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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** March 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	17.646	2.774	3.687	4.013	-	4.013	4.093	4.175	4.259	4.344	Continuing	Continuing
010A: <i>CSI - Congressional Special Interests</i>	1.315	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
240A: <i>Infectious Disease (USUHS)</i>	2.209	0.421	0.480	0.490	-	0.490	0.500	0.510	0.520	0.530	Continuing	Continuing
240B: <i>Military Operational Medicine (USUHS)</i>	6.723	1.146	1.479	1.509	-	1.509	1.539	1.570	1.602	1.634	Continuing	Continuing
240C: <i>Combat Casualty Care (USUHS)</i>	7.149	1.207	1.728	2.014	-	2.014	2.054	2.095	2.137	2.180	Continuing	Continuing
468: <i>Metabolomics, Exposure Biomarkers, and Health Outcomes (USUHS)</i>	0.250	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 \$180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

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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B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	2.879	3.687	4.013	-	4.013
Current President's Budget	2.774	3.687	4.013	-	4.013
Total Adjustments	-0.105	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.105	-			

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

Project: 468: *Metabolomics, Exposure Biomarkers, and Health Outcomes (USUHS)*

Congressional Add: *Metabolomics, Exposure Biomarkers, and Health Outcomes*

	FY 2018	FY 2019
Congressional Add Subtotals for Project: 468	0.000	-
Congressional Add Totals for all Projects	0.000	-

Change Summary Explanation

FY 2018: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601101-In-House Laboratory Independent Research (ILIR) (-\$0.105 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.105 million).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** March 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
010A: <i>CSI - Congressional Special Interests</i>	1.315	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Because of the CSI annual structure, out-year funding is not programmed.

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

N/A

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 2020 Defense Health Agency **Date:** March 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240A / <i>Infectious Disease (USUHS)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
240A: <i>Infectious Disease (USUHS)</i>	2.209	0.421	0.480	0.490	-	0.490	0.500	0.510	0.520	0.530	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 \$180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

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.

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

	FY 2018	FY 2019	FY 2020
Title: Infectious Disease	0.421	0.480	0.490
Description: 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), Cedar Virus, Hepatitis A, Helicobacter pylori, HIV, HTLV-1, Leishmaniasis, Litomosoides sigmodontis, Malaria, Neisseria gonorrhoeae, Shigella spp., Streptococcus, and Methicillin-resistant Staphylococcus aureus (MRSA).			
FY 2019 Plans: Efforts will continue within the Infectious Disease research area in FY 2019. 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.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: March 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240A / <i>Infectious Disease (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	0.421	0.480	0.490

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 2020 Defense Health Agency										Date: March 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>				Project (Number/Name) 240B / <i>Military Operational Medicine (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
240B: <i>Military Operational Medicine (USUHS)</i>	6.723	1.146	1.479	1.509	-	1.509	1.539	1.570	1.602	1.634	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 \$180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

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.

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

Title: Military Operational Medicine	FY 2018	FY 2019	FY 2020
Description: 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.	1.146	1.479	1.509
FY 2019 Plans: Efforts will continue within the Military Operational Medicine research area in FY 2019. 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.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	1.146	1.479	1.509

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: March 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240B / <i>Military Operational Medicine (USUHS)</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 2020 Defense Health Agency **Date:** March 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>				Project (Number/Name) 240C / <i>Combat Casualty Care (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
240C: <i>Combat Casualty Care (USUHS)</i>	7.149	1.207	1.728	2.014	-	2.014	2.054	2.095	2.137	2.180	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 \$180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

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.

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

Title: Combat Casualty Care	FY 2018	FY 2019	FY 2020
Description: Regenerative medicine, rehabilitation, neurological, limb loss, pain management, readiness, resilience	1.207	1.728	2.014
FY 2019 Plans: Efforts will continue within the Combat Casualty Care research area in FY 2019. 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.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Previous years reflect a programmatic reduction in RDT&E (DHP-wide).			
Accomplishments/Planned Programs Subtotals	1.207	1.728	2.014

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: March 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 240C / <i>Combat Casualty Care (USUHS)</i>

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

Remarks

D. Acquisition Strategy
N/A

E. Performance Metrics
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** March 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601101DHA / <i>In-House Laboratory Independent Research (ILIR)</i>	Project (Number/Name) 468 / <i>Metabolomics, Exposure Biomarkers, and Health Outcomes (USUHS)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
468: <i>Metabolomics, Exposure Biomarkers, and Health Outcomes (USUHS)</i>	0.250	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 \$180 million annually). Approximately 48 intramural research projects are active each year, including 18 faculty start-ups. Projects are funded on a peer-reviewed, competitive basis. Results from these studies contribute to the knowledge base intended to enable technical approaches and investment strategies within Defense Science and Technology (S&T) programs. USU enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system.

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

	FY 2018	FY 2019
Congressional Add: Metabolomics, Exposure Biomarkers, and Health Outcomes	0.000	-
FY 2018 Accomplishments: None.		
Congressional Adds Subtotals	0.000	-

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

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0601117DHA I <i>Basic Operational Medical Research Sciences</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	36.887	6.903	7.699	8.608	-	8.608	8.913	9.091	9.273	9.458	Continuing	Continuing
100A: <i>CSI - Congressional Special Interests</i>	8.349	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
371A: <i>GDF-Basic Operational Medical Research Sciences</i>	28.538	6.903	7.699	8.608	-	8.608	8.913	9.091	9.273	9.458	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 areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research and Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include military infectious diseases (JPC-2), military operational medicine (JPC-5), and combat casualty care (JPC-6). 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 0602115) or technology development (PE 0603115) funding.

In FY 2016, Congressional Special Interest (CSI) funds were provided for Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: <i>Defense Health Program I BA 2: RDT&E</i>	PE 0601117DHA I <i>Basic Operational Medical Research Sciences</i>

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	6.917	7.699	8.608	-	8.608
Current President's Budget	6.903	7.699	8.608	-	8.608
Total Adjustments	-0.014	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.000	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.014	-			

Change Summary Explanation

FY 2018: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0601117-Basic Operational Medical Research Sciences (-\$0.014 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.014 million).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i>	Project (Number/Name) 100A / <i>CSI - Congressional Special Interests</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
100A: <i>CSI - Congressional Special Interests</i>	8.349	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0601117DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
371A: <i>GDF-Basic Operational Medical Research Sciences</i>	28.538	6.903	7.699	8.608	-	8.608	8.913	9.091	9.273	9.458	Continuing	Continuing

A. Mission Description and Budget Item Justification

Basic research described here focuses on enhancement of knowledge to support capabilities identified through the Joint Capabilities Integration and Development System process and sustainment of DoD and multi-agency priority investments in science, technology, research, and development as stated in the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, and the National Strategy for Combating Antibiotic Resistance. This project supports basic research managed by the Joint Program Committees (JPCs) in the following areas: 1- Military Infectious Diseases basic research develops protection and treatment products for military relevant infectious diseases. 2- Military Operational Medicine basic research focuses on the development of medical countermeasures against operational stressors, prevention of physical and psychological injuries during training and operations, and maximizing the health, performance and fitness of Service members. 3- Combat Casualty Care basic research focuses on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facility care.

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

	FY 2018	FY 2019	FY 2020
Title: Project 371 GDF – Basic Operational Medical Research Sciences	6.903	7.699	8.608
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 2019 Plans:			
Military infectious diseases research continues to support multi-year basic research studies in bacterial diseases for the prevention, treatment and management in discovery and development of antibacterial agents for biofilms and multi-drug resistant organisms (MDROs), detection of MDROs, and biomarkers. Successful approaches are being selected for funding. Studies that address the remaining gaps related to infection caused by MDROs are ongoing. These studies support the National Action Plan for Combating Antibiotic-Resistant Bacteria.			
Military operational medicine research is continuing to characterize the biomechanical responses of brain tissue to blast waves and indirect mechanisms of blast wave-induced injury in animal models to guide the development of interventions for mitigating blast-induced brain injury. Research to define the role of individual and unit climate factors on aggression is advancing. There are current efforts to identify linkages between identified genetic markers and individual performance or health risks. Studies are advancing to understand the basic mechanisms underlying psychological resilience to inform potential future intervention and assessment work. In addition, efforts continue on epidemiological studies to identify the nature of the substance abuse problem in the military and possible unique contributing and protective factors. Efforts to identify candidate targets and neurological systems			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0601117DHA / <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 2018	FY 2019	FY 2020
<p>for treatment and diagnostic indicators of post-traumatic stress disorder (PTSD) are progressing. There are ongoing studies defining solutions to prevent, mitigate and/or recover from fatigue via electrical brain stimulation. Additionally, research is in work to identify physical, physiological and psychosocial factors that may differentially impact the performance of female versus male Service members and gender-based susceptibility to musculoskeletal injury. Mechanisms of molecular changes in the brain following exposure to inhaled toxicants are being studied.</p> <p>Combat casualty care research is focusing on developing an understanding of trauma-associated pathophysiologic (functional changes associated with injury) mechanisms using advanced hemostatic and resuscitation approaches in prolonged field care scenarios when evacuation is delayed.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	6.903	7.699	8.608

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, Defense Health Program-sponsored review and analysis meetings, quarterly and annual status reports, 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 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0602115DHA I <i>Applied Biomedical Technology</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	397.066	91.814	112.754	82.883	-	82.883	84.408	86.096	87.818	89.574	Continuing	Continuing
200A: <i>Congressional Special Interests</i>	135.390	12.700	23.100	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	6.029	2.082	1.857	1.949	-	1.949	1.989	2.029	2.070	2.111	Continuing	Continuing
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	12.958	3.830	4.051	4.132	-	4.132	4.215	4.299	4.385	4.472	Continuing	Continuing
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
372A: <i>GDF Applied Biomedical Technology</i>	208.151	65.629	74.724	67.148	-	67.148	68.357	69.724	71.119	72.542	Continuing	Continuing
447A: <i>Military HIV Research Program (Army)</i>	31.082	7.573	9.022	9.654	-	9.654	9.847	10.044	10.244	10.449	Continuing	Continuing

A. Mission Description and Budget Item Justification

This program element (PE) provides applied research funding to refine concepts and ideas into potential solutions for military health and performance problems, with a view toward evaluating technical feasibility. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD Department of Defense and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>
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consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. Funds in the PE support studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115) funding.

For the Army Medical Command: This PE funds the military HIV research program to refine identification methods for determining genetic diversity of the virus, to conduct preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and to evaluate and prepare overseas sites for clinical trials with these vaccine candidates. Funding is also provided to develop strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds through the Combating Antibiotic Resistant Bacteria - WRAIR Discovery and Wound Program.

In FY 2016, Congressional Special Interest funds were provided for Traumatic Brain Injury and Psychological Health (TBI/PH) and Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	63.550	96.754	82.883	-	82.883
Current President's Budget	91.814	112.754	82.883	-	82.883
Total Adjustments	15.086	16.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	16.506	16.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.420	-			

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

Project: 200A: *Congressional Special Interests*

Congressional Add: 426 – *CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)*

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

	FY 2018	FY 2019
	12.700	23.100
	0.000	0.000

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency	Date: February 2019
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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 0602115DHA / <i>Applied Biomedical Technology</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2018	FY 2019
Congressional Add Subtotals for Project: 200A	12.700	23.100
Congressional Add Totals for all Projects	12.700	23.100

Change Summary Explanation

FY 2018: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-\$1.420 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$1.420 million).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 200A / <i>Congressional Special Interests</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
200A: <i>Congressional Special Interests</i>	135.390	12.700	23.100	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

	FY 2018	FY 2019
Congressional Add: 426 – CSI - Peer Reviewed Traumatic Brain Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	12.700	23.100
FY 2018 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program supported studies to inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on the function, wellness, and overall quality of life for military Service members and veterans, as well as their 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, treatment, and rehabilitation. FY 2018 funds supported research in the areas of diagnosis and treatment of mental health disorders, optimization of psychological health and resilience for readiness, and suicide prevention and reduction.		
FY 2019 Plans:		
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)	0.000	0.000
FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward FY 2018 DHP core research initiatives in PE 0602115. Funds supported applied research in the areas of military operational medicine, combat casualty care, military infectious diseases, clinical and rehabilitative medicine, medical simulation and information sciences, and radiation health effects. (Project 372A).		
FY 2019 Plans:		
Congressional Adds Subtotals	12.700	23.100

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 200A / <i>Congressional Special Interests</i>

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 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 246A / <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	6.029	2.082	1.857	1.949	-	1.949	1.989	2.029	2.070	2.111	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 also 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 those 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 evaluate 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 2018	FY 2019	FY 2020
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	2.142	1.857	1.949
Description: Focus on continued establishment of in-house capabilities for an antibacterial 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) fosters partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.			
FY 2019 Plans: CARB program continues its research efforts to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit. In addition, the program continues its market analysis efforts of established, non-DoD antibiotic programs to identify other promising compounds that could potentially treat military relevant resistant bacteria, establishing partnership and intellectual property rights agreements where necessary. These promising compounds are screened against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) in order to select compounds for continued development. Specifically designed novel drugs are then synthesized to support lead optimization efforts, exploiting established in vivo (living organism) model standards to treat military relevant resistant bacteria.			
FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <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 2018	FY 2019	FY 2020
FY2020 plans continue efforts as outlined in FY 2019.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	2.142	1.857	1.949

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 Technology Readiness Level (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). The performance metric benchmark is progression of research projects to TRL 5 and their schedule to transition.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	12.958	3.830	4.051	4.132	-	4.132	4.215	4.299	4.385	4.472	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. This project area seeks to manage and support research activities designed to facilitate the clinical integration of genomic-based medicine across the AFMS. Research in genomic medicine seeks to initiate the transition of genomic research discoveries into clinical practice, specifically applying knowledge derived from the study of pharmacogenomics, cancer genomics, gene-environment interactions, and inherited disease genomics in Airmen and beneficiaries. The program funds applied research which seeks to promote 'omic'-informed personalized medicine 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. Plans are to utilize patient modeling algorithms to identify pharmacogenomics interventions that can improve patient health and reduce healthcare costs across the AFMS. Program aims to further conduct 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 is also planned. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine data is a key program component.

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

	FY 2018	FY 2019	FY 2020
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	3.975	4.051	4.132
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 project area seeks to manage and support research activities designed to facilitate the clinical integration of genomic-based medicine across the AFMS. Research in genomic medicine seeks to initiate the transition of genomic research discoveries into clinical practice, specifically applying knowledge derived from the study of pharmacogenomics, cancer genomics, gene-environment interactions, and inherited disease genomics in Airmen and beneficiaries. The program funds seeks to promote 'omic'-informed personalized medicine with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>

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

	FY 2018	FY 2019	FY 2020
<p>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. Analyze genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Plans are to utilize patient modeling algorithms to identify pharmacogenomics interventions that can improve patient health and reduce healthcare costs across the AFMS. Program aims to further conduct 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 is also planned. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine is a key program component.</p> <p>FY 2019 Plans: Provide further analysis of genetic, epigenetic, proteomic and pharmacogenetic testing to advance force health protection measures within the AFMS. Implement genomic data into secure DoD Digital BioBank.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	3.975	4.051	4.132

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).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306C / <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
372A: <i>GDF Applied Biomedical Technology</i>	208.151	65.629	74.724	67.148	-	67.148	68.357	69.724	71.119	72.542	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 for military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research is managed by the Joint Program Committees in the following areas: 1- Medical Simulation and Information Sciences applied research is developing informatics-based simulated military medical training. 2- Military Infectious Diseases applied research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine applied research goals are to develop medical countermeasures against operational stressors, prevent musculoskeletal, neurosensory, and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care applied research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facility care. 5- Radiation Health Effects applied research supports tasks for the development of radiation medical countermeasures. 6- Clinical and Rehabilitative Medicine applied research is focused on efforts to reconstruct, rehabilitate, and provide care for injured Service members.

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

	FY 2018	FY 2019	FY 2020
Title: GDF Applied Biomedical Technology	49.639	58.724	67.148
Description: Focus is 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 2019 Plans:			
Medical simulation and information sciences applied research is focusing on researching pharmacodynamics (effects of drugs and the mechanism of their action) and pharmacokinetics (movement of drugs within the body) algorithms. This research supports a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en route care training. The mathematical algorithms development are focusing on specific pharmacodynamics (effects of drugs and the mechanism of their action.) and pharmacokinetics as well as absorption, distribution, metabolism, and excretion of the pharmaceuticals and resuscitative options. Research is being conducted on high fidelity tactile haptics (recreated sense of touch in simulated settings) to improve tactile sensation and resistance realism of virtual reality systems and mannequin based medical training systems.			
Military infectious diseases research continues to support multi-year studies in bacterial diseases research, and will down-select promising efforts for further development. Multi-year studies in wound infections are being supported to address critical research focus areas such as the ability to predict infection and better treatment options for infections with MDROs and development of biomarker assays for diagnosis of infection. Novel and innovative therapeutics and delivery technologies for combat wound			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

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

	FY 2018	FY 2019	FY 2020
<p>infections are being developed. Subject matter expertise in acute respiratory diseases is being maintained. These efforts support the National Action Plan for Combating Antibiotic-Resistant Bacteria. Scientific awareness and a capability to respond to emerging infectious diseases are being maintained. Partnerships with other entities are being supported to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika).</p> <p>Military operational medicine research is collecting experimental data to validate whole-body computational models of the direct and indirect mechanism of blast brain injury. Research also focuses to determine optimal temporal spacing of repeated blast events to prevent cumulative effects and analyze changes in brain injury biomarkers. Additionally, research collecting impulse noise experimental data from volunteer subjects to validate computational models of inner ear injury. Research to inform refinements to comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency) is ongoing. Efforts to refine models of dietary supplement use patterns by Armed Forces members and determining demographic and lifestyle factors associated with dietary supplement and caffeine use along with risks and benefits of consumption are progressing. Studies to assess the physical, psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors are advancing. Research is ongoing to inform prototype development for Service member and family resilience building interventions. Studies are progressing to deliver an evidence-based substance abuse prevention and training model and screening and compliance tools. Research aimed at developing an evidence-based approach to reduce stigma and a training program to increase provider skill in assessing and treating suicidality is in progress. In addition, novel and evidence-based PTSD interventions investigations are ongoing. Adaptations in delivery of care are being studied to achieve the goal of increased accessibility. Efforts to identify and developing candidate biomarker panels indicative of PTSD treatment-related improvement, and animal/human PTSD model development are progressing. Novel compounds and existing FDA-approved medications are being analyzed for potential use in treatment of PTSD. Candidate biomarkers of exposure to inhaled or ingested toxic substances are being evaluated for utility to establish the probability of adverse health risk outcomes and refine a non-invasive tool for diagnosing pulmonary diseases. Research focuses to refine metrics for optimized operational task performance in extreme environmental conditions.</p> <p>Combat casualty care hemorrhage research is investigating new diagnostic tools and continuing the development of treatments for severe hemorrhage following injury. Research is focusing on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Research is focusing on novel oxygen carriers for use in severe casualties where blood transfusions are not available. Inflammatory modulation and other research focused on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios) are ongoing. Tactical Combat Casualty Care (TCCC) is investigating novel approaches to enable field care of casualties when evacuation is delayed. Neurotrauma research is focusing on precision medicine capabilities. This research is anticipated to improve the characterization of traumatic brain injury (TBI), and lead to the development of targeted therapies, devices and clinical guidelines to improve the care provided to TBI casualties. Treatments for extremity trauma to advance wound stabilization for prolonged</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

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

	FY 2018	FY 2019	FY 2020
<p>field care scenarios that might enhance initial treatment and improve longer term outcomes are being studied. Closed loop and decision assist technologies for burns, lung ventilation, organ support, and other complex injuries to include maxillofacial injury are progressing. Pre-hospital Tactical Combat Casualty Care research is studying the effectiveness of acute lifesaving interventions and how to improve survival for those in need of critical care on the battlefield, in acute stages of injury, and for those requiring prolonged times until reaching definitive care in the prolonged field care/pre-hospital/hospital setting. En-route care research continues to study clinically-relevant testing standards for monitors in the transport environment and to develop new non-invasive monitoring technologies.</p> <p>Radiation health effects research will conduct non-clinical research to identify therapeutic candidates for acute radiation exposure and develop data to support preparation of technical data package requirements for investigational new drug applications. Research also focuses on evaluating candidate preventative radioprotectants (drugs) to determine their feasibility and practicality as candidate solutions to military needs. Objectives include identifying mechanisms of action, efficacy and safety data in animal models for medical countermeasures for Acute Radiation Syndrome (ARS).</p> <p>Clinical and rehabilitative medicine research is selecting the most promising candidate products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries is progressing. Targets for therapies to alleviate acute, chronic, and battlefield pain and identify strategies for addressing psychosocial aspects of pain management and pain-related substance abuse will be identified. Research to identify biomarkers to implement precision medicine approaches for pain management is ongoing. Regenerative medicine research is focusing efforts on developing solutions to repair, reconstruct or regenerate tissue lost or damaged due to traumatic injury.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Increasing focus to refine potential military medical solutions to increase advanced technology development efforts.</p>			
Accomplishments/Planned Programs Subtotals	49.639	58.724	67.148

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

N/A
Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>

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. Technology Transition and Milestone A packages will be developed to facilitate product transition.

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
447A: <i>Military HIV Research Program (Army)</i>	31.082	7.573	9.022	9.654	-	9.654	9.847	10.044	10.244	10.449	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). This effort supports the Administration's priorities in the area of international scientific partnership in global health engagement. 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 U.S. Army Medical Research and Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health. 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 2018	FY 2019	FY 2020
Title: Military HIV Research Program	7.794	9.022	9.654
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 2019 Plans: The Military HIV Research Program is producing and characterizing new vaccine candidates for use in pre-clinical and clinical testing. Vaccine candidates will be evaluated to assess their ability to invoke an immune response in non-human primates by using novel delivery systems containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, B, C, D and E. The program is developing and optimizing methods of large scale production of new vaccine candidates for testing in Africa and Asia to assess candidate vaccines against diverse HIV subtypes. Efforts to identify and develop new clinical trial sites in Europe, Southeast Africa Asia and the US are ongoing in order to allow scientists the opportunity to test future vaccine candidates against predominant HIV subtypes circulating around the world.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	7.794	9.022	9.654

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 million per 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 and in-process reviews.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0602787DHA I <i>Medical Technology (AFRRI)</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	9.329	1.282	1.356	1.383	-	1.383	1.411	1.439	1.468	1.497	Continuing	Continuing
020: <i>CSI - Congressional Special Interests</i>	0.124	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
241A: <i>Biodosimetry (USUHS)</i>	1.879	0.272	0.277	0.283	-	0.283	0.289	0.295	0.301	0.307	Continuing	Continuing
241B: <i>Internal Contamination (USUHS)</i>	0.979	0.143	0.146	0.149	-	0.149	0.152	0.155	0.158	0.161	Continuing	Continuing
241C: <i>Radiation Countermeasures (USUHS)</i>	6.347	0.867	0.933	0.951	-	0.951	0.970	0.989	1.009	1.029	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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	1.331	1.356	1.383	-	1.383
Current President's Budget	1.282	1.356	1.383	-	1.383
Total Adjustments	-0.049	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.049	-			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / Medical Technology (AFRRI)	Project (Number/Name) 020 / CSI - Congressional Special Interests
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
020: CSI - Congressional Special Interests	0.124	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>				Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
241A: <i>Biodosimetry (USUHS)</i>	1.879	0.272	0.277	0.283	-	0.283	0.289	0.295	0.301	0.307	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences (USU), 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. Accomplishments/Planned Programs (\$ in Millions)

	FY 2018	FY 2019	FY 2020
Title: Biodosimetry (USUHS)	0.272	0.277	0.283
<p>Description: For the Uniformed Services University of the Health Sciences (USU), 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 for all relevant military applications.</p> <p>FY 2018 Plans:</p> <ul style="list-style-type: none"> -Establish a suite of biodosimetry assays, techniques, and standard operating procedures to support analysis of chromosomal aberrations for assessing radiation injury and dose. -Establish dose-response curve for dicentric yields, that is, frequencies of chromosome aberrations in irradiated lymphocytes using automated dicentric scoring software utility. -Perform dose response studies to measure dicentric chromosomal aberrations in irradiated lymphocytes after exposure to mixed neutron and photon radiation fields mimicking those from an improvised nuclear device at relevant distances from the epicenter. -Identify radiation-responsive biological markers (aka biomarkers) such as microRNAs and proteins that are organ-specific in a mouse model of partial-body radiation exposure. -Participate in annual performance evaluation of established techniques and procedures for radiation biodosimetry to demonstrate accuracy in dose assessment methodology such as cytogenetic assays for detecting chromosomal aberrations; implement new approaches through reassessment to enhance throughput capability for processing and scoring of chromosomal aberrations. -Establish partial-body animal radiation mouse model of acute radiation syndrome (ARS) using low linear energy transfer (LET)/ photon exposure from the small animal radiation research platform (SARRP) and assess organ-specific radiation injury biomarkers similar to ones performed earlier in low-linear energy transfer (LET) Total-body irradiation (TBI) mouse model. 			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>

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

	FY 2018	FY 2019	FY 2020
<p>-Establish partial-body animal radiation models (mouse and nonhuman primates (NHPs)) using low-LET/photon exposure with the SARRP for mice and with the linear accelerator (LINAC) radiation platform for NHPs in order to assess organ-specific radiation injury biomarkers evaluated earlier in low-LET TBI studies.</p> <p>-Establish mouse TBI model for combined hematological and proteomic biodosimetry approach following mixed-field (neutrons and photons, high-LET) in addition to one already established and evaluated for a pure photon (60 Co gamma ray, low-LET) exposure.</p> <p>-Evaluate IL-18 and IL-12, small protein signaling agents as dual radiation biomarkers in non-human primate urine sampling for assessment of radiation injury and doses, severity and lethality after TBI.</p> <p>-Develop microRNAs profile as biomarkers of radiation injury and dose by sampling urine from gamma-irradiated NHPs using microRNAs microarray and quantitative real-time polymerase chain reaction (RT-PCR) methods.</p> <p>-Compare microRNAs profiles in gamma-irradiated mouse serum and NHPs urine and identify sensitive and accurate radiation biomarkers.</p> <p>-Evaluate effects of low and moderate doses of gamma-radiation from hematopoietic and immune system of mice (in vivo) and human cells (in vitro).</p> <p>-Further evaluate mechanisms of radiation-induced lymphocyte damage.</p> <p>-Further evaluate additional hematology and leukemia biomarkers during leukemogenesis that are differentially expressed at early and late phases of transformation. Identify additional epigenetic changes that discriminate between differences in dose rate at low doses (<10 cGy).</p> <p>FY 2018 Accomplishments:</p> <p>- Evaluated several radiation-responsive protein biomarkers for early-phase and organ-specific damage in animal total-body irradiation (TBI) models: In mouse (with minimal supportive care) and nonhuman primate (with minimal and full medical supportive care consisting of G-CSF or Neupogen® [filgrastim], antibiotics, blood transfusions, etc.) in order to predict as early as possible the radiation-induced multi-organ involvement (MOI) and multi-organ failure (MOF) and late effects of exposure and acute radiation sickness (ARS) outcome in two animal models to support FDA regulatory requirement.</p> <p>-Demonstrated in mouse TBI studies that the evaluated biomarker profiles show no gender-effect as well as no dose-rate effect within a broad range (0.02 to ~2 Gy/min) reflecting the fact that the radiation dose prediction might be done strictly based on biomarker level regardless to the exposure dose-rate.</p> <p>-Identified several biomarkers of gastrointestinal (GI) injury: citrulline, citrullinated proteins (CP), bactericidal permeability increasing (BPI) protein, lipopolysaccharide binding protein (LBP), procalcitonin (PCT), intestinal fatty acid binding protein (I-FABP), diamine oxidase (DAO or histaminase) in mouse and nonhuman primate (NHP) TBI models.</p> <p>-Plasma citrulline and citrullinated proteins were identified as early biomarkers of radiation-induced gastrointestinal damage and a potential new biomarkers of late-effect kidney failure.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>

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

	FY 2018	FY 2019	FY 2020
<p>-Citrullinated proteins were demonstrated as a new predicative radiation-responsive biomarker in animal models for a prediction of the ARS outcome (AFRRI US Patent Number 9,063,148 issued on 6/23/2015).</p> <p>-Evaluated biochemical profiles in NHP TBI model revealed elevations in individual enzymes that reflect radiation-damage to the respective organs (i.e., salivary glands, pancreas, liver, muscles, kidney, etc.).</p> <p>-Confirmed that the specific biomarker levels correlate with a severity of radiation damage to different organs evaluated in complete necropsies performed in NHPs. Although, those findings need to evaluate in partial-body animal studies using either SARRP or LINAC.</p> <p>-Evaluated the IL-18 level in urine of NHPs total-body irradiated with 60Co gamma-rays and demonstrated its great utility as a non-invasive early prognostic indicator of survival facilitated rapid detection of radiation exposure that might be suitable for field-deployable biodosimetry point-of-care to determine the exposure dose in a few minutes.</p> <p>-Demonstrated that the urine IL-18 levels combined with other biomarkers measured in blood provided highly discriminatory power, specificity and sensitivity of radiation exposure.</p> <p>-Created ARS severity score response categories in mouse and NHP TBI gamma-rays studies revealed good similarities with one created in radiation accident victims.</p> <p>-Completed comparison of some results/data from the NHP dose-response TBI (gamma- and x-rays) studies with data collected in radiation accident victims and radiation therapy patients and revealed good similarities.</p> <p>-Evaluated and demonstrated the different responses of mouse hematopoietic and immune cells to low-moderate doses (0.1, 0.5, 1.0, 3.0, and 5.0 Gy) of total-body γ-irradiation (TBI). Radiation < 1 Gy can significantly damage hematopoietic stem and progenitor cells; low dose radiation-induced decrease of stem cell factor (SCF) in mouse BM and increase in circulating proinflammatory factors may be responsible for the enhanced sensitivity of hematopoietic stem and progenitor cells to radiation.</p> <p>-Developed a novel method, using long-range quantitative PCR to determine radiation-induced nuclear and mitochondria DNA damage.</p> <p>-Demonstrated the circulating microRNA (miR)-30 and miR-34 as radiation biomarkers in mice which can also be used to track radiation-induced apoptosis in human and mouse cells.</p> <p>- Established the severity of mortality and platelet depletion dependence on radiation doses and dose rates.</p> <p>- Established the severity of lymphocyte depletion and concentrations of biomarkers G-CSF, IL-18, Flt-3 ligand dependence on radiation doses.</p> <p>-Established two radiation dose-response calibration curves (60Co-gamma rays at 0.6 Gy/min and 0.1 Gy/min) for automated scoring of dicentric chromosome aberrations (DCA) that enable rapid radiation dose assessment. These studies contribute towards DoDs radiological medical preparedness by validating enhanced throughput capability via automated scoring software and laboratory competency.</p> <p>-Reported on radiation dose-responses for both total-body and partial-body irradiation up to 30 Gy using the premature chromosome condensation (PCC) assay using multiple endpoints (i.e., excess fragments, rings, length ratio, and dicentrics). Ongoing studies are evaluating the accuracy of these various endpoints using the PCC assay using blind samples.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>

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

	FY 2018	FY 2019	FY 2020
<p>-Participated as a satellite scoring laboratory in the RENE B (Realizing the European Network in Biodosimetry) RENE B ILC II exercise involving the analysis of 500 spreads in each of three samples. Preliminary analysis showed samples that our results were to be within in the acceptable range. Participated in intra- and inter-laboratory DCA/dose assessment comparison exercises with Health Canada. (Dr. Ruth Wilkins). This exercise involved the use of 10 human blood samples (exposed to various radiation doses) received from Health Canada that were cultured, stained, and scored for dicentrics using their requested triage scoring approach (n=50). Data analysis is on-going.</p> <p>-Initiated studies to compare total-body and partial-body radiation exposures using the mouse model system to evaluate candidate radiation biomarkers (i.e., proteomic, miRNA) to assess organ specific injury.</p> <p>- Reported new research findings that increases in biomarkers from blood after mixed field irradiation and gamma irradiation depended on radiation doses but not radiation dose rates. The effects also were not affected by genders. The observation is essential for establishing the biomarkers for triage and radiation dose assessment. One paper on this subject was published in Radiation Research 189:634-643, 2018.</p> <p>FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018. In addition, efforts continue for establishing a mouse Total-body irradiation (TBI) model for combined hematological (blood cells) and proteomic (proteins) biodosimetry approach following the mixed-field (neutron and photons) along with one already established and evaluated for a pure photon (60Co gamma ray, low-LET) exposure. Additionally, the following are included this plan:</p> <ul style="list-style-type: none"> - Explore the mechanisms of low-moderate doses of radiation-mediated adverse effects based on the results obtained from FY18's studies. - Evaluate and identify the molecular targets and cellular "initiating events" after low-moderate doses of radiation exposure in multiple organs and tissues of mouse and human cells. - Evaluate and identify the sensitivity of different organ to low-moderate doses of gamma radiation-induced oncogene expression and development of malignancy in in vivo and ex vivo model. - Evaluate using long-range quantitative PCR method to determine DNA damage in human and animal blood cells and assess radiation injury after different doses of gamma radiation. -Determine the mechanisms by which IL-18 induces vascular endothelium damage and multiple organ injury in mouse model and in vitro cell lines, as well as to evaluate the radioprotection/mitigation efficacy of anti-IL-18. -Perform dose response studies to measure dicentric chromosomal aberrations in irradiated lymphocytes after exposure to mixed neutron mimicking those from an improvised nuclear device at relevant distances from the epicenter. -Sustain research efforts to optimize cytogenetic assays for rapid dose assessment as well as rapid assessment the fraction of the body exposed in a radiation casualty. 			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<p>-Identify and optimize miRNA biomarkers for specific radiation sensitive organ systems (i.e., gastrointestinal system, pulmonary system, etc.).</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>				
Accomplishments/Planned Programs Subtotals		0.272	0.277	0.283
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
The program element 0602787DHA for AFRRI in addition to the three program elements: 0601115HPPE, 0602115HPPE, and 0603115HP are coordinated and integrated into the portfolio management by the Joint Program Committee-7/ Radiation Health Effects Research Program (RHERP).				
D. Acquisition Strategy				
N/A				
E. Performance Metrics				
By FY2019				
<ul style="list-style-type: none"> -Establish a mouse TBI model for combined hematological and proteomic biodosimetry approach following the mixed-field (neutrons and photons, high-LET) in addition to one already established and evaluated for a pure photon (60Co gamma-rays, low-LET) exposure. - Explore the mechanisms of low-moderate doses of radiation-mediated adverse effects based on the results obtained from FY18's studies. - Evaluate and identify the molecular targets and cellular "initiating events" after low-moderate doses of radiation exposure in multiple organs and tissues of mouse. - Evaluate and identify the sensitivity of different organ to low-moderate doses of gamma radiation-induced oncogene expression and development of malignancy. - Evaluate using long-range quantitative PCR method to determine DNA damage in human and animal blood cells and assess radiation injury after different doses of gamma radiation, as well as to evaluate the efficacy of radiation countermeasures. -Investigate the mechanisms by which IL-18 induces vascular endothelium damage and multiple organ and tissue injury. -Apply proteomic markers in various combinations in multivariate or logistic regression models for predicting radiation dose and/or ARS severity. -Demonstrate the use of centromeric probes and rapid in situ hybridization in the PCC assay to score dicentrics to enhance the robustness of dose assessment capability over a broad dose range. 				
By FY2020				

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241A / <i>Biodosimetry (USUHS)</i>
<ul style="list-style-type: none">-Establish a mouse partial-body irradiation model for combined hematological and proteomic biodosimetry approach following the mixed-field (neutrons and photons, high-LET) in addition to one already established and evaluated for a pure photon (60Co gamma-rays, low-LET) exposure.-Identify and evaluate the organ-specific radiation injury biomarkers evaluated earlier in low-LET total-body irradiation studies and partial-body biodosimetry in mouse partial-body irradiation model.-Investigate the mechanisms by which IL-18 induces vascular endothelium damage and multiple organ and tissue injury.- Explore the mechanisms of low-moderate doses of radiation-mediated tissue injury in experimental mice.- Evaluate and identify the molecular targets and cellular “initiating events” after low-moderate doses of radiation exposure in multiple organs and tissues of mouse.- Explore the mechanisms by which low-moderate doses of gamma radiation-induced malignancy in radiosensitive tissues using mouse model.- Establish an accurate and sensitive method using long-range quantitative PCR method to determine DNA damage in human and animal blood cells after mixed-field (neutron and photons) radiation exposure, as well as to evaluate the efficacy of radiation countermeasures.-Validate use of the cytogenetic biodosimetry suite of assays for radiation dose assessment in annual exercises.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRR)</i>				Project (Number/Name) 241B / <i>Internal Contamination (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
241B: <i>Internal Contamination (USUHS)</i>	0.979	0.143	0.146	0.149	-	0.149	0.152	0.155	0.158	0.161	Continuing	Continuing

A. Mission Description and Budget Item Justification

Internal Contamination (USU): For the Uniformed Services University of the Health Sciences (USU), 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 2018	FY 2019	FY 2020
Title: Internal Contamination (USUHS)	0.143	0.146	0.149
<p>Description: Radioactive material can enter the body by a variety of pathways including ingestion, inhalation, and wound contamination. While some internalized isotopes will be naturally eliminated from the body, many others are not. They remain immobile or are transported and deposited to other organs where they continually irradiate the surrounding tissue. This chronic internal radiation exposure can cause unrepairable cellular damage eventually leading to death. This Program uses innovative approaches to address this pressing health concern.</p> <p>FY 2018 Plans: Continue cytotoxicity testing of surrogate-templated molecularly imprinted polymers for extraction of radionuclide contaminants; begin assessment of extracorporeal decorporation techniques to determine blood purification and chelation efficiencies of the polymers in a laboratory rat model. Design feasibility study to assess potential of chemically-modified dendrimeric structures as radionuclide decorporation agents and to optimize the efficiency of the designed polymers as decorporation agents. Continue assessment of dendrimeric structures for further optimization as a promising radionuclide decorporation agent in regard to desired properties such as specificity, binding strength and lower cytotoxicity. Initiate a study to determine if non-toxic plant-based metal chelators can be effectively used as radionuclide decorporation agents for the treatment of internal radionuclide contamination.</p> <p>FY 2018 Accomplishments: -Molecularly imprinted polymers prepared using ternary and silica-based protocols, with zinc as the surrogate template, were able to bind cobalt from simulated serum and intestinal fluids. -Molecularly imprinted polymers prepared using silica-based protocols, with copper as the surrogate template, were able to bind uranium from simulated serum and intestinal fluids.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241B / <i>Internal Contamination (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>-Molecularly imprinted polymers prepared using europium as a surrogate template for strontium and rubidium as a surrogate template for cesium were unable to bind the appropriate metals.</p> <p>-No metal binding was observed in simulated gastric fluid because of the pH-sensitive nature of the metal: polymer interaction.</p> <p>-Molecularly imprinted polymer preparations demonstrated low cytotoxicity and did not result in the hemolysis of isolated rat red blood cells.</p> <p>FY 2019 Plans: FY2019 plans continue efforts as outlined in FY 2018. In addition, plans include the design optimization and feasibility studies to test and evaluate the potential for chemically-modified dendrimeric structures as promising radionuclide decorporation agents.</p> <p>FY 2020 Plans: FY2020 plans include initiation of feasibility of incorporating non-toxic plant-based metal chelators into a dendrimeric structure for use as potential radionuclide decorporation agents.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	0.143	0.146	0.149

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

N/A

Remarks

The program element 0602787DHA for AFRRI in addition to the three program elements: 0601115HPPE, 0602115HPPE, and 0603115HP are coordinated and integrated into the portfolio management by the Joint Program Committee-7/ Radiation Health Effects Research Program (RHERP).

