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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 20.420 | 3.552 | 4.013 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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> | 2.630 | 0.480 | 0.490 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 240B: <i>Military Operational Medicine (USUHS)</i> | 7.869 | 1.479 | 1.509 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 240C: <i>Combat Casualty Care (USUHS)</i> | 8.356 | 1.593 | 2.014 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 |

Note

Funds were adjusted to higher priority programs in FY 2021-2025.

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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| Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i> | R-1 Program Element (Number/Name) PE 0601101DHA I <i>In-House Laboratory Independent Research (ILIR)</i> |
|---|--|

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 3.687 | 4.013 | 0.000 | - | 0.000 |
| Current President's Budget | 3.552 | 4.013 | 0.000 | - | 0.000 |
| Total Adjustments | -0.135 | 0.000 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.135 | - | | | |

Change Summary Explanation

FY 2021: Programmed effort and funding transferred to other higher priority programs.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 240A: <i>Infectious Disease (USUHS)</i> | 2.630 | 0.480 | 0.490 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Infectious Disease | 0.480 | 0.490 | 0.000 |
| 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). | | | |
| FY19 Accomplishments: The overall goal of this project is to develop a prototype histone deacetylase inhibitor (HDACi) called sulforaphane (SFN) as an epigenetic, adjunctive therapy for treatment of gonorrhea. We have completed the first aim to Identify SFN-induced effectors with activity against N. gonorrhoeae (Ng) by mass spectrometry, PCR-based arrays and mechanistic studies. A manuscript will be published soon. --We have solved the first quest of the proposed research, namely whether the seasonal H1N1 and H3N2 type A and a type B influenza virus (B/Lee strain) can infect a murine lung. Of note, though our humanized DRAGA mouse proposed to be established as an influenza mouse model for human influenza viruses lacks the murine immune system and it has a fully-functional human immune system, its lungs remain 95% of murine origin (5% represented by expression of CD36 human epithelial lung cells). It | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| <p>was thus essential to carry out preliminary experiments to determine whether the murine lung (in our case, BALB/c mouse) can be infected with the seasonal influenza viruses mentioned above.</p> <p>Together, the BALB/c experiments demonstrate that (i) the murine lung (and thus expectedly the lungs of DRAGA mouse) can be infected with all the type A and B influenza viruses tested in the lab; (ii) a primary, non-lethal infection with H3N2 seasonal viruses can fully protect against a secondary infection with a highly infectious H1N1 virus.</p> <p>FY 2020 Plans: Efforts will continue within the Infectious Disease research area in FY 2020. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p> <p>FY 2021 Plans: Funds were adjusted to higher priority programs.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: As a result of directed RDT&E program reductions and reprioritization, ILIR PE 0601101 funding was eliminated.</p> | | | | |
| Accomplishments/Planned Programs Subtotals | | 0.480 | 0.490 | 0.000 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| N/A | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 240B: <i>Military Operational Medicine (USUHS)</i> | 7.869 | 1.479 | 1.509 | 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.

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Military Operational Medicine | 1.479 | 1.509 | 0.000 |
| 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. | | | |
| FY19 Accomplishments: -- Developed a network within the MHS to systematically, efficiently and effectively manage and triage (from initial medical care to tertiary care) all patients presenting with ERi [i.e. EHi and/or ER] (project 1). The primary focus is on safe return to full duty. We also intend to determine the contribution of intrinsic and extrinsic risk factors associated with ERi, and create a scoring system to triage Service Members to early return to duty or further specialty evaluation for recurrence risk (project 2), and to develop genetic and biologic screening tools for ERi that can be deployed as far forward as possible with the ultimate goal of differentiating those at risk for recurrence and those who can be returned to full duty (project 3). While projects 1 and 2 are moving forward, patients are still referred for clinical workup through the current word of mouth process. Based on case history, some of the patients are offered enrollment in the genetic screening protocol of project 3. This protocol has been ongoing for several years and compares the genome of cases of exertional injuries with the markers of malignant hyperthermia (MH) susceptibility. During the project period, we have enrolled 8 index case individuals in project 3 of the study, and genetic analysis has been started. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>--Continued development of a self-test kit for rapid diagnosis of hygiene-related urogenital infections. Our comprehensive, MWRUHSQ survey questionnaire is being used to systematically evaluate the impact of varying water and sanitation resources on urogenital health and health behaviors in active duty service women (ADSW), and their views of the female urinary diversion device (FUDD) as a way to mitigate some challenges while in the field for the purpose of enhancing our understanding of ADSW's gender-specific health needs in austere environments. Preliminarily analyzed data collected from the initial 152 participants and we have submitted a data-based manuscript describing not only our psychometric characterization (to-date), but also our findings.</p> <p>-- Developed predictive models for female Marine officer performance at The Basic School (TBS), including musculoskeletal injury (MSK-I) & graduation outcomes. Enrolled 153 Female & 1217 Males from 7 training Companies (enrolled 80% of eligible Females; exceeded estimate of 120/yr). Completed post-testing on 4 Companies: Female grad rate 89% vs. 98% for Males in our cohort. Data analysis ongoing; injury & graduation outcomes being tracked. Four research abstracts presented at national conferences.</p> <p>-- Made significant progress in elucidating and validating the role of SREBP in mediating the effect of histone deacetylase inhibitors to increase KATP channel subunit expression. We now have convincing data that 1) correlates cellular cholesterol with SUR2 gene expression, 2) demonstrates cleavage and translocation of the SREBP transcription factor, and 3) selective SREPB-dependent activation of the SUR2 promoter. In addition, we have data implicating HDI-dependent decrease in cholesterol uptake pathways (LDL receptor) and marked increase in PCSK9 (an enzyme that promotes degradation of LDL receptor suggesting a mechanism by which histone deacetylase inhibitors cause a decrease in cellular cholesterol). Finally, dominant negative suppression of SREBP function inhibits the action of histone deacetylase inhibitors.</p> <p>FY 2020 Plans: Efforts will continue within the Military Operational Medicine research area in FY 2020. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p> <p>FY 2021 Plans: Funds were adjusted to higher priority programs.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: As a result of directed RDT&E program reductions and reprioritization, ILIR PE 0601101 funding was eliminated.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 1.479 | 1.509 | 0.000 |

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

D. Acquisition Strategy
N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 240C: <i>Combat Casualty Care (USUHS)</i> | 8.356 | 1.593 | 2.014 | 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)

| | | | |
|--|----------------|----------------|----------------|
| Title: Combat Casualty Care | FY 2019 | FY 2020 | FY 2021 |
| Description: Regenerative medicine, rehabilitation, neurological, limb loss, pain management, readiness, resilience. | 1.593 | 2.014 | 0.000 |
| <p>FY19 Accomplishments:</p> <ul style="list-style-type: none"> - sought to understand the mechanisms underlying cognitive deficits that are reported to affect non-native subjects following their prolonged stay and/or work at high altitude (HA). Found that exposure to hypobaric-hypoxia triggers maladaptive responses inducing cognitive deficits and suggests potential mechanisms underlying the adverse impacts of staying or traveling at high altitude. --Training in the WAVE requires large expenses of the environment to be modeled. We developed algorithms to automatically generate complex terrain and we have also developed algorithms that permit avatars to exhibit humanly plausible reactions to environmental stimuli. Stimuli regions of interest and danger. -- Analyzing both cross sectional and prospective data to evaluate acute and longer term health outcomes. As stated above, we are utilizing Cox Proportional Hazards Regressions to compare risk for various health outcomes between different exposure groups in our cohort of Coast Guard responders who were involved in the Deepwater Horizon response. We have been analyzing the long term health data from this study. Recently, we have focused mainly on the dermal and respiratory health systems. | | | |

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| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p><i>FY 2020 Plans:</i> Efforts will continue within the Combat Casualty Care research area in FY 2020. Specific investigator-initiated projects compete for funding each year, usually with two to three-year project periods. Therefore, no detailed description of the research is possible at this time.</p> <p><i>FY 2021 Plans:</i> Funds were adjusted to higher priority programs.</p> <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> As a result of directed RDT&E program reductions and reprioritization, ILIR PE 0601101 funding was eliminated.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 1.593 | 2.014 | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 |

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

N/A

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

N/A

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D. Acquisition Strategy

N/A

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Appropriation/Budget Activity
0130: *Defense Health Program I BA 2: RDT&E*

R-1 Program Element (Number/Name)
PE 0601117DHA / *Basic Operational Medical Research Sciences*

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|--------------------|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| Total Program Element | 43.790 | 8.400 | 17.408 | 8.913 | - | 8.913 | 9.091 | 9.273 | 9.458 | 9.647 | Continuing | Continuing |
| 100A: <i>CSI - Congressional Special Interests</i> | 8.349 | 0.982 | 8.800 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 371: <i>GDF - Basic Operational Medical Research Science</i> | 35.441 | 7.418 | 8.608 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 371A: <i>GDF - BOMRS (Combat Casualty Care)</i> | - | 0.000 | 0.000 | 1.304 | - | 1.304 | 1.328 | 1.356 | 1.381 | 1.409 | Continuing | Continuing |
| 371B: <i>GDF - BOMRS (Military Operational Medicine)</i> | - | 0.000 | 0.000 | 5.498 | - | 5.498 | 5.609 | 5.720 | 5.836 | 5.953 | Continuing | Continuing |
| 371C: <i>GDF - BOMRS (Medical Simulation & Training/Health Informatics)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 371D: <i>GDF - BOMRS (Clinical and Rehabilitation Medicine)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 371E: <i>GDF - BOMRS (Military Infectious Disease)</i> | - | 0.000 | 0.000 | 2.111 | - | 2.111 | 2.154 | 2.197 | 2.241 | 2.285 | Continuing | Continuing |
| 371F: <i>GDF - BOMRS (Radiological Health Effects)</i> | - | 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-Basic 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. 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 (RDT&E) 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

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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 0601117DHA I <i>Basic Operational Medical Research Sciences</i> |
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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. 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.

| B. Program Change Summary (\$ in Millions) | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021 Base</u> | <u>FY 2021 OCO</u> | <u>FY 2021 Total</u> |
|---|-----------------------|-----------------------|----------------------------|---------------------------|-----------------------------|
| Previous President's Budget | 8.699 | 8.608 | 8.913 | - | 8.913 |
| Current President's Budget | 8.400 | 17.408 | 8.913 | - | 8.913 |
| Total Adjustments | -0.299 | 8.800 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 8.800 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.299 | - | | | |

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 100A: <i>CSI - Congressional Special Interests</i> | 8.349 | 0.982 | 8.800 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

In FY2019, the DHP funded \$982K in CSI Restoral directed research.

