asia regions.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: OCONUS Laboratory Infrastructure Support (Army)	7.572	11.823	12.487
Description: Management support for research infrastructure at selected overseas laboratories and research sites is integral to support the development and testing of improved means of predicting, detecting, preventing, and treating infectious disease threats to the US military, as well as support for surveillance, training, research, and response activities for emerging infectious disease threats that could affect Service Members in those regions.			
FY 2014 Accomplishments: Funding was applied to existing OCONUS infrastructure requirements at the Armed Forces Research Institute of Medical Sciences (AFRIMS) in Thailand, the US Army Research Unit-Kenya (USAMRU-K), and the US Army Medical Research Unit-Georgia (USAMRU-G) laboratories. Infrastructure sustainment costs consisted of the administrative functions and infrastructure support at the three laboratory sites, which support medical research and development of products such as biologics, drugs, protectants, technologies, and knowledge products to treat/prevent military-relevant endemic diseases. At USAMRU-G, funding was used to establish a new laboratory platform at the direction of the Deputy Secretary of Defense (DEPSECDEF).			
FY 2015 Plans: Infrastructure funding costs for AFRIMS and USAMRU-K laboratory support consists of administration and infrastructure support, which supports medical research and development of products such as biologics, drugs, and protectants, technologies, and knowledge products to treat/prevent military-relevant endemic diseases. Infrastructure funding for the Republic of Georgia laboratory further facilitates the establishment of this unit, as directed by the DEPSECDEF. The Concept Plan (CONPLAN) and			

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 432A / <i>OCONUS Laboratory Infrastructure Support (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
Table of Distribution and Allowances (TDA) for USAMRU-G are approved. Permanent military personnel are beginning to phase in to the unit as well as hiring of local national personnel. FY 2016 Plans: Infrastructure funding costs for AFRIMS, USAMRU-K, and USAMRU-G laboratory support will consist of administration and infrastructure support, which will support the sustainment of medical research platforms for surveillance, testing, and evaluation of products to inform the development of interventions for military-relevant endemic diseases.			
Accomplishments/Planned Programs Subtotals	7.572	11.823	12.487

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include documented analysis reflecting program execution of sustainment and modernization of the administration and infrastructure support required for general research, test, and evaluation at the laboratories in Kenya and Thailand, and a time-phased effort for establishment of the same in the Republic of Georgia.

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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 0606105HP / Medical Program-Wide Activities				Project (Number/Name) 433A / NMRC Biological Defense Research Directorate (BDRD) (Navy)			
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
433A: NMRC Biological Defense Research Directorate (BDRD) (Navy)	2.978	4.077	3.586	3.975	-	3.975	4.148	4.968	5.062	5.163	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Navy Bureau of Medicine and Surgery, this program element (PE) includes funds for the Medical Biological Defense research sub-function of the Naval Medical Research Center (NMRC) Biological Defense Research Directorate (BDRD) that relocated to Fort Detrick, Maryland under the Base Re-Alignment and Closure (BRAC) Commission 2005. Consequently, there are significant increases in the operational costs by virtue of being at Fort Detrick, a highly secure National Interagency Biodefense Campus (NIBC). Uninterrupted utilities to all buildings on NIBC are provided by a Central Utility Plant (CUP) whose capacity all partners on the NIBC are required to buy into. The annual projected costs are distributed amongst the partners based on square feet and number of occupants of the building. The NIBC campus is a fenced physical location with Entry Control Points (ECP). The partners on the campus are required to pay for the guard force manning their ECP. BDRD's ECP is ECP5 and the projected costs for the guard force.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: NMRC Biological Defense Research Directorate (BDRD) (Navy)	4.077	3.586	3.975
Description: Biological Defense Research is a completely reimbursable program. The program is sustained by competitive acquisition of research funding. The research dollars cannot pay for the increased operational costs of the program. The complete reimbursable nature of the program requires additional sustained core funding for its operational costs.			
FY 2014 Accomplishments: A significant amount of funding was used for increased costs related to the Central Utility Plant, Entry Control Point Security Force, and other operational costs for maintenance, refuse, and custodial requirements. These support functions enabled BDRD to meet its mission to protect the Warfighter from biological threat agents through the development and distribution of BW (Biological Warfare) agent detection assays, therapeutics, forensic analysis, and operation of deployable BW agent detection labs.			
FY 2015 Plans: Provide funding for the Central Utility Plant, Entry Control Points Security Force and operational costs necessary to achieve the mission critical functions of BW agent detection, analysis, and deployable BW diagnostic lab service.			
FY 2016 Plans: Provide funding for the Central Utility Plant, Entry Control Points Security Force and operational costs necessary to achieve the mission critical functions of BW agent detection, analysis, and deployable BW diagnostic lab service.			
Accomplishments/Planned Programs Subtotals	4.077	3.586	3.975

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 433A / <i>NMRC Biological Defense Research Directorate (BDRD) (Navy)</i>

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metrics include timely delivery of targeted funding support for BDRD operations, required to meet mission of developing and deploying BW assays, therapeutics, forensic analysis, and BW diagnostic lab services in response to science sponsor timelines.