D. Acquisition Strategy

N/A

E. Performance Metrics

By FY2019
-Initiate study into feasibility of chemically-modified dendrimeric structures as radionuclide decorporation agents.

By FY2020
-Continue feasibility study on the use of chemically-modified dendrimeric structures as radionuclide decorporation agents and determine if further investigation is warranted.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / Medical Technology (AFRRI)	Project (Number/Name) 241C / Radiation Countermeasures (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
241C: Radiation Countermeasures (USUHS)	6.347	0.867	0.933	0.951	-	0.951	0.970	0.989	1.009	1.029	Continuing	Continuing

A. Mission Description and Budget Item Justification

Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), 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), termed combined injury (CI). 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 preventing and 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 2018	FY 2019	FY 2020
Title: Radiation Countermeasures (USUHS)	0.867	0.933	0.951
<p>Description: For the Uniformed Services University of the Health Sciences (USU), 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), termed combined injury (CI). 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 preventing and 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.</p> <p>FY 2018 Plans:</p> <ul style="list-style-type: none"> -Test and evaluate five or more new compounds in mouse model for the development of new radiation protection (prophylactic) countermeasures. -Conduct mechanism of action studies to elucidate the cell signaling transduction pathways for promising drug substances and products as potential radiation countermeasures using cell-based assays for their characterization. -Conduct animal studies to evaluate BBT-059, a PEGylated protein analog in a mouse model for radiation countermeasures development. 			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

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

	FY 2018	FY 2019	FY 2020
<p>-Test and evaluate promising drug substances and products as radiation countermeasures to determine their efficacy and safety in irradiated gut and/or lung mouse model used for studying radiation biology.</p> <p>-Evaluate long term effects of acute radiation exposure in surviving mice after exposure to lethal dose of radiation.</p> <p>-Evaluate survival effects of ghrelin as a drug substance for radiation treatment in animal model for acute radiation syndrome (ARS).</p> <p>-Continue to evaluate and down-select lead drug substances and products and drug combinations that are effective at radiation doses producing hematopoietic (H-ARS) or gastrointestinal (GI-ARS) syndrome and identify those that are effective in treating radiation combined (e.g. burn, wound, etc.) injury in animal model of ARS.</p> <p>-Test and evaluate drug substances and products for radiation countermeasures development against mixed-field (neutron and photon) radiation exposure mimicking those from an improvised nuclear device at relevant distances from the epicenter.</p> <p>-Conduct further studies to elucidate the mechanism of action of promising drug substances and drug products against mixed-field radiation exposure using cell-based assays for their characterization.</p> <p>-Further evaluate radiation sensitivity and variation among different animal models (species).</p> <p>-Conduct exploratory studies on radiation effects when combined with insults from viruses or bacteria on the immune system and elucidate the ensuing reactive oxygen species (ROS) produced by cellular metabolism and how by using broad MAPkinase pharmacological inhibitors, antioxidants and modulators, highly selective inhibitors, etc. provide a potential treatment or drug for the radiation combined insults.</p> <p>-Establish panel of gene reporter cells system and methodologies to identify potential on and off therapeutic biological targets towards a novel strategy for developing new radiation countermeasures.</p> <p>-Continue evaluation of radiation-induced leukemia in murine model to concomitantly predict leukemia development based on epigenetic markers identified previously in FY16 and FY17 at low and high doses of radiation exposure and determine the dual benefit of administering radiation countermeasures (drug substance) for both acute and delayed effects of ionizing radiation exposure.</p> <p>FY 2018 Accomplishments:</p> <p>-Demonstrated that MAPK inhibitors can both increase and decrease production of radiation induced inflammatory cytokines and chemokines secreted by murine macrophages. This broadens the types of regulator interventions potentially available for controlling inflammation.</p> <p>-Published peer reviewed manuscript describing how commercially available gene reporter cells can be used to assay Type I interferons (IFNα/β). Potentially this can be a lower cost method with utility to screening large sample sets or high through put experimental approaches.</p> <p>-Established a material transfer agreement (MTA) with pharmaceutical drug sponsors to test a select list of drug candidates for radiation countermeasures development.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>-Completed acute toxicity study of four drug candidates. The candidates are (1) EPX-217 from Epitek, Inc, (2) MultiStem from Athersys, Inc., (3) Ketone ester from National Institute of Health, and (4) Xisomab 3G3 from Aronora Inc. These prescreened drug candidates were obtain through an interagency agreement (IAA) with the National Institute of Allergy and Infectious Diseases (NIAID) to test their survival efficacy following total body irradiation (TBI).</p> <p>-Completed acute toxicity study of PLX-R18 (Pluristem therapeutics Inc.) and BP-C2 (Meabco A/S) drug molecules. -Completed thirty day efficacy study with PLX-R18 in H-ARS mouse model, the result shows ~45% survival benefit with the drug. A confirmation study is being planned; recently PLX-R18 has received Investigational new drug (IND) status by FDA.</p> <p>- Completed evaluation of MAPK/ERK (Extracellular Signal-regulated Kinase) signaling pathway, RT²Profiler PCR Array and TGFβ / BMP Signaling Pathway. Completed assay of RT² Profiler PCR Array with spleen from irradiated animals with and without the radiation drug candidate (BBT-059) to determine the biological target of BBT-059 in the aforementioned cellular these pathways.</p> <p>-Completed analysis of blood and major organs and tissues including eye and brain harvested at 1, and 6 months post-TBI to a lethal dose of radiation in order to assess DEARE (Delayed effects of acute radiation exposure) in surviving animals treated with two radiation drug candidates (BBT-059 and TPOm).</p> <p>- Completed global profile of cellular gene responses (i.e. transcriptomic changes) in CD34+ cell populations exposed to different doses of ionizing radiation (IR) to determine the gene signature biomarkers for dose-dependent effects of IR for radiation drug.</p> <p>- Reported on the underlying mechanisms of ghrelin as a potential drug to mitigate multi-organ injury involving radiation exposure. The findings shows that Ghrelin can potentially be used as therapeutic for treating radiation injury alone or in combination with physical trauma. Two papers on hematopoietic mitigation and brain bleeding inhibition have been published in Cell Biosci 8:27, 2018 and International Journal of Molecular Science 18:1693, 2017.</p> <p>FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018. This also includes continued discovery effort in partnership with NIAID, NIH and other collaborators to advance radiobiology knowledge products and medical material products to meet the military requirements for radiation countermeasures and risk assessment and biodosimetry capabilities and their technology readiness levels for future advanced development.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019 plans.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	0.867	0.933	0.951

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

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

N/A

Remarks

The program element 0602787DHA for AFRRI in addition to the three program elements: 0601115HPPE, 0602115HPPE, and 0603115HP are coordinated and integrated into the portfolio management by the Joint Program Committee-7/ Radiation Health Effects Research Program (RHERP).

D. Acquisition Strategy

N/A

E. Performance Metrics

- By FY 2019
- FY 2019 performance metrics build on measures outlined in FY 2018 and include continued assessment of leukemia progression concomitantly with measurement of multiple epigenetic markers in serum and WBCs using microarray technology.
 - Further assess leukemia progression in mice that recovered from ARS but continued receiving countermeasures against late effects of radiation exposure; use necropsy examination to determine the cause of death at later stages.
 - Test and evaluate promising drug substances and products for radiation countermeasures development against in mixed field (neutron and photon) radiation exposure.
 - Test and evaluate promising drug substances and products for radiation countermeasures development for Radiation-Induced Gastrointestinal Syndrome (GI-ARS) in mice using the small animal radiation research platform (SARRP).
 - Conduct mouse studies to elucidate the delayed effects of acute lethal radiation exposure in drug treated survivors.
 - Continue to measure radiation-induced biomarkers such as cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of mice after Co-60 irradiation at various dose rates.
 - Continue to measure cytokines in spleen and bone marrow of mice after mixed field irradiation to study differential effects of genders and radiation dose rate.
 - Correlate radiation-induced cellular biomarkers such as mTOR-AKT and MAPK signaling network and ATP production after in vitro radiation-burn combined injury.
 - Evaluate mTOR-AKT signaling and MAPK signaling in ex vivo culture of bone marrow mesenchymal cells and in vitro small intestine cells after exposure to gamma-radiation combined with burn trauma to determine survival signaling pathways.
 - Complete assessment of MAPK pathway inhibitors in their effectiveness to alter the inflammatory response in macrophages exposed to radiation.
 - Complete assessment of ex vivo culture of human macrophage cells response to ionizing radiation, viral infection and combined injury.
 - Complete determination of the effect of ionizing radiation on cellular signaling pathways that control production of Type I interferon signaling in inflammation response.
 - Evaluate radiation quality effects on gene reporter cells. Evaluate results from pilot studies of cells with high oxidative and virus resistance.
 - Evaluate the radiation-induced IL-18 expression and activation in multiple tissues and organs using mouse model.
 - Conduct experiments to test the hypothesis that IL-18 binding protein (IL-18BP) or anti-IL-18 antibody can protect /mitigate human cells (in vitro) and mouse (in vivo) after lethal doses of total-body gamma irradiation (TBI).
 - Develop IL-18 binding protein as a novel radiation mitigative/treatment countermeasure in mouse model.
 - Test IL-18BP and G-CSF drug combination as a protection and/or mitigation/treatment drug after gamma radiation exposure.
 - Test IL-18BP and G-CSF drug combination as a protection and/or mitigation/treatment drug after mixed-field (neutron and photons) radiation exposure.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602787DHA / <i>Medical Technology (AFRRI)</i>	Project (Number/Name) 241C / <i>Radiation Countermeasures (USUHS)</i>

By FY 2020

- Continue studies in developing IL-18 BP as a novel radiation mitigative/treatment countermeasure in mouse model using different mouse strain.
- Test further IL-18BP and G-CSF combination as a protection and/or mitigation/treatment drug after gamma radiation exposure.
- Test further IL-18BP and G-CSF combination as a protection and/or mitigation/treatment drug after mixed-field (neutron and photons) radiation exposure.
- Complete measuring radiation-induced biomarkers such as cytokines, CRP, C3, IgM, PGE2, and Flt-3 ligand in serum of mice after Co-60 irradiation at various dose rates.
- Complete measuring cytokines in spleen and bone marrow of mice after mixed field irradiation to study differential effects of genders and radiation dose rate.
- Complete correlating radiation-induced cellular biomarkers such as mTOR-AKT and MAPK signaling network and ATP production after in vitro radiation-burn combined injury.
- Complete evaluating mTOR-AKT signaling and MAPK signaling in ex vivo culture of bone marrow mesenchymal cells and in vitro small intestine cells after exposure to gamma-radiation combined with burn trauma to determine survival signaling pathways.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0603002DHA I <i>Medical Advanced Technology (AFRRI)</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	2.140	0.320	0.338	0.345	-	0.345	0.352	0.359	0.366	0.373	Continuing	Continuing
030A: <i>CSI - Congressional Special Interests</i>	0.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
242A: <i>Biodosimetry (USUHS)</i>	1.266	0.187	0.202	0.206	-	0.206	0.210	0.214	0.218	0.222	Continuing	Continuing
242B: <i>Radiation Countermeasures (USUHS)</i>	0.843	0.133	0.136	0.139	-	0.139	0.142	0.145	0.148	0.151	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)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	0.332	0.338	0.345	-	0.345
Current President's Budget	0.320	0.338	0.345	-	0.345
Total Adjustments	-0.012	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.012	-			

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603002DHA / <i>Medical Advanced Technology (AFRRI)</i>
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Change Summary Explanation

FY 2018: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603002-Advanced Technology (AFRRI) (-\$0.012 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.012 million).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / Medical Advanced Technology (AFRRI)	Project (Number/Name) 030A / CSI - Congressional Special Interests
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
030A: CSI - Congressional Special Interests	0.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Because of the CSI annual structure, out-year funding is not programmed.

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

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603002DHA / <i>Medical Advanced Technology (AFRRI)</i>				Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
242A: <i>Biodosimetry (USUHS)</i>	1.266	0.187	0.202	0.206	-	0.206	0.210	0.214	0.218	0.222	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Uniformed Services University of the Health Sciences/Armed Forces Radiobiology Research Institute (USU/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. Accomplishments/Planned Programs (\$ in Millions)

	FY 2018	FY 2019	FY 2020
Title: Biodosimetry (USUHS)	0.199	0.202	0.206
<p>Description: 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.</p> <p>FY 2018 Plans: FY 2018 plans continue evaluation of radiation-induced biomarkers from the database of baboon studies as a nonhuman primate (NHP) model with utility to predict severity of hematopoietic (i.e. blood elements) acute radiation syndrome. Perform internal assessment of quality control program for radiation dose assessment by cytogenetics platform towards an eventual clinical laboratory certification. Develop algorithm using blood cell counts and biochemical biomarkers in NHP radiation dose response model. Initiate efforts to evaluate human blood samples from radiation therapy patients using panel of radiation-responsive biomarkers. Evaluate effects of radioprotectants on radiation risk categorization (RRIC) algorithm based on blood counts and blood chemistry tests using irradiated nonhuman primate archived data.</p> <p>FY 2018 Accomplishments:</p>			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>

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

	FY 2018	FY 2019	FY 2020
<p>-Published report on the utility of radiation-induced biomarker panels used to develop an algorithm based on a baboon TBI vs PBI study to predict the severity of hematopoietic (i.e. blood elements) acute radiation syndrome demonstrating proof-of-concept that prognostic biomarkers can provide early-phase diagnostic information to guide medical treatment decisions for radiological casualties with life-threatening radiation exposures.</p> <p>-Performed an internal self-assessment of the quality control program for radiation dose assessment by cytogenetics to identify remaining tasks to support an eventual request for clinical laboratory certification.</p> <p>-Initiated discussions with radiation oncologists to evaluate human blood samples from radiation therapy patients using a panel of radiation-responsive biomarkers to validate novel approaches for radiation dose and injury assessment.</p> <p>-Reported on the utility of the early-phase changes after radiation exposure on neutrophil to lymphocyte ratio in various animal (i.e., mice, dogs, rhesus monkeys, and baboons) and human radiation model systems to provide the ability to access radiation exposure.</p> <p>-Developed algorithms applying blood cell and/or biochemical markers for assessing the efficacy of radioprotectants, using archived irradiated nonhuman primate data.</p> <p>-Reported on radiation quality effects (i.e., mixed field neutron vs gamma ray exposures) on hematopoietic biomarkers using an archived baboon radiation model. Established an ARS severity scoring system using the baboon model based on hematology changes that permits assessment of radiation injury independent of radiation quality and total vs partial-body exposures.</p> <p>-Participated in interagency collaboration with REAC/TS and the Naval Dosimetry Center to further design the concepts of operation for the US Biodosimetry Network. Reported these efforts at an international biodosimetry conference.</p> <p>- Demonstrated that total body irradiation (TBI) and partial body irradiation (PBI) resulted in decreases in splenocyte counts at a similar level as shown in both deceased minipigs exposed to TBI and survived minipigs exposed to PBI. The major difference was that the levels of circulating insulin-like growth factor in dead animals were remarkably higher than that in living ones. Therefore, IGF-1 could be a good biomarker for radiation exposure and a determinant for lethality. Unlike minipigs, IGF-1 levels in blood of mice did not have such distinct difference between dead living mice.</p> <p>- Demonstrated that ATP decreased after TBI in minipigs and mice. The underlying mechanism with ATP decreases were explored successfully and understood in mice, suggesting that ATP biogenesis and maintenance after irradiation is one of major targets for developing remedial drugs in both minipigs and mice.</p> <p>FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018. In addition:</p> <p>-Sustain efforts to perform studies to validate the use of multiple parameter biodosimetry assays for optimized radiation injury and dose assessment.</p> <p>-Develop radiation injury risk and dose models based on archived human radiation accident database.</p> <p>-Continue studies to enhance throughput of cytogenetic scoring using the automated dicentric scoring software.</p> <p>-Participate in inter-comparison exercise studies to demonstrate laboratory competencies.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency	Date: February 2019
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / <i>Medical Advanced Technology (AFRRI)</i>	Project (Number/Name) 242A / <i>Biodosimetry (USUHS)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
-Engage in discussions with the Air Force to evaluate the bioeffects of exposure to high energy LINAC electrons. -Continue to readily offer the suite of AFRRI's Biodosimetry Tools to DOD customers -Initiate efforts to expand upon the AFRRI Biodosimetry Worksheet to address relevant indicators for assessment of late effects of radiation exposure. -Continue to perform the proposed mitochondrial remodeling in brain tissues by investigating fission and fusion protein markers. <i>FY 2020 Plans:</i> FY 2020 plans to continue efforts as outlined in FY 2019. In addition: -Continue efforts to obtain laboratory certification for radiation dose assessment using multiple biodosimetry assays. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	0.199	0.202	0.206

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

Remarks
The program element 0602787DHA for AFRRI in addition to the three program elements: 0601115HPPE, 0602115HPPE, and 0603115HP are coordinated and integrated into the portfolio management by the Joint Program Committee-7/ Radiation Health Effects Research Program (RHERP).

D. Acquisition Strategy
N/A

E. Performance Metrics
By FY2019
 -Perform and report on an evaluation to validate the utility of the human biomarker model.
 -Report on laboratory's competence in inter-comparison exercises for radiation dose assessment.
 - Report on recent developments and use of AFRRI's Biodosimetry Tools.
 By FY2020
 - Obtain CLIP certification for performance of the dicentric assay for dose assessment.
 - Report on use of AFRRI's suite of biodosimetry tools in a radiological exercise.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / Medical Advanced Technology (AFRRI)	Project (Number/Name) 242B / Radiation Countermeasures (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
242B: Radiation Countermeasures (USUHS)	0.843	0.133	0.136	0.139	-	0.139	0.142	0.145	0.148	0.151	Continuing	Continuing

A. Mission Description and Budget Item Justification

Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), this program supports applied research for advanced development of biomedical strategies to prevent and treat 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 preventing or 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 2018	FY 2019	FY 2020
<p>Title: Radiation Countermeasures (USUHS)</p> <p>Description: Radiation Countermeasures (USU): For the Uniformed Services University of the Health Sciences (USU), this program supports applied research for advanced development of biomedical strategies to prevent and treat 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 preventing or 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.</p> <p>FY 2018 Plans: FY 2018 plans to continue development studies in animal models for acute radiation syndrome drug discovery and development to further characterize the efficacy and safety profile of promising drug substances and products and to elucidate their mechanism of action as radiation countermeasures. Radiation countermeasure candidates such CDX-301, TPOm, PrC-210, BBT059 at various stages of preclinical development will be evaluated for advances towards clinical studies and application.</p> <p>FY 2018 Accomplishments: -Evaluated dose-dependence of radioprotective efficacy of BMT-LIPO-GT3, a new and proprietary formulation of gamma-tocotrienol (GT3), in mice.</p>	0.133	0.136	0.139

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency	Date: February 2019
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603002DHA / <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 2018	FY 2019	FY 2020
<p>-Mice experimentation conducted with a radioprotectant drug, amifostine and a PARP inhibitor, Talazoparib, for metabolomic and lipidomic studies to establish their pharmacological profiles and potential impact on radiation effects.</p> <p>FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018. In addition, there will be a continued gathering of preclinical data from animal models natural history studies for radiation toxicity and for the discovery and development of radiation countermeasures. -Detailed analysis of the metabolomic and lipidomic studies will be conducted with the samples collected in mice experiments with amifostine and a PARP inhibitor, Talazoparib. -Determination of dose reduction factor (DRF) with optimal formulation dose with BMT-LIPO-GT3 and time in relation to irradiation, study of cytokine induction in unirradiated as well as irradiated mice, and hematopoietic recovery in animals exposed to radiation.</p> <p>FY 2020 Plans: -FY 2020 plans continue efforts as outlined in FY 2019. In addition, metabolomic and lipidomic studies will be conducted with BMT-LIPO-GT3 in mice.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	0.133	0.136	0.139

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

Remarks
 The program element 0602787DHA for AFRRI in addition to the three program elements: 0601115HPPE, 0602115HPPE, and 0603115HP are coordinated and integrated into the portfolio management by the Joint Program Committee-7/ Radiation Health Effects Research Program (RHERP)

D. Acquisition Strategy
 N/A

E. Performance Metrics
 By FY 2019
 - Evaluate Nrf1, Nrf2, and ATP as biomarkers in various tissues in minipigs after 1.75 Gy.
 - Evaluate Nrf1, Nrf2, and ATP as biomarkers in various tissues in mice after 9.5 Gy.
 By FY 2020
 - Evaluate TFAM, DRP1, OPA1 and Mfn1 as biomarkers in various tissues in minipigs after 1.75 Gy.
 - Evaluate TFAM, DRP1, OPA1 and Mfn1 as biomarkers in various tissues in mice after 9.5 Gy.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	6,263.841	1,499.497	1,647.789	279.421	-	279.421	269.473	274.476	279.965	285.564	Continuing	Continuing
300A: <i>CSI - Congressional Special Interests</i>	5,000.553	1,022.296	1,122.869	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
238C: <i>Enroute Care Research & Development (Budgeted) (AF)</i>	18.642	4.479	6.833	8.088	-	8.088	8.249	8.418	8.586	8.758	Continuing	Continuing
238D: <i>Core Enroute Care R&D - Clinical Translational Focus (AF)</i>	0.997	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
238E: <i>Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)</i>	0.997	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
243A: <i>Medical Development (Lab Support) (Navy)</i>	164.298	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
247A: <i>Elimination of Malaria in Southeast Asia (CARB) (Navy)</i>	4.264	1.548	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.812
247B: <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>	2.544	1.238	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	3.782
284B: <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i>	13.716	5.327	5.523	5.633	-	5.633	5.745	5.859	5.976	6.096	Continuing	Continuing
284C: <i>Core Human Performance R&D - Clinical Translational Focus (AF)</i>	1.003	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
284D: <i>Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)</i>	1.002	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
285A: <i>Operational Medicine Research & Development (Budgeted) (AF)</i>	23.108	2.699	4.702	5.514	-	5.514	5.624	5.736	5.851	5.968	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency											Date: February 2019		
Appropriation/Budget Activity					R-1 Program Element (Number/Name)								
0130: Defense Health Program I BA 2: RDT&E					PE 0603115DHA I Medical Technology Development								
285B: Core Operational Medicine R&D - Clinical Translational Focus (AF)	0.929	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
285C: Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)	0.928	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
307B: Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)	56.140	9.504	9.725	9.919	-	9.919	10.118	10.319	10.525	10.736	0.000	Continuing	Continuing
307C: Core Force Health Protection R&D - Clinical Translational Focus (AF)	0.545	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
307D: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	0.400	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
308B: Expeditionary Medicine Research & Development (Budgeted) (AF)	15.546	4.554	4.645	4.737	-	4.737	4.833	4.929	5.028	0.000	0.000	Continuing	Continuing
308C: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	1.503	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
308D: Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)	1.502	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
309A: Regenerative Medicine (USUHS)	40.591	7.373	8.327	10.209	-	10.209	10.413	10.621	10.833	11.051	0.000	Continuing	Continuing
373A: GDF - Medical Technology Development	644.307	361.925	378.578	78.868	-	78.868	86.986	90.154	91.959	93.798	0.000	Continuing	Continuing
378A: CoE-Breast Cancer Center of Excellence (Army)	39.699	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity					R-1 Program Element (Number/Name)							
0130: Defense Health Program I BA 2: RDT&E					PE 0603115DHA I Medical Technology Development							
378B: CoE-Breast Cancer Center of Excellence (USU)	10.552	9.088	10.280	10.475	-	10.475	10.685	10.898	11.116	11.339	Continuing	Continuing
379A: CoE-Gynecological Cancer Center of Excellence (Army)	34.939	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
379B: CoE-Gynecological Cancer Center of Excellence (USU)	9.226	7.943	8.987	9.158	-	9.158	9.341	9.528	9.719	9.913	Continuing	Continuing
381A: CoE-Integrative Cardiac Health Care Center of Excellence (Army)	18.083	2.697	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
382A: CoE-Pain Center of Excellence (Army)	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
382B: CoE-Pain Center of Excellence (USUHS)	8.079	2.822	3.310	3.376	-	3.376	3.445	3.514	3.584	3.656	Continuing	Continuing
383A: CoE-Prostate Cancer Center of Excellence (USUHS)	41.822	7.250	8.203	8.359	-	8.359	8.526	8.696	8.870	9.047	Continuing	Continuing
398A: CoE-Neuroscience Center of Excellence (USUHS)	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
429A: Hard Body Armor Testing (Army)	1.356	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
431A: Underbody Blast Testing (Army)	40.611	8.000	10.800	9.200	-	9.200	1.400	0.000	0.000	0.000	-	-
448A: Military HIV Research Program (Army)	25.095	6.359	7.360	7.877	-	7.877	8.035	8.196	8.361	8.528	Continuing	Continuing
830A: Deployed Warfighter Protection (Army)	28.983	5.123	5.930	6.345	-	6.345	6.473	6.601	6.733	6.868	Continuing	Continuing
478: Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	0.000	14.766	14.754	18.556	-	18.556	18.639	18.724	19.098	19.480	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity					R-1 Program Element (Number/Name)								
0130: <i>Defense Health Program I BA 2: RDT&E</i>					PE 0603115DHA / <i>Medical Technology Development</i>								
479: <i>Framingham Longitudinal Study (USUHS)</i>	0.000	4.920	4.920	4.920	-	4.920	4.920	4.920	5.018	5.118	Continuing	Continuing	
499: <i>MHS Financial System Acquisition</i>	1.766	13.456	21.129	15.373	-	15.373	1.971	2.011	2.051	2.092	Continuing	Continuing	
381: <i>CoE - Integrative Cardiac Health Care (USUHS)</i>	0.000	0.000	2.914	3.118	-	3.118	3.180	3.244	3.309	3.375	Continuing	Continuing	
504: <i>WRAIR Vaccine Production Facility Research</i>	0.000	0.000	8.000	8.152	-	8.152	8.315	8.481	8.651	8.824	Continuing	Continuing	
506: <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>	-	0.000	0.000	11.904	-	11.904	12.141	12.385	12.631	12.883	Continuing	Continuing	
507: <i>Brain Injury and Disease Prevention, Treatment and Research (USUHS)</i>	-	0.000	0.000	13.317	-	13.317	13.583	13.855	14.132	14.415	Continuing	Continuing	
508: <i>Psychological Health and Resilience (USUHS)</i>	-	0.000	0.000	7.000	-	7.000	7.140	7.283	7.428	7.577	Continuing	Continuing	
509: <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>	-	0.000	0.000	19.323	-	19.323	19.710	20.104	20.505	20.916	Continuing	Continuing	

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development: This program element (PE) provides funding 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 areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency	Date: February 2019
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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 0603115DHA / <i>Medical Technology Development</i>
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capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1), military infectious diseases (JPC-2), military operational medicine (JPC-5), combat casualty care (JPC-6), radiation health effects (JPC-7), and clinical and rehabilitative medicine (JPC-8). 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.

The military human immunodeficiency virus (HIV) research project provides funds 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.

The Armed Forces Pest Management Board Deployed Warfighter Protection program provides for the development of new or improved protection of military personnel from insects and tick vectors of disease pathogens.

Three Centers of Excellence (CoE) receive medical technology development funds. Management of the Breast and Gynecological Cancer CoEs transfer from the Army to the Uniformed Services University beginning in FY 2017. The Cardiac Health CoE (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular disease at an early stage to ultimately discover a signature for cardiovascular 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.