In FY 2018, the DHP funded 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 2019 | FY 2020 | FY 2021 |
| Title: CSI - Restoral | 0.982 | 8.800 | - |
| Description: CSI Restoral for directed research in GDF - Basic 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. | | | |
| FY 2020 Plans: In FY2020, the DHP funded \$8,800K in CSI Restoral directed research. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: N/A | | | |
| Accomplishments/Planned Programs Subtotals | 0.982 | 8.800 | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i> | | | | Project (Number/Name) 371 / <i>GDF - Basic Operational Medical Research Science</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 371: <i>GDF - Basic Operational Medical Research Science</i> | 35.441 | 7.418 | 8.608 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Project 371 GDF – Basic Operational Medical Research Sciences | 7.418 | 8.608 | 0.000 |
| 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 2020 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 will continue to characterize the biomechanical responses of brain tissue to blast waves and indirect mechanisms of blast wave-induced injury in animal models that will guide the development of interventions for mitigating blast-induced brain injury. Conducting research to define the role of individual and unit climate factors on aggression. Identifying linkages between identified genetic markers and individual performance or health risks. Conducting studies to understand the basic mechanisms underlying psychological resilience to inform potential future intervention and assessment work. Conducting epidemiological studies to identify the nature of the substance abuse problem in the military and possible unique contributing and protective factors. Identifying candidate targets and neurological systems for treatment and diagnostic indicators | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i> | Project (Number/Name) 371 / <i>GDF - Basic Operational Medical Research Science</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>of post-traumatic stress disorder (PTSD). Defining solutions to prevent, mitigate and/or recover from fatigue via electrical brain stimulation. Identifying physical, physiological and psychosocial factors that may differentially impact the performance of female versus male Service members and gender-based susceptibility to musculoskeletal injury. Studying mechanisms of molecular changes in the brain following exposure to inhaled toxicants.</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 2021 Plans: N/A</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned to PE 0601117DHA Project Codes 371A-F.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 7.418 | 8.608 | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| 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 - BOMRS (Combat Casualty Care)</i> | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|--|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 371A: <i>GDF - BOMRS (Combat Casualty Care)</i> | - | 0.000 | 0.000 | 1.304 | - | 1.304 | 1.328 | 1.356 | 1.381 | 1.409 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Basic research described here focuses on the enhancement of knowledge to support capabilities identified through the Joint Capabilities Integration 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, and the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care) | 0.000 | 0.000 | 1.304 |
| Description: Joint Battlefield Healthcare activities are focused on developing and understanding of acute and long-term trauma-associated pathophysiology mechanisms to include advanced hemostatic and resuscitative approaches to prolonged field care, enroute care, wound healing and recovery, and neurotrauma. | | | |
| FY 2020 Plans: N/A | | | |
| FY 2021 Plans: Joint Battlefield Healthcare activities are focused on developing and understanding of acute and long-term trauma-associated pathophysiology mechanisms to include advanced hemostatic and resuscitative approaches to prolonged field care, enroute care, wound healing and recovery, and neurotrauma. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 371. | | | |
| Accomplishments/Planned Programs Subtotals | | | 1.304 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 371B / <i>GDF - BOMRS (Military Operational Medicine)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 371B: <i>GDF - BOMRS (Military Operational Medicine)</i> | - | 0.000 | 0.000 | 5.498 | - | 5.498 | 5.609 | 5.720 | 5.836 | 5.953 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Conduct scientific studies and experimentation directed toward increasing fundamental knowledge and understanding to support the development of medical countermeasures against combat stressors, prevention of physical and psychological injuries and maximizing the health, performance and fitness of service members during training and from point of injury through role of care four.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Military Health and Recovery (Formerly Military Operational Medicine) | - | - | 5.498 |
| Description: Efforts include injury prevention and recovery, optimized cognition and fatigue management, physiological health and resilience, and performance in extreme environments. Activities will continue to focus on: injury prevention and recovery related to blunt, blast, and accelerative injuries; injury prevention and recovery related to musculoskeletal injury; performance nutrition and weight balance; operational systems toxicology for environmental health hazards; and, fatigue, cognitive health and performance. | | | |
| FY 2021 Plans: Efforts include injury prevention and recovery, optimized cognition and fatigue management, physiological health and resilience, and performance in extreme environments. Activities will continue to focus on: injury prevention and recovery related to blunt, blast, and accelerative injuries; injury prevention and recovery related to musculoskeletal injury; performance nutrition and weight balance; operational systems toxicology for environmental health hazards; and, fatigue, cognitive health and performance. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 371. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 5.498 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0601117DHA / Basic Operational Medical Research Sciences | | | | Project (Number/Name) 371C / GDF - BOMRS (Medical Simulation & Training/Health Informatics) | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|--|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 371C: GDF - BOMRS (Medical Simulation & Training/Health Informatics) | - | 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

N/A

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics) | - | - | 0.000 |
| Description: N/A | | | |
| FY 2021 Plans: N/A | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 371. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 371D / <i>GDF - BOMRS (Clinical and Rehabilitation Medicine)</i> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 371D: <i>GDF - BOMRS (Clinical and Rehabilitation Medicine)</i> | - | 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

N/A

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Clinical and Rehabilitation Medicine | - | - | 0.000 |
| Description: N/A | | | |
| FY 2021 Plans: N/A | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 371. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i> | | | | Project (Number/Name) 371E / <i>GDF - BOMRS (Military Infectious Disease)</i> | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|---|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 371E: <i>GDF - BOMRS (Military Infectious Disease)</i> | - | 0.000 | 0.000 | 2.111 | - | 2.111 | 2.154 | 2.197 | 2.241 | 2.285 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Basic research focused on the development of products for the prevention and treatment of military relevant infectious diseases.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Military Infectious Disease | - | - | 2.111 |
| Description: Military infectious diseases activities continue to support studies in bacterial diseases for the prevention and treatment of infections with multidrug-resistant (MDR) bacterial pathogens. In addition, to responding to emerging infectious diseases and acute respiratory diseases. | | | |
| FY 2021 Plans: Military infectious diseases activities continue to support studies in bacterial diseases for the prevention and treatment of infections with multidrug-resistant (MDR) bacterial pathogens. In addition, to responding to emerging infectious diseases and acute respiratory diseases. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 371. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 2.111 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|---|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0601117DHA / <i>Basic Operational Medical Research Sciences</i> | Project (Number/Name) 371F / <i>GDF - BOMRS (Radiological Health Effects)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 371F: <i>GDF - BOMRS (Radiological Health Effects)</i> | - | 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

N/A

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Radiological Health Effects | - | - | 0.000 |
| Description: N/A | | | |
| FY 2021 Plans: N/A | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 371. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

Appropriation/Budget Activity
0130: *Defense Health Program I BA 2: RDT&E*

R-1 Program Element (Number/Name)
PE 0602115DHA I *Applied Biomedical Technology*

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|--------------------|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| Total Program Element | 488.880 | 107.837 | 175.032 | 72.573 | - | 72.573 | 74.024 | 75.505 | 77.015 | 78.560 | Continuing | Continuing |
| 200A: <i>Congressional Special Interests</i> | 148.090 | 38.026 | 92.149 | 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> | 8.111 | 1.813 | 1.949 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i> | 16.788 | 2.609 | 0.716 | 0.151 | - | 0.151 | 0.000 | 0.000 | 0.000 | 0.000 | 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 | 3.416 | 4.064 | - | 4.064 | 4.299 | 4.385 | 4.473 | 4.567 | Continuing | Continuing |
| 447A: <i>Military HIV Research Program (Army)</i> | 38.655 | 8.808 | 9.654 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 372: <i>GDF - Applied Biomedical Technology</i> | 273.780 | 56.581 | 67.148 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 372A: <i>GDF - ABT (Combat Casualty Care)</i> | - | 0.000 | 0.000 | 14.855 | - | 14.855 | 15.151 | 15.453 | 15.763 | 16.078 | Continuing | Continuing |
| 372B: <i>GDF - ABT (Military Operational Medicine)</i> | - | 0.000 | 0.000 | 26.255 | - | 26.255 | 26.779 | 27.316 | 27.862 | 28.419 | Continuing | Continuing |
| 372C: <i>GDF - ABT (Medical Simulation & Training/Health Informatics)</i> | - | 0.000 | 0.000 | 10.611 | - | 10.611 | 10.826 | 11.041 | 11.263 | 11.488 | Continuing | Continuing |
| 372D: <i>GDF - ABT (Clinical and Rehabilitation Medicine)</i> | - | 0.000 | 0.000 | 7.064 | - | 7.064 | 7.204 | 7.350 | 7.495 | 7.645 | Continuing | Continuing |

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | | | | | |
| 372E: <i>GDF - ABT (Military Infectious Disease)</i> | - | 0.000 | 0.000 | 8.607 | - | 8.607 | 8.779 | 8.954 | 9.133 | 9.316 | Continuing | Continuing |
| 372F: <i>GDF - ABT (Radiological Health Effects)</i> | - | 0.000 | 0.000 | 0.966 | - | 0.966 | 0.986 | 1.006 | 1.026 | 1.047 | 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 and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation (RDT&E) 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. 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. 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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 <i>Applied Biomedical Technology</i> |
|---|--|

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 112.754 | 82.883 | 84.408 | - | 84.408 |
| Current President's Budget | 107.837 | 175.032 | 72.573 | - | 72.573 |
| Total Adjustments | -4.917 | 92.149 | -11.835 | - | -11.835 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 92.149 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -4.917 | - | | | |
| • Reprogrammings | - | - | -11.835 | - | -11.835 |

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

Project: 200A: *Congressional Special Interests*

Congressional Add: *PC426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)*

Congressional Add: *PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)*

Congressional Add Subtotals for Project: 200A

Congressional Add Totals for all Projects

| | FY 2019 | FY 2020 |
|--|----------------|----------------|
| | | |
| | 22.318 | 59.000 |
| | 15.708 | 33.149 |
| | 38.026 | 92.149 |
| | 38.026 | 92.149 |