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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 0606105HP / Medical Program-Wide Activities				Project (Number/Name) 442A / USARIEM Pike's Peak IO&T (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
442A: USARIEM Pike's Peak IO&T (Army)	-	0.186	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) research, development, test and evaluation (RDT&E) costs associated with MILCON for the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: USARIEM Pike's Peak IO&T (Army)	0.186	-	-
Description: Supports the initial outfitting and transition (IO&T) research, development, test and evaluation (RDT&E) costs associated with MILCON for the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado.			
FY 2014 Accomplishments: Provided for purchase of equipment designated as Category C (CAT C) government furnished and government installed (GFGI) equipment purchased from other than MILCON appropriations. It also provided for transition funds that are extraordinary operational costs incurred as a direct result of the MILCON project, and that are not part of the normal operational costs.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.186	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Metric includes completed and documented analysis by the performer reflecting program execution and completion dates based on approved phasing.

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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 0606105HP / Medical Program-Wide Activities				Project (Number/Name) 600A / 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
600A: CSI - Congressional Special Interests	-	-	5.967	-	-	-	-	-	-	-	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) 0606105 - Medical Program-Wide Activities. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 476A – Program Increase: Restore Core Research Funding Reduction (Army)	-	3.757
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 Program-Wide ActivitiesProgram Element (PE) - 0606105.		
Congressional Add: 476B – Program Increase: Restore Core Research Funding Reduction (Army)	-	1.314
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 Program-Wide ActivitiesProgram Element (PE) - 0606105.		
Congressional Add: 476C – Program Increase: Restore Core Research Funding Reduction (Navy)	-	0.896
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 Program-Wide ActivitiesProgram Element (PE) - 0606105.		
Congressional Adds Subtotals	-	5.967

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

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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 0606105HP / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 600A / <i>CSI - Congressional Special Interests</i>

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>							
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	22.323	15.097	17.474	17.356	-	17.356	17.647	19.663	20.037	20.439	Continuing	Continuing
377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i>	22.323	13.761	15.092	17.356	-	17.356	17.647	19.663	20.037	20.439	Continuing	Continuing
457A: <i>AF Advanced Technology Development – Rapid Technology Transition</i>	0.000	1.336	-	-	-	-	-	-	-	-	Continuing	Continuing
700A: <i>CSI - Congressional Special Interests</i>	0.000	-	2.382	-	-	-	-	-	-	-	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 or that 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 family of 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, 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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	14.646	15.092	17.356	-	17.356
Current President's Budget	15.097	17.474	17.356	-	17.356
Total Adjustments	0.451	2.382	-	-	-
• Congressional General Reductions	-	-	-	-	-
• Congressional Directed Reductions	-	-	-	-	-
• Congressional Rescissions	-	-	-	-	-
• Congressional Adds	-	2.382	-	-	-
• Congressional Directed Transfers	-	-	-	-	-
• Reprogrammings	1.375	-	-	-	-
• SBIR/STTR Transfer	-0.924	-	-	-	-

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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0607100HP I <i>Medical Products and Capabilities Enhancement Activities</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 700A: *CSI - Congressional Special Interests*

Congressional Add: 467A – *Program Increase: Restore Core Research Funding Reduction (GDF)*

Congressional Add Subtotals for Project: 700A

Congressional Add Totals for all Projects

	FY 2014	FY 2015
	-	2.382
	-	2.382
	-	2.382

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.924 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.924 million).

FY 2014: OMNIBUS Prior Approval Reprogramming (FY 14-11 PA) from Defense Health Program, Operations and Maintenance (DHP O&M) Appropriation (-\$1.375 million) to DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (+\$1.375 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (+\$2.382 million).

FY 2016: No Change.