In FY 2017, Congressional Special Interest (CSI) funds were added to support peer-reviewed research programs: Amyotrophic Lateral Sclerosis (ALS), Autism, Bone Marrow Failure Disease, Ovarian Cancer, Multiple Sclerosis, Cancer, Lung Cancer, Orthopedic, Spinal Cord, 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, Reconstructive Transplant, Tuberous Sclerosis Complex, Duchenne Muscular Dystrophy, Epilepsy, and Tick-borne diseases. CSI funds were also provided for Joint Warfighter Medical Research, Orthotics and Prosthetics Outcomes, Trauma Clinic Research, HIV/AIDS Program Increase, Global HIV/AIDS Prevention, and Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency	Date: February 2019
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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 0603115DHA / <i>Medical Technology Development</i>
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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: En-Route 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. Therefore, the En-Route care thrust area studies include investigation on the impact of transport on patient and providers (including cabin altitude, noise, vibration, and environmental issues affecting physiology on the aircraft), patient safety factors during transport, medical technologies for use during transport, and research to support education and training with simulation for En-Route care providers. The Human Performance thrust area focuses on optimizing airmen physical and psychological performance, assessing the physical and cognitive demands on the operator (pilot/aircrew), facilitating a safe aviation environment through technology and equipment assessment, and improving/sustaining airmen performance through training. 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 Occupational Hazard Exposure (Includes Flight Hazards and Integrated Risk), Targeted Risk Identification, Mitigation and Treatment (Formerly Pathogen ID and Novel Therapeutics and includes Big Data), FHP Technologies Development and Assessment (Assay and disease detection), and Health Surveillance, Infection, Injury & Immunity. FHP also includes Innovations and Personalized Medicine. 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 (CNRM), the Pain CoE, the Breast Cancer CoE, and the Gynecological Cancer 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. CNRM brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to 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 FY17, the Breast Cancer CoE funding line and the Gynecological Cancer CoE funding line are transferred from the Army to USUHS.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	245.936	274.920	269.421	-	269.421
Current President's Budget	245.936	274.920	269.421	-	269.421
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1,087.454	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

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 - *Peer-Reviewed Ovarian Cancer Research*

Congressional Add: 328A - *Peer-Reviewed Multiple Sclerosis Research*

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

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

Congressional Add: 337A - *Peer-Reviewed Orthopaedic 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*

Congressional Add: 400A - *Peer-Reviewed Medical Research*

Congressional Add: 417A - *Peer-Reviewed Alzheimer Research*

	FY 2018	FY 2019
	9.665	10.000
	7.248	7.500
	2.900	3.000
	19.329	20.000
	5.799	6.000
	77.316	90.000
	13.530	14.000
	28.994	30.000
	28.994	30.000
	14.497	20.000
	105.947	99.269
	125.638	130.000
	96.645	100.000
	20.332	22.000
	3.865	4.000
	319.039	350.000
	14.497	15.000

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2018	FY 2019
Congressional Add: 439A - <i>Joint Warfighter Medical Research</i>	26.695	27.500
Congressional Add: 452A - <i>Peer-Reviewed Reconstructive Transplant Research</i>	11.597	12.000
Congressional Add: 454A - <i>Orthotics and Prosthetics Outcomes Research</i>	9.665	10.000
Congressional Add: 456A - <i>HIV/AIDS Program</i>	12.473	12.900
Congressional Add: 459A - <i>Peer-Reviewed Epilepsy Research</i>	7.248	7.500
Congressional Add: 463A – <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i>	0.000	-
Congressional Add: 495 - <i>Peer-Reviewed Tick-Borne Disease Research</i>	4.832	5.000
Congressional Add: 496 - <i>Trauma Clinical Research Program</i>	9.665	10.000
Congressional Add: 501 - <i>Peer-Reviewed Hearing Restoration Research (Army)</i>	9.665	10.000
Congressional Add: 502 - <i>CSI - Peer-Reviewed Kidney Cancer Research (Army)</i>	14.497	20.000
Congressional Add: 503 - <i>CSI - Peer-Reviewed Lupus Research (Army)</i>	4.832	5.000
Congressional Add: 540A - <i>Global HIV/AIDS Prevention (Navy)</i>	8.000	8.000
Congressional Add: 660A - <i>Tuberous Sclerosis Complex (TSC)</i>	5.799	6.000
Congressional Add: 790A - <i>Peer-Reviewed Duchenne Muscular Dystrophy</i>	3.093	3.200
Congressional Add: 512 - <i>Peer-Reviewed Melanoma Research</i>	-	10.000
Congressional Add: 513 - <i>Chronic Pain Management</i>	-	10.000
Congressional Add: 514 - <i>Combat Readiness Medical Research</i>	-	15.000
Congressional Add Subtotals for Project: 300A	1,022.296	1,122.869
Project: 506: <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>		
Congressional Add:	0.000	-
Congressional Add Subtotals for Project: 506	0.000	-
Project: 509: <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>		
Congressional Add:	0.000	-
Congressional Add Subtotals for Project: 509	0.000	-
Congressional Add Totals for all Projects	1,022.296	1,122.869

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0603115DHA I <i>Medical Technology Development</i>
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Change Summary Explanation

- Realigns the management and associated DHP RDT&E resources for the Integrative Cardiac Health Care CoE from Army DHP to USUHS in FY19 and beyond (FY19, \$2.914M).
- Realigns funds within existing resources to provide dedicated funding for ongoing medical research at Walter Reed Army Institute of Research (WRAIR) Vaccine Production Facility in FY19 and beyond (FY19, \$+8.0M).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 300A / CSI - Congressional Special Interests			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
300A: <i>CSI - Congressional Special Interests</i>	5,000.553	1,022.296	1,122.869	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

	FY 2018	FY 2019
Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research	9.665	10.000
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for research in Amyotrophic Lateral Sclerosis (ALS). ALS is a degenerative neurological 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 released in May 2018: the Therapeutic Development Award and the Therapeutic Idea Award. Applications were received in August 2018 followed by scientific peer review in October 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 293A - Autism Research	7.248	7.500
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Autism research. The Autism Research Program seeks 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. Three award mechanisms were released in June 2018: the Clinical Trial Award, the Clinical Translational Research Award, and the Idea Development Award. Applications will be received in October 2018 followed by scientific peer review in January 2019. Funding recommendations will be made at programmatic review in March 2019. Awards will be made by September 2019.		
FY 2019 Plans:		
Congressional Add: 296A - Bone Marrow Failure Disease Research	2.900	3.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
<p><i>FY 2018 Accomplishments:</i> This Congressional Special Interest initiative provided funds for bone marrow failure diseases research. The mission of the Bone Marrow Failure Research 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 FY 2018, applications were accepted through one funding opportunity, the Idea Development Award, released in May 2018 . Applications will be received in October 2018 followed by scientific peer review in November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019.</p> <p><i>FY 2019 Plans:</i></p>		
<p><i>Congressional Add:</i> 310A - Peer-Reviewed Ovarian Cancer Research</p> <p><i>FY 2018 Accomplishments:</i> This Congressional Special Interest initiative provided funds for ovarian cancer research. In striving to achieve the goal of eliminating ovarian cancer, the Ovarian Cancer Research Program (OCRP) challenges the research community to address high impact, innovative research. The FY 2018 OCRP solicited innovative ideas that provide new paradigms, leverage critical resources, facilitate synergistic, multidisciplinary partnerships, and cultivate the next generation of investigators in ovarian cancer. Four award mechanisms were released in May 2018: Pilot Award, Clinical Development Award, Investigator-Initiated Research Award, and the Ovarian Cancer Academy Award recruiting Early-Career Investigators. Applications were received in August 2018 for the Pilot Award and in September 2018 for the remaining three mechanisms. Scientific peer review will be in October 2018. Funding recommendations will be made at the programmatic reviews in December 2018. Awards will be made by September 2019.</p> <p><i>FY 2019 Plans:</i></p>	19.329	20.000
<p><i>Congressional Add:</i> 328A - Peer- Reviewed Multiple Sclerosis Research</p> <p><i>FY 2018 Accomplishments:</i> This Congressional Special Interest initiative provided funds for Multiple Sclerosis (MS) research. The mission of the Multiple Sclerosis Research Program (MSRP) is to support pioneering concepts and high-impact research relevant to the prevention, etiology, pathogenesis, assessment, and treatment of MS. The FY 2018 MSRP solicited applications that address the following areas: Obstacles of Remyelination (nervous system repair) and/or Obstacles to Axonal Protection in MS; Biological Correlates of Disease Activity and Progression in MS; and MS Symptoms (Biology, Measurement, or Treatment). Two award mechanisms were released in June 2018: Exploration Hypothesis Development Award, and Investigator-Initiated Research Award. Applications were received in October 2018 followed by scientific peer review in December</p>	5.799	6.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 335A - Peer-Reviewed Cancer Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for the study of cancers designated by Congress: adrenal cancer; bladder cancer; blood cancers; brain cancer; colorectal cancer; immunotherapy; Listeria-based regimens for cancer; liver cancer, lymphoma; melanoma and other skin cancers; mesothelioma; myeloma; neuroblastoma; pancreatic cancer; pediatric brain tumors; cancers in children, adolescences and young adults; and stomach cancer. The goal of the Peer-Reviewed Cancer Research Program is to improve the quality of life by decreasing the impact of cancer on Service members, their families, and the American public. Four award mechanisms were released in May and June 2018: Career Development Award, Idea Award with Special Focus, Translational Team Science Award, and Expansion Award. Applications will be received in September 2018 followed by scientific peer review in November/December 2018. Funding recommendations will be made at programmatic review in February 2019. Awards will be made by September 2019. FY 2019 Plans:	77.316	90.000
Congressional Add: 336A - Peer-Reviewed Lung Cancer Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for lung cancer research. The Lung Cancer Research Program is a broadly-competed, peer-reviewed research program with the goal to eradicate deaths from lung cancer to better the health and welfare of military Service members, Veterans, their families, and the American public. Five award mechanisms were released in May 2018: Career Development Award, Concept Award, Idea Development Award, Investigator-Initiated Translation Research Award, and Translational Research Partnership Award. Applications were/will be received in August and September 2018 followed by scientific peer review in October and November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019. FY 2019 Plans:	13.530	14.000
Congressional Add: 337A - Peer-Reviewed Orthopaedic Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for 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 goal of the FY	28.994	30.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
2018 Peer-Reviewed Orthopaedic Research Program was to provide all Warriors affected by orthopedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function. Five award mechanisms were released in May 2018: Clinical Trial Award, Clinical Translational Research Award, Integrated Clinical Trial Award, Expansion Award, and Applied Research Award. Pre-applications were received in July 2018 and applications will be received in September 2018, followed by scientific peer review in November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 338A - Peer-Reviewed Spinal Cord Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for spinal cord injury (SCI) research. The FY 2018 Spinal Cord Injury Research Program challenged the scientific community to design research that will foster new directions for and address neglected issues in the field of SCI research with particular focus on three areas: (1) pre-hospital, prolonged field care, en route care, and early hospital management of SCI; (2) development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery; and (3) identification and validation of best practices in SCI. Five award mechanisms were released in June 2018: Clinical Research Development Award, Clinical Trial Award, Investigator-Initiated Research Award, Qualitative Research Award, and Translational Research Award. Pre-applications were received August 2018 and applications will be received in November 2018, followed by scientific peer review in January 2019. Funding recommendations will be made at programmatic review in March 2019. Awards will be made by September 2019. FY 2019 Plans:	28.994	30.000
Congressional Add: 339A - Peer-Reviewed Vision Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for vision restoration research. The Peer-Reviewed Vision Research Program supported research targeting the causes, effects and treatments of eye damage, visual deficits due to traumatic brain injury (TBI) and diseases that, despite their different mechanisms of 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 anticipated to support restoration and maintenance of visual function to ensure and sustain combat readiness and directly benefit the lives of military, Veteran, and civilian populations. The FY 2018 Vision Research Program focused on the following areas: (1) mitigation and treatment of damage to ocular structures and the visual system consistent to military-relevant injuries and diseases incident to military service; (2) vision restoration and regeneration; and (3) knowledge,	14.497	20.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
capabilities, and equipment for early responders to diagnose and mitigate military-relevant eye injuries and diseases in austere or remote environments. Two award mechanisms were released in April 2018: Clinical Trial Award and Technology/Therapeutic Development Award. Applications will be received in October 2018, followed by scientific peer review in January 2019, and programmatic review in March 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (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 FY 2018 Traumatic Brain Injury and Psychological Health (TBI/PH) Research Program were to support projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Veterans, address Congressional intent, enable significant research collaborations, and complement ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. FY 2018 funds supported research in the following areas: diagnosis and treatment of mental health disorders; optimization of psychological health and resilience for readiness; neurotrauma, neuroprotection, and neurodiagnostics; and sensory system traumatic injury, restoration, and rehabilitation. In addition, funding opportunities were released to solicit research in the areas of complex TBI rehabilitation research, long-term impact of military-relevant brain injury consortium research, and peer-to-peer support programs/interventions research. Awards will be made by September 2019. FY 2019 Plans:	105.947	99.269
Congressional Add: 380A - Peer-Reviewed Breast Cancer Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for breast cancer research. The FY 2018 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 nine overarching challenges, which were focused on preventing breast cancer, identifying determinants of breast cancer initiation, risk, or susceptibility, distinguishing deadly from non-deadly breast cancers, conquering the problems of over-diagnosis and over-treatment, identifying what drives breast cancer growth and determining how to stop it, identifying why some breast cancers become metastatic, determining how to prevent recurrence,	125.638	130.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
<p>revolutionizing treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival, and eliminating the mortality associated with metastatic breast cancer. Program Announcements for six award mechanisms were released in May and August 2018: Breakthrough Award Levels 1 and 2, Breakthrough Award Levels 3 and 4, Distinguished Investigator Award, Era of Hope Scholar Award, Innovator Award, and Breakthrough Fellowship Award. Application submission deadlines were in June, August, and December 2018, scientific peer reviews in August and October 2018 and February 2019, and programmatic reviews in October and December 2018 and January, April, and May 2019. Awards will be made by September 2019.</p> <p>FY 2019 Plans:</p>		
<p>Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research</p> <p>FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for prostate cancer research. The vision for the FY 2018 Prostate Cancer Research Program (PCRP) was 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 PCRP solicited research applications addressing four overarching challenges: (1) distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer; (2) develop strategies to prevent progression to lethal 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 were solicited in the areas of: data science and analytics; imaging and targeted radionuclide therapy; population science; precision medicine, screening, and surveillance; survivorship, including psychosocial impact on the patient and family; therapy and mechanisms of resistance and response; and tumor and microenvironment biology. Seven award mechanisms were released in May 2018: Clinical Consortium Award, Early Investigator Research Award, Health Disparity Research Award, Idea Development Award, Impact Award, Prostate Cancer Pathology Resource Network Award, and Physician Research Award. Applications were/will be received in August, September, and October 2018, followed by scientific peer reviews in October, November, and December 2018. Funding recommendations will be made at programmatic reviews in January and February 2019. Awards will be made by September 2019.</p> <p>FY 2019 Plans:</p>	96.645	100.000
<p>Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research</p> <p>FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Gulf War Illness research. The vision for the FY 2018 Gulf War Illness Research Program was improving the health and lives</p>	20.332	22.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
of Veterans who have Gulf War Illness by funding research to identify effective treatments, improve clinical definition and diagnosis, and to better understand the underlying biology and symptoms of Gulf War Illness. Four award mechanisms were released in May 2018: Biorepository Resource Network Award, Clinical Consortium Award, Investigator-Initiated Focused Research Award, and Qualitative Research Award. Applications will be received in September 2018 followed by scientific peer review in November 2018. Funding recommendations will be made at programmatic review in January 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 396A - Research in Alcohol and Substance Use Disorders FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for alcohol and substance use disorders (ASUD) research. The goal of the FY 2018 Alcohol and Substance Abuse Disorders Research Program was to identify and develop new medications to improve treatment outcomes for ASUD, especially related to traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD). In support, the Consortium Award Program Announcement was released in June 2018. Applications were received in September 2018, followed by scientific peer review in November 2018 and programmatic review in January 2019. Awards will be made by September 2019. FY 2019 Plans:	3.865	4.000
Congressional Add: 400A - Peer-Reviewed Medical Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for military-relevant research in Congressionally directed topic areas toward the goal of improving the health and well-being of all military Service members, Veterans, and beneficiaries. The 52 Congressionally-directed topics for FY 2018 were: Acute Lung Injury, Antimicrobial Resistance, Arthritis, Burn Pit Exposure, Cardiomyopathy, Cerebellar Ataxia, Chronic Migraine and Post-traumatic Headache, Chronic Pain Management, Congenital Heart Disease, Constrictive Bronchiolitis, Diabetes, Dystonia, Eating Disorders, Emerging Infectious Diseases, Endometriosis, Epidermolysis Bullosa, Focal Segmental Glomerulosclerosis, Fragile X, Frontotemporal Degeneration, Guillain-Barre Syndrome, Hepatitis B and C, Hereditary Angioedema, Hydrocephalus, Immunomonitoring of Intestinal Transplants, Inflammatory Bowel Diseases, Interstitial Cystitis, Lung Injury, Malaria, Metals Toxicology, Mitochondrial Disease, Musculoskeletal Disorders, Myotonic Dystrophy, Non-Opioid Pain Management, Nutrition Optimization, Pancreatitis, Pathogen-Inactivated Blood Products, Post-Traumatic Osteoarthritis, Pressure Ulcers, Pulmonary Fibrosis, Respiratory Health, Rett Syndrome, Rheumatoid Arthritis, Scleroderma, Sleep Disorders, Spinal Muscular Atrophy, Sustained-Release Drug Delivery, Tinnitus, Tissue Regeneration, Tuberculosis, Vaccine Development for Infectious Diseases, Vascular Malformations, and Women's Heart	319.039	350.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
Disease. Five award mechanisms were offered in FY 2018: Clinical Trial Award, Discovery Award, Focused Program Award, Investigator- Initiated Research Award, and Technology/Therapeutic Development Award. For the Discovery Award, application receipt occurred in August 2018, scientific peer review was conducted in August - September 2018, and funding recommendations will be made during programmatic review in November 2018. For the remaining mechanisms, application receipt will occur in October 2018, peer review will be conducted in November - December 2018, and funding recommendations will be made during programmatic review in February 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 417A - Peer-Reviewed Alzheimer Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Alzheimer's disease (AD) research. The FY 2018 Peer-Reviewed Alzheimer's Research Program (PRARP) sought to: (1) address the long-term consequences of traumatic brain injury (TBI) as they pertain to AD and AD-related dementias (ADRD); and (2) reduce the burden on AD/ADRD-affected individuals and caregivers, especially in the military and Veteran communities. Four award mechanisms were released in July 2018: Convergence Science Research Award, Quality of Life Research Award, New Investigator Award, and Research Partnership Award. Applications will be received in September 2018, followed by peer review in November 2018. Funding recommendations will be made at programmatic review in February 2019. Awards will be made by September 2019. FY 2019 Plans:	14.497	15.000
Congressional Add: 439A - Joint Warfighter Medical Research FY 2018 Accomplishments: The FY 2018 Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising projects previously funded by Congressional Special Interest initiatives. The focus is 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 FY 2018 JWMRP supported military medical research in medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine. FY 2019 Plans:	26.695	27.500
Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for reconstructive transplantation research. The FY 2018 Reconstructive Transplant Research Program (RTRP) focused	11.597	12.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
on research in reconstructive transplantation for the refinement of approaches for hand, face, and other vascularized composite tissue allografts, which includes multiple body system components such as skin, muscle, tendon, nerves, bone, and blood vessels. In addition, the RTRP focused on research aimed toward improving access to reconstructive transplants, and on immunomodulation strategies that can reduce the need for immunosuppression regimens. Four award mechanisms were released in August 2018: Concept Award, Investigator-Initiated Research Award (IIRA), Technology Development Award (TDA), and Qualitative Research Award (QRA). Applications will be received in December 2018. Peer review will take place in January 2019, and Programmatic Review will take place in March - April 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for orthotics and prosthetics outcomes research. The goal of the FY 2018 Orthotics and Prosthetics Outcomes Research Program was to support research that evaluates the comparative effectiveness of orthotic and prosthetic devices using patient-centric outcomes for Service members and Veterans who have undergone limb amputation. The program focused on outcomes-based best practices through analysis of the merits of prosthetic and orthotic devices currently available, and not on the development of new, or the improvement of existing, technology. The program intent was to generate clinically useful evidence to enhance and optimize patient outcomes. One award mechanism was released in September 2018: Orthotics and Prosthetics Outcomes Research Award. Pre-applications will be received in October 2018 and applications in January 2019. Scientific peer review will be held in February 2019, and programmatic review will occur in April 2019. Awards will be made by September 2019. FY 2019 Plans:	9.665	10.000
Congressional Add: 456A - HIV/AIDS Program FY 2018 Accomplishments: FY 2019 Plans:	12.473	12.900
Congressional Add: 459A - Peer-Reviewed Epilepsy Research FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for traumatic brain injury (TBI)-related epilepsy research. The FY 2018 Peer Reviewed Epilepsy Research Program supported studies to examine the interconnection between TBI and epilepsy in four scientific focus areas: (1) epidemiology; (2) markers and mechanisms of post traumatic epilepsy; (3) models of post-traumatic epilepsy; and (4) research	7.248	7.500

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
<p>into psychogenic (non-epileptic) seizures. Two award mechanisms were released for FY 2018: the Idea Development Award and Epilepsy Risk Factors Award. Applications were received in September 2018. Peer review will be held in November 2018, and programmatic review in February 2019. Awards will be made by September 2019.</p> <p>FY 2019 Plans:</p>		
<p>Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF)</p> <p>FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward FY 2018 DHP core research initiatives in PE 0603115. Funds supported medical technology development efforts in the areas of military operational medicine, combat casualty care, military infectious diseases, clinical and rehabilitative medicine, medical simulation and information sciences, and radiation health effects. (Project 373A).</p>	0.000	-
<p>Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research</p> <p>FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for tick-borne diseases research. The FY 2018 Peer Reviewed Tick-Borne Disease Research Program’s mission was to support research focused on understanding the pathogenesis of Lyme disease and other tick-borne illnesses and on delivering innovative solutions to prevent and better diagnose and treat their manifestations. Two funding opportunities were released in May 2018: Idea Award and Investigator-Initiated Research Award. Pre-applications were received in July 2018 and applications will be received in October 2018. Scientific peer review will be held in December 2018, and funding recommendations will be made at programmatic review in February 2019. Awards will be made by September 2019.</p> <p>FY 2019 Plans:</p>	4.832	5.000
<p>Congressional Add: 496 -Trauma Clinical Research Program</p> <p>FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for advancing trauma clinical research. Through a competitive Request for Proposals (RFP) process, the Department of Defense (DoD) has created a coordinated, multi-institutional clinical research network of civilian and military trauma centers to address the military relevant priorities and gaps in trauma care. The Indefinite Deliverable Indefinite Quantity (IDIQ) contract established the Linking Investigations in Trauma and Emergency Services (LITES) trauma research network. The LITES network creates a standing research consortium of US trauma systems and centers with the capability to conduct prospective, multicenter, injury care and outcomes research of relevance to the DoD. The LITES network is led by the University of Pittsburgh and features nine partnering sites, and the network has to ability to expand or contract based on the research performed. During FY18, a panel of subject matter experts from the DoD (including representatives from the Combat Casualty Care</p>	9.665	10.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
Research Program of the US Army Medical Research and Materiel Command and the US Army Institute of Surgical Research) and other Federal agencies relevant to the research performed or to be performed by the LITES network was established to support research oversight and generation of task orders. New DoD-relevant research task orders for the LITES network will be executed by September 2019. FY 2019 Plans:		
Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army) FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds to pursue promising, necessary research for treatment of burdensome and very prevalent auditory system injury. The vision of the Hearing Restoration Research Program is to improve the operational effectiveness, medial readiness and quality of life of Service members and Veterans with auditory system injuries. The mission of the program is to advance the science of hearing restoration by delivering groundbreaking research and solutions that remove barriers to successful treatment of auditory system injury. Two program announcements will be released in September 2018: Translational Research Award and Focused Research Award. Applications will be received in November 2018 with peer review in January 2019 and programmatic review in March 2019. Awards will be made by September 2019. FY 2019 Plans:	9.665	10.000
Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army) FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for research into kidney cancer. The vision of the Kidney Cancer Research Program is to eliminate kidney cancer. Four program announcements will be released in October 2018: Idea Development Award, Concept Award, Translational Research Partnership Award, and the Consortium Development Award. Applications will be received in January 2019 with peer review in February 2019 and programmatic review in April 2019. Awards will be made by September 2019. FY 2019 Plans:	14.497	20.000
Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army) FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for research into lupus. The vision of the Lupus Research Program is to cure lupus through partnership of scientists, clinicians, and consumers. Two program announcements will be released in October 2018: Concept Award and Idea	4.832	5.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 300A / <i>CSI - Congressional Special Interests</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019
Award. Applications will be received in January 2019 with peer review in February 2019 and programmatic review in April 2019. Awards will be made by September 2019. FY 2019 Plans:		
Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) FY 2018 Accomplishments: FY 2019 Plans:	8.000	8.000
Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Tuberous Sclerosis Complex (TSC) research. The FY 2018 Tuberous Sclerosis Complex Research Program (TSCRCP) sought to support 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. Three award mechanisms were released in May 2018: Idea Development Award, Exploration-Hypothesis Development Award, and Clinical Translational Research Award. Applications were received in July 2018, followed by scientific peer review in September 2018. Funding recommendations will be made at programmatic review in November 2018. Awards will be made by September 2019. FY 2019 Plans:	5.799	6.000
Congressional Add: 790A - Peer-Reviewed Duchenne Muscular Dystrophy FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for Duchenne Muscular Dystrophy (DMD) research. DMD is caused by gene mutations in skeletal muscle proteins, and affects approximately 1 in 3,600 boys causing muscle degeneration and eventual death. The goal of the FY 2018 Duchenne Muscular Dystrophy Research Program was to preserve and improve the function and quality of life, and to extend the lifespan of all individuals with Duchenne by supporting research for the discovery, development, and clinical testing of novel therapeutics. Two award mechanisms were released in May 2018: Career Development Award and Investigator-Initiated Research Award. Applications will be received in October 2018 with scientific peer review to be conducted in January 2019 followed by programmatic review in March 2019. Awards will be made by September 2019. FY 2019 Plans:	3.093	3.200
Congressional Add: 512 - Peer-Reviewed Melanoma Research	-	10.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019
FY 2019 Plans: Not yet established.		
Congressional Add: 513 - Chronic Pain Management FY 2019 Plans: Not yet established.	-	10.000
Congressional Add: 514 - Combat Readiness Medical Research FY 2019 Plans: Not yet established	-	15.000
Congressional Adds Subtotals	1,022.296	1,122.869

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
238C: <i>Enroute Care Research & Development (Budgeted) (AF)</i>	18.642	4.479	6.833	8.088	-	8.088	8.249	8.418	8.586	8.758	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 injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into products. The sub-project areas include: Impact of Transport on patients and providers (physiological effects of transport factors on patients and crew and impact of transport times on En-Route Trauma and Resuscitative Care), patient safety (includes En-Route data analytics and the optimization of patient care), medical technologies which includes technology advances and clinical assessment at altitude, and research to support En-Route education and training with simulation.

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

	FY 2018	FY 2019	FY 2020
Title: Enroute Care Research & Development (Budgeted) (AF)	4.479	6.833	8.088
<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 injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into products. The sub-project areas include: Impact of Transport on patients and providers (physiological effects of transport factors on patients and crew and impact of transport times on En-Route Trauma and Resuscitative Care), patient safety (includes En-Route data analytics and the optimization of patient care), medical technologies which includes technology advances and clinical assessment at altitude, and research to support En-Route education and training with simulation.</p> <p>FY 2019 Plans: 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. Continue austere, pre-transport, qualitative clinical testing. Continue to identify independent predictors that are associated with increased survival among patients in a combat theater and update clinical practice and training guidelines to support resulting best practices. Evaluate mechanisms for neuroprotection including hydroxocobalamin in a hemorrhagic model of global and traumatic brain ischemia and to understand and therapeutically target the physiological response associated with prolonged field care and extended hold time. Perform service-connected life trajectory comparison of psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients. Establish database for medical evacuation treatment indicators with care and resolution outcomes. Discovery, refinement, and implementation of advanced genetics, epigenetics, and transcriptome technologies to predict resiliency and to enhance point-of-care medical and aeromedical decision making.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Enroute Care Research & Development (Budgeted) (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>In addition, plans are to complete multicenter closed-loop ventilation device trials. Evaluate mechanisms for neuroprotection including hydroxocobalamin in a hemorrhagic model of global and traumatic brain ischemia and to understand and therapeutically target the physiological response associated with prolonged field care and extended hold time. Perform service-connected life trajectory comparison of psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients. Establish database for medical evacuation treatment indicators with care and resolution outcomes. Discovery, refinement, and implementation of advanced genetics, epigenetics, and transcriptome technologies to predict resiliency and to enhance point-of-care medical and aeromedical decision making. Evaluate the influence of altitude, oxygenation, and sedation on neurodegeneration following traumatic brain injury (TBI). Initiate a retrospective study of patients with traumatic brain injury transported by critical care transport team (CCATT). Assess the effects of aeromedical evacuation on the risk of vasospasm following TBI. Continue with developing research objectives and end states focused in the AE PoR Core Capability Areas (CCAs): Clinical En Route Care and Patient Safety; En Route Care Education, Training and Simulation; En Route Care Medical Technologies; Impact of Transport; and Clinical/Patient Decision Support and Monitoring.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Slight increase due to additional efforts to complete multicenter closed-loop ventilation trials as outlined in the FY 2019 Base plans.</p>			
Accomplishments/Planned Programs Subtotals	4.479	6.833	8.088

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807714HP: <i>Other Consolidated Health Support</i>	14.655	-	-	-	-	-	-	-	-	-	Continuing Continuing

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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 238C / <i>Enroute Care 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development			Project (Number/Name) 238D / Core Enroute Care R&D - Clinical Translational Focus (AF)				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
238D: Core Enroute Care R&D - Clinical Translational Focus (AF)	0.997	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 238E / Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
238E: Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)	0.997	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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

N/A

Remarks

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

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 243A / Medical Development (Lab Support) (Navy)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
243A: Medical Development (Lab Support) (Navy)	164.298	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

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, the labs focus on 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 2018	FY 2019	FY 2020
Title: Medical Development (Lab Support) (Navy)	0.000	-	-
Description: Funding in this project code covers 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. Excluded costs include military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 247A / Elimination of Malaria in Southeast Asia (CARB) (Navy)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
247A: Elimination of Malaria in Southeast Asia (CARB) (Navy)	4.264	1.548	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.812

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: Combat Antibiotic Resistance Bacteria (CARB); Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

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

	FY 2018	FY 2019	FY 2020
Title: Elimination of Malaria in Southeast Asia (CARB) (Navy)	1.548	0.000	-
<p>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.</p> <p>FY 2018 Accomplishments: Enhanced surveillance activities with the Ministry of Health were continued at sites in central Vietnam and on the Laos border. This project has identified risk factors among forest goers, similar to US military personnel in terms of age, health and activity, associated with acquiring malaria. Preliminary data from 2015 and 2016 presented at the American Society of Tropical Medicine and Hygiene (Nov 2016); this information will inform future studies on malaria interventions. To continue work in Vietnam with the Ministry of Health a 2-year work plan was approved in Jul 2016. Continued recruitment of Vietnam-Australia-US military collaborative study to characterize drug resistance in central Vietnam. Preliminary data, indicating no drug resistance present at study site, presented at the USPACOM Asia Pacific Military Health Exchange in Kuantan, Malaysia (Aug 2016). Cross sectional study protocol approved by Vietnam Ministry of Defense; this project started in Q1 FY17 targeting people served by military clinics in Gai Lia Province, a remote area on the Cambodia border.</p> <p>FY 2019 Plans:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
<p>Building on partnerships with the Ministries of Health and Defense surveillance activities will continue in border areas with known malaria drug resistance. Surveillance efforts will be augmented by pilot testing intervention products and packages that could be utilized by the Vietnam National Malaria Control Program and the US DoD to inform malaria prevention and control programs. Surveillance and malaria control/elimination products and strategies will be evaluated using approaches harmonized with the World Health Organization and US DoD Defense Malaria Assistance Program. Study results and recommendations will be reported in refereed professional journals and policy recommendations submitted to the Vietnamese and US Governments. The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following.</p> <p><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following.</p>				
Accomplishments/Planned Programs Subtotals		1.548	0.000	-
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 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 247B / Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
247B: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	2.544	1.238	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	3.782

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. Through systematic biology, it will develop 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 Naval Medical Research Center (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 largest infectious disease hospital in Egypt, Abbassia Fever Hospital, provides critical severe infection and antimicrobial resistance data from the North African Theater. This project supports (both directly and indirectly) Global Health Security Agenda priorities: Combat Antibiotic Resistance Bacteria (CARB); Prevent Avoidable Epidemics; Detect Threats Early; and Respond Rapidly and Effectively to biological threats of international concern.

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

	FY 2018	FY 2019	FY 2020
Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)	1.238	0.000	-
<p>Description: This project seeks to demonstrate that the impact of sepsis from resistant and other high risk organisms in Egypt can be mitigated through the 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.</p> <p>FY 2018 Accomplishments: FY 2018 efforts supported continued enrollment of severely ill patients in an observational study in Cambodia at Takeo Provincial Hospital and in Ghana at Komfo Anoyke Teaching Hospital (KATH). 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,</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
<p>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 were considered for enrollment. Laboratory testing augmented the testing routinely performed at the hospital microbiology laboratory, and included diagnostic tests (e.g. blood cultures, malaria smears, HIV tests, and serology), molecular diagnostics, and assays measuring the host-response (RNA sequencing, proteomics, and metabolomics). Sophisticated analytic and statistical approaches are being applied to the complex data set to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways.</p> <p>The Vietnam-Australia-US military study of drug resistance patterns in Central Vietnam was closed in Jan 2017 due to a lower than expected malaria burden. Preliminary data supports previous findings, reported in FY16, that there is no resistance for 1st choice malaria drug treatments. Additionally, a review of Vietnam malaria burden, control measures and environmental factors was initiated; the preliminary findings suggest increased average daily temperature was a primary factor of decreased malaria rates. Recruitment for the cross-sectional study in Gai Lia Province (on the border with Cambodia) started in Dec 2016 and was completed in Feb 2017. Sample and data analysis are ongoing, however, preliminary results from the >3,000 participants indicate the rate of patients without symptoms, but still carrying malaria parasite, was >1.25% in this study population, representing a silent malaria transmission risk in this forested, border region on the Cambodia-Vietnam border. The study of Vietnamese workers returning from Africa was initiated in Q2 FY17 with concurrent records review was stated for malaria patients recently returned from Africa presenting for care at two referral medical facilities in Ha Noi in 2014-2016. Preliminary results were accepted for presentation at the Joint International Tropical Medicine Meeting in Bangkok, Thailand from 06-08 Dec 2017. These data suggest delayed malaria clearance in patients returning from Africa was likely due to delayed medical treatment and not from malaria drug resistance.</p> <p>FY 2019 Plans: FY18/19 funding will continue the support of the observational study at the Takeo Provincial Hospital in Cambodia and Komfo Anoke Teaching Hospital in Ghana. It will also support the translation of observational studies at the Abbassia Fever Hospital to develop sophisticated analytical and statistical approaches to identify diagnostic and prognostic markers for sepsis and to investigate common pathogenic pathways. Additionally, antimicrobial resistance patterns determined from the observational studies will be combined with prognostic markers for sepsis and common pathogenic pathway data to achieve improved patient outcomes. The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: The project will be completed by the end of FY19, therefore, no funding is budgeted in the years following.</p>			
Accomplishments/Planned Programs Subtotals	1.238	0.000	-

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 247B / <i>Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy)</i>

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

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 284B / USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
284B: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	13.716	5.327	5.523	5.633	-	5.633	5.745	5.859	5.976	6.096	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 2018	FY 2019	FY 2020
Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)	5.327	5.523	5.633
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 2019 Plans: Continue implementation of the Optimization of AF Human Capital Research Plan focused on medical readiness to support airman mission alignment. Advance understanding of appropriate selection pertaining to new accessions, job placement, injury reduction and retention. Continue assessment and validation of standards across research lines in the areas vision, psychological, and physical physiological for high risk and high demand airman career fields. Develop model to assess and validate return of investment on embedded medics. Work to characterize at risk mission sets and operator/aircrew needs to optimize performance in high altitude environment to inform operational changes and determine safe altitudes for long-term exposures. Advance understanding of neuroprotection and/or neurotreatment therapies designed to mitigate hyperoxemic brain injury/effects.			
FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
FY 2020 plans continue efforts as outlined in FY 2019.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	5.327	5.523	5.633

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 284C / Core Human Performance R&D - Clinical Translational Focus (AF)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
284C: Core Human Performance R&D - Clinical Translational Focus (AF)	1.003	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 training and operational environments such as the mitigation of Musculoskeletal Injury on personnel in Air Force Basic Training and high demand operations. The sub-project areas include: Cognitive Performance which includes assessing Impact of Recurrent Hypobaric Exposure, Physical Performance and Targeted Conditioning which includes providing Evidence Based Prevention Strategies and Health Programs for Optimal Performance, and Identification of Clinical Solutions to Mitigate Operational and Environmental Challenges to Performance. Optimization of Human Capital Selection: Prognostic parameters to the success of airmen in various career field in particular sustain Airmen Trainee Health. These will include selection in mental, social, and physical determinants. These also may include genomic indicators that might suggest physical and mental resiliency to different occupational stressors (tasks, environment, etc....) and indicators to recovery to baseline to different occupational stressors or frank injury/disease.

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

N/A

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

N/A

Remarks

SEE PROJECT CODE 284B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 284C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 284D / <i>Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
284D: <i>Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF)</i>	1.002	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 AF missions. This work addresses unique Air Force operational environments such as the mitigation of physiological and cognitive demand on personnel involved in both piloted and remote piloted aircraft operations. Understanding and measuring aviation performance and developing injury prevention strategies to optimize performance of AF personnel. Identification and mitigation of stress on personnel involved in Intelligence, Surveillance, and Reconnaissance operations. The sub-project areas include: Air Force Aircrew Physiology and Cognition Performance which includes pilot performance monitoring, interventions and fatigue management. AF unique Physical, Psychological, Behavioral and 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. Optimization of Human Capital, Advancing Medical Readiness for Optimal Performance, and Identification of techniques, treatments, and technical solutions to mitigate Operational and Environmental Challenges to Performance.