Change Summary Explanation

FY 2021: Programmed effort and funding transferred to the Department of the Army (PE 0602115A Project EB2) as part of the Readiness Transfer for FY 2021.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 200A: <i>Congressional Special Interests</i> | 148.090 | 38.026 | 92.149 | 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 2019 | FY 2020 |
|---|---------|---------|
| <i>Congressional Add:</i> PC426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army) | 22.318 | 59.000 |
| <i>FY 2019 Accomplishments:</i> 426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army) | | |
| <i>FY 2020 Plans:</i> 426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army) | | |
| <i>Congressional Add:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF) | 15.708 | 33.149 |
| <i>FY 2019 Accomplishments:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF) | | |
| <i>FY 2020 Plans:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF) | | |
| Congressional Adds Subtotals | 38.026 | 92.149 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i> | 8.111 | 1.813 | 1.949 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army) | 1.813 | 1.949 | 0.000 |
| 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 2020 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 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Programmed effort and funding transferred to the Department of the Army (PE 0602115A Project EB2) as part of the Readiness Transfer for FY 2021. | | | |
| <i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 1.813 | 1.949 | 0.000 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i> | 16.788 | 2.609 | 0.716 | 0.151 | - | 0.151 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Advanced Diagnostics & Therapeutics Research & Development (AF) | 2.609 | 0.716 | 0.151 |
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <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 2020 Plans: Research will continue examining Mesenchymal Stem Cell (MSC)-derived exosomes as modulators of peripheral nerve regeneration and repair. Studies will continue evaluating portable Raman microscopy and surface-enhanced Raman scattering (SERS) technology for the rapid detection of microbial water contamination. Analyses will continue assessing mitigation strategies of radiofrequency-induced auditory dysfunction using a MSC-derived exosome-based approach.</p> <p>FY 2021 Plans: Mitigation strategies for radiofrequency-induced auditory dysfunction will be demonstrated using a MSC-derived exosome-based approach. FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding shifts over the FYDP into Project Code 306D- Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF) reflect deliberate focusing on future readiness mission.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 2.609 | 0.716 | 0.151 |

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| C. Other Program Funding Summary (\$ in Millions) |
| N/A |
| Remarks |
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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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.)

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i> | 1.728 | 0.000 | 3.416 | 4.064 | - | 4.064 | 4.299 | 4.385 | 4.473 | 4.567 | 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. Research will assess and analyze the diverse attributes of humans (cognitive, behavioral, physiological) and operational environments (chemical, physical, psychological, biological, radiological stressors) to drive optimal performance and care of our Airmen. Research will focus on identifying environmental hazards associated with unique AF environments, determine the risk of those hazards on AF operations and identify ways to mitigate those negative impacts. Research will investigate how the flight environment affects the processes of life, the ability to maintain homeostasis, the risk for injury or secondary insult, and seek to ameliorate these stressors to optimize Airman health, safety and performance.

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF) | 0.000 | 3.416 | 4.064 |
| Description: Define, develop, validate, and deliver attribute-linked solutions to better address the Force Generation readiness requirements of our Air Force by optimizing operator cognitive, behavioral, and physiological alignment to their mission, shaping medically-relevant screening, risk-assessment and retention criteria, improving operator and mission readiness through data driven risk analysis and mitigation actions, and promoting enhancements in the delivery of precision-based operational care. Identify and characterize environmental hazards associated with Air Force mission environments, determine the risk of those hazards on Air Force operations, and identify ways to mitigate those negative impacts. Conduct applied research investigating the negative effects of flight on health and safety to develop candidate technologies and knowledge to mitigate those effects and optimize mission readiness and warfighter return to duty. | | | |
| FY 2020 Plans: Evaluate current knowledge associated with sensory, psychological/behavioral, health status, physiologic and environmental attributes that show potential linkages to operational performance. Assess relevant environmental attributes and biomarkers that impact high performing Airmen. Identify operational characteristics associated for use in mapping attributes to operational performance. Characterize Aircrew physiologic response to high performance aircraft (HPA) flight stressors relevant to Unexplained Physiologic Events (UPE). Understand the exposure-based pathophysiology behind the high-rates of neck and back | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>pain and injury among Air Force operators and identify ameliorating solutions. Conduct Epidemiologic analysis of Fighter/Attack/Trainer aircraft operator health issues. Identify emerging chemical contaminants in the aircraft environment control system/life support systems and the impact on operational performance. Study effects of single and multiple AE transport exposure on high-incidence rate clinical presentations. Investigate methods to optimize flight profiles to minimize oxygen and care requirements, improve patient post-flight outcomes and optimize warfighter return to duty.</p> <p><i>FY 2021 Plans:</i> Continue to assess relevant environmental biomarkers that impact high performing Airmen. Continue to identify operational characteristics associated for use in mapping sensory, psychological/behavioral, health status, physiologic and environmental attributes to operational performance. Continue to characterize Aircrew physiologic response to flight stressors relevant to Unexplained Physiologic Events (UPE), acute and chronic accelerative force exposure risk assessment, and aerospace exposure. Continue identification of specific risk to contaminant exposure during flight with human testing. Continue to study effects of AE transport exposure on high-incidence rate clinical presentations. Investigate methods to optimize flight profiles to minimize oxygen and care requirements, improve patient post-flight outcomes and optimize warfighter return to duty.</p> <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Funding shifts over the FYDP from Project Code 306B- Advanced Diagnostics & Therapeutics Research & Development (AF) to reflect deliberate focusing on future readiness mission.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 3.416 | 4.064 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 447A: <i>Military HIV Research Program (Army)</i> | 38.655 | 8.808 | 9.654 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Military HIV Research Program | 8.808 | 9.654 | 0.000 |
| 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 2020 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 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0602115A Project EB2) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 8.808 | 9.654 | 0.000 |

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

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | | | | Project (Number/Name) 372 / <i>GDF - Applied Biomedical Technology</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 372: <i>GDF - Applied Biomedical Technology</i> | 273.780 | 56.581 | 67.148 | 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 - 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 2019 | FY 2020 | FY 2021 |
| Title: GDF Applied Biomedical Technology | 56.581 | 67.148 | 0.000 |
| 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 2020 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 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372 / <i>GDF - Applied Biomedical Technology</i> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <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</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372 / <i>GDF - Applied Biomedical Technology</i> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>to improve the care provided to TBI casualties. Treatments for extremity trauma to advance wound stabilization for prolonged 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 2021 Plans: Efforts realigned to PE 06021115DHA Project Codes 372A-F.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned to PE 06021115DHA Project Codes 372A-F.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 56.581 | 67.148 | 0.000 |

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

| |
|----------------|
| N/A |
| Remarks |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372 / <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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372A / <i>GDF - ABT (Combat Casualty Care)</i> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 372A: <i>GDF - ABT (Combat Casualty Care)</i> | - | 0.000 | 0.000 | 14.855 | - | 14.855 | 15.151 | 15.453 | 15.763 | 16.078 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Applied biomedical research will focus on refining concepts and ideas into potential solutions for military problems and conducting analysis of alternatives to select the best potential solutions for further advanced technology development. Joint battlefield healthcare applied research is focused on optimizing survivability and recovery in injured Service members across the spectrum of care from point of injury through enroute care and facility care.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care) | 0.000 | 0.000 | 14.855 |
| Description: Joint Battlefield Healthcare applied research activities are focused on investigating new diagnostic tools and treatments for prolonged battlefield hemorrhage control, novel approaches for evaluation and treatment of neurotrauma, the role of precision medicine for care for wounded, burn and severe trauma treatments and long term care, and clinically relevant devices and processes related to evacuation and enroute care. | | | |
| FY 2020 Plans: N/A | | | |
| FY 2021 Plans: Joint Battlefield Healthcare applied research activities are focused on investigating new diagnostic tools and treatments for prolonged battlefield hemorrhage control, novel approaches for evaluation and treatment of neurotrauma, the role of precision medicine for care for wounded, burn and severe trauma treatments and long term care, and clinically relevant devices and processes related to evacuation and enroute care. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 372. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | 14.855 |

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

N/A

Remarks

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372A / <i>GDF - ABT (Combat Casualty Care)</i> |

D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | | | | Project (Number/Name) 372B / <i>GDF - ABT (Military Operational Medicine)</i> | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|---|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 372B: <i>GDF - ABT (Military Operational Medicine)</i> | - | 0.000 | 0.000 | 26.255 | - | 26.255 | 26.779 | 27.316 | 27.862 | 28.419 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Conduct studies and experimentation to meet a military medical need. Efforts are directed toward expanding and applying knowledge to develop or improve devices, systems, processes or methods that support medical countermeasures against operational stressors, or that prevent musculoskeletal, neurosensory, and psychological injuries during training and from point of injury through role of care four.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Military Health and Recovery (Formerly Military Operational Medicine) | 0.000 | 0.000 | 26.255 |
| Description: Studies, investigations, and non-system specific technology effort focus on: injury prevention and recovery; optimized cognition and fatigue management; psychological health and resilience; and performance in extreme environments. Activities will continue to focus on: injury prevention and recovery related to blunt, blast, and accelerative injuries; injury prevention and recovery related to musculoskeletal injury; fatigue, cognitive health and performance; human operator health and performance in complex systems; performance nutrition and weight balance; operational systems toxicology for environmental health hazards; protection and performance sustainment in extreme environments; and optimization of psychological health and resilience. | | | |
| FY 2020 Plans: N/A | | | |
| FY 2021 Plans: Studies, investigations, and non-system specific technology effort focus on: injury prevention and recovery; optimized cognition and fatigue management; psychological health and resilience; and performance in extreme environments. Activities will continue to focus on: injury prevention and recovery related to blunt, blast, and accelerative injuries; injury prevention and recovery related to musculoskeletal injury; fatigue, cognitive health and performance; human operator health and performance in complex systems; performance nutrition and weight balance; operational systems toxicology for environmental health hazards; protection and performance sustainment in extreme environments; and optimization of psychological health and resilience. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 372. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | 26.255 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372B / <i>GDF - ABT (Military Operational Medicine)</i> |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | | | | Project (Number/Name) 372C / <i>GDF - ABT (Medical Simulation & Training/Health Informatics)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 372C: <i>GDF - ABT (Medical Simulation & Training/Health Informatics)</i> | - | 0.000 | 0.000 | 10.611 | - | 10.611 | 10.826 | 11.041 | 11.263 | 11.488 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Conduct studies and experimentation to meet a military medical need. Efforts are directed toward expanding and applying knowledge to develop or improve devices, systems, processes or methods that support medical simulation to increase military medical personnel's knowledge, skills and abilities to deliver combat casualty care support to manage patient injury and illness and to conduct patient movement from point of injury through role of care four.