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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 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>				Project (Number/Name) 377A / <i>GDF-Medical Products and Capabilities Enhancement Activities</i>			
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
377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i>	22.323	13.761	15.092	17.356	-	17.356	17.647	19.663	20.037	20.439	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 or that 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 (3) analyses of clinical intervention outcomes to enhance and improve military unique clinical practice guidelines. Efforts address the Military Health System family of 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, Office of Management and Budget Combat Casualty Care Assessment, National Defense Authorization Acts, etc.) and others as appropriate.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities	13.761	15.092	17.356
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 2014 Accomplishments:			
Completed sensor characterization of fielded sensor systems. Conducted additional mobility studies to enhance existing injury prediction models. Developed an improved Blast Exposure and Concussion Incident Report search/characterization capability. Completed scheduled system enhancements to the Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Dismounted Incident Collaboration Environment (DICE). Collected data to evaluate the effectiveness of Army Combat Uniforms treated with permethrin as a barrier to ticks and mosquitoes following extended periods of use. Evaluated FDA-approved commercial products to control severe junctional (e.g., groin, pelvis) bleeding. Analyzed outcomes of the use of regional anesthesia for combat casualty care in the U.S. Military Healthcare System from 2003-2012. Evaluated an anti-rotational device to control rotational movement of a litter during patient evacuation by helicopter, and tested commercially available lightweight carbon fiber spine boards (for immobilization and transport of injured persons) to find alternatives to the large, bulky ones currently in use. Carried out assessments of commercially available negative pressure wound therapy devices for cost effectiveness, portability, durability, and logistical footprint as compared to the current device in sets, kits, and outfits in order to			

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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 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>	Project (Number/Name) 377A / <i>GDF-Medical Products and Capabilities Enhancement Activities</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2014	FY 2015	FY 2016
<p>make a recommendation for a Joint product of choice. Completed study assessing the safe use of mechanical ventilators in low pressure environments such as altitudes used for air evacuation of patients.</p> <p>FY 2015 Plans: Utilize medical Information Management/Information Technology systems that analyze data from fielded blast sensor systems to assess sensor characterization data of fielded sensor systems. Incorporate results of mobility studies into Operational Requirements-based Casualty Assessment (ORCA) model. Expand test and evaluation and implementation of system enhancements to the JTAPIC DICE. Analyze data on the effectiveness of Army Combat Uniforms treated with permethrin, as a barrier to ticks and mosquitoes, following extended periods of use. Enroll volunteers in a study to determine prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine (a synthetic drug compound to treat malaria). Initiate study to assess whether a current method of monitoring traumatic brain injury (TBI) patients may worsen clinical outcomes. Begin enrollment in a study to retrospectively evaluate the effectiveness of the Defense and Veterans Brain Injury (DVBIC) Progressive Return to Activity Clinical Recommendation Tool for service members following concussion/mild TBI.</p> <p>FY 2016 Plans: Will analyze data regarding prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine, and make recommendations for appropriate testing prior to using primaquine to treat relapse. Will continue enrollment and begin data analysis on DVBIC study.</p>			
Accomplishments/Planned Programs Subtotals	13.761	15.092	17.356

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

Integrate product improvements and enhancements resulting from funded efforts. Use post marketing studies and surveillance to survey impact.

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.

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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 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>	Project (Number/Name) 457A / <i>AF Advanced Technology Development – Rapid Technology Transition</i>
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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
457A: <i>AF Advanced Technology Development – Rapid Technology Transition</i>	-	1.336	-	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Air Force -Medical Products and Capabilities Enhancement Activities: Funds will support (1) developmental upgrades to medical systems and products that have been fielded or that 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.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: AF Advanced Technology Development – Rapid Technology Transition	1.336	-	-
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 2014 Accomplishments: Due to late receipt of funding, FY 2014 accomplishments for this initiative has not yet been finalized.			
FY 2015 Plans: No funding programmed.			
FY 2016 Plans: No funding programmed.			
Accomplishments/Planned Programs Subtotals	1.336	-	-

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

UNCLASSIFIED

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 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>				Project (Number/Name) 700A / <i>CSI - Congressional Special Interests</i>			
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
700A: <i>CSI - Congressional Special Interests</i>	-	-	2.382	-	-	-	-	-	-	-	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) 0607100 - Medical Products and Capabilities Enhancement Activities. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
Congressional Add: 467A – Program Increase: Restore Core Research Funding Reduction (GDF)	-	2.382
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 restoration of core research initiatives in the Medical Products and Capabilities Enhancement Activities Program Element (PE) - 06071000.		
Congressional Adds Subtotals	-	2.382

C. Other Program Funding Summary (\$ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A