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

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 285A / Operational Medicine Research & Development (Budgeted) (AF)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
285A: Operational Medicine Research & Development (Budgeted) (AF)	23.108	2.699	4.702	5.514	-	5.514	5.624	5.736	5.851	5.968	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 2018	FY 2019	FY 2020
Title: Operational Medicine Research & Development (Air Force)	2.699	4.702	5.514
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 2019 Plans: Provide guidance on the clinical impact of the new cell-based therapies as applied to improvements in fat grafting for warfighters requiring IED and burn wound reconstruction, and beneficiaries with other traumatic injuries. Evaluate silica encapsulated monomers for self-healing dental materials. Characterize Type 2 Diabetes prevention and care in the MHS. Assess proneuroregenerative therapies and collateral sensory reinnervation in peripheral nerve injuries. Evaluate triggable release, reloadable, smart hydrogels for graft targeted immunotherapy in reconstructive transplantation. Examine diabetes self-management education via telemedicine in the USAF. Examine Eustachian Tube Dysfunction (ETD).			
Compare aeromedical care service delivery methods assessing for efficacy and efficiency in promoting beneficial outcomes in operators and their families. Continue research program to identify biomarkers of traumatic brain injury in warfighters using minimally invasive sample collection methods to improve aeromedical patient care. Develop autonomously designed DNA-based therapeutic interventions against emergent infectious diseases. Evaluate integrated operational medicine approach to characterize individualized aeromedical care.			
FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 285A / <i>Operational Medicine Research & Development (Budgeted) (AF)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
FY 2020 plans continue efforts as outlined in FY 2019.				
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Increase reflects right-sizing the program funding to reflect the actual execution of the program.				
Accomplishments/Planned Programs Subtotals		2.699	4.702	5.514
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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
285B: <i>Core Operational Medicine R&D - Clinical Translational Focus (AF)</i>	0.929	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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

N/A

Remarks

SEE PROJECT CODE 285A PROGRAM FUNDING SUMMARY FOR PROJECT CODE 285B WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
<i>285C: Core Operational Medicine R&D - Aerospace/ Human Performance Focus (AF)</i>	0.928	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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

N/A

Remarks

SEE PROJECT CODE 285A PROGRAM FUNDING SUMMARY FOR PROJECT CODE 285C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 307B / Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
307B: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)	56.140	9.504	9.725	9.919	-	9.919	10.118	10.319	10.525	10.736	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 2018	FY 2019	FY 2020
Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force)	9.504	9.725	9.919
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 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
<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 2019 Plans: Develop Force and Individual Comprehensive Health Protection System (FInCH) that knows an individual health threat environment and assesses, documents, and informs actions on a real-time basis. Continue to evaluate leading causes of missed training time and medical attrition from training, significantly affect military readiness, to improve the health and well-being of trainees and active duty service members; save significant money from the associated medical and non-medical costs, including long-term disability costs; and improve operational readiness by eliminating disruptions in the training pipeline. Continue study to evaluate breath biomarkers as diagnostic for influenza A. Examine alternate tinnitus management techniques using blood-oxygen-level-dependent MRI with neurofeedback. Evaluate genetic markers for musculoskeletal injuries and ailments. Develop capabilities for remote sensing of environmental hazards. Develop capabilities to efficiently and effectively continuously monitor personnel exposures, securely transmit the information and capture in searchable database for future reference. Perform assessment of subtle cognitive and respiratory effects of low-level exposures from low-level exposures in the challenging environments associated with AI operations. Initiate development of automated algorithms that incorporate environmental sensor and risk assessment to determine appropriate mitigation actions in real time as hazards are presented in-flight and in ground operations. Continue early detection, real time prediction of bioenvironmental impact, disease outbreak and intervention, data analytics and information sharing. Continue development and demonstration of the rapid transition of analytics tools that convert a multitude of health related data sources into actionable information based on operational context. Develop a communications platform that can collect exposure and health care data from multiple sources and transmit that data in a compressed format.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	9.504	9.725	9.919

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 307B / <i>Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 307C / Core Force Health Protection R&D - Clinical Translational Focus (AF)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
307C: Core Force Health Protection R&D - Clinical Translational Focus (AF)	0.545	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 307C / <i>Core Force Health Protection R&D - Clinical Translational Focus (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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 307D / Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
307D: Core Force Health Protection R&D - Aerospace Medicine/Human Performance Focus (AF)	0.400	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
308B: <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>	15.546	4.554	4.645	4.737	-	4.737	4.833	4.929	5.028	0.000	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 2018	FY 2019	FY 2020
Title: Expeditionary Medicine Research & Development (Air Force)	4.554	4.645	-
<p>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.</p> <p>FY 2019 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 cryopreserved blood products, rhabdomyolysis, neuroprotection, and ischemia-reperfusion injury. Transition multi-channel negative pressure wound treatment system to advanced development. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Continue to evaluate novel hemorrhage control products that utilize alternative technologies to active hemostatic coatings to provide a lower-cost, safer and more versatile solution to various hemorrhage control pathologies across the continuum of care. Demonstrate feasibility of training AHR to Level II/III emergency care providers to increase survivability of hemorrhage induced traumatic cardiac arrest. Evaluate Cell-free DNA as an Injury Severity Marker in traumatic brain injury and acute lung injury. Assess the use of the Abdominal Aortic and Junctional Tourniquet (AAJT) during CPR after traumatic cardiac</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 308B / <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i>

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

	FY 2018	FY 2019	FY 2020
<p>arrest and as a Stop-Gap for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) insertion. Determine the comparative benefit of prolonged exposure to an FDA approved complement inhibitor in a pre-/early hospital swine model of polytrauma. Evaluate sustained release, stimuli responsive, smart hydrogels for prevention, modulation and management of acute pain. Continue characterization of early biomarkers in a swine model of polytrauma. Optimize REBOA and ECLS to treat combat relevant trauma at ground level and high altitude. Compare utility of standard left lateral thoracotomy vs. modified bilateral “clam shell” thoracotomy by emergency physicians. Evaluate hydroxocobalamin for neuroprotection and survival in a hemorrhagic swine model of traumatic brain ischemia. Evaluation of Stem-Cell Based Therapeutics for protection from Acute Lung Injury and Acute Respiratory Distress Syndrome. Assessment of a pharmacologic blockade of Interleukin-1 (IL-1) signaling to promote systemic and cerebral protection after hemorrhagic shock and traumatic brain injury. Evaluation of the mitigation of burn injury severity and infection rates using a novel dressing that targets multiple burn-related pathologies. Evaluation of prolonged field care resuscitation guided by blood pressure versus cerebral perfusion in a swine model of hemorrhage and traumatic brain injury. Evaluate the efficacy of prophylactically reducing post-trauma sepsis risks with TLR8 agonists.</p> <p>Transition multi-channel negative pressure wound treatment system to advanced development. Support advanced development of TS-VIS if necessary. Continuation of studies to test and compare point of care testing devices for field use. Continue identification of biomarkers and development of decision support algorithms which predict the need for life saving interventions and non-invasively estimate current and future intracranial pressure and neurologic status. Continue research addressing needs related to Expeditionary Casualty Care and Expeditionary Logistics. Investigate lifesaving hemorrhage control product that can be introduced to the field of combat casualty care as lifesaving interventions. Investigate novel targeted intravascular therapeutics which provides hemorrhage control. Pilot the use of ECMO and developing closed loop control. Continue to investigate small molecules which modulate the immune system and the response to trauma.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	4.554	4.645	-

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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development			Project (Number/Name) 308C / Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
308C: Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)	1.503	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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

N/A

Remarks

SEE PROJECT CODE 308B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 308C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 308D / Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
308D: Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)	1.502	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

N/A

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

N/A

Remarks

SEE PROJECT CODE 308B PROGRAM FUNDING SUMMARY FOR PROJECT CODE 308D WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 309A / Regenerative Medicine (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
309A: <i>Regenerative Medicine (USUHS)</i>	40.591	7.373	8.327	10.209	-	10.209	10.413	10.621	10.833	11.051	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Regenerative Medicine (USUHS)	7.373	8.327	10.209
<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 119 research projects.</p>			
<p>FY 2019 Plans: FY19 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) Develop Clinical Trials Unit and expand clinical research capability to increase the number of interventional trials ; (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 FY19 funding; (5) Disseminate findings of CNRM basic, translational, and clinical research; (6) Host CNRM retreat and internal 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; (12) Participate on the Traumatic Brain Injury (TBI) Research Synergy Board (RSB) and contribute to the TBI "Unity of Effort" to strategically strengthen and accelerate TBI research on "America's Health Campus;" (13) Utilize Biospecimen Bank of blood specimens linked to MRI and clinical assessment data in longitudinal studies of TBI patients and relevant comparison cohorts; (14) Brain Tissue Repository of brains donated from military TBI patients, including state-of-the-art neuropathological analysis of blast cases and relevant</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 309A / <i>Regenerative Medicine (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
comparison cohorts; (15) Deployment of multi-modal forms of advanced imaging technology for diagnosis of TBI, with and without co-morbid PTSD, including MRI-PET, hyperacute MRI, and novel diffusion imaging techniques such as Mean Apparent Propagator; (16) Creation of Work flow pipeline for accurate and efficient analysis of neuroimaging data relevant to TBI, including quantitative analysis of microhemorrhages, traumatic meningeal injury, and white matter abnormalities; (17) Utilize multiple animal models involving multiple species for improved analysis of acute and chronic effects of TBI relevant to the warfighter, including blast exposure, repetitive injury, and stress conditions.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Previous years reflect a programmatic reduction in RDT&E (DHP-wide).			
Accomplishments/Planned Programs Subtotals	7.373	8.327	10.209

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0806721HP: <i>Uniformed Services University of the Health Sciences</i>	9.458	9.647	9.840	-	9.840	10.036	10.236	-	-	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

E. Performance Metrics
Center for Neuroscience and Regenerative Medicine: In FY16 through FY19, 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 373A / GDF - Medical Technology Development			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
373A: GDF - Medical Technology Development	644.307	361.925	378.578	78.868	-	78.868	86.986	90.154	91.959	93.798	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Technology Development provides funds for development of 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. Medical technology development is managed by six Joint Program Committees: 1- Medical Simulation and Information Sciences research aims to coordinate health information technology, simulation, and training research across the Military Health System. Technology development efforts are directed toward the medical simulation task. 2- Military Infectious Diseases research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine research goals are to develop and validate medical countermeasures against operational stressors, prevent physical and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care research is optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facilities care. 5- Radiation Health Effects research focuses on technology development of acute radiation exposure medical countermeasures development. 6- Clinical and Rehabilitative Medicine research is developing knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service members. Technology development efforts are directed against tasks in neuromusculoskeletal rehabilitation, pain management, regenerative medicine, and sensory systems.

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

	FY 2018	FY 2019	FY 2020
Title: GDF – Medical Technology Development	126.790	128.578	78.868
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 2019 Plans: Medical simulation and information sciences technology maturation progressing to focus on developing and integrating pharmacodynamics (effects of drugs and the mechanism of their action) and pharmacokinetics (movement of drugs within the body) algorithms into an open source physiology research engine used to support a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en-route care training. It will incorporate the side effects of the drugs and drug on drug interactions to elicit how to deal with additional acute reactions. This repository is designed to improve medical simulation and training. Research will also continue to focus on assessment system tools with emphasis on combat casualty care training. Continuing efforts to optimize synthetic materials used in part-task mannequins, full body mannequins, or peripherals that could be used on the Advanced Modular Manikin in order to better represent tissues under different environments.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

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

	FY 2018	FY 2019	FY 2020
<p>Military infectious diseases progressing research supporting the inter-service efforts between DoD clinical and research and development groups to develop novel and innovative therapeutics and delivery technologies for combat wound infections. Ongoing multi-year studies addressing critical research focus areas in wound infections, such as improved treatment options for infections with multi-drug resistant organisms, to be supported. These efforts will be in alignment with the National Action Plan for Combating Antibiotic-Resistant Bacteria. Results of studies to develop antibacterial agents and clinical practice guidelines for better wound infection management to be evaluated for down-selection. Efforts continuing aimed at partnering with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika).</p> <p>Military operational medicine: Researchers will continue to collect blast exposure data to validate whole body models of blast injury exposure in the training environment. Research progresses to refine and improve predictive auditory injury models in order to update acoustic injury standards for health hazard assessment. Efforts to develop tools to optimize return to duty after lower extremity (foot and ankle) injury, and head supported mass acute injury predictive models for mounted and dismounted environments are ongoing. Progressing data collecting to improve multisensory cueing criteria for aircrew performance optimization in degraded visual environments. Research focuses to evaluate longitudinal data collected for dietary supplement use with correlation to usage patterns with associated negative and positive health effects. Research focuses to provide guidance on the effects of healthy cooking for food choice behaviors, nutritional status, and psychological states in Wounded Warriors and their families. Also, studies continue evaluating the physical demands associated with selection to historically male military occupations to develop gender-neutral Military Occupational Specialty assignment standards. Ongoing research aimed at delivering assessment, prevention, and treatment interventions and tools that mitigate substance abuse, including prescription drug misuse and alcohol and other drug abuse. Efforts toward delivery of interventions to prevent suicide behaviors and conduct clinical trials to test the efficacy of the interventions are progressing. Studies aimed at delivering resilience building/prevention programs focused on education, skills, and novel service delivery methods for Service member and Family resilience are ongoing. Newly developed and existing large-scale PTSD datasets and state-of-the-art analytic methods are being used to produce individualized treatment guidelines for PTSD as well as PTSD-related sleep disturbances. Candidate biomarkers validation of exposure to inhaled or ingested toxic substances and develop medical guidance for risk assessment of adverse health outcomes are ongoing. Research continues its focus to provide validated metrics for optimized operational task performance in extreme environments. Efforts to validate novel methods for estimating thermal strain from non-invasive measures are progressing.</p> <p>Combat casualty care hemorrhage research will continue to evaluate immune system modulating drugs to treat hemorrhagic shock with a focus on the time period 4 to 72 hours post injury (relevant to prolonged field care). In addition, progressing work on the pathophysiological (functional changes associated with injury) impacts of using advanced hemorrhage (bleeding) control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Animal studies are ongoing to evaluate oxygen delivery solutions infused to maintain survivability for potential use in severe casualties where blood transfusion</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

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

	FY 2018	FY 2019	FY 2020
<p>is not available. Neurotrauma research will continue to focus on the development of novel technologies to better assess, monitor and maintain the stability of more severely injured TBI casualties closer to point of injury and during prolonged field care. Precision medicine research to improve the characterization of TBI, develop targeted therapies, devices, clinical guidelines, the impact of pre-injury conditions and the environment to improve the care provided to TBI casualties continues. Furthermore, neurotrauma research to investigate the impact of pre-injury conditions and the environment on Service member response to treatment and recovery following TBI. The program is leveraging data from Combat Operations to improve management of TBI by correlating injury events and medical records. Treatments for extremity trauma to develop specialized fracture stabilization techniques, address treatments for organ support and stabilization of craniomaxillofacial wounds will proceed to mature. Pre-hospital Tactical Combat Casualty Care will develop enhanced surgical procedures and equipment. En Route Care research will progress the development of specifications for an integrated system to support safe patient care and hand-offs, and the development of expanded en route care interventions and treatment capabilities. The military medical photonics program continues to develop light-based technologies and systems for combat casualty care, to include applications to detect blood pooling in the abdomen and oxygen content in the pulmonary artery. Photochemical cross-linking (the use of light to create new molecular bonds) to strengthen veins for grafting to arteries and the post-surgical benefits of photochemical bonding (the use of light to create new molecular bonds) in reducing scarring and adhesions are being studied. Research is being conducted on miniaturized sensors and actuators which can be inserted or implanted for important new kinds of diagnostic and therapeutic benefit. Radiation health effects research will continue to evaluate therapeutic candidates and radioprotectants for acute radiation exposure, and develop data to support preparation of a technical data package for investigational new drug applications. Research will develop data to support qualification of models for use in FDA approved trials. Objectives will include demonstrating improved survivability following high doses of radiation exposure with treatment at 24 hours and less after exposure.</p> <p>Clinical and rehabilitative medicine will conduct early human trials of promising products, evaluate preclinical safety of promising treatments, and test FDA-licensed products in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Will support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation outcomes after Service-related injuries. Will assess chronic pain risk factors and evaluate novel therapeutics and devices for pain management. Will assess preclinical and early clinical safety and efficacy of technologies designed to alter or regulate immune functions, skin substitutes to treat burn injury, treatments for volumetric muscle loss, treatments for segmental bone defects, and strategies for stabilization or regeneration of neuromuscular junctions for nerve injury.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Project 373A funding was realigned to establish new enduring research efforts at the Uniformed Services University of the Health Sciences beginning in FY2020.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 373A / <i>GDF - Medical Technology Development</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Health Research for Improved Medical Readiness and Healthcare Delivery (Project 506) - Brain Injury and Disease Prevention, Treatment and Research (Project 507) - Psychological Health and Resilience (Project 508) - Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (Project 509) <p>Realignment eliminated certain research focus areas within Combat Casualty Care (JPC-6) and Clinical Rehabilitative Medicine (JPC-8) and reduced research in Military Operational Medicine (JPC-5). Eliminated research focus areas include: Extremity Trauma, Maxillofacial Trauma, Systems of Critical Care Delivery, Pain Management, Regenerative Medicine and Sensory Systems (Vision, Hearing and Balance).</p>			
Accomplishments/Planned Programs Subtotals	126.790	128.578	78.868

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

N/A

Remarks

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 products into advanced development.

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports, and Program Sponsor Representative's progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with medical technology development funding is 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 378A / CoE-Breast Cancer Center of Excellence (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
378A: CoE-Breast Cancer Center of Excellence (Army)	39.699	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Breast Cancer Center of Excellence 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 2018	FY 2019	FY 2020
Title: Breast Cancer Center of Excellence	0.000	0.000	-
Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2019 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
378B: <i>CoE-Breast Cancer Center of Excellence (USU)</i>	10.552	9.088	10.280	10.475	-	10.475	10.685	10.898	11.116	11.339	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Breast Cancer CoE 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.

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

	FY 2018	FY 2019	FY 2020
Title: Breast Cancer Center of Excellence	9.088	10.280	10.475
Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.			
FY 2019 Plans: The Breast Cancer CoE will identify and consent patients (to include patients at high risk for development of breast cancer) annually to the MCC ORIEN research study, with special focus on active duty females as a Force Protection / Readiness sustainment issue to the DoD. Will continue to accrue patients annually to the "core" BC-COE protocols through consenting patients in the main BC-COE clinical sites, with the main site being the Breast Center at the Murtha Cancer Center of Walter Reed NMMC, the military's largest and only NAPBC (National Accreditation Program for Breast Centers) approved breast center in the entire DoD MHS. Will acquire through consented protocol acquisitions, over 5,000 specimens annually (neo-plastic and non-neoplastic breast tissues and tumors, lymph nodes, metastatic deposits, blood and its components, bone marrow) on patients with all types of breast diseases and cancer. Will bank these biospecimens in the BC-COE Biorepository as the substrate for all molecular analyses carried out in BC-COE labs, as outlined in the BC-COE Core Protocols. Will utilize the repository as the basis for intramural and extramural collaborations for secondary usage research. Will continue to conduct integrative profiling research, for protein-expression based, clinically relevant breast cancer stratification on active case IHC assays of a panel of 20 ImmunoHistoChemical (IHA) biomarker and IHC assays of a panel of 27 biomarkers named Connectivity Map EnHigh Density TMA analysis of biomarkers associated with the development of endocrine resistance. Will continue to focus breast cancer studies on two special patients groups bearing poor outcomes, who are enriched in the military active-duty military population: young women, and African American women. Will continue to conduct breast cancer heterogeneity studies, including cellular heterogeneity of tumor development environment and lineage heterogeneity within one physical cancer tumor. Focus areas will be (Breast Cancer Immunome, identification of molecular factors in tumor epithelium and stroma contributing to tumor etiology and breast cancer tumor heterogeneity study through Whole Genome Sequencing. Will conduct studies on mechanistic			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>understanding of breast cancer development from other perspectives, including genetic dispositions, exposure to environmental risks, access to healthcare, and impact of certain life style factors as well as comorbidities. Will continue to conduct breast cancer drug target studies focusing on the triple negative and HER2 subtypes, using 2D and 3D tissue culturing systems and human breast cancer tissues, respectively. Will further develop the informatics infrastructure system to support the evolving needs of Breast Cancer-COE research which will include developing the replacement system for the Clinical Laboratory Workflow System that was implemented years ago, develop and improve data QA programs and SOPs and improve the Data Warehouse for Translational Research by integrating data generated by internal scientists, through collaborations, and those available in the public as needed to facilitate integrative data analysis. The Breast Cancer COE will also continue its Collaborative Translational Research Program. CBCP will fund breast specific collaborative research that addresses problems with translational potential with a focus on environmental factors and the tumor microenvironment. The translational research program will consist of numerous investigators pursuing basic research on breast specific cancer etiology and biology or translational cancer research studies. CBCP will seek to establish support of novel intramural research that has the potential to improve breast cancer outcomes. The goal is to promote collaborative translational research efforts among translational science laboratories at the Clinical Breast Care Project, WRNNMC-MCC, WRI and NCI.</p> <p><i>FY 2020 Plans:</i> FY 2020 plans continue efforts as outlined in FY 2019.</p> <p><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing Adjustment</p>			
Accomplishments/Planned Programs Subtotals	9.088	10.280	10.475

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 379A / CoE-Gynecological Cancer Center of Excellence (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
379A: CoE-Gynecological Cancer Center of Excellence (Army)	34.939	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>Title: Gynecological Cancer Center of Excellence (Army)</p> <p>Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease.</p> <p>FY 2019 Plans: No funding programmed.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: N/A</p>	0.000	0.000	-
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

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 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 379B / <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
379B: <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>	9.226	7.943	8.987	9.158	-	9.158	9.341	9.528	9.719	9.913	Continuing	Continuing

Note

The Gynecologic Cancer Center of Excellence (GYN-COE) utilizes a program project type of strategy with overarching objectives to advance knowledge, prevention strategies, companion biomarkers and assays, treatments and interventions across the continuum of care in gynecologic oncology. Our twelve program projects run in parallel rather than in sequence with advances implemented over five years rather than 12 months. Some subprojects target discovery investigations and mechanistic studies whereas others focus on clinical evaluations, population studies and further development leading to deployment. The introduction of new subprojects and maturation of other subprojects allows the GYN-COE to continue to emphasize military and clinical relevance, prioritize bench to bedside translation, and infuse in advances in science, medicine and technology to meet our objectives. This is why the GYN-COE FY17 and FY18 plans are similar.

A. Mission Description and Budget Item Justification

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

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

Title: Gynecological Cancer Center of Excellence	FY 2018	FY 2019	FY 2020
	7.943	8.987	9.158
Description: The Gynecological Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecological disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecological disease.			
FY 2019 Plans:			
The FY2019 program will continue to develop novel strategies for prevention, early detection, and precision treatment of gynecologic cancers by identifying molecular alterations in these diseases. We will deeply interrogate ovarian and uterine cancer looking at the complex interplay of tumor cells and the surrounding stroma (or physiologic niche) that supports carcinogenesis (the initiation, progression, and metastatic spread of cancer) as well as the molecular landscape of primary versus metastatic disease. These investigations will facilitate development of clinical biomarkers and assays for gynecologic malignancies throughout the spectrum of care and improve early diagnosis and clinical care. Beyond the above studies, we will continue to build on studies examining molecular determinants of recurrent versus non-recurrent disease and how distribution or disease and post-surgical tumor residual influences outcome. Deep proteogenomic analyses will extend current state of the art to reveal clinically actionable data to improve readiness by earlier detection and prevention of disease in the active duty force and decrease the economic			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 379B / <i>CoE-Gynecological Cancer Center of Excellence (USU)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>burden of disease in the MHS which his typically diagnosed at late stages and treated without great specificity. We will expand collaborations in investigations of racial and ethnic disparities, risk, outcome, natural history, lifestyle, staging and treatment in cancer including gynecologic malignancies. Under the broad umbrella of outreach and patient reported outcomes research, an overarching goal during this period is to advance patient awareness, education, support and survivorship to improve quality of life, patient experience and mitigate effects. These efforts enhance the experience of care, ensure readiness of the fighting force, and improve beneficiary health adding value while decreasing cost for the Department of Defense.</p> <p><i>FY 2020 Plans:</i> FY 2020 plans continue efforts as outlined in FY 2019.</p> <p><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing Adjustment.</p>			
Accomplishments/Planned Programs Subtotals	7.943	8.987	9.158

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 into training curriculum throughout the Military Health System, and other applicable means.

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, presentation at national and international meetings, 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 381A / <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
381A: <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>	18.083	2.697	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Integrative 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 2018	FY 2019	FY 2020
Title: Integrative Cardiac Health Center of Excellence (Army)	2.697	0.000	-
Description: The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by combining biomolecular research with lifestyle change strategies to detect CVD at an early stage, and identifying markers of increased risk for heart attack in Service members.			
FY 2019 Plans: No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.			
FY 2019 to FY 2020 Increase/Decrease Statement: No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.			
Accomplishments/Planned Programs Subtotals	2.697	0.000	-

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

N/A

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 381A / <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i>

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
382A: <i>CoE-Pain Center of Excellence (Army)</i>	6.436	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 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 FY 2015, the Pain CoE funding line is transferred from Army to USUHS.

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

	FY 2018	FY 2019	FY 2020
Title: Pain Center of Excellence (Army)	0.000	0.000	-
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 2019 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

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 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 382A / <i>CoE-Pain Center of Excellence (Army)</i>

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 382B / CoE-Pain Center of Excellence (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
382B: CoE-Pain Center of Excellence (USUHS)	8.079	2.822	3.310	3.376	-	3.376	3.445	3.514	3.584	3.656	Continuing	Continuing

A. Mission Description and Budget Item Justification

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. 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 FY 2015, management of the Pain CoE was transferred from Army to USUHS.

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

	FY 2018	FY 2019	FY 2020
Title: Pain Center of Excellence (USUHS)	2.822	3.310	3.376
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 its impact on rehabilitation and recovery.			
FY 2019 Plans: The DVCIPM will continue to focus on further building and streamlining the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) and apply for funding for data analysis. Continue to foster collaborative relationships and focus on complementary and integrative pain management (CIPM) through clinical assimilation studies of modalities such as: battlefield acupuncture (BFA); yoga and massage; evaluation of novel analgesics; and interventional technologies for improved pain management. DVCIPM will seek additional funding to sustain the Pain Education Program, as well as support the increasing requirements for the MHS DVCIPM's designation as a MHS CoE, and DVCIPM's recognized track record of effective facilitating collaborations across the Uniformed Services, VA, and Civilian Medicine has resulted in an ever-growing number of tasks.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	2.822	3.310	3.376

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 382B / <i>CoE-Pain Center of Excellence (USUHS)</i>

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 383A / <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
383A: <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i>	41.822	7.250	8.203	8.359	-	8.359	8.526	8.696	8.870	9.047	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Center for Prostate Disease Research (CPDR) is an interdisciplinary translational cancer research program of the Department of Surgery, Uniformed Services University of the Health Sciences (USU), the Walter Reed National Military Medical Center (WRNMMC), the Murtha Cancer Center, and the Urology Service at WRNMMC. The CPDR conducts state-of-the-art clinical and translational research with emphasis on precision medicine to enhance the readiness of active duty personnel juxtaposed with the continuum of medical care for military retirees and beneficiaries. The CPDR enriches the training of the next generation of physicians/scientists who directly benefit the quality, outcomes, and stability of the military health care delivery system. Ground-breaking discoveries through strong academic and clinical research; e.g., over 24 yrs. and 450 publications) have led to major advances in translational prostate cancer research and treatment. The CPDR integrates expertise of urologic and medical oncologists, cancer biologists, genitourinary pathologists, epidemiologists, bio-statisticians, medical technologists, research nurses, patient educators, bioinformaticians, and program management specialists. All these areas of expertise provide state-of-the-art resources for in-house and collaborative research in prostate cancer. The program is also committed to translational research training for future generations of physicians and scientists at leading DoD medical institutions (USU, WRNMMC, JPC, NMCS, MAMC, SAMMC, and TAMC).

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

	FY 2018	FY 2019	FY 2020
Title: CoE-Prostate Cancer Center of Excellence (USUHS)	7.250	8.203	8.359
Description: The CPDR is at the forefront of “cutting-edge” clinical, basic science and epidemiologic research. The emphasis is on improving diagnosis, prognosis and treatment of prostate cancer involving new modalities such as MRI guided biopsy, gene-based biomarkers, and precision medicine strategies targeting causal gene alterations in prostate cancer. The CPDR multi-center database is a unique programmatic resource, enrolling over 27,500 DoD health care beneficiaries under suspicion for prostate cancer, with longitudinal follow up to 23 years. This database continues to highlight emerging issues in prostate cancer management such e.g., treatment outcomes, racial/ethnic differences, quality of life and discovery of novel molecular prognostic markers. In light of current issues related to overtreatment of early detected prostate cancers and poorly understood biology of prostate cancer, CPDR’s long-term biospecimen banks, high-impact discoveries and collaborations are leading towards better diagnostic and prognostic molecular markers and therapeutic targets with promise in improving the management of the disease. The CPDR’s health disparity research focus has uniquely benefited from studying a prostate cancer patient cohort, with a high representation of African American men, in an equal-access military health care system. Ground-breaking studies of the most validated prostate cancer gene, ERG, in over 1,500+ patients provide the first definitive information on prostate cancer biology underscoring racial/ethnic differences with potential to enhance personalized medicine. The CPDR’s state-of-the-art research infrastructure and framework is providing education and training for over 100 next generation physicians, scientists, medical and graduate students within DoD medical institutions.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
<p><i>FY 2019 Plans:</i></p> <p>Precision Medicine Focus:</p> <p>Continue to leverage long term assets of DoD patient database (30K subjects with up to 25 yrs of follow up) and biospecimen bank (230K aliquots) towards delineation of molecular markers to enhance treatment decisions through precision medicine with emphasis on racially diverse patients in equal access military healthcare system.</p> <p>Define prostate cancer prevention strategies by addressing the role of predisposing conditions military-specific exposures and genetic components in prostate cancer onset and progression of service members.</p> <p>Validate prediction models for disease progression, quality of life, and overall survival across the spectrum of cancer treatments and determine factors that predict definitive treatment for patients initially managed on active surveillance.</p> <p>Develop modalities for diagnosing and prognosing clinically significant prostate cancers to reduce over diagnosis and treatment, through molecular/clinico-pathologic prognostic signatures of MRI-ultrasound fusion image guided biopsy specimens.</p> <p>Enhance pre/post-operative follow-up for cancer diagnosis, progression, pain, mobility deficits and restoration of function through the CoE's long-term database.</p> <p>Continue to strengthen the Cancer Moonshot and APOLLO prostate cancer proteogenomics discovery and targeted therapy focus under the Murtha Cancer Center aligned with the national cancer precision medicine initiatives.</p> <p>Validate prognostic biomarker panels developed from biofluid-based metabolome, proteome and lipidome analyses addressing the limitations of currently used serum PSA diagnostic test in multi-center validation setting.</p> <p>Health Disparity Research:</p> <p>Continue to lead discoveries of prostate cancer causing genes for diagnosing, prognosing and targeted therapy of racially diverse DoD prostate cancer patients with indolent and aggressive disease. Leverage established key collaborations with DoD academy and industry to integrate whole genome, whole-transcriptome sequencing, proteome, lipidome and metabolome analyses on a large CPDR cohort of African American and Caucasian American patients.</p> <p>Delineate the prostate cancer genomic landscape of under studied African American, Asian and Hispanic patients towards the development of broadly applicable diagnostic, prognostic markers and treatment approaches.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
<p>Develop innovative experimental models for establishing the mechanisms of newly discovered race/ethnicity associated prostate cancer genes towards ethnicity-informed therapeutic strategies.</p> <p>Continue to leverage established collaborations with NCI investigators addressing race/ethnicity associated genetic predisposition for metastatic prostate cancer.</p> <p>Development of Molecular Diagnostic and Prognostic Tools: Strengthen the CoE's unique DoD prostate cancer research resources by employing advanced informatics and logistic platforms for enhancing the integration of clinical, biospecimen and molecular databases towards the development of diagnostic and prognostic tools.</p> <p>Validate in multi-center setting the prognostic utility of CoE developed prostate cancer biomarkers including urine exosome-based mRNA panels, serum multi-omics based panels, cytogenetic tests and the ERG monoclonal antibody (e.g., urine exosomes clinical trial in collaboration with the Exosome Diagnostics Inc.).</p> <p>Continue to enhance knowledge of prostate cancer driver genes as exemplified by CoE leadership in the discovery/delineation of biological function and biomarker/ therapeutic utility of the most common prostate cancer gene, ERG.</p> <p>Expand the research on serum and urine based protein and omics-defined biomarkers including serum antigen- autoantibody-based and mass spectrometry-based detections.</p> <p>Novel Strategies for Stratification and Treatment of Prostate Cancers: Continue to employ state-of-the-art clinical trials and research evaluating novel therapies for androgen axis inhibitors and immuno/radiation therapy complemented by emerging approaches targeting newly discovered prostate cancer driver gene alterations (e.g., ERG and DNA repair gene defects).</p> <p>Evaluate strategies for enhancing immunotherapy of advanced prostate cancer.</p> <p>Complete developments of new small molecule ERG inhibitors in collaboration with Stanford Medical School to enter Phase I clinical trials.</p> <p>Develop innovative cell culture, engineered mouse models and tumorigenicity models for defining the mechanisms of prostate cancer driver genes with the objective of discovering new therapeutic opportunities.</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2018	FY 2019	FY 2020
<p>Leverage newly developed concepts of combination therapies targeting adaptive mechanisms of prostate cancer progression, e.g., androgen receptor (and its modulator, PMEPA1) in combination of TGF-beta inhibitors or NOTCH1 inhibitors in the context of early stage and advanced disease.</p> <p>Develop multi-center evaluation of the CPDR androgen receptor function index (ARFI) gene panel towards earlier and more effective stratification of patients for androgen axis targeting drugs.</p> <p>Education and Training Program: Leverage the strong track record in translational research training of the next generation of physicians, researchers, medical researchers at DoD institutions, e.g., WRNMMC urology residents, post-doctoral fellows, USU Capstone medical and graduate students.</p> <p>Enhance patient education focusing on quality-of-life, active surveillance and new treatment opportunities and integration with patient support groups.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.</p>				
Accomplishments/Planned Programs Subtotals		7.250	8.203	8.359
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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 398A / CoE-Neuroscience Center of Excellence (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
398A: CoE-Neuroscience Center of Excellence (USUHS)	3.679	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

Note

The Center for Excellence in Neuroscience Project is closed. All future projects will be supported by This project was consumed under the Center for Neuroscience and Regenerative Medicine (CNRM).