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

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics) | 0.000 | 0.000 | 10.611 |
| <p>Description: Studies, investigations, and non-system specific technology efforts focused on tissue models, technologies that simulate medical condition progress over time, technologies that simulate injury, technologies that replicate warfighter bio-physiology, and, technologies that simulate high-fidelity combat casualty care scenarios. Activities will continue to focus on tissue models that accurately simulate the feel, pliability, flexibility, and responsiveness of live tissue; technologies that simulate the degradation or worsening of a medical condition over time, as well as simulate the improvement of a medical condition over time; technologies that simulate injury, especially hemorrhage, fractures, and ocular damage; technologies that accurately reflect warfighter bodily characteristics and are rugged enough to simulate patient care and movement throughout the entire continuum of care; technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care.</p> <p>FY 2020 Plans: N/A</p> <p>FY 2021 Plans: Studies, investigations, and non-system specific technology efforts focused on tissue models, technologies that simulate medical condition progress over time, technologies that simulate injury, technologies that replicate warfighter bio-physiology, and, technologies that simulate high-fidelity combat casualty care scenarios. Activities will continue to focus on tissue models that accurately simulate the feel, pliability, flexibility, and responsiveness of live tissue; technologies that simulate the degradation or worsening of a medical condition over time, as well as simulate the improvement of a medical condition over time; technologies that simulate injury, especially hemorrhage, fractures, and ocular damage; technologies that accurately reflect warfighter bodily characteristics and are rugged enough to simulate patient care and movement throughout the entire continuum of care;</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372C / <i>GDF - ABT (Medical Simulation & Training/Health Informatics)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 372. | | | | |
| Accomplishments/Planned Programs Subtotals | | 0.000 | 0.000 | 10.611 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| N/A | | | | |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | | | | Project (Number/Name) 372D / <i>GDF - ABT (Clinical and Rehabilitation Medicine)</i> | | | |
|---|-------------|---------|---------|--------------|--|---------------|---------|---------|--|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 372D: <i>GDF - ABT (Clinical and Rehabilitation Medicine)</i> | - | 0.000 | 0.000 | 7.064 | - | 7.064 | 7.204 | 7.350 | 7.495 | 7.645 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Clinical and rehabilitative medicine activities for products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory systems.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Clinical and Rehabilitation Medicine | 0.000 | 0.000 | 7.064 |
| Description: Applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries continues to progress. Targets for therapies to alleviate acute, chronic, and battlefield pain. Continue to focus efforts on developing solutions to repair, reconstruct or regenerate tissue lost or damaged due to traumatic injury, as well as, optimize restoration and rehabilitation of hearing and balance. | | | |
| FY 2020 Plans: N/A | | | |
| FY 2021 Plans: Applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries continues to progress. Targets for therapies to alleviate acute, chronic, and battlefield pain. Continue to focus efforts on developing solutions to repair, reconstruct or regenerate tissue lost or damaged due to traumatic injury, as well as, optimize restoration and rehabilitation of hearing and balance. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 372. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | 7.064 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372E / <i>GDF - ABT (Military Infectious Disease)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 372E: <i>GDF - ABT (Military Infectious Disease)</i> | - | 0.000 | 0.000 | 8.607 | - | 8.607 | 8.779 | 8.954 | 9.133 | 9.316 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Military infectious diseases activities continue to support studies in bacterial diseases research, and will down-select promising efforts for further development.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Military Infectious Disease | 0.000 | 0.000 | 8.607 |
| Description: Multi-year studies in wound infections continue to address the ability to predict infection and better treatment options for infections with multidrug-resistant (MDR) bacterial pathogens. Novel and innovative therapeutics and delivery technologies for combat wounds. | | | |
| FY 2020 Plans: N/A | | | |
| FY 2021 Plans: Multi-year studies in wound infections continue to address the ability to predict infection and better treatment options for infections with multidrug-resistant (MDR) bacterial pathogens. Novel and innovative therapeutics and delivery technologies for combat wounds. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 372. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | 8.607 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372F / <i>GDF - ABT (Radiological Health Effects)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 372F: <i>GDF - ABT (Radiological Health Effects)</i> | - | 0.000 | 0.000 | 0.966 | - | 0.966 | 0.986 | 1.006 | 1.026 | 1.047 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Support the discovery and development of medical capabilities to counter the threat of harmful radiation exposure. Research will be focused on countermeasures for acute radiation exposure leading toward identification of candidates for pre-exposure prophylaxis.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Radiological Health Effects | 0.000 | 0.000 | 0.966 |
| Description: Research will support discovery of one to two Medical Countermeasures (MCMs) candidates to development toward Technology Readiness Level 6 (TRL-6) in support of transition to the advanced developer. In addition to identifying MCM candidates, this research will provide a fundamental understanding of the effects of radiation exposure. MCM identification will also be supported by the development and characterization on animal models to support FDA compliance, and also the identification and characterization of biomarkers to identify druggable targets and to support characterization of the mechanism of action of candidate MCMs | | | |
| FY 2020 Plans: N/A | | | |
| FY 2021 Plans: Research will support discovery of one to two Medical Countermeasures (MCMs) candidates to development toward Technology Readiness Level 6 (TRL-6) in support of transition to the advanced developer. In addition to identifying MCM candidates, this research will provide a fundamental understanding of the effects of radiation exposure. MCM identification will also be supported by the development and characterization on animal models to support FDA compliance, and also the identification and characterization of biomarkers to identify druggable targets and to support characterization of the mechanism of action of candidate MCMs | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 372. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | 0.966 |

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

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i> | Project (Number/Name) 372F / <i>GDF - ABT (Radiological Health Effects)</i> |

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

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 10.611 | 1.307 | 1.383 | 1.411 | - | 1.411 | 1.439 | 1.468 | 1.497 | 1.527 | 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> | 2.151 | 0.277 | 0.283 | 0.289 | - | 0.289 | 0.295 | 0.301 | 0.307 | 0.313 | Continuing | Continuing |
| 241B: <i>Internal Contamination (USUHS)</i> | 1.122 | 0.146 | 0.149 | 0.152 | - | 0.152 | 0.155 | 0.158 | 0.161 | 0.164 | Continuing | Continuing |
| 241C: <i>Radiation Countermeasures (USUHS)</i> | 7.214 | 0.884 | 0.951 | 0.970 | - | 0.970 | 0.989 | 1.009 | 1.029 | 1.050 | 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 1.356 | 1.383 | 1.411 | - | 1.411 |
| Current President's Budget | 1.307 | 1.383 | 1.411 | - | 1.411 |
| 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 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602787DHA / Medical Technology (AFRRI) | Project (Number/Name) 020 / CSI - Congressional Special Interests |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0602787DHA / Medical Technology (AFRRI) | | | | Project (Number/Name) 241A / Biodosimetry (USUHS) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 241A: <i>Biodosimetry (USUHS)</i> | 2.151 | 0.277 | 0.283 | 0.289 | - | 0.289 | 0.295 | 0.301 | 0.307 | 0.313 | 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 2019 | FY 2020 | FY 2021 |
| Title: Biodosimetry (USUHS) | 0.277 | 0.283 | 0.289 |
| <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 2019 Accomplishments:</p> <ul style="list-style-type: none"> - Reported on a proteomic algorithm to predict hematological acute radiation syndrome (H-ARS) severity using a baboon radiation model; these findings support the utility of point-of-care proteomic devices to triage radiation casualties identifying individuals at risk of life-threatening exposures and requiring immediate medical treatment. -- Initiated studies to expose blood lymphocytes to LINAC electrons in lieu of fission neutrons. - Evaluated the utility of length ratio of chromosomes using automated scoring as an endpoint using the premature chromosome condensation (PCC) assay to rapidly assess the radiation dose and fraction of the body exposed. -- Continued efforts to apply centromeric sequence protein nucleic acid (PNA) probes to identify dicentric chromosomes using the PCC assay. -- Reported findings demonstrating differential effects of mixed-field (i.e., 5.5 neutrons to gamma rays) vs. gamma rays on hematology blood count changes following exposure to radiation. Established a consensus baboon radiation database using mixed field and gamma ray exposure for H-ARS severity. Developed an algorithm to predict H-ARS severity based on blood cell count changes, independent of whether exposures were from mixed-field or gamma rays only. These results support the concept to employ H-ARS severity assessment using blood cell counts to assess radiation exposure following nuclear incident. - Completed experimental studies on effects of low-to-moderate doses of gamma radiation on mouse hematopoietic system. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>- Demonstrated that 0.5 Gy of total-body γ-irradiation (TBI) is a threshold dose for hematopoietic and immune system injury in CD2F1 mice.</p> <p>- Developed a novel method to measure radiation-induced DNA damage in cells using long range quantitative PCR.</p> <p>- Demonstrated that IL-18 is a useful radiation biomarker for radiation injury.</p> <p>FY 2020 Plans:</p> <p>- 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.</p> <p>- Predict radiation dose absorbed by different organs by identifying and evaluating 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.</p> <p>- 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.</p> <p>- Explore further the mechanisms of low-moderate doses of radiation-mediated injury in experimental mice and human and mouse cells.</p> <p>- Explore the mechanisms by which low-moderate doses of gamma radiation-induced malignancy in radiosensitive tissues using mouse model and in vitro human and mouse cells.</p> <p>- Develop 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.</p> <p>- Investigate the mechanisms by which IL-18 induces vascular endothelium damage and multiple organ and cell injury in in vivo and ex vivo studies.</p> <p>- Enhance rapid dose and injury assessment using the biodosimetry suite of assays.</p> <p>- Analyze tissues collected from male and female mice exposed to either mixed field radiation or Co-60 radiation including different radiation doses and dose rates.</p> <p>FY 2021 Plans:</p> <p>FY 2021 plans continue efforts as outlined in FY 2020 in addition to the following:</p> <p>-- Evaluate the use of the hematological algorithms using archived animal and human databases to provide prognostic diagnostic capability of radiation injury assessment.</p> <p>-- Compare various PCC endpoints for their utility to predict the fraction of the body exposed to radiation to determine those that could best provide rapid and accurate diagnostic information.</p> <p>- Evaluate utility of long range QPCR (LR-QPCR) and primer extension blockade enabled QPCR (PEBE-QPCR) to quantitatively measure radiation-induced DNA damage in mammalian cells</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <ul style="list-style-type: none"> - Develop IL-18 as a useful biomarker to monitor and track the lesions from radiation exposure and the efficacy of radiation-mitigation. - Investigate the mechanisms by which IL-18 signaling induces mouse tissue and cell injury after radiation and IL-18BP's mitigative effects. <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.277 | 0.283 | 0.289 |

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602787DHA / Medical Technology (AFRRI) | Project (Number/Name) 241B / Internal Contamination (USUHS) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 241B: <i>Internal Contamination (USUHS)</i> | 1.122 | 0.146 | 0.149 | 0.152 | - | 0.152 | 0.155 | 0.158 | 0.161 | 0.164 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Internal Contamination (USUHS) | 0.146 | 0.149 | 0.152 |
| 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. | | | |
| FY 2019 Accomplishments: AFRRI/USUHS Report AFR-B5-3530: Molecularly Imprinted Polymers for Internal Radionuclide Decontamination. | | | |
| 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. | | | |
| FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020 in addition to the following: initiation of feasibility studies of incorporating non-toxic plant-based metal chelators into a dendrimeric structure for use as potential radionuclide decorporation agents. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 0.146 | 0.149 | 0.152 |

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

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0602787DHA / Medical Technology (AFRRI) | Project (Number/Name) 241C / Radiation Countermeasures (USUHS) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 241C: Radiation Countermeasures (USUHS) | 7.214 | 0.884 | 0.951 | 0.970 | - | 0.970 | 0.989 | 1.009 | 1.029 | 1.050 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Radiation Countermeasures (USUHS) | 0.884 | 0.951 | 0.970 |
| 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. | | | |
| FY 2019 Accomplishments: - Reported translational research findings on Ghrelin therapy for mitigation of small intestine injury by sustaining granulocyte-colony stimulating factor (G-CSF), keratinocyte chemoattractant (KC) and macrophage inflammatory protein 1-alpha (MIP-1α), and decreased interleukin-18 (IL-18) in small intestine after combined radiation injury (CI). Ghrelin mitigating small intestinal injury induced by CI was confirmed by histology examination and reduction of cell death biomarker in small intestine. - Reported research findings on radiation injury (RI) and CI induced brain hemorrhage in cerebrum and cerebellum by reducing circulating platelets and brain energy production and increasing brain inflammation and cell death signals, | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>- Demonstrated in an animal model that combinational therapy of Ghrelin and Neulasta inhibited brain hemorrhage from RI and CI by recovering energy production, inhibiting inflammation, and blocking cell death signals in brain as well as increasing platelets in circulation.</p> <p>-Reported animal test/evaluation findings on radiation drug candidate, BBT-059, developed by Bolder Biotechnology, protected mice from radiation-induced gastro-intestinal injury, significantly increased serum citrulline, reduced inflammatory serum amyloid A (SAA) levels and bacterial translocation in liver and spleen. In addition, research findings showed that animals treated with BBT-059 survived up to 12 months post-radiation exposure from lethal and supra-lethal dose (delayed effects of acute radiation exposure, DEARE) with no histological changes in major organs including heart, kidney, brain, and liver.</p> <p>-Reported animal test/evaluation findings on radiation drug candidate, PLX-R18, developed by Pluristem Therapeutics, demonstrated significant increase in 30-day survival when it was administered two doses on day 1 pre and day 3 post-radiation. In addition, research findings showed that PLX-R18 protected mice from radiation induced hematopoietic acute radiation syndrome, significantly accelerated recovery of peripheral blood and bone marrow progenitor cells.</p> <p>- Completed animal test toxicity study of IL-18BP as a putative radiation drug and found no toxicity after subcutaneous (SC) injection from 0.25 mg/kg to 5.0 mg/kg to CD2F1 mice.</p> <p>- Demonstrated that a single injection of rhIL-18BP (1.5mg/kg) to mice at 24 h, 48 or 72 h post-total-body irradiation (TBI) exhibited a delayed mortality time in comparison with vehicle control-treated mice. In addition, IL-18BP (1.5 mg/kg, 48 h post-radiation) significantly increased bone marrow hematopoietic stem and progenitor cell clonogenicity and blood platelet number in mice after 9 or 10 Gy (LD70/30 and LD90/30) TBI. Also, two doses injection of rhIL-18BP (1.5mg/kg) to mice at 48 h and 5 days post-9 Gy TBI significantly increased 30-day survival of mice in comparison of vehicle-control injected and irradiated mice.</p> <p>-Completed studies on the radiation-dependent effects on the human HSC proteome by in vitro methods; a few but promising radiation-induced protein biomarkers have been identified.</p> <p>-Generated additional translational information on radiation-induced biomarker signature using samples obtained from irradiated large animal model. This work is being done using transcriptomics and metabolomics/lipidomics platforms.</p> <p>-Successfully initiated a radiation induced microbiome study using irradiated murine model samples This work will continue by using bacterial DNA analysis as well as metabolomics/lipidomics.</p> <p>FY 2020 Plans: FY 2020 plans are:</p> <ul style="list-style-type: none"> - Initiate a new proposed project to investigate molecular mechanisms underlying the differential responses to high-linear energy transfer (LET) radiation between males and females. - Examine and analyze organ injury in small intestine and bone marrow of mice exposed to mixed-field radiation. - Start proteomic analysis of 25 cytokines/chemokines and C3 in bone marrow, spleen and small intestine. - Assess pathological changes in major organs in one and six months post-total body radiation (TBI) in male and female C57BL/6 mice. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <ul style="list-style-type: none"> - Continue to evaluate radiation-induced biomarker signature using large animal model samples and state of the art techniques: transcriptomics, metabolomics/lipidomics. - Continue to evaluate radiation induced microbiome using irradiated murine model samples. This will be done using transcriptomics and metabolomics/lipidomics platforms. - Establish Gut-on-chip model to minimize the use of animals in radiation biology research. <p>FY 2021 Plans: FY2021 plans continue efforts as outlined in FY2020 in addition to the following:</p> <ul style="list-style-type: none"> - Further investigate radiation effects on the molecular pathway of AKT-MAPK cross talk. - Evaluate long-term differential expression of micro-RNAs in C57BL/6 mice (male and female) and mini-pig after radiation. - Determine the DEARE (delayed effects of acute radiation exposure) effects on the gut microbiome compositions and host-microbiome relationship and identify gender differences. - Evaluate the pharmacokinetic of IL-18BP in mouse. - Evaluate the radiation mitigative effects of IL-18BP in different mouse model. - Determine the dose reduction factor (DRF) of IL-18BP in irradiated mice. - Evaluate the effects and mechanisms of IL-18BP on survival of mouse gastrointestinal systems after lethal doses of TBI. <p>FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.884 | 0.951 | 0.970 |

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

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 2.460 | 0.325 | 0.345 | 0.352 | - | 0.352 | 0.359 | 0.366 | 0.373 | 0.380 | 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> | 1.453 | 0.195 | 0.206 | 0.210 | - | 0.210 | 0.214 | 0.218 | 0.222 | 0.226 | Continuing | Continuing |
| 242B: <i>Radiation Countermeasures (USUHS)</i> | 0.976 | 0.130 | 0.139 | 0.142 | - | 0.142 | 0.145 | 0.148 | 0.151 | 0.154 | 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 0.338 | 0.345 | 0.352 | - | 0.352 |
| Current President's Budget | 0.325 | 0.345 | 0.352 | - | 0.352 |
| Total Adjustments | -0.013 | 0.000 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.013 | - | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603002DHA / <i>Medical Advanced Technology (AFRRI)</i> | | | | Project (Number/Name) 030A / <i>CSI - Congressional Special Interests</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 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 |

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

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 242A: <i>Biodosimetry (USUHS)</i> | 1.453 | 0.195 | 0.206 | 0.210 | - | 0.210 | 0.214 | 0.218 | 0.222 | 0.226 | 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 2019 | FY 2020 | FY 2021 |
| Title: Biodosimetry (USUHS) | 0.195 | 0.206 | 0.210 |
| <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 2019 Accomplishments: Attained major technical advances using “automated dicentrics scoring” to enhance radiation dose assessment to include: submission of technical publication reporting on the establishment of dose-response calibration curves following exposure to three different dose rates of 60Co gamma rays; established x-ray calibration curve (i.e., 250 kVp, 0.6 Gy/min); and automated dicentrics scoring performance evaluation using well-defined blind tests samples that showed an overall scoring of 103 ± 3.8 %, which justifies use of the automated dicentrics scoring in triage dose assessments. Reported on findings from inter-laboratory exercise triage (n=50 spreads) dose assessments from AFRRI and institutional collaborator from Health Canada. Preliminary findings from this exercise (INTCO6-2018) showed accurate dose predictions within 0.6 Gy of the actual dose. These findings expand AFRRI’s verified dicentrics scorers and demonstrate laboratory competence,</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>consistent with the guidance from the relevant (International Organization for Standardization) ISO standards. Results from AFRRI's 3-4 years' experience participating in the inter-comparison exercises with Health Canada is being written up for publication.</p> <p>Introduced a novel parameter, Hematological Index of Radiation Injury (HIRI), to distinguish individuals from exposure to <2 Gy vs. >2 Gy of radiation by a single CBC with differential in the early time period after a suspected exposure. Validated the HIRI algorithm using archived data from both an animal model (i.e., Macaque nonhuman primate exposed to 60Co gamma rays) and human radiation accidents. Filed an invention disclosure that was followed by the submission of a provisional patent application linking the HIRI algorithm with applications on hand-held and benchtop blood cell counters to aide first-response in triaging suspected individuals exposed to ionizing radiation.</p> <p>Reported research findings on MicroRNA 34a (MiR-34a) as applicable biomarker for increased expression in small intestine of mice that were exposed to mixed-field (neutrons+gamma) radiation.</p> <p>FY 2020 Plans: FY 2020 plans continue efforts to validate the use of multiple parameter biodosimetry assays for optimized radiation injury and dose assessment in addition to the following: Continue to develop and validate the HIRI algorithm for use in triaging suspected radiological casualties; sustain cytogenetic biodosimetry laboratory participation in inter-comparison exercises performing dose assessment to document laboratory proficiency; obtain dose-responses for automated scoring of dicentric yields in blood exposed to high-energy LINAC electrons; and continue efforts to obtain laboratory certification for radiation dose assessment using multiple biodosimetry assays.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020 in addition to the following: expand the validation of cytogenetic assays for dose assessment using the premature chromosome condensation (PCC) assay as a secondary endpoint for radiation dose and partial-body assessment; investigate differential effects on organ injury such as bone marrow and small intestine between males and females after mixed-field and pure gamma radiation will be evaluated; and initiate 25 cytokine profile measurements for correlation with effects of radiation exposure.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.195 | 0.206 | 0.210 |