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 2018	FY 2019	FY 2020
Title: CoE-Neuroscience Center of Excellence (USUHS)	0.000	0.000	0.000
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 2019 Plans:			
FY 2020 Plans:			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

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

N/A

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i>

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 429A / Hard Body Armor Testing (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
429A: Hard Body Armor Testing (Army)	1.356	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

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)

	FY 2018	FY 2019	FY 2020
Title: Hard Body Armor	0.000	0.000	-
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 2019 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

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 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 431A / <i>Underbody Blast Testing (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
431A: <i>Underbody Blast Testing (Army)</i>	40.611	8.000	10.800	9.200	-	9.200	1.400	0.000	0.000	0.000	-	-

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), 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 (LFT&E) 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 Warrior 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 2018	FY 2019	FY 2020
Title: Underbody Blast Testing	8.000	10.800	9.200
Description: Testing will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and 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 LFT&E crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.			
FY 2019 Plans: Biofidelity response corridors will be used to validate second generation prototypes of the WIAMan. Human injury assessment curves will continue to be developed for the lower extremities, pelvis and spine from laboratory testing that created thresholds of cadaveric fractures and subsequent severe injuries (i.e., complex fractures). Laboratory testing to generate female post mortem human subject injury tolerances will continue and will be used to inform the analysis of alternatives for developing a female specific manikin.			
FY 2020 Plans: Human Injury Probability Curves, Injury Assessment Reference Curves, and Female cadaver testing will be completed and the WIMAN research team will report on ways to account for female skeletal properties in the ATD. WIAMan Post-Mortem			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 431A / <i>Underbody Blast Testing (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Human Subject data will be cataloged and stored at the Army Research Lab Engineering Analysis Branch (EAB) for Verification, Validation and Accreditation activities for Live Fire vehicle testing. Data sharing will be coordinated with medical research labs.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	8.000	10.800	9.200

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

Remarks

D. Acquisition Strategy

Produce BRC and human injury probability curves for human skeletal response and tolerance in the military UBB environment and transition them to the Program Execution Office for Simulation, Training and Instrumentation for use in the development of the WIAMan UBB test manikin and for general use in the research, development, test and evaluation community. Develop injury assessment reference curves for use with WIAMan manikin to support vehicle and protection technology acquisition decisions.

E. Performance Metrics

Principal Investigators (PIs) 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 periodic progress reviews 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 448A / Military HIV Research Program (Army)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
448A: Military HIV Research Program (Army)	25.095	6.359	7.360	7.877	-	7.877	8.035	8.196	8.361	8.528	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project funds research to develop candidate Human Immunodeficiency Virus (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 U.S. 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 vaccine in a small study (to demonstrate early proof-of-concept); and third, to demonstrate effectiveness in large, diverse human population clinical 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 advanced developers for completion of effectiveness testing in larger populations. This program is jointly managed through an Interagency Agreement between the U.S. Army Medical Research and Materiel Command and the National Institute of Allergy and Infectious Diseases. 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 2018	FY 2019	FY 2020
Title: Military HIV Research Program	6.359	7.360	7.877
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. In addition, program also aims to develop other prevention and treatment strategies to mitigate the HIV epidemic globally. This project down-selects one or more vaccine candidates that are optimized through pre-clinical studies in non-human primates and conducts human clinical trials in Africa, Asia and the U.S. to test for safety and immunogenicity (ability to invoke an immune response), and early proof of concept efficacy testing.			
FY 2019 Plans: The Military HIV research program is conducting Early Capture HIV Cohort studies in Europe and Asia with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high-risk volunteers. Human population studies in Asia, Europe and West Africa are being conducted to provide knowledge about the earliest HIV events to inform vaccine development. Human clinical trials in Africa, Asia and the U.S. designed to test for safety, immunogenicity and early proof of concept efficacy of candidate vaccines are ongoing.			
FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 448A / <i>Military HIV Research Program (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
FY 2020 plans continue efforts as outlined in FY 2019.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	6.359	7.360	7.877

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 will be 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, and in-process reviews.

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 830A / Deployed Warfighter Protection (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
830A: <i>Deployed Warfighter Protection (Army)</i>	28.983	5.123	5.930	6.345	-	6.345	6.473	6.601	6.733	6.868	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 transmit malaria, dengue, chikungunya and other emerging infectious diseases 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. The AFPMB partners with the President's Malaria Initiative and the World Health Organization Global Malaria Program to lead development of new tools for insect-borne disease prevention.

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

	FY 2018	FY 2019	FY 2020
Title: Deployed Warfighter Protection	5.123	5.930	6.345
Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects.			
FY 2019 Plans: The Deployed Warfighter Protection research project continues to conduct translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to enhance protection from biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. The AFPMB Vector Control Capabilities Gap Analysis (completed in FY 2016) will continue to be used to inform the development of functional and performance requirements for future acquisition programs. In addition, the AFPMB continues to develop the necessary test and evaluation plans to determine a candidate product's ability to meet its stated requirements..			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	5.123	5.930	6.345

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 830A / <i>Deployed Warfighter Protection (Army)</i>

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

Remarks

D. Acquisition Strategy

Develop, mature and field new or improved products and strategies that protect U.S. forces from disease-carrying insects. Identify acquisition-based research and development requirements in a Capability Needs Assessment. Refine target product profiles and performance criteria. 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, AFPMB, USAMMDA, DLA and relevant Program Executive Offices 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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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
478: <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>	0.000	14.766	14.754	18.556	-	18.556	18.639	18.724	19.098	19.480	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)

DoD's Cancer Moonshot requirement is a mission of the Murtha Cancer Center (MCC) at USU under the authority of a tri-federal Memorandum of Agreement signed July 2016 by the Acting Assistant Secretary of Defense for Health Affairs (DoD), the Under Secretary of Health, Department of Veterans Affairs(VHA), and the Acting Director of the National Cancer Institute (NIH), for a tri-federal program of Clinical Proteogenomics Cancer Research. DoD's Cancer Moonshot promotes readiness and mission accomplishment of the active duty service member (ADSM) force, as well as military beneficiaries, retirees, and veterans. There are about 1,000 ASDMs who are stricken with a new cancer diagnosis annually, and MCC serves as the DoD's Health Affairs-approved Center of Excellence for cancer care and research for these ASDMs. MCC's mission is to bring translational cancer research to all patients in order to improve their health and mission performance, and to help prevent, screen, detect, and treat cancer; minimize side effects of cancer treatments; and return to duty ASDMs stricken with cancer, as well all other DoD beneficiaries. DoD's Cancer Moonshot initiative allows for the provision of state-of-the-art molecular analysis of tumors and blood of cancer patients which will result in increased force readiness through more targeted treatment of cancers with fewer side effects, as well as better screening for cancer risk and development.

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

	FY 2018	FY 2019	FY 2020
Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)	14.766	14.754	18.556
Description: Description: DoD's Cancer Moonshot at USU's MCC is a research program consisting of two overall projects, the first known as APOLLO (Applied Organizational Learning and Outcomes), and the second as DoD Framingham.			
APOLLO is a novel high-throughput molecular analysis of every DNA (gene), RNA, and protein expression molecule in cancer patient tumors. Such analysis has never been done on a large scale across multiple cancer types, and small pilot studies demonstrate that the APOLLO project will result in unprecedented findings across all types of cancer (with specific focus on cancers of the greatest threat to ASDMs). These new findings will be identified by using state-of-the-art tissue collection procedures in the operating rooms of all patients undergoing cancer surgery at MCC collection protocol sites (e.g.. Walter Reed NMMC;NMC Portsmouth; NMC San Diego; Womack AMC; Keesler AFB) and, then, sequencing the entire DNA genome and RNA sequence at USU, while analyzing the entire protein expression profile of these same cancers in MCC's Proteomics Laboratory, as well as other affiliated protein laboratories. The vast molecular data that will be derived from these analyses (in the terabyte			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>

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

	FY 2018	FY 2019	FY 2020
<p>and petabyte range and beyond) will be linked to clinical patient data as well as treatment outcomes data. These combined data sets will be housed in National Cancer Institute (NCI) secure cloud-based servers with restricted access for analytics by teams of bioinformatics experts (i.e., from government, university, and corporate entities) across the United States working on this endeavor. This complete bio molecular (global) expression profiling of thousands of cancers of all types seen in military treatment and other facilities will predictably result in a myriad of new discoveries regarding the way cancers develop, progress, respond to treatment, evade treatment, and spread. It also will result in new ways to combat cancers and minimize side effects of cancer treatment, as well as identify novel cancer screening and prevention opportunities, while focusing on militarily-relevant cancers and ADSMs with cancer, distinguishing it from any effort that might develop in the future in a civilian organization, as none of this scale exists today. There are five specific APOLLO sub-projects, which are classified based on the organ type of cancer under study: APOLLO 1 = Lung cancer; APOLLO 2 = Gynecological cancer; APOLLO 3 = Prostate cancer; APOLLO 4 = Breast cancer; and APOLLO 5 = all other cancer types.</p> <p>Both of these projects in the DoD Cancer Moonshot program were specifically developed to focus on ADSM with cancer (readiness), utilize molecular laboratories that are American owned and operated (U.S. DoD and DOE), keep all sensitive de-identified clinical and molecular data on U.S. government computers and servers for maximum data security and analysis (through the NCI), and benefit the nation through any and all discoveries that are made.</p> <p>FY 2019 Plans: APOLLO - FY 2019 plans continue efforts as outlined in FY 2018 to collect 1,000 cancer specimens (all cancer types) and run them through the DNA, RNA, and protein molecular analysis lab platforms of USU, and perform initial data analytics on the results. Perform final data analytics on previously analyzed APOLLO samples. In addition, identify Framingham 3 serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Previous years reflect program start-up, FY 2020 and out reflect full funding.</p>			
Accomplishments/Planned Programs Subtotals	14.766	14.754	18.556

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

N/A

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 478 / <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i>

D. Acquisition Strategy

N/A

E. Performance Metrics

To be determined.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 479 / Framingham Longitudinal Study (USUHS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
479: Framingham Longitudinal Study (USUHS)	0.000	4.920	4.920	4.920	-	4.920	4.920	4.920	5.018	5.118	Continuing	Continuing

A. Mission Description and Budget Item Justification

DoD Cancer Moonshot Program - DoD Framingham

DoD's Cancer Moonshot requirement is a mission of the Murtha Cancer Center (MCC) at USU under the authority of a tri-federal Memorandum of Agreement signed July 2016 by the Acting Assistant Secretary of Defense for Health Affairs (DoD), the Under Secretary of Health, Department of Veterans Affairs(VHA), and the Acting Director of the National Cancer Institute (NIH), for a tri-federal program of Clinical Proteogenomics Cancer Research. DoD's Cancer Moonshot promotes readiness and mission accomplishment of the active duty service member (ADSM) force, as well as military beneficiaries, retirees, and veterans. There are about 1,000 ASDMs who are stricken with a new cancer diagnosis annually, and MCC serves as the DoD's Health Affairs-approved Center of Excellence for cancer care and research for these ASDMs. MCC's mission is to bring translational cancer research to all patients in order to improve their health and mission performance, and to help prevent, screen, detect, and treat cancer; minimize side effects of cancer treatments; and return to duty ASDMs stricken with cancer, as well all other DoD beneficiaries. DoD's Cancer Moonshot initiative allows for the provision of state-of-the-art molecular analysis of tumors and blood of cancer patients which will result in increased force readiness through more targeted treatment of cancers with fewer side effects, as well as better screening for cancer risk and development.

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

	FY 2018	FY 2019	FY 2020
Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study	4.920	4.920	4.920
Description: DoD Framingham is a novel project that is enabled by the blood serum specimens stored at the DoD Serum Repository at the Armed Forces Health Surveillance Branch (AFHSB) in Silver Spring, Maryland. This facility stores blood serum drawn from over 10 million ASDMs who were required to undergo mandatory semiannual blood testing for the last 25 years, resulting in this repository with over 65 million blood serum specimens. MCC tumor registry data, which includes every ADSM who developed cancer while on active duty, is matched to data in the Serum Repository. This allows MCC to identify the blood serum of ASDMs who ultimately develop cancer at key times, i.e., before they had cancer, during their cancer treatment, and after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADSM who developed certain types of cancer over a ten-year period of time are then sent to the Nation's foremost protein identification (mass spectroscopy) center, i.e., the Pacific Northwest National Laboratory (PNNL) run by the Department of Energy (DOE). This enables identification of the entire proteome circulating in the blood serum of these cancer patients before, during, and after cancer diagnosis. Comparing the proteomes will allow for identification of new protein biomarkers and indicators of treatment response and failure both of individual patients and across all patients with a specific type of cancer. Smaller studies of this nature done by MCC researchers have proven that this is an effective strategy to identify novel diagnostic and treatment protein expression biomarkers that can be assayed in new blood tests for cancer. This			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 479 / <i>Framingham Longitudinal Study (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>project will do it “at scale”, i.e. in large numbers of active duty cancer patients (who are otherwise healthy and therefore do not have the “confounding” protein markers of old age, diabetes, and other medical issues). By using serums that go back many years before the ADSM was diagnosed with cancer, the earliest markers of cancer that will be identified, and assays will be performed by another U.S. governmental agency with the best protein detection and analysis tools in the world. Eight specific DoD Framingham sub-projects, classified based on the organ type of cancer, will be conducted: Framingham 1 = Oropharyngeal cancer; Framingham 2 = Lymphoma; Framingham 3 = Bladder cancer; Framingham 4 = Kidney cancer; and Framinghams 5 through 8 subtypes will be determined by MCC and NCI experts in the coming months.</p> <p>Both the APOLLO and Framingham projects in the DoD Cancer Moonshot program were specifically developed to focus on ADSM with cancer (readiness), utilize molecular laboratories that are American owned and operated (U.S. DoD and DOE), keep all sensitive de-identified clinical and molecular data on U.S. government computers and servers for maximum data security and analysis (through the NCI), and benefit the nation through any and all discoveries that are made.</p> <p><i>FY 2019 Plans:</i> Identify Framingham 3 serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results.</p> <p><i>FY 2020 Plans:</i> Continue to identify Framingham serum specimens and conduct serum protein analysis lab platform, and perform initial data analytics on the results.</p>			
Accomplishments/Planned Programs Subtotals	4.920	4.920	4.920

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

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance Metrics to be determined.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 499 / MHS Financial System Acquisition
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
499: MHS Financial System Acquisition	1.766	13.456	21.129	15.373	-	15.373	1.971	2.011	2.051	2.092	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Health Program (DHP) appropriations' distribution and execution of funding is currently dispersed amongst multiple, disparate accounting systems, which is in direct conflict with Financial Improvement Audit Readiness (FIAR) guidance prioritizing the standardization of financial management systems and business processes. Currently DHP funding is distributed and executed across three disparate systems.

The current Defense Health Agency (DHA) structure hinders the overarching goal for audit ready initiatives and agency standard financial business processes. The identified solution for DHA to meet these challenges is to deploy a single operational financial management system (FMS) with minimal mission and business impact. DHA is researching a system that will accommodate standard and medically-required business processes. The goal is to transition financial operations to a platform that allows for consistency across the DHA, enabling standardized processes, data collection, and reporting.

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

	FY 2018	FY 2019	FY 2020
Title: MHS Financial System Acquisition	13.456	21.129	15.373
Description: The goal is to transition financial operations to a platform that allows for consistency across the Defense Health Agency, enabling standardized processes, data collection, and reporting.			
FY 2019 Plans: FY 2019 plans continue efforts as outlined in FY 2018.			
FY 2020 Plans: FY 2019 to FY 2020 Increase/Decrease Statement: Additional research funding necessary to continue the consolidation all DHP appropriations into a single Financial Management System (FMS) system to provide the following capabilities:			
Accomplishments/Planned Programs Subtotals	13.456	21.129	15.373

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA 3: PE 0807721 <i>Replacement & Modernization</i>	9.031	10.409	22.611	-	22.611	0.000	0.000	0.000	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 499 / <i>MHS Financial System Acquisition</i>

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
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Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

E. Performance Metrics

Performance metrics to be determined.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 381 / CoE - Integrative Cardiac Health Care (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
381: CoE - Integrative Cardiac Health Care (USUHS)	0.000	0.000	2.914	3.118	-	3.118	3.180	3.244	3.309	3.375	Continuing	Continuing

A. Mission Description and Budget Item Justification

The USU Integrative Cardiac Health Program is a Center of Excellence whose mission is to:

1. Improve force health by an improved understanding of the CVD risk susceptibility and adoption of healthy lifestyles in military-specific populations (e.g. Wounded Warriors) through leading-edge research using novel tools and biotechnologies.
2. Investigate and create transformational models of practical and personalized CVD prevention tracks as an adjunct to traditional care for dissemination to MHS.
3. Refine individualized prevention strategies through "big Data" modeling to define the most cost-effective and sustainable approaches in promoting CV health throughout the military lifecycle.
4. Identify precise strategies for early detection, monitoring and reduction of preclinical/clinical CV and related chronic disease risks for improved clinical outcomes.

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

	FY 2018	FY 2019	FY 2020
<p>Title: Integrative Cardiac Health Center of Excellence</p> <p>Description: USU is a "central focal point for health-related education and training, research and scholarship, and leadership support to operational military units around the world" and is the ideal engine to establish a strategic partnership to address cardiovascular health.</p> <p>FY 2019 Plans: The Integrative Cardiac Health Center of Excellence (IChP) will continue development and refinement of clinical decision support tools and new models for cardiovascular and overall health; will conduct research studies to improve the health of the Active Duty force by investigating the effectiveness of personalized (gender specific) interventions specifically designed for the military and the effects of these interventions on preclinical atherosclerosis (plaque in arteries). Precision medicine efforts exploring novel biomolecular markers and tests as indicators for early (preclinical) cardiovascular disease risk assessment will continue. Will characterize new clinical phenotypes; detect cardiovascular disease in early stages when it is more likely to be reversible. IChP will collaborate with Walter Reed Bethesda Cardiovascular Service, the Mayo Clinic, Abbott Laboratories, and Integrative Systems Biology for these efforts. IChP will use this information to tailor personalized health interventions and build resiliency in the military population before disease affects quality of life. The Wounded Warriors project will continue to examine cardiovascular risk in the amputee and injured Warfighter and begin analysis of bio-samples collected to detect novel biomolecular markers. Study is designed to significantly advance the precision of risk detection and lead to an improvement of current interventions and patient outcomes.</p> <p>FY 2020 Plans:</p>	0.000	2.914	3.118

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 381 / <i>CoE - Integrative Cardiac Health Care (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
FY 2020 plans continue efforts as outlined in FY 2019.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals	0.000	2.914	3.118

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 has been 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. Additional performance metrics may be developed after the strategic alliance has been formalized.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 504 / WRAIR Vaccine Production Facility Research
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
504: WRAIR Vaccine Production Facility Research	0.000	0.000	8.000	8.152	-	8.152	8.315	8.481	8.651	8.824	Continuing	Continuing

A. Mission Description and Budget Item Justification

The WRAIR Vaccine Pilot Bioproduction Facility (PBF) is the Department of Defense’s only facility capable of producing good manufacturing practices (GMP) quality biologic products for use in early phase clinical trials. The mission of the WRAIR PBF is to support the development and licensure of vaccines and relevant biologics critical to the global health of our Warfighters serving domestically or abroad in compliance with US Food and Drug Administration (FDA) regulations. Funding supports a baseline level of preparedness for vaccine production and improved response-time in the setting of known and emerging infectious disease threats needing a preventive countermeasure while working with a collaborative network of partners. This project supports vaccine development efforts of strategic importance to the DoD, including Service medical research and development programs, those of other DoD organization such as the Defense Threat Reduction Agency and the Defense Advanced Research Projects Agency, and pandemic biopreparedness for emerging infectious disease threats in the Global Health Security Agenda.

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

	FY 2018	FY 2019	FY 2020
Title: WRAIR Vaccine Production Facility	-	8.000	8.152
Description: The WRAIR Vaccine Pilot Bioproduction Facility (PBF) will focus on the manufacture of early phase clinical materials for vaccine production from varied platforms, such as live virus, conjugates, recombinant proteins, DNA, and monoclonal antibody approaches that: (a) expand collaborative partnerships for product development that meet DoD requirements; (b) open active intramural-based discovery efforts of new products for development; and (c) initiate and extend strategic partnerships with external collaborators (Government and industry) to develop/co-develop potential new biologic approaches to pandemic disease preparedness.			
FY 2019 Plans: Complete commissioning and validation of the renovated facility and resume vaccine and biologic production efforts.			
FY 2020 Plans: The WRAIR PBF program will continue vaccine and biologic production efforts for use in early phase clinical trials to assess safety and effectiveness of candidate vaccines.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	-	8.000	8.152

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 504 / <i>WRAIR Vaccine Production Facility Research</i>

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

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of the WRAIR PBF program is measured by the number of products used in clinical trials, number of pilot lots produced (for USG, DoD, and non-federal partners), number of doses vialled, and other biologics produced. Additionally, the WRAIR PBF program will conduct an annual research review during which a panel of DoD subject matter experts provide input on programmatic alignment and strategic priorities.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development	Project (Number/Name) 506 / Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)	-	0.000	0.000	11.904	-	11.904	12.141	12.385	12.631	12.883	Continuing	Continuing

A. Mission Description and Budget Item Justification

The “Health Research for Improved Medical Readiness and Healthcare Delivery” program at USUHS is to answer fundamental questions of importance to the military mission of the Department of Defense in five (5) distinct portfolio areas: health services research, global health engagement, precision medicine, women’s health, and infectious disease clinical research.

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

	FY 2018	FY 2019	FY 2020
Title: Health Research for Improved Medical Readiness and Healthcare Delivery	0.000	0.000	11.904
Description: The objective of Health Services Research is to build capacity to conduct health services research (HSR) within the MHS. The program will address the lack of system-wide health care evidence to support policy and decision making and insufficient health services research capability to analyze MHS data for improving medical readiness and efficient, effective, quality and safe healthcare.			
Global Health Engagement (GHE) research is related to operational efforts and advanced technology development efforts that will meet the needs of the Joint Force in either improving the understanding and/or execution of DoD GHE, or utilizing DoD health research activities to engage a partner nation/partner nations in support of Theater Campaign Plan objectives to further research. The GHE research needs of the warfighter are expressed by the regular demand signal of the Joint Force through the Joint Staff Surgeon’s Office and the Combatant Commands Surgeons’ Offices.			
Precision Medicine will provide standardized genome profiling services across the MHS. It will provide genomic data analysis and storage under DoD security and privacy compliance policies in order to provide cutting edge genomic information to clinicians and improve health care of warfighter.			
The military Women’s Health research program mission is to develop and guide best practices for the clinical care of women in the military system, through medical research. This research program will identify priorities that utilize novel and well-defined methods in the areas of personalized medicine and population science and focuses on basic, clinical and translational research.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 506 / <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>Infectious Disease Clinical Research is multicenter infectious diseases clinical research focusing on high-impact cohorts and interventional trials, to inform and improve care of the Warfighter. The focus is on emerging infections, antimicrobial resistance, and other high priority infections impacting military readiness in US and abroad. It also will generate research evidence to inform warfighter care, develop DoD clinical practice guidance, assess cost effectiveness of interventions, and assist force health protection policy development.</p> <p>FY 2019 Plans: Funding for this program is being executed by MRMC in FY19.</p> <p>FY 2020 Plans: Health Services Research: <ul style="list-style-type: none"> - Define research priorities: Health economics, geographic variation, provider induced demand, disparities, improving care to populations of patients, outcome studies, program evaluation. - Improve policy and practice in the MHS through knowledge translation. Global Health Engagement: <ul style="list-style-type: none"> - Improve the efficacy of military medical engagements with partner nations in achieving military outcomes - Improve the readiness of the Joint Force to conduct GHE activities in support of Geographic Combatant Commands and national security objectives - Improve the quality of tools and capabilities available to commanders for conducting international security cooperation and cooperative health security engagements Precision Medicine: <ul style="list-style-type: none"> - Enable single collection site of genomic data for DoD Precision Medicine studies to contribute towards population medicine innovation. - Improve utility for supercomputing infrastructure supporting clinical activities. Women's Health research: <ul style="list-style-type: none"> - Support research projects in the areas of reproductive health, pain, mental health, cardiovascular disease, cancer, human performance and readiness standards, nutrient and energy requirements for servicewomen, medical simulation violence against women, opioid use and, clinical practice guidelines. Infectious Disease Research:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 506 / <i>Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
- Execute multisite research through a robust sustainable MHS research network, with capability to execute FDA-regulated clinical trials. - Translate generated high quality evidence as follows: Develop new and refined DoD clinical practice guidance in support of Force Health Protection, inform DoD and National policies related to the prevention and management of infectious diseases, and provide direct support of infection threat assessment and mitigation efforts to the Geographic Combatant Commands in collaboration with Military Public Health authorities. FY 2019 to FY 2020 Increase/Decrease Statement: Funding increase is the result of a realignment of funds in FY 2020 from MRMC to USUHS in FY 2020 for health services research, global health engagement, precision medicine, women's health and infectious disease clinical research.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	11.904

	FY 2018	FY 2019
Congressional Add:	0.000	-
FY 2018 Accomplishments:		
Congressional Adds Subtotals	0.000	-

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

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development			Project (Number/Name) 507 / Brain Injury and Disease Prevention, Treatment and Research (USUHS)				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
507: Brain Injury and Disease Prevention, Treatment and Research (USUHS)	-	0.000	0.000	13.317	-	13.317	13.583	13.855	14.132	14.415	Continuing	Continuing

A. Mission Description and Budget Item Justification

This program supports drug discovery for chronic traumatic and encephalopathy/neurodegenerative disease.

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

	FY 2018	FY 2019	FY 2020
Title: Brain Injury and Disease Prevention, Treatment and Research	0.000	0.000	13.317
<p>Description: Brain Injury and Disease Prevention, Treatment and Research is focused upon identifying drugs that will interfere with pathological tau prion formation in the brains of service members who are at risk for developing CTE and other neurodegenerative diseases following repeated TBI. Service members who have served in combat and have received repeated impact and/or blast TBIs are at risk for developing chronic traumatic encephalopathy (CTE) and other neurodegenerative diseases which are associated with significant persistent behavioral/neurologic manifestations. Currently, there are no validated means for diagnosing these problems in living patients or drugs to effectively treat them. The overall mission of this program is to develop drug candidates that will effectively block the formation of brain tau prions that can be entered into clinical trials for the prevention and/or treatment of CTE and other neurodegenerative disorders in at-risk active duty and retired service members.</p> <p>FY 2019 Plans: None</p> <p>FY 2020 Plans: The USUHS plans for FY 2020 are to:</p> <ul style="list-style-type: none"> - Screen for drug candidates that interfere with brain tau prion formation, a defining feature of CTE and other neurodegenerative diseases and maximize their bioavailability and therapeutic effectiveness. - Identify compounds that will enter the brain and bind with aggregated tau prions and can be used as PET tracers for diagnosis and markers of disease progression. - Develop animal models of tau prion formation to test efficacy of putative drug candidates - Using candidate drugs identified under this program, prepare to initiate clinical trials in at-risk service members for the treatment or prevention of CTE and other tau prion-related disorders. <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 507 / <i>Brain Injury and Disease Prevention, Treatment and Research (USUHS)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Funds increase is the result of a baseline realignment of funds in from GDF starting in FY 2020 for brain injury and disease prevention, treatment, and research.				
Accomplishments/Planned Programs Subtotals		0.000	0.000	13.317
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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development				Project (Number/Name) 508 / Psychological Health and Resilience (USUHS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
508: Psychological Health and Resilience (USUHS)	-	0.000	0.000	7.000	-	7.000	7.140	7.283	7.428	7.577	Continuing	Continuing

A. Mission Description and Budget Item Justification

The “Psychological Health and Resilience” 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 prevention, treatment and recovery of warfighters and families in behavioral and mental health, which are critical to force health and readiness. Research is necessary to guide policy and ensure optimal delivery of behavioral health training and services across the continuum of care and deployment cycle. Threats addressed by this research component include post-traumatic stress disorder (PTSD), suicide, family separation, and family violence.

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

	FY 2018	FY 2019	FY 2020
Title:	0.000	0.000	7.000
Description: STARRS-LS, the longitudinal successor to the groundbreaking Army STARRS research conducted from 2009 to 2015, is the largest study of military suicide ever undertaken, and in addition has yielded a wealth of information about a variety of other health issues relevant to the military. STARRS-LS seeks to extend the original effort by continuing to follow the original participants, expanding the Historical Administrative Data Study and using Big Data techniques to develop knowledge from it, and by combining survey and health outcome data with genetic analyses from samples provided by research participants.			
FY 2019 Plans: None			
FY 2020 Plans: - Maintaining the current data and biospecimens for future analyses -- Historical Administrative Data Study (HADS), survey data, and biorepository. - Conduct future wave of data collection from original STARRS-LS Army sample and link to historical data records. - Develop prediction algorithms for suicide attempts and other outcomes. - Provide the resultant knowledge to the Army and DoD for use in modifying recruitment algorithms and developing targeted early preventive intervention programs for Soldiers at high risk of adverse outcomes.			
FY 2019 to FY 2020 Increase/Decrease Statement: Funds increase is the result of a baseline realignment of funds in from GDF starting in FY 2020 for Psychological Health and Resilience programs.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	7.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 508 / <i>Psychological Health and Resilience (USUHS)</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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>				Project (Number/Name) 509 / <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
509: <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>	-	0.000	0.000	19.323	-	19.323	19.710	20.104	20.505	20.916	Continuing	Continuing

A. Mission Description and Budget Item Justification

The “Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness” program at USUHS is designed to answer fundamental questions of importance to the military medical mission of the Department of Defense in the three portfolio areas: Transforming Technology for the Warfighter (TTW), Surgical Critical Care, and the Rehabilitation Sciences Research.

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

	FY 2018	FY 2019	FY 2020
Title: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness	0.000	0.000	19.323
Description: The TTW program aims to support highly collaborative advanced technology projects by bringing together industry, academia and civilian medical centers including minority serving institutions with experience in solving defense and civilian health problems. Supported projects will focus on the 3 principal medical areas for defense health (Combat Casualty Care, Military Operational Medicine, and Clinical and Rehabilitative Medicine) with an emphasis on direct relevance to identified military needs, translational potential and clear strategy for product commercialization with a low to medium risk – high reward payoff. Additionally, for USU, the TTW program will cultivate, establish and leverage partnerships between USU faculty/investigators and industry, academia and civilian medical centers including minority serving institutions. Results from the TTW program will increase DoD’s workforce capability, DoD’s access to leading edge technologies and leverage industry knowledge and funded research data for warfighter medical needs.			
Surgical Critical Care (SC2i) will enroll critically ill patients, leveraging deep medical and –omics data to develop Clinical Decision Support Tools (CDSTs) that will improve clinical outcomes and lower resource utilization across military and civilian healthcare systems. The CDSTs will further assist readiness by either accelerating return to duty (abridged length-of-stay across the ICU, general ward, and rehabilitation continuum of care) and curbing medical resource burdens.			
Rehabilitation Sciences Research supports clinical and translational research efforts dedicated to enhancing the rehabilitative care of the wounded warrior, particularly those with orthopedic trauma, amputation and neurological injury. Research focus areas include: 1) Identifying and mitigating barriers to successful rehabilitation, return to duty and community reintegration; 2) Improved pain management to support active participation in rehabilitation; 3) Applying Advanced Technologies to augment			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 509 / <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>rehabilitation methods and outcomes assessments; 4) Developing and testing advanced technologies to restore individual functional independence; 5) Regenerative Rehabilitation translational products for war-related trauma.</p> <p>FY 2019 Plans: None</p> <p>FY 2020 Plans: Transforming Technology for the Warfighter: - Support the advancement of medical technologies such as 1) wearable devices (e.g. enhanced performance monitoring using biosensors), 2) operational injuries (e.g. TBI, blast injuries, trauma care), 3) rehabilitation (e.g. regenerative medicine, wound healing), 4) precision medicine (e.g. omics, biomarkers), and 5) rapid treatment and diagnostics at point of injury. - Cultivate, establish and leverage partnerships with industry, academia and civilian medical centers including minority serving institutions to create, innovate and advance disruptive medical technologies to address warfighter medical needs.</p> <p>Surgical Critical Care: - SC2i will leverage a databank to develop, validate, and/or deploy eleven (11) predictive algorithms for conditions associated with high mortality and morbidity (e.g. timing of closure of extremity and open abdominal injuries, venous thromboembolism, pneumonia, bacteremia, acute kidney injury, acute respiratory distress syndrome, heterotopic ossification, small bowel obstruction, acute appendicitis, and vasospasm for severe traumatic brain injuries). - It will support robust medical education and training to ensure the battlefield surgeons of tomorrow are appropriately trained in the use of clinical and biomarker-based CDSTs.</p> <p>Rehabilitation Sciences Research: - Define the optimal rehabilitation strategies and prosthetic selection, fitting and training for wounded warriors with osseointegration (direct skeletal attachment of a prosthesis) - Examine the clinical efficacy of virtual and augmented reality applications to enhance rehabilitation of individuals with extremity dysfunction and acquired brain injury. - Develop clinical applicable tools to objectively assess gait for individuals with lower limb amputation and dysfunction - Explore potential rehabilitative interventions to mitigate heterotopic ossification formation from blast thru translatable model - Understand the bio-psycho-social and genetic factors that influence symptomatology and response to novel treatments for individuals with TBI, Amputation, and PTSD, including phantom limb pain, secondary back pain, and post-concussive symptoms.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i>	Project (Number/Name) 509 / <i>Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Funds increase is the result of a baseline realignment of funds in from GDF in FY 2020 for Transforming Technologies for the Warfighter, Surgical Critical Care, and Rehabilitation Sciences Research.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	19.323
	FY 2018	FY 2019	
Congressional Add:	0.000	-	
FY 2018 Accomplishments:			
Congressional Adds Subtotals	0.000	-	

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

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	1,124.362	139.995	161.094	128.055	-	128.055	132.331	142.252	145.097	147.999	Continuing	Continuing
374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	798.039	93.174	112.213	124.055	-	124.055	128.251	138.090	140.852	143.669	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	311.560	42.967	44.881	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
434A: <i>Medical Products Support and Advanced Concept Development (AF)</i>	14.763	3.854	4.000	4.000	-	4.000	4.080	4.162	4.245	4.330	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Medical Products Support and Advanced Concept Development: This program element (PE) provides funding to support: 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 (MHS), and 5-medical simulation and training system technologies. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of Department of Defense and multiagency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the MHS. The program also supports the Interagency Strategic Plan for Research and Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine. As the research efforts mature, the most promising will transition to medical products and support systems development funding, PE 0605145.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>
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The Army Medical Command received FY 2016 DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury/ Psychological Health, Joint Warfighter Medical Research, and Core Research funding. Because of the CSI annual structure, out-year funding is not programmed.

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. The viability of S&T and translational research with a materiel component cannot be ensured without correctly programmed funding for logical progression and transition of those activities in the product development lifecycle. This PE 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.

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	99.039	116.213	128.055	-	128.055
Current President's Budget	139.995	161.094	128.055	-	128.055
Total Adjustments	33.596	42.249	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-0.760	-1.316			
• Congressional Rescissions	-	-			
• Congressional Adds	37.276	43.565			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-2.920	-			

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

Congressional Add: PC 540 - *CSI HIV/AIDS Prevention Program*

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

	FY 2018	FY 2019
	2.312	2.631
	21.679	22.500
	17.111	18.434
	0.000	-
Congressional Add Subtotals for Project: 400Z	41.102	43.565
Congressional Add Totals for all Projects	41.102	43.565

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency Date: February 2019

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

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-\$13.403 million) to DHP RDTE PE 0603115-Medical Technology Development for the rebalancing of the Joint Program Committees (+\$13.403 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-\$9.738 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+\$9.738 million).