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| C. Other Program Funding Summary (\$ in Millions) N/A |
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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603002DHA / Medical Advanced Technology (AFRRI) | | | | Project (Number/Name) 242B / Radiation Countermeasures (USUHS) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 242B: Radiation Countermeasures (USUHS) | 0.976 | 0.130 | 0.139 | 0.142 | - | 0.142 | 0.145 | 0.148 | 0.151 | 0.154 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Radiation Countermeasures (USUHS) | 0.130 | 0.139 | 0.142 |
| <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 2019 Accomplishments:</p> <ul style="list-style-type: none"> - Demonstrated an important finding that radiation injury (RI) and combined radiation injury (CI) significantly reduced nuclear respiratory factor 1 and 2 (NRF1/2) and mitochondrial complexes I-V, thereby leading to decreases in energy production in mouse brain. -Reported data on RI and CI decreased dynamin-related protein 1 (DRP1) and mitofusin 1 (Mfn1), resulting in mitochondrial remodeling in mouse brain. In addition, reported data showed RI and CI decreased AKT activation in mouse brain. - Reported data on combinational therapy of Ghrelin and Neulasta recovered energy production by recovering NRF1/2, mitochondrial complex III, shape integrity and pro-survival signal molecules in mouse brain. <p>FY 2020 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | Date: February 2020 |
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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> |
|--|--|---|

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>-FY 2020 plans are: continued gathering of preclinical data from animal models natural history studies for radiation toxicity and for the discovery and development of radiation countermeasures; conduct detailed analysis of the metabolomic and lipidomic studies with the samples collected in mice experiments with amifostine and a PARP inhibitor, Talazoparib; and 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><i>FY 2021 Plans:</i> FY 2021 plans continue efforts as outlined in FY 2020 in addition to the following: Commence investigation of energy production in mouse small intestine exposed to high-LET radiation.</p> <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.130 | 0.139 | 0.142 |

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
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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
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| Appropriation/Budget Activity 0130: Defense Health Program I BA 2: RDT&E | | | | | R-1 Program Element (Number/Name) PE 0603115DHA I Medical Technology Development | | | | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 7,763.338 | 1,594.929 | 1,782.072 | 225.250 | - | 225.250 | 235.197 | 240.220 | 245.344 | 250.580 | Continuing | Continuing |
| 300A: CSI - Congressional Special Interests | 6,018.979 | 1,328.026 | 1,502.651 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |
| 238C: Enroute Care Research & Development (Budgeted) (AF) | 23.121 | 8.237 | 9.391 | 11.250 | - | 11.250 | 12.675 | 12.866 | 13.122 | 13.387 | Continuing | Continuing |
| 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 |
| 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 |
| 243A: Medical Development (Lab Support) (Navy) | 164.298 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - |
| 247A: Elimination of Malaria in Southeast Asia (CARB) (Navy) | 5.812 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 5.812 |
| 247B: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | 3.782 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 3.782 |
| 284B: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF) | 19.043 | 7.300 | 8.576 | 10.418 | - | 10.418 | 11.122 | 11.471 | 11.700 | 11.934 | Continuing | Continuing |
| 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 |
| 284D: Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF) | 1.002 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 285A: Operational Medicine Research & Development (Budgeted) (AF) | 25.807 | 4.082 | 4.089 | 0.232 | - | 0.232 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | | |
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| 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) | 65.644 | 6.928 | 8.199 | 10.046 | - | 10.046 | 11.463 | 11.630 | 11.862 | 12.098 | | 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) | 20.100 | 4.881 | 3.636 | 2.623 | - | 2.623 | 0.000 | 0.000 | 0.000 | 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) | 47.964 | 8.033 | 10.209 | 10.413 | - | 10.413 | 10.621 | 10.833 | 11.051 | 11.271 | | 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 |
| 378B: CoE-Breast Cancer Center of Excellence (USU) | 19.640 | 9.916 | 10.475 | 10.685 | - | 10.685 | 10.898 | 11.116 | 11.339 | 11.566 | | Continuing | Continuing |

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | | Date: February 2020 | | |
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| Appropriation/Budget Activity | | | | | R-1 Program Element (Number/Name) | | | | | | | | |
| 0130: Defense Health Program I BA 2: RDT&E | | | | | PE 0603115DHA I Medical Technology Development | | | | | | | | |
| 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 | 0.000 | Continuing | Continuing |
| 379B: CoE-Gynecological Cancer Center of Excellence (USU) | 17.169 | 8.668 | 9.158 | 9.341 | - | 9.341 | 9.528 | 9.719 | 9.913 | 10.111 | | Continuing | Continuing |
| 381A: CoE-Integrative Cardiac Health Care Center of Excellence (Army) | 20.780 | 0.000 | 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) | 10.901 | 3.202 | 3.376 | 1.945 | - | 1.945 | 2.014 | 2.084 | 2.156 | 2.229 | | Continuing | Continuing |
| 383A: CoE-Prostate Cancer Center of Excellence (USUHS) | 49.072 | 7.921 | 8.359 | 8.526 | - | 8.526 | 8.696 | 8.870 | 9.047 | 9.228 | | 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) | 48.611 | 10.800 | 9.200 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | - | - | - |
| 448A: Military HIV Research Program (Army) | 31.454 | 7.185 | 7.877 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | | Continuing | Continuing |
| 830A: Deployed Warfighter Protection (Army) | 34.106 | 5.713 | 6.345 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | | Continuing | Continuing |
| 478: Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS) | 14.766 | 14.237 | 18.556 | 18.640 | - | 18.640 | 18.724 | 19.098 | 19.480 | 19.870 | | Continuing | Continuing |
| 479: Framingham Longitudinal Study (USUHS) | 4.920 | 4.746 | 4.920 | 4.920 | - | 4.920 | 4.920 | 5.018 | 5.118 | 5.220 | | Continuing | Continuing |

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
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| Appropriation/Budget Activity | | | | | R-1 Program Element (Number/Name) | | | | | | | |
| 0130: Defense Health Program I BA 2: RDT&E | | | | | PE 0603115DHA I Medical Technology Development | | | | | | | |
| 499: MHS Financial System Acquisition (DHA) | 15.222 | 20.358 | 15.373 | 1.971 | - | 1.971 | 6.011 | 6.051 | 6.092 | 6.143 | Continuing | Continuing |
| 381: CoE - Integrative Cardiac Health Care (USUHS) | 0.000 | 2.811 | 3.118 | 1.680 | - | 1.680 | 1.744 | 1.809 | 1.875 | 1.943 | Continuing | Continuing |
| 504: WRAIR Vaccine Production Facility Research (Army) | 0.000 | 8.000 | 8.152 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS) | 0.000 | 0.000 | 11.904 | 11.141 | - | 11.141 | 11.385 | 11.631 | 11.883 | 12.141 | Continuing | Continuing |
| 507: Brain Injury and Disease Prevention, Treatment and Research (USUHS) | 0.000 | 0.000 | 13.317 | 13.583 | - | 13.583 | 13.855 | 14.132 | 14.415 | 14.703 | Continuing | Continuing |
| 508: Psychological Health and Resilience (USUHS) | 0.000 | 0.000 | 7.000 | 7.140 | - | 7.140 | 7.283 | 7.428 | 7.577 | 7.729 | Continuing | Continuing |
| 509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS) | 0.000 | 0.000 | 19.323 | 13.710 | - | 13.710 | 14.104 | 14.505 | 14.916 | 15.334 | Continuing | Continuing |
| 373: GDF - Medical Technology Development | 1,006.232 | 123.885 | 78.868 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 373A: GDF - MTD (Combat Casualty Care) | - | 0.000 | 0.000 | 11.168 | - | 11.168 | 15.736 | 16.756 | 19.649 | 20.114 | Continuing | Continuing |
| 373B: GDF - MTD (Military Operational Medicine) | - | 0.000 | 0.000 | 23.255 | - | 23.255 | 19.046 | 19.116 | 18.151 | 18.557 | Continuing | Continuing |
| 373C: GDF - MTD (Medical Simulation & Training/Health Informatics) | - | 0.000 | 0.000 | 12.613 | - | 12.613 | 13.044 | 13.339 | 13.637 | 13.942 | Continuing | Continuing |
| 373D: GDF - MTD (Clinical and Rehabilitation Medicine) | - | 0.000 | 0.000 | 13.040 | - | 13.040 | 14.980 | 15.034 | 14.275 | 14.595 | Continuing | Continuing |
| 373E: GDF - MTD (Military Infectious Disease) | - | 0.000 | 0.000 | 6.409 | - | 6.409 | 6.630 | 6.779 | 6.932 | 7.087 | Continuing | Continuing |

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | | | | | |
| 373F: <i>GDF - MTD (Radiological Health Effects)</i> | - | 0.000 | 0.000 | 0.501 | - | 0.501 | 0.518 | 0.531 | 0.542 | 0.554 | Continuing | Continuing |
| 373G: <i>GDF - MTD (Military Medical Photonics)</i> | - | 0.000 | 0.000 | 10.000 | - | 10.000 | 10.200 | 10.404 | 10.612 | 10.824 | 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 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. 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.

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency | Date: February 2020 |
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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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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 (CoEs) 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.

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

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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> |
|---|---|

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.