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-\$7.000 million) as a result of DoD CIO Health Information Technology Optimization review.

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-\$2.394 million) to DHP RDTE PE 0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+2.394 million).

FY 2018: Realignment from GDF DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-\$8.343 million) to DHP RDTE PE 0603115-Medical Technology Development, Uniformed Services University, Applied Proteogenomics Organization Learning and Outcomes (APOLLO) Consortium (+\$8.343 million) so support the White House-directed Cancer Moonshot initiative.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	798.039	93.174	112.213	124.055	-	124.055	128.251	138.090	140.852	143.669	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force -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. Medical products advanced concept development is managed by the Joint Program Committees (JPCs) in the following areas: 1- The Medical Simulation and Information Sciences 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, quality, and patient safety through improved decision making via training, education, and informatics. 2- The Military Infectious Diseases JPC supports the advanced development of systems to rapidly detect pathogens (infectious agents), 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- The Military Operational Medicine JPC supports clinical assessments related to interventions for post-traumatic stress disorder, nutrition and dietary supplementation to promote health and resilience, real-time physiological status monitoring, interventions for hearing loss and tinnitus, enhancement of military family and community health and resilience techniques, validation trials for suicide prevention, and the accomplishment of related field studies with end users. 4- Combat Casualty Care JPC supports clinical trials such as those assessing biomarkers (biological indicators) for Traumatic Brain Injury (TBI), and advanced product development related to hemorrhage, extremity trauma, pre-hospital combat casualty care, and en route care. 5- Clinical and Rehabilitative Medicine JPC supports clinical research related to pain management and regenerative medicine.

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

	FY 2018	FY 2019	FY 2020
Title: GDF – Medical Product Support and Advanced Concept Development	95.039	113.529	124.055
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 2019 Plans:			
Medical simulation and information sciences will conduct engineering and manufacturing development in two primary research tasks: medical simulation and health information technology and informatics (HITI). Under the medical simulation task: Will continue the development of low and mid fidelity peripherals that attach or insert onto the core manikin. Research will continue on the underlying architecture to support the development of the future Joint Evacuation and Transport Simulation (JETS) System of			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <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 2018	FY 2019	FY 2020
<p>Systems. Research will continue on the integration of virtual standardized patients and virtual technology applications to represent a broader range of burn training scenarios with increased physiological responsiveness to not only the user's actions but also further environmental exposure. Will continue efforts to transition technology products and services to external stakeholders in order to address operational medicine health information technology capability gaps, such as capturing and transmitting point of injury data to improve quality of care and patient safety.</p> <p>Military infectious diseases research will continue to support studies aligning to the National Action Plan for Combating Antibiotic-Resistant Bacteria. Will continue to support the ongoing development of prototype diagnostic devices and the evaluation of assay performance in an operational environment to detect pathogen associated nucleic acids, proteins and toxins. Efforts will involve prospective collection and evaluation of standardized clinical data including therapy, microbiology, and clinical outcomes of combat-related injuries across treatment facilities. Will continue to support optimization and clinical validation studies for a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel to be used on the Next Generation Diagnostic System. Will continue to support Adenovirus vaccine production modernization efforts.</p> <p>Military Operational Medicine: Will continue to develop guidance regarding calcium and vitamin D intake to support optimal bone health during training. Will continue to optimize and validate brief cognitive behavior therapies for decreasing suicide. Will conduct advanced development on a real-time physiological status monitoring system that integrates algorithms and sensors into actionable real-time physiological status, health, and readiness information. Continue to advance technologies that support the Integrated Soldier Sensor System to include sensor(s) quantifying the impact of energy expenditure and physical load on Soldier Service members' performance, improved metabolic monitoring in training environments, and the assessment of cognitive status in operational settings via the monitoring of fatigue and nutritional status. Will initiate a clinical study for pharmaceutical (drug) interventions for noise induced hearing loss. Will continue to prepare for study assessing new pharmacotherapeutics to foster recovery of Service members and Veterans with combat-related posttraumatic stress disorder. Will complete assessment on a biomarker panel to predict the risk of Acute Mountain Sickness for Service members who rapidly ascent to high altitude to perform their mission.</p> <p>Clinical and rehabilitative medicine: Will continue efforts in the areas of military-relevant pain management focusing on the validation of non-pharmacologic approaches to managing pain. Will continue to conduct studies pursuing a route of administration change for ketamine, a pain management product for use after surgery, from intravenous to oral transmucosal. Will prepare for initiation of a burn trauma clinical study related to functional skin regeneration</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <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 2018	FY 2019	FY 2020
<p>Tri-Service Translational Research will continue studies at Military Treatment Facilities and intramural organizations recommended for funding Applications will be solicited to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and clinical and rehabilitative medicine.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Increasing focus to transition promising military medical solutions and technologies to the field.</p>			
Accomplishments/Planned Programs Subtotals	95.039	113.529	124.055

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 is evaluated through In-Progress Reviews, Defense Health Program-sponsored review and analysis meetings, quarterly and annual status reports, and is subject to Program Office or Program Sponsor Representatives progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with the DoD Instruction 5000 series on the Operation of the Defense Acquisition System. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of Technology Readiness Level 7.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
400Z: <i>CSI - Congressional Special Interests</i>	311.560	42.967	44.881	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

	FY 2018	FY 2019
Congressional Add: 427A - Traumatic Brain Injury / Psychological Health	2.312	2.631
FY 2018 Accomplishments: This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (TBI) on the function, wellness, and overall quality of life, including interventions across the deployment lifecycle for Service members and Veterans, as well as their family members, caregivers, and communities. Key priorities of the FY 2018 Traumatic Brain Injury and Psychological Health (TBI/PH) Research Program were supporting projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families; enabling significant research collaborations; and complementing ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. FY 2018 funds supported research in medical simulation and training toward enhanced resilience.		
FY 2019 Plans:		
Congressional Add: 441A - Joint Warfighter Medical Research Program	21.679	22.500
FY 2018 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) 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 JWMRP directly supports military medical research in military infectious diseases, combat casualty care, military operational medicine, medical simulation		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <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 2018	FY 2019
and information sciences, and clinical and rehabilitative medicine. FY 2018 funding supported the continuation of promising research previously funded through the JWMPRP. FY 2019 Plans:		
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF) FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0604110. Funds supported medical products support and advanced concept development in the areas of combat casualty care, military infectious diseases, and clinical and rehabilitative medicine. (Project 374A). FY 2019 Plans:	17.111	18.434
Congressional Add: PC 540 - CSI HIV/AIDS Prevention Program FY 2018 Accomplishments:	0.000	-
Congressional Adds Subtotals	41.102	43.565

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
434A: <i>Medical Products Support and Advanced Concept Development (AF)</i>	14.763	3.854	4.000	4.000	-	4.000	4.080	4.162	4.245	4.330	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 transition of those technologies to operators in the field. Development, Modification, and Enhancement projects will emphasize technologies supporting Expeditionary Medicine, Human Performance, En-Route Care, Force Health Protection, and Operational Medicine. Funding provides critical flexibility to make and act on materiel 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. Program 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.

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

	FY 2018	FY 2019	FY 2020
Title: Medical Products Support and Advanced Concept Development (AF)	4.000	4.000	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 address capability gaps and requirements with affordable state-of-the art commercial technologies in support of the operational mission. Provide core capability to logically progress initiatives and concepts from S&T and translational/knowledge-focused programs (6.1-6.3) into materiel solutions and conduct the advanced development and transition activities needed to ensure those products are fielded in an effective, affordable, timely and efficient manner.			
FY 2019 Plans:			
Begin advanced development and refinement of variable-flow aortic hemostasis and resuscitation balloon treatment for combat casualty care in developing a prototype field catheter with packaging and inserts for testing in preparation of FDA approval and pending clinical trials. Continue assessment and development of Medical Modernization efforts including, but not limited to, automated/autonomous control of oxygen and ventilation intervention for patient care; continue developing a commercially-available system for producing upon-demand sterile water for injection and Intravenous (IV) solutions in deployed EMEDS and Naval vessels using onsite/onboard water sources that will eventually include reconstitution of dried human plasma when			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 434A / <i>Medical Products Support and Advanced Concept Development (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
available commercially; technology that utilizes elemental oxygen to cause immediate coagulation in wounds at the point of injury, and ruggedized, portable materiel products for use in expeditionary settings.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
Accomplishments/Planned Programs Subtotals	4.000	4.000	4.000

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

N/A

Remarks

D. Acquisition Strategy

Partnership with the USAMRMC, Navy Medical Research Center (NMRC), AFRL, AFLCMC, Department of the Interior (interagency cooperative agreements and use award of delivery orders and task assignments) and medical technology consortiums to perform engineering, manufacturing, and prototype development IDIQ vehicles to include those awarded under SBIR phase III provisions or similar. 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. Will utilize industry-standard project management processes and DoD Acquisition process managed by the Air Force Life Cycle Management Center (AFLCMC), Wright-Patterson AFB.

E. Performance Metrics

Achievement of affordable and effective fielded medical technologies and capabilities for warfighter; achievement of required TRL for each advanced concept development/product support project and fulfillment of established key performance parameters (KPPs) for projects.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity **R-1 Program Element (Number/Name)**
 0130: *Defense Health Program I BA 2: RDT&E* PE 0605013DHA I *Information Technology Development*

COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	323.828	24.398	25.228	23.780	-	23.780	19.844	20.062	19.815	20.212	Continuing	Continuing
239B: <i>Health Services Data Warehouse (Air Force)</i>	1.766	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
239F: <i>IM/IT Test Bed (Air Force)</i>	7.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
239G: <i>MHS Information Portal (MIP)</i>	2.803	1.384	1.461	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
239H: <i>IM/IT Test Bed (Air Force) at DHA</i>	1.769	2.141	2.686	2.740	-	2.740	2.795	2.851	2.908	2.966	Continuing	Continuing
283C: <i>Medical Operational Data System (MODS) (Army)</i>	8.393	2.606	2.732	2.759	-	2.759	2.787	2.842	2.899	2.957	Continuing	Continuing
283D: <i>Army Medicine CIO Management Operations</i>	1.175	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283H: <i>Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)</i>	0.125	0.077	0.080	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283J: <i>Antibiotic Resistance Monitoring and Research (ARMoR-D)</i>	2.460	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283L: <i>Pharmacovigilance Defense Application System</i>	1.024	0.337	0.350	0.350	-	0.350	0.350	0.350	0.357	0.364	Continuing	Continuing
283M: <i>Business Intelligence Competency Center (BICC)</i>	1.488	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283N: <i>Corporate Dental System (CDS)</i>	0.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
283P: <i>Mobile HealthCare Environment (MHCE)</i>	0.662	0.402	0.331	0.473	-	0.473	0.364	0.378	0.385	0.393	Continuing	Continuing
385A: <i>Integrated Electronic Health Record Inc 1 (Tri-Service)</i>	146.417	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency											Date: February 2019		
Appropriation/Budget Activity					R-1 Program Element (Number/Name)								
0130: Defense Health Program I BA 2: RDT&E					PE 0605013DHA I Information Technology Development								
386A: Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)	14.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423A: Defense Center of Excellence (FHP&RP)	3.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423B: Defense Center of Excellence (Army)	0.996	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
423C: Defense Center of Excellence (T2T/PBH TERM) (DHA)	1.318	1.344	1.422	1.450	-	1.450	1.478	1.509	1.539	1.570		Continuing	Continuing
435A: NICOE Continuity Management Tool	2.855	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
446A: Disability Mediation Service (DMS)	1.286	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480B: Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service)	0.585	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480C: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)	17.732	2.278	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480D: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)	13.967	5.805	5.559	3.868	-	3.868	7.700	7.675	7.181	7.325		Continuing	Continuing
480F: Executive Information/ Decision Support (EI/DS) (Tri-Service)	5.936	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480G: Health Artifact and Image Management Solution (HAIMS) (Tri-Service)	8.123	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480K: Integrated Federal Health Registry Framework (Tri-Service)	4.065	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency											Date: February 2019		
Appropriation/Budget Activity					R-1 Program Element (Number/Name)								
0130: Defense Health Program I BA 2: RDT&E					PE 0605013DHA I Information Technology Development								
480M: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	28.731	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480P: Other Related Technical Activities (Tri-Service)	4.807	3.371	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480Y: Clinical Case Management (Tri-Service)	2.925	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
481A: Theater Enterprise Wide Logistics System (TEWLS) Tri-Service)	5.127	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
482A: E-Commerce (DHA)	13.193	3.568	4.200	4.284	-	4.284	4.370	4.457	4.546	4.637	4.637	Continuing	Continuing
490I: Navy Medicine Chief Information Officer	6.237	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
490J: Navy Medicine Online	5.259	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480A: Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)	5.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480Z: Patient Reported Outcomes Clinical Record (Previous known as PASTOR) (Tri-Service)	0.798	0.519	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
480R: Joint Disability Evaluation System IT (DHA)	0.429	0.566	0.666	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
485: Legacy Data Repository (DHA-C)	0.000	0.000	5.741	5.856	-	5.856	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
505: Military Health System Virtual Health Program (MHS VHP)	-	0.000	0.000	2.000	-	2.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
Program MDAP/MAIS Code: Project MDAP/MAIS Code(s): 465													

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency Date: February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>
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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 Medical Operational Data System (MODS); Army Medicine CIO Management Operations; Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM); Antibiotic Resistance Monitoring and Research (ARMoR-D); Pharmacovigilance Defense Application System (PVDAS); Mobile HealthCare Environment (MHCE); and the Defense Center of Excellence (DCoE).

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.

Defense Health Agency (DHA) Health Information Technology (HIT) [previously known as Tri-Service IM/IT] - DHA HIT RDT&E activities includes funding for development/integration, modernization, test and evaluation for the Defense Health Agency initiatives, and any special interest that are shared within all centralized components of the Defense Health Program (DHP).

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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity	R-1 Program Element (Number/Name)				
0130: <i>Defense Health Program I BA 2: RDT&E</i>	PE 0605013DHA I <i>Information Technology Development</i>				

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	25.323	25.228	26.497	-	26.497
Current President's Budget	24.398	25.228	23.780	-	23.780
Total Adjustments	-0.925	0.000	-2.717	-	-2.717
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.925	-			
• MHS IT Reform initiative	-	-	-5.376	-	-5.376
• Component adds	-	-	2.659	-	2.659

Change Summary Explanation

Funding added for the new initiative Military Health System Virtual Health Program (+2.000M) and ILER (+0.659M) offset by reductions associated with MHS IT Reform (-5.376M) initiative.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 239B / <i>Health Services Data Warehouse (Air Force)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
239B: <i>Health Services Data Warehouse (Air Force)</i>	1.766	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: 239B - Health Services Data Warehouse	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	0.000	0.000	0.000	-	0.000	0.000	-	-	-	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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 239F / <i>IM/IT Test Bed (Air Force)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
239F: <i>IM/IT Test Bed (Air Force)</i>	7.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

Title: 239F IM/IT Test Bed (Air Force)	FY 2018	FY 2019	FY 2020
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.	0.000	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• N/A: N/A	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 239F / <i>IM/IT Test Bed (Air Force)</i>

<u>E. Performance Metrics</u> N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 239G / <i>MHS Information Portal (MIP)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
239G: <i>MHS Information Portal (MIP)</i>	2.803	1.384	1.461	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The MIP enterprise solution supports Military Health System (MHS) strategic goals and facilitates informed decision-making through the delivery of robust information services and data in a timely, relevant, and actionable manner. MIP will serve as a hub for patient information, clinical decision support tools, medical readiness innovation, clinical research, and centralized, advanced operational and clinical analytics. MIP is a three-layer Defense Business System for reporting and analysis repository consisting of information used throughout the MHS from the operational to strategic level. Input from several source systems is aggregated, rationalized and normalized allowing a range of capabilities for users for near real-time reporting, deep dive analytics, and statistical analysis. MIP provides clinical information data warehousing (DW) modules, enabling Defense Health Agency to monitor, extract, and make available clinical/business data from Military Treatment Facilities (MTFs). Replaces Clinical Enterprise Intelligence Program (CEIP).

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

	FY 2018	FY 2019	FY 2020
Title: MHS Information Portal	1.384	1.461	-
Description: MIP will serve as a hub for patient information, clinical decision support tools, medical readiness innovation, clinical research, and centralized, advanced operational and clinical analytics			
FY 2019 Plans: Continue MHS Data Customer Service Initiative: Increase customer engagement, productivity, and satisfaction by expanding collaboration tools, streamlining processes, and providing data valet service with data and tools experts. CHAS Global and COHORT consolidation to increase performance and provide efficiencies. Consolidate P4I capabilities/requirements into CEIP.			
FY 2019 to FY 2020 Increase/Decrease Statement: Decrease as funding and functionality are moved to other initiatives as part of the Military Health System Health Information Technology Enterprise Reform.			
Accomplishments/Planned Programs Subtotals	1.384	1.461	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 239G / <i>MHS Information Portal (MIP)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807793DHA: <i>MHS Tri-Service Information</i>	31.191	28.319	0.000	-	0.000	0.000	0.000	0.000	0.000	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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 239H / <i>IM/IT Test Bed (Air Force) at DHA</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
239H: <i>IM/IT Test Bed (Air Force) at DHA</i>	1.769	2.141	2.686	2.740	-	2.740	2.795	2.851	2.908	2.966	Continuing	Continuing

A. Mission Description and Budget Item Justification

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.

Previously reported under initiative IM/IT Test Bed (Air Force) Project Code 239F.

Operational control of funding was transferred from Air Force Medical Information Technology (IT) to Defense Health Agency Health Information Technology (DHA HIT) with the stand up of Defense Health Agency beginning in FY16. However, functionality for operational testing will remain with Air Force Medical IT. Funding will be transferred to Air Force Medical IT during year of execution.

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

	FY 2018	FY 2019	FY 2020
Title: Operational Testing Service	2.141	2.686	2.740
Description: A dedicated operational testing service, Test Bed conduct tests on various Air Force Medical Systems (AFMS). It provides risk controlled testing for designated core & interim medical applications in an operationally realistic environment.			
FY 2019 Plans: As in prior years, DHA will transfer funding to AF Medical IT during year of execution. AF will continue to test the DHMSM Electronic Health Record, JOMIS, Legacy TMIP, DMIX and HAIMS. Multi-Service Operational Test and Evaluation(s) will be conducted for the DHMSM Fixed Facility sites and the JOMIS Operational Medicine locations. Plans are to continue capability development & fielding efforts for half a dozen other ACAT III programs, initiate the Risk Management Framework reaccreditation for AF SG5T VPN for virtualization of IT Test Bed, and participate in at least half a dozen AF SG HPTs and requirement reviews, similar to FY18.			
FY 2020 Plans: As in prior years, DHA will transfer funding to AF Medical IT during year of execution. AF will continue to test the DHMSM Electronic Health Record, JOMIS, Legacy TMIP, DMIX and HAIMS. Multi-Service Operational Test and Evaluation(s) will be conducted for the DHMSM Fixed Facility sites and the JOMIS Operational Medicine locations. Plans are to continue capability			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 239H / <i>IM/IT Test Bed (Air Force) at DHA</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
development & fielding efforts for half a dozen other ACAT III programs, initiate the Risk Management Framework reaccreditation for AF SG5T VPN for virtualization of IT Test Bed, and participate in at least half a dozen AF SG HPTs and requirement reviews, similar to FY18. FY 2019 to FY 2020 Increase/Decrease Statement: Inflation.			
Accomplishments/Planned Programs Subtotals	2.141	2.686	2.740

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

N/A

Remarks

D. Acquisition Strategy

Operational control of funding was transferred from Air Force Medical Information Technology (IT) to Defense Health Agency Health Information Technology (DHA HIT) with the stand up of Defense Health Agency beginning in FY16. However, functionality for operational testing will remain with Air Force Medical IT. Funding will be transferred to Air Force Medical IT during year of execution.

E. Performance Metrics

As determined by and based on the requirements for Air Force Medical IT operational testing.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283C: <i>Medical Operational Data System (MODS) (Army)</i>	8.393	2.606	2.732	2.759	-	2.759	2.787	2.842	2.899	2.957	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 2018	FY 2019	FY 2020
Title: Medical Operational Data System (MODS)	2.606	2.732	2.759
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 2019 Plans: FY 2019 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. These technology upgrades will support the system's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the MHS.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	2.606	2.732	2.759

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020 Base</u>	<u>FY 2020 OCO</u>	<u>FY 2020 Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	13.385	13.628	13.878	-	13.878	13.937	14.076	14.358	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283C / <i>Medical Operational Data System (MODS) (Army)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	0.300	0.400	0.200	-	0.200	0.202	0.204	0.208	-	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

1. 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.
2. 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.
3. 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.
4. 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).
5. MEASURE: Organizational and individual impact of Data Warehouse, 3TOOAD, and Robust Business Intelligence.
METRIC: >= 8.5 avg. benchmark score (0 to 10 scale) on quarterly quality and impact surveys from users.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 283D / <i>Army Medicine CIO Management Operations</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283D: <i>Army Medicine CIO Management Operations</i>	1.175	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

Title: 283D - Army Medicine CIO Management Operations	FY 2018	FY 2019	FY 2020
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.	0.000	0.000	0.000
FY 2019 Plans: No funding programmed.			
FY 2020 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020 Base</u>	<u>FY 2020 OCO</u>	<u>FY 2020 Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	19.430	8.705	3.936	-	3.936	5.626	8.143	11.088	-	Continuing	Continuing
• BA-1, 0807721HP: <i>Replacement/Modernization</i>	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283D / <i>Army Medicine CIO Management Operations</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807798HP: <i>Management Headquarters</i>	2.784	2.830	2.880	-	2.880	2.879	2.882	2.884	-	Continuing	Continuing
• BA-1, 0807796HP: <i>Base Operations</i>	0.522	0.536	0.536	-	0.536	0.536	0.536	0.536	-	Continuing	Continuing

Remarks

Controls for AMCMO were reduced to support the Desktop to Datacenter initiative that transferred funding to DHA HIT, per the FY18 POM MOA.

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283H: <i>Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)</i>	0.125	0.077	0.080	0.000	-	0.000	0.000	0.000	0.000	0.000	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 2018	FY 2019	FY 2020
Title: Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM)	0.077	0.080	0.000
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 2019 Plans: FY 2019 funds will be used to support any further enhancements that may be required after the Behavioral Health Recovery Management(BHRM) self-service functionality is put into production during Fiscal Year 2018.			
FY 2020 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: End of program.			
Accomplishments/Planned Programs Subtotals	0.077	0.080	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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)

Line Item	FY 2018	FY 2019	FY 2020	FY 2020	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	Cost To	
			Base	OCO	Total					Complete	Total Cost
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing
• BA-1, 0807714HP: <i>other health Activities</i>	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing
• BA-1, 0807793DHA: <i>MHS Tri-Service Information Management/ Information Technology (IM/IT)</i>	0.074	0.074	0.074	-	0.074	0.074	0.074	0.074	-	Continuing	Continuing

Remarks

BAG 104 funding moved to DHA starting on 01 Oct 2015 per FY 2016 POM MOA.
 BAG 103 funding moved to DHA starting on 01 Oct 2016 per FY 2017 POM MOA. Moving DCoE to DHA (BA-1, 0807714HP)

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

FY 2018
 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283J / <i>Antibiotic Resistance Monitoring and Research (ARMoR-D)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283J: <i>Antibiotic Resistance Monitoring and Research (ARMoR-D)</i>	2.460	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Note

In FY 2018, the title of project code 283J is changed from "Multi-Drug Resistant Surveillance Network (MSRN)" to "Antibiotic Resistance Monitoring and Research (ARMoR-D)".

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 Antibiotic Resistance Monitoring and Research (ARMoR-D) program includes development projects for Army Service level support. Specifically, the ARMoR-D is the Enterprise Antibiotic Resistant Bacteria program, which collects, characterizes, and conducts epidemiologic surveillance of highly resistant bacteria. ARMoR-D promotes best clinical practices, enhances performance improvement, and focuses infection control strategies.

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

	FY 2018	FY 2019	FY 2020
Title: Antibiotic Resistance Monitoring and Research (ARMoR-D)	0.000	0.000	0.000
Description: ARMoR-D is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection.			
FY 2019 Plans: No funding programmed.			
FY 2020 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283J / <i>Antibiotic Resistance Monitoring and Research (ARMoR-D)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	0.757	0.684	0.700	-	0.700	0.719	0.735	0.829	-	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

Business metrics:

1. Turn-around time from receipt of isolate shipment to initial test results being available on ARMoR-D 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283L: <i>Pharmacovigilance Defense Application System</i>	1.024	0.337	0.350	0.350	-	0.350	0.350	0.350	0.357	0.364	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 2018	FY 2019	FY 2020
Title: Pharmacovigilance Defense Application System (PVDAS)	0.337	0.350	0.350
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 2019 Plans: Funding will be used to implement the testing of the drug surveillance and data visualization capabilities that were developed during Fiscal Year 2018.			
FY 2020 Plans: Funding will be used to implement the testing of the drug surveillance and data visualization capabilities that were developed during Fiscal Year 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals	0.337	0.350	0.350

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing
• BA-1, 0807714HP: <i>Other Health Activities</i>	0.974	1.036	2.048	-	2.048	1.134	1.222	1.258	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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)

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807798HP: <i>Management Headquarters</i>	1.550	1.600	1.650	-	1.650	1.700	1.700	1.752	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 283M / <i>Business Intelligence Competency Center (BICC)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283M: <i>Business Intelligence Competency Center (BICC)</i>	1.488	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Business Intelligence Competency Center (BICC)	0.000	0.000	0.000
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 2019 Plans: No funding programmed.			
FY 2020 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A.			
Accomplishments/Planned Programs Subtotals			0.000

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283M / <i>Business Intelligence Competency Center (BICC)</i>

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
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Remarks

O&M Funding transferred to DHA starting on 01OCT2015, per FY16POM MOA.

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 283N / <i>Corporate Dental System (CDS)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283N: <i>Corporate Dental System (CDS)</i>	0.709	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

	FY 2018	FY 2019	FY 2020
Title: Corporate Dental System (CDS)	0.000	-	-
Description: The Corporate Dental System (CDS) is the Dental digital web based DICOM image capture and viewing application.			
Accomplishments/Planned Programs Subtotals			
	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	0.112	0.114	0.115	-	0.115	0.117	-	-	-	Continuing	Continuing
• BA-1, 0807715HP: <i>Dental Care Activities</i>	13.051	13.386	13.656	-	13.656	13.851	-	-	-	Continuing	Continuing
• BA-3, 0807721HP: <i>Replacement/Modernization</i>	0.600	0.600	0.600	-	0.600	0.600	-	-	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283P / <i>Mobile HealthCare Environment (MHCE)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
283P: <i>Mobile HealthCare Environment (MHCE)</i>	0.662	0.402	0.331	0.473	-	0.473	0.364	0.378	0.385	0.393	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 2018	FY 2019	FY 2020
Title: Mobile HealthCare Environment (MHCE)	0.402	0.331	0.473
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 2019 Plans: FY 2019 funding will be utilized to finalize the expansion of the MHCE functionality deployed in FY 2017-2018, which will be the data exchange with other systems, specifically a patient's personal health record, and enterprise systems such as their electronic health record. These system enhancements will support the Army's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the Military Health System.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: N/A			
Accomplishments/Planned Programs Subtotals			0.473

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

	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i>	1.416	1.477	1.551	-	1.551	1.561	1.571	1.571	-	Continuing	Continuing

Remarks

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 283P / <i>Mobile HealthCare Environment (MHCE)</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

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
385A: <i>Integrated Electronic Health Record Inc 1 (Tri-Service)</i>	146.417	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Project 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 2018	FY 2019	FY 2020
Title: Integrated Electronic Health Record (iEHR) Inc 1 (Tri-Service)	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

None planned.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 386A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
386A: <i>Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)</i>	14.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)	0.000	-	-
Description: Work with Department of Veterans Affairs (VA), Department of Health & Human Services (HHS), and Private Sector to expand VLER.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 386A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH (Tri-Service)</i>

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 423A / <i>Defense Center of Excellence (FHP&RP)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
423A: <i>Defense Center of Excellence (FHP&RP)</i>	3.464	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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 2018	FY 2019	FY 2020
Title: Defense Center Of Excellence (FHP&RP)	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 423A / <i>Defense Center of Excellence (FHP&RP)</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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 423B / <i>Defense Center of Excellence (Army)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
423B: <i>Defense Center of Excellence (Army)</i>	0.996	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Note

Transferred from FHP&R (Project Code 423A) to Army (Project Code 423B) in FY 2015.
 Transferred from Army (Project Code 423B) to DHA (Project Code 423C) in FY 2017.

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury is administratively managed under the US Army Medical Command (MEDCOM) that provides guidance across DoD programs related to psychological health (PH) and traumatic brain injury (TBI) issues. 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. Management of IMIT funds are transferred from Army to DHA effective in FY 2017.

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

	FY 2018	FY 2019	FY 2020
Title: Defense Center of Excellence (Army)	0.000	0.000	0.000
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 2019 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 423B / <i>Defense Center of Excellence (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
No funding programmed.			
<i>FY 2020 Plans:</i> No funding programmed.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> N/A			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020 Base</u>	<u>FY 2020 OCO</u>	<u>FY 2020 Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i>	-	-	-	-	-	-	-	-	-	-	-
• BA-1, 0807724HP: <i>Military Unique - Other Medical</i>	-	-	-	-	-	-	-	-	-	-	-

Remarks
Transferred from Army (Project Code 423B) to DHA (Project Code 423C) in FY 2017.

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 423C / <i>Defense Center of Excellence (T2T/PBH TERM) (DHA)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
423C: <i>Defense Center of Excellence (T2T/PBH TERM) (DHA)</i>	1.318	1.344	1.422	1.450	-	1.450	1.478	1.509	1.539	1.570	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE) provides the Military Health System with current and emerging psychological health and traumatic brain injury clinical and educational information. DCOE identifies gaps and prioritize needs in psychological health and TBI research, and then translate that research into clinical practice to improve patient outcomes.

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

	FY 2018	FY 2019	FY 2020
Title: Defense Center of Excellence (DHA) T2T and PBH TERM	1.344	1.422	1.450
<p>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.</p> <p>Telehealth and Technology Toolkit (T2T): This project will organize a toolkit of components in the areas of PH and telehealth that can be used both within and outside DoD. The focus of the toolkit is NOT to develop duplicative components, but allow room for collaboration and remote access to tools. The T2 Toolkit consists of mobile applications, 3-Dimensional applications (apps), and supporting websites. These applications will combine to create a system that covers many areas of Psychological Health (PH) for the Department of Defense, family members.</p> <p>Psychological and Behavioral Health – Tools for Evaluation, Risk and Management (PBH-TERM) is a web-based psychological and behavioral health (BH) information technology application which supports evidence-based, standardized and integrated BH initiatives and program evaluation.</p> <p>FY 2019 Plans: Develop six mobile applications, three websites, 2 3D applications and one data warehouse. Complete the deployment of the progressive web application framework to Fort Detrick. Create mobile & web microservices to further develop the mobile platform into the DHA mobile solution with a low code environment. This contains reusable components that any developer can use thus reducing the amount of coding.</p> <p>FY 2020 Plans:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 423C / <i>Defense Center of Excellence (T2T/PBH TERM) (DHA)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Develop six mobile applications, three websites, 2 3D applications and one data warehouse. Further develop microservices for the web/mobile platform. FY 2019 to FY 2020 Increase/Decrease Statement: Inflation.				
Accomplishments/Planned Programs Subtotals		1.344	1.422	1.450
C. Other Program Funding Summary (\$ in Millions) N/A				
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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 435A / <i>NICoE Continuity Management Tool</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
435A: <i>NICoE Continuity Management Tool</i>	2.855	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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:

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development	Project (Number/Name) 435A / NICOE Continuity Management Tool
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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 2018	FY 2019	FY 2020
Title: NICOE Continuity Management Tool	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals			
	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• 4187 807783: NCMT	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4187 807781: NCMT	4.332	-	-	-	-	-	-	-	-	Continuing	Continuing
• 1690 807781: HEIS	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4859 807781: JMED	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4940 807781: JTFCMI	43.267	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4940 807720: JTFCMI	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4273 807781: Engineering and Deployment	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4280 807721: Engineering and Deployment	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4361 807781: IA Operational Resiliency	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4126 807781: Computer Network Defense	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• 4111 807781: <i>Computer Network Defense</i>	0.502	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4165 807781: <i>Computer Network Defense</i>	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4177 807781: <i>Computer Network Defense</i>	0.000	-	-	-	-	-	-	-	-	Continuing	Continuing
• 4364 807781: <i>Workforce Development</i>	0.000	-	-	-	-	-	-	-	-	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
- 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development				Project (Number/Name) 446A / Disability Mediation Service (DMS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
446A: Disability Mediation Service (DMS)	1.286	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Disability Mediation Service (DMS)	0.000	-	-
<p>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.</p> <p>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.</p> <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</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 446A / <i>Disability Mediation Service (DMS)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
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."			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480B: <i>Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service)</i>	0.585	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Defense Medical Human Resources System (internet) (DMHRSi) (Tri-Service)	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480C: <i>Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)</i>	17.732	2.278	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Purpose: DMLSS provides a standard Department of Defense (DoD) medical logistics system. DMLSS suite of applications provides healthcare driven capability to support medical logistics needs for critical medical commodities - pharmaceuticals and medical/surgical supplies across 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) – Troop Support Medical and the Military Health System (MHS) providing an industry to practitioner supply chain for the medical commodity. The DMLSS DLA Wholesale (DMLSS-W) applications are funded by DLA while the garrison medical treatment facilities and theater applications are funded by the Defense Health Program.

Goal: The current DMLSS system provides full spectrum capability for medical logistics management.

Benefits: 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 MTF physical plant and supports the Joint Commission accreditation requirements. DMLSS, in coordination with Joint Operational Medicine Information Systems (JOMIS), is providing to Services and Combatant Commanders the logistics capabilities necessary to rapidly project and sustain joint medical capabilities for medical logistics management of theater medical materiel operations. 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 lower levels of care, and allows non-logisticians to electronically exchange catalog, order, and status information with their supply activity. The Joint Medical Asset Repository (JMAR) provides Enterprise asset visibility and business intelligence tool. JMAR is web-based application that provides Enterprise medical logistics (MEDLOG) asset visibility, transactional data and business intelligence (BI) and Decision Support (DS) across the MHS.

Stakeholders: MHS and DLA troop support. Customers: medical logisticians, biomedical technicians, clinical staff, and facilities management personnel in MTFs

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

	FY 2018	FY 2019	FY 2020
Title: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)	2.278	-	-
Description: In FY 2019, DMLSS will continue work started in FY 2018 using FY 2018 RDT&E. Plans are to continue the development of FDA recall alerts medical material quality control capability.			
Accomplishments/Planned Programs Subtotals	2.278	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency			Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480C / <i>Defense Medical Logistics Standard Support (DMLSS) (Tri-Service)</i>	

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u>			<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u>	
			<u>Base</u>	<u>OCO</u>	<u>Total</u>					<u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807793DHA: <i>MHS Tri-Service Information</i>	35.624	36.143	35.494	-	35.494	35.206	35.961	36.680	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480D: <i>Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)</i>	13.967	5.805	5.559	3.868	-	3.868	7.700	7.675	7.181	7.325	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 2018	FY 2019	FY 2020
Title: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)	5.805	5.559	3.868
Description: Configure, enhance, and interface DOEHRS-IH modules.			
FY 2019 Plans: Major development tasks planned include DOEHRS-IH to DOEHRS-HC Interface, Data Entry User Interface (GUI Enhancements) and Critical User Enhancements.			
FY 2020 Plans: Major development tasks planned include DOEHRS-IH interface to the Defense Medical Logistics Standard Support (DMLSS), IH Thermal Stress and Critical User Enhancements. Funding will be used for Individual Longitudinal Exposure Record (ILER) which will support increased DoD and VA data integration, development of additional DoD and VA user-specific functionality based on business case analyses, data exchange and integration with new electronic health records, and a platform to absorb an expected increase in "all hazards" exposure assessments as sensor and wearable technology advances.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480D / <i>Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Decrease as funding and functionality are moved to other initiatives as part of the Military Health System Health Information Technology Enterprise Reform offset with plus up for new module called ILER.			
Accomplishments/Planned Programs Subtotals	5.805	5.559	3.868

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

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480F: <i>Executive Information/Decision Support (EI/DS) (Tri-Service)</i>	5.936	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

EI/DS was 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. EI/DS has been broken apart into 4 separate initiatives beginning in FY17. These initiatives are (1) ESSENCE, (2) PHIMT, (3) CEIS, and (PCOS).

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

	FY 2018	FY 2019	FY 2020
Title: Executive Information/Decision Support (EI/DS) (Tri-Service)	0.000	-	-
Description: Development, modernization, upgrades and testing for various EI/DS modules. EI/DS has been broken apart into 4 separate initiatives beginning in FY17. These initiatives are (1) ESSENCE, (2) PHIMT, (3) CEIS, and (PCOS).			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

N/A

Remarks

D. Acquisition Strategy

Not applicable.

E. Performance Metrics

Not applicable.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480G / <i>Health Artifact and Image Management Solution (HAIMS) (Tri-Service)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480G: <i>Health Artifact and Image Management Solution (HAIMS) (Tri-Service)</i>	8.123	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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).

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

	FY 2018	FY 2019	FY 2020
Title: Health Artifact and Image Management Solution (HAIMS) (Tri-Service)	0.000	-	-
Description: Integrate new functionality into HAIMS.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

N/A

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480K / <i>Integrated Federal Health Registry Framework (Tri-Service)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480K: <i>Integrated Federal Health Registry Framework (Tri-Service)</i>	4.065	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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; Defense Health Agency-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 National Capital Region-National Intrepid Center of Excellence). 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.

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

	FY 2018	FY 2019	FY 2020
Title: integrated Health Registry Framework (Tri-Service)	0.000	-	-
Description: Develop, integrate and test a common registry.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

N/A

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480M: <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>	28.731	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	0.000	-	-
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 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			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480M / <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<p>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.</p> <p>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.</p>				
Accomplishments/Planned Programs Subtotals		0.000	-	-
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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480P / <i>Other Related Technical Activities (Tri-Service)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480P: <i>Other Related Technical Activities (Tri-Service)</i>	4.807	3.371	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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 cannot be associated with any one individual Tri-Service initiative, which includes enterprise Messaging and other common IT services requirements. Additionally, in standing up the new Defense Health Agency (DHA) on October 1, 2013, one of the signature efforts of the reorganization is the establishment of a Shared Services model for the delivery of enterprise-wide support services to the Military Health System (MHS). One of the five shared services in DHA is Health Information Technology (HIT). The MHS Shared Services Portfolio Rationalization (MHS SSPR) is an initiative to capture those costs which need to be called out separately to implement the share services HIT portfolio rationalization.

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

	FY 2018	FY 2019	FY 2020
Title: Other Related Technical Activities (Tri-Service)	3.371	-	-
Description: Activities common to multiple or all Tri-Service systems/programs and cannot be associated with any one individual Tri-Service initiative, which includes MHS SSPR. Funding in FY17 used for AACE Mobile Development.			
Accomplishments/Planned Programs Subtotals	3.371	-	-

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

N/A

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 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480Y: <i>Clinical Case Management (Tri-Service)</i>	2.925	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Clinical Case Management (Tri-Service)	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
481A: <i>Theater Enterprise Wide Logistics System (TEWLS) Tri-Service</i>	5.127	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Theater Enterprise Wide Logistics System (TEWLS) Tri-Service	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 482A / <i>E-Commerce (DHA)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
482A: <i>E-Commerce (DHA)</i>	13.193	3.568	4.200	4.284	-	4.284	4.370	4.457	4.546	4.637	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 2018	FY 2019	FY 2020
Title: E-Commerce (DHA)	3.568	4.200	4.284
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-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			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 482A / <i>E-Commerce (DHA)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
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.			
<i>FY 2019 Plans:</i> In FY19, plans include more modernization to healthcare financial processing, contracts, and reporting as well as adapting to health care policy and guidance. This funding will help to improve operational efficiency for DHA personnel in areas of new health care contracts, processing changes to requirements, and improving private sector care assessments and deliverable processing. Other plans include accounting improvements and better budget management. There will also be software changes, mandated by Congress and the DoD to accommodate financial application policy modifications, BEA SFIS changes, and PDS compliance			
<i>FY 2020 Plans:</i> Plans include more modernization to healthcare financial processing, contracts, and reporting as well as adapting to health care policy and guidance			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Inflation.			
Accomplishments/Planned Programs Subtotals	3.568	4.200	4.284

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807752HP:	0.132	0.132	0.132	-	0.132	0.132	0.135	0.138	-	Continuing	Continuing
<i>Miscellaneous Support Activities</i>											
• BA-3, 0807721HP:	0.000	0.550	0.561	-	0.561	0.571	0.583	0.595	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development	Project (Number/Name) 4901 / Navy Medicine Chief Information Officer
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
4901: Navy Medicine Chief Information Officer	6.237	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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)

	FY 2018	FY 2019	FY 2020
Title: Navy Medicine Chief Information Officer (CIO) Management Operations	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807781HP: Non-Central Information Management/Information Technology	83.778	68.129	71.102	-	71.102	72.458	-	-	-	Continuing	Continuing
• BA-1, PE 0807795HP: Base Communications - CONUS	17.458	17.793	18.151	-	18.151	18.505	-	-	-	Continuing	Continuing
• BA-1, PE 0807995HP: Base Communications - OCONUS	2.599	2.646	2.696	-	2.696	2.750	-	-	-	Continuing	Continuing
• BA-3, PE 0807721HP: Replacement/Modernization	0.000	0.000	0.000	-	0.000	0.000	-	-	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 490J / <i>Navy Medicine Online</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
490J: <i>Navy Medicine Online</i>	5.259	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Navy Medicine Online System (NMO) is the designated data broker for Navy Medicine. Previous to FY 2016 Navy used funding to provide support on various initiatives. Funding transferred to Defense Health Agency starting in FY 2016. FY 2016 funding will be used for application platform usability and interoperability to deliver apps for patients and staff.

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

	FY 2018	FY 2019	FY 2020
Title: Navy Medicine Online (NMO)	0.000	-	-
Description: The Navy Medicine Online System (NMO) is the designated data broker for Navy Medicine. Funding transferred to Defense Health Agency starting in FY 2016.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development	Project (Number/Name) 480A / Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480A: <i>Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)</i>	5.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

ESSENCE is the global, MHS monitoring capability for the early detection of health threats to force readiness. The Armed Forces Health Surveillance Center (AFHSC), the Service-specific public health centers, and Medical Treatment Facilities (MTFs) worldwide use ESSENCE on a daily basis to monitor the health status of the Military Health System (MHS) population in a time of concerns about possible biomedical terrorist attack and naturally occurring emerging infections. ESSENCE monitors the direct care MHS population, containing data on over 9 million lives. ESSENCE facilitates recognition and investigation of Tri-Service Reportable Medical Events and permits access to aggregate data and individual data to analyze the epidemiologic characteristics of health events of interest for Medical situational awareness.

This initiative is a split investment from the original Executive Information/Decision Support (EI/DS) initiative for reporting purposes.

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

	FY 2018	FY 2019	FY 2020
Title: Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE)	0.000	-	-
Description: Web-based syndromic surveillance used worldwide to identify rapid or unusual increases in certain syndromes. Automatically alerts users to these unusual increases and uses geographic information system mapping to display occurrences geographically.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1: 0807793DHA: MHS Tri-Service Information	6.609	6.711	6.769	-	6.769	6.874	7.024	7.164	-	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 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480A / <i>Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) (Tri-Service)</i>

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development	Project (Number/Name) 480Z / Patient Reported Outcomes Clinical Record (Previous known as PASTOR) (Tri-Service)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480Z: Patient Reported Outcomes Clinical Record (Previous known as PASTOR) (Tri-Service)	0.798	0.519	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

In FY2019, PASTOR name changed to Patient Reported Outcomes Clinical Record (PROCR).

A Clinical Decision Support tool to facilitate clinical management and optimize patient care by providing clinicians the ability to track patient reported outcome data as patients proceed through the clinical continuum of care. The need for standardized clinical assessments extended to business process improvements, clinical decision support, and individual and population-based outcome improvements by using validated instruments to measure patient reported outcomes and clinical treatment data in the routine delivery of care. PROCR leverages computer adaptive testing scales of the National Institutes of Health Patient Reported Outcomes Measurement Information System to fulfill two essential clinical needs: (1) seamless communication of assessment results in an actionable manner and (2) data repository for clinical research and health utilization studies.

Capabilities focus on two care communities: pain-related psychosocial factors & treatment history; and musculoskeletal (MSK) health. PROCR helps meet the 2010 National Defense Authorization Act (NDAA) recommendation for “performance measures used to determine the effectiveness of the policy in improving pain care for beneficiaries enrolled in the military health care system.”. PROCR capabilities include, but are not limited to:

- Create, store, deliver, and maintain patient reported responses to outcome measurement questions
- Patient to complete questionnaire with computer adaptive testing on self-entered electronic data device either through the internet, via a patient portal or in the clinic setting
- Staff to view the patient self- entered data (i.e., dashboard, visual representation, trends reports, and summaries)
- Provide decision support for staff based on data collected from patient (i.e., identify risk or potential problems, summarizing key information, follow trends over time, medication order sets, evaluate effectiveness of interventions).

Replaces Pain Assessment Screening Tool Outcome Registry (PASTOR)

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

	FY 2018	FY 2019	FY 2020
Title: Patient Reported Outcomes Clinical Record (PROCR)	0.519	-	-
Description: Current capabilities completed with advanced concept technology re-modernization funding, reported under the MHS Information Technology Research Projects (MHSITRP) initiative, at pilot facilities include:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 480Z / <i>Patient Reported Outcomes Clinical Record (Previous known as PASTOR) (Tri-Service)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> • Capability to create, store, deliver, and maintain patient reported responses to outcome measurement questions. • Capability for patient to complete questionnaire with computer adaptive testing on self-entered electronic data device either through the internet, via a patient portal or in the clinic setting. • Capability for staff to view the patient self- entered data (ie. dashboard, visual representation, trends reports, and summaries). • Capability to provide decision support for staff based on data collected from patient (i.e. identify risk or potential problems, summarizing key information, follow trends over time, medication order sets, evaluate effectiveness of interventions). • Capability to identify and enroll patients in a pain management registry (which is a part of the PASTOR package and maintained at Madigan). 			
Accomplishments/Planned Programs Subtotals	0.519	-	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development	Project (Number/Name) 480R / Joint Disability Evaluation System IT (DHA)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
480R: <i>Joint Disability Evaluation System IT (DHA)</i>	0.429	0.566	0.666	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

JDES-IT will provide case level management, tracking and reporting capability that will provide Disability Evaluation System (DES) processors and stakeholders increased transparency of a case through an automated IT solution. Case files and DES information will be electronically transferred and shared within Service components, between the Services, and with Veterans Affairs. The future environment would also include information exchange capability with existing Human Resources (HR) and medical systems to reduce duplicative entry. Funding previously reported under Disability Mediation Service prior to finalize decision on the JDES-IT.

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

	FY 2018	FY 2019	FY 2020
Title: Joint Disability Evaluation System IT (JDES-IT)	0.566	0.666	-
Description: JDES-IT will provide case level management, tracking and reporting capability that will provide Disability Evaluation System (DES) processors and stakeholders increased transparency of a case through an automated IT solution.			
FY 2019 Plans: Capability is being satisfied in HAIMS in FY 20. In FY 19 will be the year to transition the capability into HAIMS.			
FY 2019 to FY 2020 Increase/Decrease Statement: Capability is being satisfied in HAIMS in FY 20.			
Accomplishments/Planned Programs Subtotals	0.566	0.666	-

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

N/A

Remarks

D. Acquisition Strategy

Not applicable.

E. Performance Metrics

Not applicable.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 485 / <i>Legacy Data Repository (DHA-C)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
485: <i>Legacy Data Repository (DHA-C)</i>	0.000	0.000	5.741	5.856	-	5.856	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Legacy Data Repository (LDR) will provide the strategy, analysis, and solution to assume data management and governance for legacy Clinical and Business data for Defense Health Agency’s Solutions Delivery Division systems that will be decommissioned as the Military Health System (MHS) Genesis electronic health record is deployed.

As MHS Genesis deploys to each site, legacy systems cannot decommission without a legacy data repository to safely and securely migrate data – absence a LDR solution negates and ignores the underlying requirement. Clinicians without access to legacy patient history can create a direct patient safety issue. The legacy component of a patient’s Legal Medical Record will no longer be accessible once MHS Genesis rolls out.

LDR will identify, capture, organize, disseminate, and synthesize required legacy data needed to support medical information requirements for Business Intelligence (BI), Continuity of Care, and Archival in support of Defense Health Modernization Systems (DHMS) deployment plans, legacy system decommissioning plans, and operations and sustainment activities within their areas of responsibility.

This initial investment would allow the MHS to realize cost savings by decommissioning systems with overlapping capabilities to MHS Genesis, and reduce the legacy system footprint across the enterprise. Further, LDR would make legacy data available for clinicians through a clinical viewer to compliment the longitudinal record of MHS Genesis. This project will enable clinicians to holistically view a service member's medical record through both MHS Genesis and a legacy viewer. Downstream system dependent on legacy data would also be benefited through a persistence of this information.

As the LDR takes responsibility for legacy data, it must be retained within a flexible, scalable, and cost effective platform, but must also maintain the discipline of existing MHS data governance and management standards. While meeting these data governance and management standards, legacy data will be maintained in a variety of formats and degrees of normalization and structuring (i.e. discrete data, document, object, and file level).

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

	FY 2018	FY 2019	FY 2020
Title: Legacy Data Repository	-	5.741	5.856
Description: LDR will identify, capture, organize, disseminate, and synthesize required legacy data needed to support medical information requirements for Business Intelligence (BI), Continuity of Care, and Archival in support of Defense Health Modernization Systems (DHMS) deployment plans, legacy system decommissioning plans, and operations and sustainment activities within their areas of responsibility.			
FY 2019 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 485 / <i>Legacy Data Repository (DHA-C)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>Complete RMF Process</p> <ul style="list-style-type: none"> • Step 1: System Categorization • Step 2: Select Controls • Step 3 ATO Activity Kickoff • Step 3: Implement • Complete Annual Review <p>Data Migration</p> <ul style="list-style-type: none"> • Identify Data mapping based on FY18 Data Architecture activities • Map out ETL process, Data Quality Checks, and final validation • Delivery final Data Migration Plan • Implement <p>System Development</p> <ul style="list-style-type: none"> • Configure staging area, landing zone, and operational data store • Deliver iterative/Agile plan for front end development and data delivery elements • Conduct Systems Requirements Review (SRR) for Presentation Layer • Conduct Preliminary Design Review (PDR) for Presentation Layer • Complete Critical Design Review (CDR) for Presentation Layer • Document and Deliver Test Strategy and OT&E Plan <p>FY 2020 Plans:</p> <p>Finalize RMF - Complete RMF Control Packages (1-3)</p> <p>Begin System Development (Phase 1 of 2)</p> <ul style="list-style-type: none"> • Project Kick Off – Create KO report • Develop initial product backlog and review criteria for minimal viable product (MVP) with government • Complete Development Sprints – At each sprint deliver the following: Product backlog burndown chart, development velocity metrics, sprint burndown chart, and meeting minutes for the sprint planning, sprint review, and product backlog planning meetings. • Phase 1 Delivery – Create System Engineer Risk Assessment and document Promote to the Field (PTTF) authority approval. • Software Hand-Off Code Freeze and software Installation GO LIVE – Deliver software delivery report for each layer (presentation, logic, and data). <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p> <p>RDT&E slightly increases in accordance with the cost estimate to complete in FY20.</p>			
Accomplishments/Planned Programs Subtotals	-	5.741	5.856

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 485 / <i>Legacy Data Repository (DHA-C)</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>				Project (Number/Name) 505 / <i>Military Health System Virtual Health Program (MHS VHP)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
505: <i>Military Health System Virtual Health Program (MHS VHP)</i>	-	0.000	0.000	2.000	-	2.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Purpose: Establish a unified MHS program to augment military medicine with robust 'anywhere' virtual health capabilities. The program will include three distinct capabilities in order to meet its initial expected business outcome. The first capability will incorporate secure clinical VTC (synchronous visits) to enable a provider in one location to offer diagnosis and treatment to a patient in another location. Synchronous visits can take place between a provider and patient at different MTFs, or at the patient's location (e.g. their home or other location deemed appropriate by the provider). Synchronous visits at the patient's location can be conducted for primary or specialty care. Primary and Specialty Care appointments via synchronous visits will enable health care anytime, anywhere. The second capability incorporates an Asynchronous secure portal or teleconsultation portal, to enable a pool of specialty care providers globally to deliver timely clinical advice, primarily in operational settings where expertise is scarce, but also in garrison when needed. The portal facilitates 'store and forward' transmission of electronic medical information and associated digital images between health care providers. Specialty clinicians provide expert advice and guidance to the patient's attending physicians, assisting them in the disposition or local treatment options. The third capability is remote health monitoring, to collect, track, and transmit biometric data from the patient via a secure portal to an MTF. The data is accessed by a care coordinator or health care provider at the MTF to provide real-time medical interventions that can improve a patient's health and quality of life.

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

	FY 2018	FY 2019	FY 2020
Title: Military Health System Virtual Health Program (MHS VHP)	-	-	2.000
Description: GOAL: The MHS VHP will connect our beneficiaries to health care globally to increase readiness, access, quality, and patient safety.			
BENEFIT: Using VH, the best of MHS Medicine across the world can be brought to the patient wherever they are – deployed or in garrison. As a modality without geographic limits, VH extends access to quality primary care, behavioral health, and medical specialty care to remote locations where beneficiaries may be geographically separated from comprehensive Military Treatment Facility (MTF) based care, and where such care is not readily available in the surrounding community. Additionally, VH can help the MHS use its clinical capacity more effectively; cross-leveraging clinical expertise when and where it is needed.			
FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i>	Project (Number/Name) 505 / <i>Military Health System Virtual Health Program (MHS VHP)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Initial research and development of interfaces, potential software purchases that will enable integration of MHS Virtual Health Enterprise platform to DoD Electronic Health Record as well as other Enterprise system, and potential customization needed to meet Military Health Systems unique requirements. Identify future requirements that will be funded by RDTE in FY21 and out. <i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> Start up of new version of the program begins in FY20.				
Accomplishments/Planned Programs Subtotals		-	-	2.000
C. Other Program Funding Summary (\$ in Millions) N/A				
Remarks				
D. Acquisition Strategy To be determined as program matures.				
E. Performance Metrics To be determined as program matures.				

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605023DHA I <i>Integrated Electronic Health Record (iEHR)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	48.426	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
444A: <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>	41.148	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
444B: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>	4.720	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
449A: <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>	2.558	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Program MDAP/MAIS Code:
Project 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 2020 Defense Health Agency	Date: February 2019
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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 0605023DHA I <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	0.000	-	0.000
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	0.000	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605023DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
444A: <i>Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX)</i>	41.148	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Project 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 2018	FY 2019	FY 2020
Title: Integrated Electronic Health Record Inc 1/ Defense Medical Information Exchange (DMIX) (Tri-Service)	0.000	-	-
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 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605023DHA / <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 2018	FY 2019	FY 2020
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).			
<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. 			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, PE 0807784DHA: <i>Information Technology Development -</i>	16.303	16.529	17.986	-	17.986	16.912	17.253	17.598	-	Continuing	Continuing
• BA-3, 0807784DHA: <i>Replacement/Modernization</i>	0.000	0.000	0.000	-	0.000	0.000	0.000	-	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605023DHA / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 444B / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
444B: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>	4.720	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: DoD Healthcare Management System Modernization (DHMSM)	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605023DHA / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 444B / <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605023DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
449A: <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>	2.558	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Virtual Lifetime Electronic Record (VLER) HEALTH	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, PE 0807784: <i>Integrated Electronic Health Record (iEHR)</i>	0.000	0.000	0.000	-	0.000	0.000	-	-	-	Continuing	Continuing
• BA-3, PE 0807784: <i>Replacement/ Modernization, Integrated Electronic Health Record</i>	0.000	0.000	0.000	-	0.000	0.000	-	-	-	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 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605023DHA / <i>Integrated Electronic Health Record (iEHR)</i>	Project (Number/Name) 449A / <i>Virtual Lifetime Electronic Record (VLER) HEALTH</i>

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605025DHA / <i>Theater Medical Information Program - Joint (TMIP-J)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	66.524	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
445A: <i>Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)</i>	45.186	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
445B: <i>Operational Medicine Support</i>	21.338	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Program MDAP/MAIS Code:
Project MDAP/MAIS Code(s): M07

A. Mission Description and Budget Item Justification

TMIP-J is a suite of system applications that is currently deployed to all Services as the primary healthcare information technology (IT) system supporting the Warfighter. TMIP-J integrates components of the Service's sustaining base systems and the medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of Theater and deployed forces. 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 provides input to a service member's longitudinal health record. TMIP-J provides information at the point of injury and to the Theater tactical and strategic decision makers through data capture and transmission to a single Theater Management Data Store (TMDS). Using TMDS, TMIP-J provides the integration with external systems for medical logistics, patient movement and tracking, and medical command and control and medical situational awareness. TMIP-J system components integrate to specific tactical requirements, providing for availability in no- and low- communications environment through store and forward capture and transmission technology. The Theater Medical Information Program - Joint (TMIP-J) is in sustainment; Full Deployment declared May 2016.

B. Program Change Summary (\$ in Millions)

	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020 Base</u>	<u>FY 2020 OCO</u>	<u>FY 2020 Total</u>
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	0.000	-	0.000
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency Date: February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605025DHA / <i>Theater Medical Information Program - Joint (TMIP-J)</i>
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Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605025-Theater Medical Information Program - Joint (TMIP-J) (-\$0.762 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.762 million).

FY 2017: No change

FY 2018: No change.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605025DHA / Theater Medical Information Program - Joint (TMIP-J)	Project (Number/Name) 445A / Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
445A: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	45.186	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

Project MDAP/MAIS Code: M07

A. Mission Description and Budget Item Justification

TMIP-J is a suite of system applications that is currently deployed to all Services as the primary healthcare information technology (IT) system supporting the Warfighter. TMIP-J integrates components of the Service's sustaining base systems and the medical information systems to ensure timely interoperable medical support for mobilization, deployment and sustainment of Theater and deployed forces. 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 provides input to a service member's longitudinal health record. TMIP-J provides information at the point of injury and to the Theater tactical and strategic decision makers through data capture and transmission to a single Theater Management Data Store (TMDS). Using TMDS, TMIP-J provides the integration with external systems for medical logistics, patient movement and tracking, and medical command and control and medical situational awareness. TMIP-J system components integrate to specific tactical requirements, providing for availability in no- and low- communications environment through store and forward capture and transmission technology. The Theater Medical Information Program - Joint (TMIP-J) is in sustainment; Full Deployment declared May 2016.

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 2018	FY 2019	FY 2020
Title: Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)	0.000	-	-
Description: The Theater Medical Information Program - Joint (TMIP-J) is in sustainment; Full Deployment declared May 2016.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-1, 0807793DHA: MHS Tri-Service Information	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	Continuing	Continuing
• BA-1, 0807744DHA: Theater Medical Information Program - Joint (TMIP-J)	57.378	73.433	32.176	-	32.176	27.119	27.663	28.218	-	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605025DHA / Theater Medical Information Program - Joint (TMIP-J)	Project (Number/Name) 445A / Theater Medical Information Program - Joint (TMIP-J) (Tri-Service)

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

Line Item	FY 2018	FY 2019	FY 2020	FY 2020	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	Cost To	Total Cost
			Base	OCO	Total					Complete	
• BA-3, 0807744DHA: <i>Theater Medical Information Program - Joint (TMIP-J)</i>	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605025DHA / Theater Medical Information Program - Joint (TMIP-J)	Project (Number/Name) 445B / Operational Medicine Support
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
445B: <i>Operational Medicine Support</i>	21.338	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Support Joint Operational Medicine Information System (JOMIS).

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

	FY 2018	FY 2019	FY 2020
Title: Operational Medicine Support	0.000	-	-
Description: Support Joint Operational Medicine Information System (JOMIS).			
Accomplishments/Planned Programs Subtotals			
	0.000	-	-

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

Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• BA-3, 0807744DHA: Theater Medical Information Program - Joint	0.000	0.000	0.000	-	0.000	0.000	0.000	-	-	Continuing	Continuing
• BA-1, 0807744DHA **: Theater Medical Information Program - Joint	57.326	36.947	32.107	-	32.107	27.049	27.592	-	-	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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605026DHA I <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	739.255	40.996	28.326	38.256	-	38.256	18.336	15.751	6.012	6.132	Continuing	Continuing
483A: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>	739.255	40.996	28.326	38.256	-	38.256	18.336	15.751	6.012	6.132	Continuing	Continuing

Program MDAP/MAIS Code:
Project MDAP/MAIS Code(s): 496

A. Mission Description and Budget Item Justification

DHMSM will replace the DoD legacy healthcare management systems with a commercial off-the-shelf capability that is open, modular, and standards-based with 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 Electronic Health Record (EHR) will support the following healthcare activities for DoD's practitioners and beneficiaries:

- Clinical workflow and provider clinical decision support;
- Capture, maintain, use, protect, preserve and share health data and information;
- 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
- Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research.

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	42.549	28.326	15.771	-	15.771
Current President's Budget	40.996	28.326	38.256	-	38.256
Total Adjustments	-1.553	0.000	22.485	-	22.485
• Congressional General Reductions	-	-	-	-	-
• Congressional Directed Reductions	-	-	-	-	-
• Congressional Rescissions	-	-	-	-	-
• Congressional Adds	-	-	-	-	-
• Congressional Directed Transfers	-	-	-	-	-
• Reprogrammings	-	-	-	-	-
• SBIR/STTR Transfer	-1.553	-	-	-	-
• Funding added for the implementation of the Cerner Patient Accounting Module (CPAM)	-	-	0.770	-	0.770

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency	Date: February 2019
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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 0605026DHA I <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM)</i>
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• Realignment of funding in preparation for Full Deployment Decision.	-	-	21.715	-	21.715
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Change Summary Explanation

Funding added for the implementation of the Cerner Patient Accounting Module (CPAM) (FY 2020, \$+0.770M).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605026DHA / <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>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
483A: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i>	739.255	40.996	28.326	38.256	-	38.256	18.336	15.751	6.012	6.132	Continuing	Continuing

Project MDAP/MAIS Code: 496

A. Mission Description and Budget Item Justification

The DHMSM program acquired an integrated inpatient/outpatient Best of Suite (BoS) electronic health record (EHR) solution, augmented by the Best of Breed (BoB) product(s). The 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. The anticipated benefits include: 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 all DoD operational environments.

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

	FY 2018	FY 2019	FY 2020
Title: DoD Healthcare Management System Modernization (DHMSM) Program	40.996	28.326	38.256
<p>Description: DHMSM will replace the DoD legacy healthcare management systems with a commercial off-the-shelf capability that is open, modular, and standards-based. DHMSM will support the Department's goals of net-centricity 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 practitioners and beneficiaries:</p> <ul style="list-style-type: none"> • Clinical workflow and provider clinical decision support; • Capture, maintain, use, protect, preserve and share health data and information; • 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 • Analysis and management of health information from multiple perspectives to include population health, military medical readiness, clinical quality, disease management, and medical research. <p>FY 2019 Plans: FY19 RDT&E:</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency	Date: February 2019
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605026DHA / <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>
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B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> • Conduct Test Planning of new interfaces, patches, and of semi-annual releases. • Support configuration efforts for approved enhancements. <p>FY19 Procurement:</p> <ul style="list-style-type: none"> • Purchase required commercial software licenses and multiple deployments of the modernized DHMSM EHR to MTFs. • Support Deployment activities to include site visits, localized configuration, deployment activities and on-site deployment support for multiple Wave Deployments (each containing multiple MTFs and Clinics). <p>FY19 O&M:</p> <ul style="list-style-type: none"> • Operate and maintain DHMSM system, including recurring configuration, integration, and test activities, software license maintenance, hardware refresh, system hosting, and recurring change management and training as applicable. • Continue business management operations and contract management oversight. <p><i>FY 2020 Plans:</i> FY20 RDT&E:</p> <ul style="list-style-type: none"> • Conduct Test Planning of new interfaces, patches, and of semi-annual releases. • Support configuration efforts for approved enhancements. <p>FY20 Procurement:</p> <ul style="list-style-type: none"> • Purchase required commercial software licenses and multiple deployments of the modernized DHMSM EHR to MTFs. • Support Deployment activities to include site visits, localized configuration, deployment activities and on-site deployment support for multiple Wave Deployments (each containing multiple MTFs and Clinics). <p>FY20 O&M:</p> <ul style="list-style-type: none"> • Operate and maintain DHMSM system, including recurring configuration, integration, and test activities, software license maintenance, hardware refresh, system hosting, and recurring change management and training as applicable. 			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605026DHA / <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 2018	FY 2019	FY 2020
• Continue business management operations and contract management oversight.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> FY20 RDT&E funds increase in preparation for Full Deployment Decision.			
Accomplishments/Planned Programs Subtotals	40.996	28.326	38.256

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

N/A

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605039DHA / PE 0605039HP / <i>DoD Medical Information Exchange and Interoperability</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	10.157	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
458A: <i>DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)</i>	10.157	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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).

- DMIX established a roadmap outlining the future of health data sharing and viewer capabilities for DoD in support of the guidance provided by the President, Congress, and the Secretary of Defense. The roadmap defined a plan to provide a single viewer to be used by DoD and VA that displays an integrated view of a patient’s medical history. The viewer leverages existing inherited DoD data-sharing capabilities, and a VA-provided data service in order to collect the patient’s health data from the respective, authoritative data stores. Of the various existing viewers, VA and DoD decided to evolve Joint Legacy Viewer (JLV) as the single viewer for use by both Departments. By adopting JLV as a common viewer between DoD and VA, DMIX met the National Defense Authorization Act FY 2014 (NDAA 2014) requirement for “an integrated display of data” which allows DoD to sunset inherited legacy viewers.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency	Date: February 2019
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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 0605039DHA / PE 0605039HP / DoD Medical Information Exchange and Interoperability
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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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	0.000	-	0.000
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605039-DoD Medical Information Exchange and Interoperability (-\$0.843 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.843 million).

FY 2017: No change.

FY 2018: No change.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605039DHA / PE 0605039HP / DoD Medical Information Exchange and Interoperability	Project (Number/Name) 458A / DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
458A: DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)	10.157	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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) 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 2018	FY 2019	FY 2020
Title: Defense Medical Information Exchange (DMIX) Program	0.000	-	-
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.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency	Date: February 2019
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605039DHA / PE 0605039HP / <i>DoD Medical Information Exchange and Interoperability</i>	Project (Number/Name) 458A / <i>DoD Medical Information Exchange and Interoperability / Defense Medical Information Exchange (DMIX)</i>
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• BA-1, 0807788HP: <i>DoD Medical Information Exchange and Interoperability</i>	45.387	47.047	47.613	-	47.613	46.901	47.839	48.799	-	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.

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0605045DHA I <i>Joint Operational Medicine Information System (JOMIS)</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	62.914	65.047	78.136	59.902	-	59.902	49.260	50.199	48.436	0.000	Continuing	Continuing
447A: <i>Joint Operational Medicine Information System (JOMIS)</i>	62.914	65.047	78.136	59.902	-	59.902	49.260	50.199	48.436	0.000	Continuing	Continuing

Program MDAP/MAIS Code: 521

A. Mission Description and Budget Item Justification

The JOMIS Program will modernize, deploy, and sustain the DoD's operational medicine information systems using MHS GENESIS, while developing and fielding new theater capabilities that enable comprehensive health services to meet Warfighter requirements for military medical operations. JOMIS - MHS GENESIS is intended to function in constrained, intermittent, and non-existent communications environments while providing access to authoritative sources of clinical data. The JOMIS Program is declared Joint Interest for capability requirements to be executed under the Joint Capabilities Integration and Development System (JCIDS), with oversight by the Joint Staff J8 (Force Structure, Resources and Assessments) and the Joint Requirements Oversight Council (JROC).

The JOMIS Increment 1 Program is planned to deliver the MHS GENESIS Electronic Health Record (EHR) to meet the healthcare and dental documentation requirements validated by the JCIDS approved Theater Medical Information Requirements (TMIR) Capabilities Development Document (CDD) signed February 28, 2017. JOMIS Increment 1 is planned to deliver MHS GENESIS to replace/retire the legacy AHLTA-T and TC2 systems (under TMIP-J). The JOMIS Increment 1 Program is pre-Milestone B.

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	87.511	78.136	59.902	-	59.902
Current President's Budget	65.047	78.136	59.902	-	59.902
Total Adjustments	-21.483	0.000	0.000	-	0.000
• Congressional General Reductions	-	-	-	-	-
• Congressional Directed Reductions	-	-	-	-	-
• Congressional Rescissions	-20.000	-	-	-	-
• Congressional Adds	-	-	-	-	-
• Congressional Directed Transfers	-	-	-	-	-
• Reprogrammings	-	-	-	-	-
• SBIR/STTR Transfer	-2.464	-	-	-	-
• Navy Medical IT add to JOMIS	0.981	-	-	-	-

Change Summary Explanation

Increase to the JOMIS, RDT&E, Project Code 0605045 will primarily fund the integration of MHS GENESIS with the legacy TMIP-J components not replaced by MHS GENESIS, system test and evaluation activities, and supporting systems engineering/program management

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605045DHA / Joint Operational Medicine Information System (JOMIS)				Project (Number/Name) 447A / Joint Operational Medicine Information System (JOMIS)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
447A: Joint Operational Medicine Information System (JOMIS)	62.914	65.047	78.136	59.902	-	59.902	49.260	50.199	48.436	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The purpose of the Department of Defense (DoD) Joint Operational Medicine Information Systems (JOMIS) Program is to modernize, deploy, and sustain the DoD's operational medicine information systems using MHS GENESIS Electronic Health Record (EHR), while developing and fielding new theater capabilities that enable comprehensive health services to meet Warfighter requirements for military medical operations. JOMIS is intended to function in constrained, intermittent, and non-existent communications environments while providing access to authoritative sources of clinical data. The JOMIS Program is declared Joint Interest for capability requirements to be executed under the Joint Capabilities Integration and Development System (JCIDS) and the oversight of the Joint Requirements Oversight Council (JROC).