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 1,647.789 | 279.421 | 269.473 | - | 269.473 |
| Current President's Budget | 1,594.929 | 1,782.072 | 225.250 | - | 225.250 |
| Total Adjustments | -52.860 | 1,502.651 | -44.223 | - | -44.223 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 1,502.651 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -52.860 | - | | | |
| • Reprogrammings | - | - | -24.223 | - | -24.223 |
| • Directed Reduction | - | - | -20.000 | - | -20.000 |

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

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

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

Congressional Add: 293A - *Autism Research*

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

Congressional Add: 310A - *Peer-Reviewed Ovarian Cancer Research*

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

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

| | FY 2019 | FY 2020 |
|--|----------------|----------------|
| | 9.665 | 20.000 |
| | 7.248 | 15.000 |
| | 2.899 | 3.000 |
| | 19.329 | 35.000 |
| | 5.799 | 16.000 |
| | 86.951 | 110.000 |

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | |
|---|---|
| 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> |
|---|---|

| Congressional Add Details (\$ in Millions, and Includes General Reductions) | FY 2019 | FY 2020 |
|--|----------------|----------------|
| Congressional Add: 336A - <i>Peer-Reviewed Lung Cancer Research</i> | 13.530 | 14.000 |
| Congressional Add: 337A - <i>Peer-Reviewed Orthopaedic Research</i> | 28.994 | 30.000 |
| Congressional Add: 338A - <i>Peer-Reviewed Spinal Cord Research</i> | 28.994 | 40.000 |
| Congressional Add: 339A - <i>Peer-Reviewed Vision Research</i> | 19.314 | 20.000 |
| Congressional Add: 352A - <i>Traumatic Brain Injury/Psychological Health Research</i> | 96.102 | 106.000 |
| Congressional Add: 380A - <i>Peer-Reviewed Breast Cancer Research</i> | 125.639 | 150.000 |
| Congressional Add: 390A - <i>Peer-Reviewed Prostate Cancer Research</i> | 96.645 | 110.000 |
| Congressional Add: 392A - <i>Gulf War Illness Peer-Reviewed Research</i> | 21.295 | 22.000 |
| Congressional Add: 396A - <i>Research in Alcohol and Substance Use Disorders</i> | 3.866 | 0.000 |
| Congressional Add: 400A - <i>Peer-Reviewed Medical Research</i> | 338.309 | 360.000 |
| Congressional Add: 417A - <i>Peer-Reviewed Alzheimer Research</i> | 14.497 | 15.000 |
| Congressional Add: 439A - <i>Joint Warfighter Medical Research</i> | 26.589 | 30.000 |
| 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 | 15.000 |
| Congressional Add: 456A - <i>HIV/AIDS Program</i> | 12.473 | 15.000 |
| Congressional Add: 459A - <i>Peer-Reviewed Epilepsy Research</i> | 7.248 | 12.000 |
| Congressional Add: 463A - <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i> | 242.336 | 188.151 |
| Congressional Add: 495 - <i>Peer-Reviewed Tick-Borne Disease Research</i> | 4.832 | 7.000 |
| 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> | 19.314 | 40.000 |
| Congressional Add: 503 - <i>CSI - Peer-Reviewed Lupus Research (Army)</i> | 4.832 | 10.000 |
| 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 | 10.000 |
| Congressional Add: 512 - <i>Peer-Reviewed Melanoma Research</i> | 9.665 | 20.000 |
| Congressional Add: 513 - <i>Chronic Pain Management</i> | 9.665 | 15.000 |

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 <i>Medical Technology Development</i> |
|---|---|

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

Congressional Add: 514 - *Combat Readiness Medical Research*
 Congressional Add: 515 - *Peer-Reviewed Pancreatic Cancer Research*
 Congressional Add: 516 - *Peer-Reviewed Rare Cancers Research*
 Congressional Add: 517 - *Peer-Reviewed Scleroderma Research*

Congressional Add Subtotals for Project: 300A

Congressional Add Totals for all Projects

| | FY 2019 | FY 2020 |
|---|-----------|-----------|
| | 14.512 | 10.000 |
| | 0.000 | 6.000 |
| | 0.000 | 7.500 |
| | 0.000 | 5.000 |
| Congressional Add Subtotals for Project: 300A | 1,328.026 | 1,502.651 |
| Congressional Add Totals for all Projects | 1,328.026 | 1,502.651 |

Change Summary Explanation

FY 2021: Programmed effort and funding transferred to other higher priority programs.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|-----------|-----------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 300A: CSI - Congressional Special Interests | 6,018.979 | 1,328.026 | 1,502.651 | 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 2019 | FY 2020 |
|---|---------|---------|
| Congressional Add: 245A - Amyotrophic Lateral Sclerosis (ALS) Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 9.665 | 20.000 |
| Congressional Add: 293A - Autism Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 7.248 | 15.000 |
| Congressional Add: 296A - Bone Marrow Failure Disease Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 2.899 | 3.000 |
| Congressional Add: 310A - Peer-Reviewed Ovarian Cancer Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 19.329 | 35.000 |
| Congressional Add: 328A - Peer- Reviewed Multiple Sclerosis Research <i>FY 2019 Accomplishments:</i> N/A <i>FY 2020 Plans:</i> N/A | 5.799 | 16.000 |
| Congressional Add: 335A - Peer-Reviewed Cancer Research | 86.951 | 110.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 336A - Peer-Reviewed Lung Cancer Research | 13.530 | 14.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 337A - Peer-Reviewed Orthopaedic Research | 28.994 | 30.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 338A - Peer-Reviewed Spinal Cord Research | 28.994 | 40.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 339A - Peer-Reviewed Vision Research | 19.314 | 20.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 352A - Traumatic Brain Injury/Psychological Health Research | 96.102 | 106.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 380A - Peer-Reviewed Breast Cancer Research | 125.639 | 150.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 390A - Peer-Reviewed Prostate Cancer Research | 96.645 | 110.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 392A - Gulf War Illness Peer-Reviewed Research | 21.295 | 22.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 396A - Research in Alcohol and Substance Use Disorders | 3.866 | 0.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 400A - Peer-Reviewed Medical Research | 338.309 | 360.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 417A - Peer-Reviewed Alzheimer Research | 14.497 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 439A - Joint Warfighter Medical Research | 26.589 | 30.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 452A - Peer-Reviewed Reconstructive Transplant Research | 11.597 | 12.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 454A - Orthotics and Prosthetics Outcomes Research | 9.665 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 456A - HIV/AIDS Program | 12.473 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 459A - Peer-Reviewed Epilepsy Research | 7.248 | 12.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 463A – Program Increase: Restore Core Research Funding Reduction (GDF) | 242.336 | 188.151 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 495 - Peer-Reviewed Tick-Borne Disease Research | 4.832 | 7.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 496 -Trauma Clinical Research Program | 9.665 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 501 - Peer-Reviewed Hearing Restoration Research (Army) | 9.665 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 502 - CSI - Peer-Reviewed Kidney Cancer Research (Army) | 19.314 | 40.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 503 - CSI - Peer-Reviewed Lupus Research (Army) | 4.832 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 540A - Global HIV/AIDS Prevention (Navy) | 8.000 | 8.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 660A - Tuberous Sclerosis Complex (TSC) | 5.799 | 6.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 790A - Peer-Reviewed Duchenne Muscular Dystrophy | 3.093 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 512 - Peer-Reviewed Melanoma Research | 9.665 | 20.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 513 - Chronic Pain Management | 9.665 | 15.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 514 - Combat Readiness Medical Research | 14.512 | 10.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 515 - Peer-Reviewed Pancreatic Cancer Research | 0.000 | 6.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 516 - Peer-Reviewed Rare Cancers Research | 0.000 | 7.500 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Add: 517 - Peer-Reviewed Scleroderma Research | 0.000 | 5.000 |
| <i>FY 2019 Accomplishments:</i> N/A | | |
| <i>FY 2020 Plans:</i> N/A | | |
| Congressional Adds Subtotals | 1,328.026 | 1,502.651 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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.

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 238C: <i>Enroute Care Research & Development (Budgeted) (AF)</i> | 23.121 | 8.237 | 9.391 | 11.250 | - | 11.250 | 12.675 | 12.866 | 13.122 | 13.387 | 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 2019 | FY 2020 | FY 2021 |
| Title: Enroute Care Research & Development (Budgeted) (AF) | 8.237 | 9.391 | 11.250 |
| 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. | | | |
| FY 2020 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. Plans are to complete multicenter closed-loop ventilation device trials. 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 the influence of altitude, oxygenation, and sedation on neurodegeneration following traumatic brain injury (TBI). Analyses will be conducted assessing the critical impact of hypobaria after hemorrhage and resuscitation. 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. 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. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Perform service-connected life trajectory comparison of psychiatric aeromedical evacuation and non-psychiatric aeromedical evacuation patients. Studies will evaluate post-traumatic stress disorder reduction using intravenous corticosteroids with analysis of biomarkers using metabolomics. 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> <p>Continue with developing research objectives and end states focused on 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 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020. Analyses will demonstrate the critical impact of hypobaria after hemorrhage and resuscitation.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Increased funding resulting from realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF) to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 8.237 | 9.391 | 11.250 |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
| • BA-1, PE 0807714HP: <i>Other Consolidated Health Support</i> | - | - | - | - | - | - | - | - | - | - | - |
| 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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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.)

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | | | Project (Number/Name) 238E / <i>Core Enroute Care R&D - Aerospace Medicine/Human Performance Focus (AF)</i> | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 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 |

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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 247A: Elimination of Malaria in Southeast Asia (CARB) (Navy) | 5.812 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Elimination of Malaria in Southeast Asia (CARB) (Navy) | 0.000 | - | - |
| Description: This project seeks to demonstrate that malaria can be eliminated in a specific geographically defined area of endemicity through a comprehensive multi-disciplined approach including enhanced surveillance, operations research to maximize the impact of intervention strategies, and quality improvement of current tools for malaria elimination. The demonstration will focus on Vietnam where multi-drug resistant malaria is prevalent and as such represents a significant threat to US personnel. Additionally, the Vietnamese military and Ministry of Health have a high level of interest in malaria control and will collaborate in the malaria elimination demonstration project significantly improving the chances of success of this project. FY 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. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 247B: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | 3.782 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Mitigate the Global Impact of Sepsis Through ACESO (CARB) (Navy) | 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <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> | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 284B: <i>USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)</i> | 19.043 | 7.300 | 8.576 | 10.418 | - | 10.418 | 11.122 | 11.471 | 11.700 | 11.934 | 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 2019 | FY 2020 | FY 2021 |
| Title: USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF) | 7.300 | 8.576 | 10.418 |
| 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 2020 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 of vision, psychology, and physiology 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. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Additional studies will examine the influence of lower extremity stress fracture on the career trajectories of USAF Basic Military Trainees.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Increased funding resulting from realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF)to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 7.300 | 8.576 | 10.418 |

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 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 284D / Core Human Performance R&D - Aerospace Medicine/Human Performance Focus (AF) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 284D: Core Human Performance R&D - Aerospace Medicine/ Human Performance Focus (AF) | 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.)