The goals of the JOMIS Increment 1 Program are to:

- Meet existing and emerging operational medicine requirements in the theater
- Fully leverage MHS GENESIS for medical care in Theater
- Provide two way information flow between garrison and theater environments in support of a longitudinal health record

Anticipated benefits of the JOMIS Increment 1 Program include:

- Delivery of uniform clinical information across both garrison and theater environments through the use of MHS GENESIS EHR
- Enhancements to the clinical care and information captured at all levels of care in tactical environments
- Transmission of critical information to the combatant commander, the evacuation chain for combat and non-combat casualties

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

	FY 2018	FY 2019	FY 2020
Title: Joint Operational Medicine Information System (JOMIS)	65.047	78.136	59.902
Description: Specific contribution to mission delivery: JOMIS Increment 1 Program will serve as the primary tactical system to meet the needs of the Warfighter by enabling the provision of coordinated healthcare services. MHS GENESIS is planned to provide for key capabilities in Healthcare Services & Documentation (including Blood Management and Dental Services and Documentation. The JOMIS Increment 1 Program will also integrate MHS GENESIS for interoperability with existing Theater system capabilities for Medical Logistics, Patient Movement and Evacuation, Medical Situational Awareness and Medical Command & Control.			
FY 2019 Plans: FY19 RDT&E:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency	Date: February 2019
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605045DHA / <i>Joint Operational Medicine Information System (JOMIS)</i>	Project (Number/Name) 447A / <i>Joint Operational Medicine Information System (JOMIS)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
<p>- Continue software development, configuration, and other activities related to Military Health Systems (MHS) Genesis and Theater Medical Information Program-Joint (TMIP-J) Gold Disk integration.</p> <p>- Conduct cybersecurity requirements (Initial Authority to Test (IATT), Red Team Assessments, Authority to Operate (ATO), and annual reviews).</p> <p>- Support Department of Defense Healthcare Management System Modernization (DHMSM) Program Management Office (PMO) for Contractor Testing and Development Test (DT) of MHS Genesis Gold Disk.</p> <p>FY19 O&M:</p> <p>- Continue support of Program Management Office (PMO).</p> <p>- Continue program management support from the Air Force, Army, Marine Corps, and Navy.</p> <p>- Continue operation and maintenance of Operational Medicine (OM) Government Approved Laboratory (GAL) Testing Facility.</p> <p>- Continue sustainment activities for all TMIP-J legacy systems prior to delivery of JOMIS.</p> <p>FY 2020 Plans:</p> <p>FY 20 RDT&E:</p> <p>- Continue software development, configuration, and other activities related to Military Health Systems (MHS) Genesis and Theater Medical Information Program-Joint (TMIP-J) Gold Disk integration.</p> <p>- Begin Developmental Test (DT) activities.</p> <p>- Support Department of Defense Healthcare Management System Modernization (DHMSM) Program Management Office (PMO) for Contractor Testing and DT of MHS Genesis Gold Disk.</p> <p>- Continue OM GAL efforts to support planning activities, user readiness, user training, and change management activities for the Initial Operating Capability (IOC) sites.</p> <p>- Continue engineering and program management support from the Air Force, Army, Marine Corps, and Navy.</p> <p>FY20 Procurement:</p> <p>- Support Operational Medicine (OM) Government Approved Laboratory (GAL) infrastructure: Software (SW) maintenance, hardware (HW) procurement/refresh/maintenance; includes additional operational medicine (OpMed) Mobile & Theater Blood requirements.</p> <p>FY20 O&M:</p> <p>- Prepare analyses and acquisition documentation in support of Test and Evaluation Authority to Proceed (ATP) Milestone Event.</p> <p>- Continue decomposition into Requirements Definition Package (RDP) to inform JOMIS Increment 1 and the delivery of future increments capability.</p> <p>- Continue support of Program Management Office (PMO).</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605045DHA / <i>Joint Operational Medicine Information System (JOMIS)</i>	Project (Number/Name) 447A / <i>Joint Operational Medicine Information System (JOMIS)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Operate and maintain OM GAL Testing Facility. - Fund sustainment of TMIP-J legacy systems prior to delivery of JOMIS. - Continue engineering and program management support from the Air Force, Army, Marine Corps, and Navy. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Reflects the program's updated strategy and timeline.</p>				
Accomplishments/Planned Programs Subtotals		65.047	78.136	59.902
C. Other Program Funding Summary (\$ in Millions)				
N/A				
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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605145DHA / <i>Medical Products and Support Systems Development</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	115.424	20.254	25.745	21.589	-	21.589	22.022	22.462	22.911	23.369	Continuing	Continuing
375A: <i>GDF-Medical Products and Support System Development</i>	75.378	19.507	24.871	20.654	-	20.654	21.068	21.489	21.919	22.357	Continuing	Continuing
399A: <i>Hyperbaric Oxygen Therapy Clinical Trial (Army)</i>	27.015	0.747	0.874	0.935	-	0.935	0.954	0.973	0.992	1.012	Continuing	Continuing
500A: <i>CSI - Congressional Special Interests</i>	13.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force – Medical Products and Support Systems Development: This program element (PE) provides funding for system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping Department of Defense (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 approval, a requirement for use of all medical products. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP sponsored research. The JPCs supported by this PE include medical simulation and information sciences (JPC-1), military operational medicine (JPC-5) combat casualty care (JPC-6), and clinical and rehabilitative medicine (JPC-8). 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605145DHA / <i>Medical Products and Support Systems Development</i>
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The Army Medical Command received DHP Congressional Special Interest (CSI) research funding to Core Research Funding. Because of the CSI annual structure, out-year funding is not programmed.

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	15.219	20.295	21.589	-	21.589
Current President's Budget	20.254	25.745	21.589	-	21.589
Total Adjustments	4.728	5.450	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	5.043	5.450			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.315	-			

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

Project: 500A: *CSI - Congressional Special Interests*

Congressional Add: 465A - *Program Increase: Core Research Funding*

Congressional Add Subtotals for Project: 500A

Congressional Add Totals for all Projects

	FY 2018	FY 2019
	5.350	-
	5.350	-
	5.350	-

Change Summary Explanation

FY 2018: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-\$0.315 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.315 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-\$0.376 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.376 million).

FY 2017: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+\$0.145 million).

FY 2017: Realignment from DHP RDTE PE 0605145 (-\$0.913 million) to DHP RDTE PE 0603115 for rebalancing JPC portfolios (+\$0.913 million).

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency Date: February 2019

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: Defense Health Program I BA 2: RDT&E	PE 0605145DHA I Medical Products and Support Systems Development

FY 2017: Realignment from DHP RDTE PE 0605145 (-\$0.633 million) to DHP RDTE PE 0603115 for Breast, GYN and Prostate Cancer Centers of Excellence (+\$0.633 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0605145-Medical Products and Support Systems Development (+\$0.594 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+\$0.594 million).

FY 2018: No changes.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605145DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
375A: <i>GDF-Medical Products and Support System Development</i>	75.378	19.507	24.871	20.654	-	20.654	21.068	21.489	21.919	22.357	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Support Systems Development: Activities conducted in this project are intended to support system development and demonstration prior to initial full rate production and fielding of commodities. Medical products and support systems development is managed by the following Joint Program Committees (JPCs). 1- The Medical Simulation and Information Sciences JPC seeks to improve military medical training through informatics based training and education. This involves simulation, educational gaming, and health-focused and objective training metrics. Within this JPC, the Combat Casualty Training Initiative supports the testing and evaluation of innovative medical simulation technologies with the goal of improving healthcare access, availability, continuity, cost effectiveness, quality, and patient safety through improved decision-making. 2 - The Military Operational Medicine JPC supports the testing and evaluation of real-time physiological (normal function of living organisms and their parts) status monitoring in order to provide actionable patient information. 3- The Combat Casualty Care JPC seeks Food and Drug Administration (FDA) approval of methods, drugs and devices through human clinical trials. Within this JPC, advanced product development to improve the quality of care is ongoing within the areas of hemorrhage, shock, and coagulopathy of trauma. In addition, the traumatic brain injury (TBI) neurotrauma and brain dysfunction area is validating TBI therapeutics and testing new imaging techniques, battlefield devices for operational decision making, and behavioral physiologic assessment tools for mild TBI. 4- The Clinical Rehabilitation Medicine JPC seeks FDA approval of fast-acting, easily dispensed oral battlefield pain management products that have minimal side effects.

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

	FY 2018	FY 2019	FY 2020
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	14.464	19.421	20.654
Description: GDF-Medical Products and Support Systems Development: 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).			
FY 2019 Plans:			
Military operational medicine will continue the development of a real-time physiological status monitoring system that integrates algorithms and sensors into actionable real-time physiological status, health, and readiness information.			
Combat casualty care will continue clinical studies supporting FDA clearance of a device using ultraviolet light to kill infectious organisms present in fresh whole blood collected on the battlefield for transfusion into casualties. Will continue clinical studies			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / <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 2018	FY 2019	FY 2020
in humans in support of a FDA Biologic License Application for a spray-dried plasma product. Will continue clinical studies on the Wound Stasis System, a product to control non-compressible hemorrhage within a body cavity. FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.				
Accomplishments/Planned Programs Subtotals		14.464	19.421	20.654
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 and Phase 3 clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.				
E. Performance Metrics Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, and quarterly and annual status reports and is subject to Program Office or Program Sponsor Representatives progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with DoD Instruction 5000 series on the Operation of the Defense Acquisition System. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of Technology Readiness Level 8 and/or the achievement of established Key Performance Parameters.				

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605145DHA / Medical Products and Support Systems Development				Project (Number/Name) 399A / Hyperbaric Oxygen Therapy Clinical Trial (Army)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
399A: Hyperbaric Oxygen Therapy Clinical Trial (Army)	27.015	0.747	0.874	0.935	-	0.935	0.954	0.973	0.992	1.012	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials focus on research related to the development of treatment modalities using HBO2 for chronic post-concussion syndrome after mild traumatic brain injury (mTBI). Three HBO2 human clinical trials were 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: 1- A pilot phase II (narrow population safety and effectiveness) study of hyperbaric oxygen for persistent post-concussive symptoms after mild traumatic brain injury (HOPPS), 2- Brain Injury and Mechanisms of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (BIMA), and 3- Development of Normative Datasets for Assessments Planned for Use in Patients with Mild Traumatic Brain Injury (Normal). A fourth retrospective study, Long Term Follow-up (LTFU), is focused on the lessons learned from long-term follow-up of subjects enrolled in the Department of Defense (DoD) primary HBO2 trials. To support these protocols, four HBO2 study sites were established within the Military Health System. Each of the research sites consisted 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 staging trailer. This information is intended to inform DoD policy decisions regarding the use of HBO2 therapy as a treatment for mTBI.

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

	FY 2018	FY 2019	FY 2020
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	0.755	0.874	0.935
Description: The Hyperbaric Oxygen (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 2019 Plans: Secondary and tertiary phases of the Genome-Exploration protocol are ongoing to validate and refine small RNA biomarkers for use as diagnostic tools to differentiate personnel with mTBI from those with mTBI and coexisting PTSD. Residual BIMA and Normal study blood specimens will be stored and dispensed as necessary to support DoD research efforts.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	0.755	0.874	0.935

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 399A / <i>Hyperbaric Oxygen Therapy Clinical Trial (Army)</i>

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

N/A

Remarks

D. Acquisition Strategy

The acquisition outcome of this effort is a knowledge product, with the results intended to inform DoD mTBI treatment and reimbursement policies. The decision to pursue FDA registration/off-label application of an existing drug-device combination product will be made as part of a formal decision by leadership after the DoD HBO2 trial results are reviewed. If future work using HBO2 proves beneficial in the treatment of PTSD this knowledge product would inform DoD treatment and reimbursement policies.

E. Performance Metrics

The HBO2 Program Management Office monitors the performance of contracts through review of monthly, yearly and final progress reports to ensure that milestones are met, deliverables will be transitioned on schedule and within budget and in accordance with DoD Instruction 5000. The HBO2 Executive Committee meets bi-monthly to evaluate the direction of the science, discuss future actions, and resolve any current or potential issues or areas of concern.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605145DHA / <i>Medical Products and Support Systems Development</i>				Project (Number/Name) 500A / <i>CSI - Congressional Special Interests</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
500A: <i>CSI - Congressional Special Interests</i>	13.031	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

	FY 2018	FY 2019
Congressional Add: 465A - Program Increase: Core Research Funding	5.350	-
FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0605145 in the areas of military operational medicine and combat casualty care.		
Congressional Adds Subtotals	5.350	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605502DHA I <i>Small Business Innovation Research (SBIR) Program</i>
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	299.600	55.405	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
470A: <i>Small Business Innovation Research (SBIR) (Army)</i>	275.975	48.577	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
470B: <i>Small Business Technology Transfer (STTR) Program</i>	23.625	6.828	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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 Department of Defense (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.

The Small Business Technology Transfer (STTR) program was established in the DHP, RDT&E appropriation during FY 2015, and is funded in the year of execution. The STTR Program, although modeled substantially on the SBIR Program, is a separate program and is separately financed. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations. The mission of the STTR program is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy. The programs' goals are to stimulate technological innovation, foster technology transfer through cooperative research and development between small businesses and research institutions, and increase private sector commercialization of innovations derived from federal research and development.

Both the SBIR and STTR programs address the President's multi-agency science and technology priority of innovation in life sciences, biology, and neuroscience through coordination with the Joint Program Committees, which manage multi-Service DHP-sponsored research.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: <i>Defense Health Program I BA 2: RDT&E</i>	PE 0605502DHA I <i>Small Business Innovation Research (SBIR) Program</i>

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	55.405	0.000	0.000	-	0.000
Total Adjustments	55.405	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	55.405	-			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605502DHA / <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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
470A: <i>Small Business Innovation Research (SBIR) (Army)</i>	275.975	48.577	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Defense Health Agency (DHA) Small Business Innovation Research (SBIR) Program can participate in any of the three (FY.1, FY.2, and FY.3) Department of Defense (DoD) SBIR Broad Agency Announcements (BAA). The process begins with a call for topics to the Joint Program Committees (JPCs), multi-Service committees established to manage research, development, test and evaluation for DHA sponsored research. DHA SBIR topics are submitted directly to the US Army Medical Research and Materiel Command (USAMRMC) and then forwarded to the JPCs for review and internal ranking. Topic Authors brief their topics at a Topic Review Meeting attended by DHA Research& Development Directorate (J9) SBIR Program Director (PD) and personnel from the supporting USAMRMC offices. Approved DHA SBIR topics are published in DoD SBIR BAAs. Small businesses submit proposals against topics which are then evaluated by a Technical Evaluation Team (TET) made up of a Team Chief and Technical Evaluators. TETs recommend proposals for selection. All recommended proposals are reviewed by the JPCs and the DHA SBIR PD. Phase I proposal selections are announced and contract negotiations begin. Phase I contracts are awarded up to \$150K for 6 months. Follow-on Phase II projects can be awarded up to \$1M for 24 months. This process ensures the SBIR program addresses the multi-agency science and technology priority of innovation in life sciences, biology, and neuroscience.

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

	FY 2018	FY 2019	FY 2020
Title: Small Business Innovation Research (SBIR) Program	48.577	0.000	0.000
Description: The program funds small business proposals chosen to enhance military medical research and information technology research. For FY 2018, twelve DHA SBIR topics were developed for the 2018.1, 2018.2 DoD SBIR Broad Agency Announcements (BAA). Funding for each topic was based on the technical merits of the proposals submitted.			
FY 2019 Plans: No funding programmed. The DHA SBIR program is funded in the year of execution.			
FY 2020 Plans: No funding programmed. The DHA SBIR program is funded in the year of execution.			
FY 2019 to FY 2020 Increase/Decrease Statement: No funding programmed. The DHA SBIR program is funded in the year of execution.			
Accomplishments/Planned Programs Subtotals	48.577	0.000	0.000

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605502DHA / <i>Small Business Innovation Research (SBIR) Program</i>	Project (Number/Name) 470A / <i>Small Business Innovation Research (SBIR) (Army)</i>

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

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 Food and Drug Administration 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-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605502DHA / <i>Small Business Innovation Research (SBIR) Program</i>				Project (Number/Name) 470B / <i>Small Business Technology Transfer (STTR) Program</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
470B: <i>Small Business Technology Transfer (STTR) Program</i>	23.625	6.828	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Small Business Technology Transfer (STTR) is a program that expands funding opportunities in the federal innovation research and development arena. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations. The program funds small business proposals that partner with a research institution, are technically meritorious, and enhance Joint Program Committee (JPC) research and development efforts. The DHA STTR Program can participate in any of the three (FY.A, FY.B, and FY.C) Department of Defense (DoD) STTR BAAs. The process begins with a call for topics to the JPCs. DHA STTR topics are submitted directly to US Army Medical Research and Materiel Command (USAMRMC) and then forwarded to the JPCs for review and internal ranking. Topic Authors brief their topics at a Topic Review Meeting attended by the DHA Research & Development Directorate (J9) STTR Program Director (PD) and personnel from the supporting USAMRMC offices. Approved DHA STTR topics are published in the DoD STTR BAA. Small businesses submit proposals against topics which are then evaluated by a Technical Evaluation Team (TET) made up of a Team Chief and Technical Evaluators. TETs recommend proposals for selection. All recommended proposals are reviewed by the JPCs and the DHA STTR PD. Phase I proposal selections are announced and contract negotiations begin. Phase I contracts are awarded up to \$150K for 6 months. Follow-on Phase II projects can be awarded up to \$1M for 24 months. This process ensures the STTR program addresses the multi-agency science and technology priority of innovation in life sciences, biology, and neuroscience.

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

	FY 2018	FY 2019	FY 2020
Title: Small Business Technology Transfer (STTR) Program	6.828	0.000	0.000
Description: STTR Program offers funding opportunities in federal research and development to small businesses. The program aims to stimulate technological innovation in DoD research and development, strengthen the role of small business in meeting DoD research and development needs, foster and encourage participation by minority and disadvantaged persons in technological innovation, and increase the commercial application of DoD-supported research or research and development results. For FY 2018, two topics were developed for the 2018.A, 2018.B DoD STTR Broad Agency Announcement (BAA). Funding for the topics was based on the merits of responses to the BAA.			
FY 2019 Plans: No funding programmed. The DHA STTR program is funded in the year of execution.			
FY 2020 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605502DHA / <i>Small Business Innovation Research (SBIR) Program</i>	Project (Number/Name) 470B / <i>Small Business Technology Transfer (STTR) Program</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
No funding programmed. The DHA STTR program is funded in the year of execution.			
<i>FY 2019 to FY 2020 Increase/Decrease Statement:</i> No funding programmed. The DHA SBIR program is funded in the year of execution.			
Accomplishments/Planned Programs Subtotals	6.828	0.000	0.000

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

N/A

Remarks

D. Acquisition Strategy

Test and evaluate commercially developed prototypes funded by the STTR program to ensure military and regulatory requirements are met prior to production and fielding, to include Food and Drug Administration 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0606105DHA / <i>Medical Program-Wide Activities</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	319.567	75.432	70.755	67.219	-	67.219	68.563	69.934	71.333	72.760	Continuing	Continuing
305T: <i>USAMRIID IO&T (Army)</i>	96.315	13.365	0.455	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
368A: <i>Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)</i>	18.869	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
397T: <i>USAMRICD IO&T (Army)</i>	35.693	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
401A: <i>CONUS Laboratory Support Clinical Infrastructure (Army)</i>	28.538	5.155	5.253	5.358	-	5.358	5.465	5.574	5.685	5.799	Continuing	Continuing
432A: <i>OCONUS Laboratory Infrastructure Support (Army)</i>	52.183	11.003	13.218	14.144	-	14.144	14.427	14.715	15.010	15.309	Continuing	Continuing
433A: <i>NMRC Biological Defense Research Directorate (BDRD) (Navy)</i>	14.722	2.968	3.109	5.163	-	5.163	5.266	5.371	5.479	5.589	Continuing	Continuing
442A: <i>USARIEM Pike's Peak IO&T (Army)</i>	0.420	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
600A: <i>CSI - Congressional Special Interests</i>	27.613	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
494A: <i>Medical Development (Lab Support) (Navy)</i>	43.548	35.941	41.720	42.554	-	42.554	43.405	44.274	45.159	46.063	Continuing	Continuing
376A: <i>GDF - Medical Program-Wide Activities</i>	1.666	7.000	7.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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 and outside the continental US laboratories and clinical trial sites; work is done in collaboration with DoD Military Treatment Facilities. This program element does not fund research. It funds the infrastructure support staff enabling research scientists to conduct bio-surveillance and early-to-late-stage clinical investigations into biologics, drugs, protectants, device technologies, and knowledge products. 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 medical laboratories funded under multi-year military construction (MILCON) projects. These IO&T funds are designated as appropriations other than MILCON.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0606105DHA I <i>Medical Program-Wide Activities</i>
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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).

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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	63.755	63.755	67.219	-	67.219
Current President's Budget	75.432	70.755	67.219	-	67.219
Total Adjustments	11.882	7.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	7.000	7.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	4.882	-			
• SBIR/STTR Transfer	-	-			

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

Project: 600A: *CSI - Congressional Special Interests*

Congressional Add: *PC 476 - CSI Core Restoral Medical Program-wide Activities (Navy)*

Congressional Add: *PC 476 - CSI Core Restoral Medical Program-wide Activities (Army)*

Congressional Add: *PC 466 - CSI Core Restoral Medical Program-wide Activities*

Congressional Add Subtotals for Project: 600A

Congressional Add Totals for all Projects

	FY 2018	FY 2019
	0.000	-
	0.000	-
	7.000	-
	7.000	-
	7.000	-

Change Summary Explanation

FY 2017: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+\$16.649 million).

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency Date: February 2019

Appropriation/Budget Activity	R-1 Program Element (Number/Name)
0130: <i>Defense Health Program / BA 2: RDT&E</i>	PE 0606105DHA / <i>Medical Program-Wide Activities</i>

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0606105-Medical Program-Wide Activities (-\$0.796 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$0.796 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0603115-Medical Technology Development (-\$38.211 million) to DHP RDT&E, PE 0606105-Medical Program-Wide Activities (+\$38.211 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) PE 0606105-Medical Program-Wide Activities (-\$5.191 million) to DHP O&M, BAG 3 - Private Sector Care (+\$5.191 million).

FY 2017: Pike's Peak Investment, PE 0606105-Medical Program-Wide Activities (+\$0.234 million).

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities	Project (Number/Name) 305T / USAMRIID IO&T (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
305T: USAMRIID IO&T (Army)	96.315	13.365	0.455	0.000	-	0.000	0.000	0.000	0.000	0.000	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 2018	FY 2019	FY 2020
Title: USAMRIID IO&T (Army)	13.708	0.455	0.000
Description: US Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland, IO&T costs associated with MILCON.			
FY 2019 Plans: Requested funds provide for the completion of the IO&T program associated with the USAMRIID MILCON project.			
FY 2020 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: USAMRIID IO&T program completed in FY 2019.			
Accomplishments/Planned Programs Subtotals	13.708	0.455	0.000

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / 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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
368A: Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)	18.869	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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 2018	FY 2019	FY 2020
Title: Pacific-Based Joint Information Technology Center - Maui (JITC-Maui) (HIT)	0.000	-	-
Description: Management support for research projects at Pacific Joint Information Technology Center (JITC).			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities	Project (Number/Name) 397T / USAMRICD IO&T (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
397T: USAMRICD IO&T (Army)	35.693	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) costs associated with military construction (MILCON) for the US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, Maryland.

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

	FY 2018	FY 2019	FY 2020
Title: USAMRICD IO&T (Army)	0.000	0.000	-
Description: The USAMRICD, Aberdeen Proving Ground, Maryland, IO&T costs associated with MILCON.			
FY 2019 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: No funding programmed in FY19 or FY20.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	-

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 research, development, test and evaluation 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities				Project (Number/Name) 401A / CONUS Laboratory Support Clinical Infrastructure (Army)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
401A: CONUS Laboratory Support Clinical Infrastructure (Army)	28.538	5.155	5.253	5.358	-	5.358	5.465	5.574	5.685	5.799	Continuing	Continuing

A. Mission Description and Budget Item Justification

Continental United States 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 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 research, development, test, and evaluation (RDT&E) research funds.

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

	FY 2018	FY 2019	FY 2020
Title: CONUS Laboratory Support Clinical Infrastructure (Army)	5.155	5.253	5.358
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 2019 Plans: The CONUS Laboratory Support Clinical Infrastructure project supports efforts for military medical research. These efforts will include support staff engaged in multiple clinical investigations and performing critical roles in research subject engagement, development and review of research protocols, and the creation, analysis, and communication of research data. Examples of the clinical research specialties to be supported by the program are: clinical research associate, study coordinator, human subjects protection scientist, budget analyst, computer information technology and management specialist, biomedical scientist/molecular biologist, statistician, database manager, biostatistics/bioinformatics analyst, biobank manager, research assistant, and clinical research coordinator. Efforts with the funding will include: support for clinical investigations, submission for external funding applications, sustainment of a Clinical Investigation Committee to review research protocols and provide research support services, solicitation of collaborative research partnerships with non-federal organizations, utilization of funding opportunities database to assist MTF investigators, and identification of ways to improve submission competitiveness.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / <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 2018	FY 2019	FY 2020
N/A			
Accomplishments/Planned Programs Subtotals	5.155	5.253	5.358

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, MTFs, 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 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities				Project (Number/Name) 432A / OCONUS Laboratory Infrastructure Support (Army)			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
432A: OCONUS Laboratory Infrastructure Support (Army)	52.183	11.003	13.218	14.144	-	14.144	14.427	14.715	15.010	15.309	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 Directorate-Kenya (USAMRD-K) in Nairobi, Kenya, the US Army Medical Research Directorate-Georgia (USAMRD-G) in Tbilisi, Georgia, and the US Army Medical Directorate-Armed Forces Research Institute of Medical Sciences (USAMD-AFRIMS) in Bangkok, Thailand. USAMRD-G is the newest laboratory, and provides 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 2018	FY 2019	FY 2020
Title: OCONUS Laboratory Infrastructure Support (Army)	11.419	13.218	14.144
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. Supported OCONUS laboratories are the US Army Medical Directorate-Armed Forces Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand; the US Army Research Directorate-Kenya (USAMRD-K) in Nairobi, Kenya; and the US Army Medical Research Directorate-Georgia (USAMRD-G) in Tbilisi, Georgia.			
FY 2019 Plans: Funding provides for the sustainment of the administration and infrastructure support for USAMD-AFRIMS, USAMRD-K, and USAMRD-G laboratories. These laboratories provide medical research platforms for surveillance, testing, and evaluation of products to inform the development of interventions for military-relevant endemic diseases. Administration and infrastructure support efforts include resource management, logistics, safety, information technology activities, salaries, utilities, maintenance, transportation, shipping, vehicle maintenance and generator fuel.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 432A / <i>OCONUS Laboratory Infrastructure Support (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	11.419	13.218	14.144

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, Thailand, and Georgia.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities	Project (Number/Name) 433A / NMRC Biological Defense Research Directorate (BDRD) (Navy)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
433A: NMRC Biological Defense Research Directorate (BDRD) (Navy)	14.722	2.968	3.109	5.163	-	5.163	5.266	5.371	5.479	5.589	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) at Fort Detrick, Maryland. Operational costs are significant 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. Further, the NIBC campus is a fenced physical location with Entry Control Points (ECP). The partners on the campus, therefore, are required to pay for the guard force manning their ECP.

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

	FY 2018	FY 2019	FY 2020
Title: NMRC Biological Defense Research Directorate (BDRD) (Navy)	2.968	3.109	5.163
Description: Funding for this project code provides core funding for facility and security requirements in support of Biological Defense Research. The remainder of the program is sustained by the competitive acquisition of research funding.			
FY 2019 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 2020 Plans: Continue to 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 2019 to FY 2020 Increase/Decrease Statement: Funding for Biological Defense Research continues 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. Increase reflects pricing adjustments.			
Accomplishments/Planned Programs Subtotals	2.968	3.109	5.163

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

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / <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)

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities	Project (Number/Name) 442A / USARIEM Pike's Peak IO&T (Army)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
442A: USARIEM Pike's Peak IO&T (Army)	0.420	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding supports the initial outfitting and transition (IO&T) research, development, test and evaluation (RDT&E) costs associated with military construction (MILCON) for the US Army Research Institute of Environmental Medicine (USARIEM) at Pike's Peak, Colorado.

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

	FY 2018	FY 2019	FY 2020
Title: USARIEM Pike's Peak IO&T (Army)	0.000	0.000	0.000
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 2019 Plans: No funding programmed.			
FY 2020 Plans: No funding programmed.			
FY 2019 to FY 2020 Increase/Decrease Statement: No funding programmed.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities				Project (Number/Name) 600A / CSI - Congressional Special Interests			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
600A: CSI - Congressional Special Interests	27.613	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2017 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 2018	FY 2019
Congressional Add: PC 476 - CSI Core Restoral Medical Program-wide Activities (Navy)	0.000	-
FY 2018 Accomplishments:		
Congressional Add: PC 476 - CSI Core Restoral Medical Program-wide Activities (Army)	0.000	-
FY 2018 Accomplishments:		
Congressional Add: PC 466 - CSI Core Restoral Medical Program-wide Activities	7.000	-
FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0606105. Funds supported the CONUS Laboratory Support Clinical Infrastructure (401A).		
Congressional Adds Subtotals	7.000	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities	Project (Number/Name) 494A / Medical Development (Lab Support) (Navy)
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
494A: Medical Development (Lab Support) (Navy)	43.548	35.941	41.720	42.554	-	42.554	43.405	44.274	45.159	46.063	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, the labs focus on 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 2018	FY 2019	FY 2020
Title: Medical Development (Lab Support) (Navy)	35.941	41.720	42.554
Description: Funding in this project code covers 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. Excluded costs include military manpower and related costs, non-RDT&E base operating costs, and military construction costs, which are included in other appropriate programs. FY 2018 Accomplishments: Provided operating support for 8 medical RDT&E labs across 15 research focus areas with the goal of developing products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter. Requested funding enabled the labs to meet or exceed science performance metric objectives.			
FY 2019 Plans: Continue to provide operating support for 8 medical RDT&E labs across 15 research focus areas with the goal of developing products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter. Requested funding will enable the labs to meet or exceed science performance metric objectives.			
FY 2020 Plans: Continue to provide operating support for 8 medical RDT&E labs across 15 research focus areas with the goal of developing products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter. Requested funding will enable the labs to meet or exceed science performance metric objectives.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / <i>Medical Program-Wide Activities</i>	Project (Number/Name) 494A / <i>Medical Development (Lab Support) (Navy)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Funding for Biological Defense Research continues to provide operating support for 8 medical RDT&E labs across 15 research focus areas with the goal of developing products and strategies that protect, treat, rehabilitate and enhance the performance of the Warfighter. Requested funding will enable the labs to meet or exceed science performance metric objectives. Increase reflects pricing adjustments.			
Accomplishments/Planned Programs Subtotals	35.941	41.720	42.554

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0606105DHA / Medical Program-Wide Activities	Project (Number/Name) 376A / GDF - Medical Program-Wide Activities
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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
376A: GDF - Medical Program-Wide Activities	1.666	7.000	7.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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 and outside the continental US laboratories and clinical trial sites. Work is done in collaboration with DoD Military Treatment Facilities. This project does not fund research. It funds the infrastructure support staff enabling research scientists to conduct bio-surveillance and early-to-late-stage clinical investigations into biologics, drugs, protectants, device technologies, and knowledge products. 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 medical laboratories funded under multi-year military construction (MILCON) projects. These IO&T funds are designated as appropriations other than MILCON.

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

	FY 2018	FY 2019	FY 2020
Title: 376A: GDF – Medical Program-Wide Activities	0.000	-	-
Accomplishments/Planned Programs Subtotals	0.000	-	-

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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0607100DHA I <i>Medical Products and Capabilities Enhancement Activities</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	84.838	13.438	15.714	16.819	-	16.819	17.215	17.619	17.971	18.330	Continuing	Continuing
377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i>	81.120	13.438	15.714	16.819	-	16.819	17.215	17.619	17.971	18.330	Continuing	Continuing
457A: <i>AF Advanced Technology Development – Rapid Technology Transition</i>	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
700A: <i>CSI - Congressional Special Interests</i>	2.382	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	13.438	15.714	16.819	-	16.819
Current President's Budget	13.438	15.714	16.819	-	16.819
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-	-	-	-
• Congressional Directed Reductions	-	-	-	-	-
• Congressional Rescissions	-	-	-	-	-
• Congressional Adds	-	-	-	-	-
• Congressional Directed Transfers	-	-	-	-	-
• Reprogrammings	-	-	-	-	-
• SBIR/STTR Transfer	-	-	-	-	-

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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency Date: February 2019

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0607100DHA / <i>Medical Products and Capabilities Enhancement Activities</i>
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Change Summary Explanation

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

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

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

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

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0607100DHA / Medical Products and Capabilities Enhancement Activities				Project (Number/Name) 377A / GDF-Medical Products and Capabilities Enhancement Activities			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
377A: GDF-Medical Products and Capabilities Enhancement Activities	81.120	13.438	15.714	16.819	-	16.819	17.215	17.619	17.971	18.330	Continuing	Continuing

A. Mission Description and Budget Item Justification

The goal of the Medical Products and Capabilities Enhancement Activity is to test, evaluate, and support enhancement of existing medical products and medically-related IT systems within the areas of medical simulation, infectious disease, tactical combat casualty care, military operational medicine, and clinical and rehabilitative medicine.

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

	FY 2018	FY 2019	FY 2020
Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities	13.438	15.714	16.819
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 2019 Plans: Funds will be used to enhance, modify, upgrade, test, and evaluate fielded medical materiel and practices.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	13.438	15.714	16.819

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

N/A

Remarks

D. Acquisition Strategy

Integrate product improvements and enhancements resulting from post marketing studies and surveillance.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0607100DHA / <i>Medical Products and Capabilities Enhancement Activities</i>	Project (Number/Name) 377A / <i>GDF-Medical Products and Capabilities Enhancement Activities</i>

E. Performance Metrics

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. 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 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0607100DHA / <i>Medical Products and Capabilities Enhancement Activities</i>				Project (Number/Name) 457A / <i>AF Advanced Technology Development – Rapid Technology Transition</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
<i>457A: AF Advanced Technology Development – Rapid Technology Transition</i>	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

	FY 2018	FY 2019	FY 2020
Title: AF Advanced Technology Development – Rapid Technology Transition	0.000	-	-
Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

N/A

Remarks

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

D. Acquisition Strategy

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

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency **Date:** February 2019

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0607100DHA / <i>Medical Products and Capabilities Enhancement Activities</i>				Project (Number/Name) 700A / <i>CSI - Congressional Special Interests</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
<i>700A: CSI - Congressional Special Interests</i>	2.382	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

No FY 2017 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0607100 - Medical Products and Capabilities Enhancement Activities.

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A