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 285A: Operational Medicine Research & Development (Budgeted) (AF) | 25.807 | 4.082 | 4.089 | 0.232 | - | 0.232 | 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)

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Operational Medicine Research & Development (Air Force) | 4.082 | 4.089 | 0.232 |
| 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 2020 Plans: The analysis of genotypes and phenotypes on NIH databases for Air Force precision medicine applications will continue, including the identification of risk factors for pulmonary disorders by associating genomic polymorphisms with pulmonary diseases including asthma, COPD and sarcoidosis. Research will continue on the development of a silica encapsulated dental polymeric material that upon degradation, damage, or fracture, self-repairs the injury. The current military separation and retirement practices by health care providers will be investigated, including assessment and communication of diabetes risk to separating or retiring members and counseling regarding how to minimize risk. Continued research includes the development of an exportable Diabetes Self-Management Education (DSME) methodology that can be used throughout the Military Health System (MHS) to support national diabetes education and support standards for patient care. Triggerable release, reloadable, smart hydrogels for graft targeted immunotherapy in reconstructive transplantation will continue to be performed and evaluated. | | | |
| FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020. Research will continue developing diabetes tools, education, and coaching techniques to reduce the cost of patient care and improve outcomes in patients with Type 2 diabetes. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Reduced funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF)to focus on future readiness mission and operational medical capabilities required to support the warfighter. | | | |
| Accomplishments/Planned Programs Subtotals | 4.082 | 4.089 | 0.232 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|---|----------------|----------------------------|-------------------------|-------------------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 285C / <i>Core Operational Medicine R&D - Aerospace/Human Performance Focus (AF)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 285C: <i>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.)

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 307B: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF) | 65.644 | 6.928 | 8.199 | 10.046 | - | 10.046 | 11.463 | 11.630 | 11.862 | 12.098 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force) | 6.928 | 8.199 | 10.046 |
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <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>Recently, research supporting flight line simulations helped guide infrastructure changes at fighter base to accommodate the receipt of aircraft and minimize heat damage to air/ground crews and other jets. Sensors entered into testing to guide methodology for base-level pilot breathing air characterization.</p> <p>FY 2020 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 study to evaluate breath biomarkers as diagnostic for influenza A. Continue comprehensive evaluation of known naturally occurring genetic variations and experimentally induced mutations in mammalian genes that confer varying degrees of resistance to infectious diseases. A database and software interface will continue to be constructed to allow preventive medicine physicians at training bases to query training population data for epidemiologic purposes. 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>Additionally, a tiered research plan will be built to address the medical challenges of RF exposure and further validate the clinical guidance and training for clinicians to diagnose and treat greater potential RF weapons insult/injury exposure. The Program will</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>evaluate groundbreaking technologies, therapies and tools to detect, diagnose and deter DE or RFR exposure and to prevent, preserve and protect cells, tissues and organ system functions and homeostasis from the disruptive and damaging effects of directed energy (DE). An MRI and biomarker model for DE exposure will be developed for medical evaluation.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding changes reflect a realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF) to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 6.928 | 8.199 | 10.046 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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.)

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 308B: <i>Expeditionary Medicine Research & Development (Budgeted) (AF)</i> | 20.100 | 4.881 | 3.636 | 2.623 | - | 2.623 | 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)

| | | | |
|---|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: Expeditionary Medicine Research & Development (Air Force) | 4.881 | 3.636 | 2.623 |
| <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 2020 Plans: Smart polymer-based systems for graft-targeted immunotherapy will continue to be developed to minimize systemic immunosuppression in reconstructive transplantation. Research will continue to evaluate therapies to restore and augment peripheral nerve regeneration and optimize sensory/motor reinnervation for restoration of battlefield injuries applicable to replantation, transplantation, and isolated nerve injuries. Work will continue on the development of VentRight, portable ventilation monitoring combining inline flow, pressure, and CO2 sensors, pulse oximetry, and advanced analytic algorithms for soldiers with respiratory failure, guiding resuscitation by medics or untrained providers in austere conditions or at central MTF.</p> <p>The autonomous selective organ perfusion (ASOP) platform will be evaluated for prolonged field and enroute care applications. Research on the use of intramuscular tranexamic acid (TXA) will continue in a model of hemorrhagic shock and prolonged</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>field care/delayed evacuation. The ability of gold standard and field portable Virtual Reality will continue to improve or augment pain reduction in combat relevant environments. A reproducible protocol for utilizing teleophthalmology will be developed and standardized, assessing the cyber and data security of teleophthalmology devices, and creating a teleophthalmology training program for military ophthalmologists. Methods will be devised and evaluated to capture thrombi due to complications from REBOA treatment. Research will continue to determine if current medical logistic practices need to be reevaluated for storage of medications in high humidity and extreme temperatures used at point-of-injury.</p> <p>FY 2021 Plans: The autonomous selective organ perfusion (ASOP) platform will continue to be evaluated for prolonged field and enroute care applications. Forward operating base ocular trauma telemedicine triage and stabilization will continue. Studies will continue to evaluate strategies to treat occult non-compressible torso hemorrhage.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Reduced funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element(PE) 0603115DHA- Medical Technology Development among Project Codes 285A- Operational Medicine Research & Development (AF),308B- Expeditionary Medicine Research & Development (AF),238C- Enroute Care Research & Development (AF), 284B- USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (AF), and 307B- Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (AF)to focus on future readiness mission and operational medical capabilities required to support the warfighter.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 4.881 | 3.636 | 2.623 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
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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) 308C / <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i> | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 308C: <i>Core Expeditionary Medicine R&D - Clinical Translational Focus (AF)</i> | 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.)

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
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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) 308D / <i>Core Expeditionary Medicine R&D - Aerospace/Human Performance Focus (AF)</i> | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 308D: <i>Core Expeditionary Medicine R&D - Aerospace/ Human Performance Focus (AF)</i> | 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.)

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 309A / Regenerative Medicine (USUHS) | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|--|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 309A: <i>Regenerative Medicine (USUHS)</i> | 47.964 | 8.033 | 10.209 | 10.413 | - | 10.413 | 10.621 | 10.833 | 11.051 | 11.271 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Regenerative Medicine (USUHS) | 8.033 | 10.209 | 10.413 |
| <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>FY19 Accomplishments:</p> <ul style="list-style-type: none"> - Biorepositories for biomarker analysis of fluids (107,060 specimens) and neuropathology (126 brain donations), specialized for analysis of TBI in Service Members. - Continued hosting of the annual two-day National Capital Area TBI Research Symposium with no registration fees and an average of 400 participants from the Department of Defense, the Department of Health and Human Services, the Department of Veterans Affairs, and local academic institutions to share TBI research advances and to develop collaborative interactions. The Symposium's program development is led by CNRM, with representatives from Johns Hopkins University, University of Maryland, Howard University, Virginia Commonwealth University, the University of Virginia, and Georgetown University. - Continued hosting of the one-day center-wide Retreat attended by approximately 140 persons from CNRM and, also, leadership and staff from ten other TBI research organizations in the Washington D.C. area. The Retreat's purpose is to have CNRM's stakeholders come together to facilitate discussion, networking, and collaboration and, to create an opportunity for CNRM stakeholders to listen to and interact with TBI patients, caregivers, and advocates. - Awarded five (5) new clinical trials: <ol style="list-style-type: none"> 1. Reconsolidation of Traumatic Memories to Resolve Post-Traumatic Stress Disorder 2. Improving sleep in Veterans with TBI: Integrating bright light therapy and blood-based brain biomarkers 3. Mobile Application to Counteract Depression and Concussion 4. Individualized Connectome-targeted rTMS for Depression Associated with Traumatic Brain Injury | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>5. Internet Cognitive Behavioral Therapy for TBI-related Insomnia</p> <p>- Awarded three (3) new strategic project cores:</p> <p>1. The Neuropathology-Neuroradiology Integration Core: A partnering of the Neuropathology Core with Dr. Peter Basser’s Section on Quantitative Imaging and Tissue Sciences laboratory at NIH to develop and test novel magnetic resonance imaging (MRI) approaches that could potentially identify TBI-related structural abnormalities in vivo.</p> <p>2. The Translational Therapeutics Core: A state-of-the-science paradigm for the preclinical testing of traumatic brain injury (TBI) treatments intended to alleviate highly relevant post-injury symptoms experienced by Service Members. This core will work to develop a proof-of-concept complex, chronic model of TBI in mice to test the effectiveness of novel treatment options.</p> <p>3. The Optimizing Ferret TBI Experiment: A standardized, complex TBI paradigm in ferrets that incorporates novel pre-and post-injury behavioral tests to evaluate changes in mood, headache, and sleep. Soon, this model will test the efficacy of candidate treatments.</p> <p>- Completion of the 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.</p> <p>- Expansion of its research agenda to include Operational Research, which focuses on optimizing warfighter brain health in operational environments and consists of two initiatives: Monitoring Blast Exposures and Environmental Overpressure Events, and Prolonged Field Care. These initiatives explore field-based brain health concerns such as blast overpressure exposure, impact/acceleration events, and the development of countermeasures for severe brain injuries, such as subdural hemorrhage, in austere environments.</p> <p>- Continued involvement in the “Comprehensive Strategy and Action Plan for Warfighter Brain Health.” This strategy includes six (6) lines of effort which are: Research, Surveillance and Prevention; Diagnosis, Treatment, Rehabilitation, and Reintegration; Outreach, Education, and Training; Long Term Effects of Traumatic Brain Injury (TBI); and Section 734, NDAA FY 18. The USU will lead three (3) of the Comprehensive Strategy for Warfighter Brain Health’s six (6) lines of effort. These three (3) lines of effort are Research; Long Term Effects of TBI; and Section 734, NDAA FY 18. Our leadership is involved in each of these three (3) lines of effort.</p> <p>- Creation of the USU/NIH Traumatic Brain Injury Research Consortium (TBIRC) to unify, streamline, and ensure visibility of all TBI-related research programs within the USU’s research enterprise. The creation of the TBIRC will enhance the USU’s development and implementation of the initiatives within the “Comprehensive Strategy for Warfighter Brain Health.” Additionally, alignment of the USU’s various TBI research programs with CNRM will allow these programs to benefit from the scientific oversight and expertise of CNRM’s NIH partners. Doing so will, ideally, accelerate progress to the benefit of America’s warfighters and the citizens of the United States.</p> <p>FY 2020 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>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 FY20 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 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.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Price adjustment.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 8.033 | 10.209 | 10.413 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|---|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA-1, 0806721HP: <i>Uniformed Services University of the Health Sciences</i> | 9.647 | 9.840 | 10.036 | - | 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 378A / <i>CoE-Breast Cancer Center of Excellence (Army)</i> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 378A: <i>CoE-Breast Cancer Center of Excellence (Army)</i> | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Breast Cancer Center of Excellence | 0.000 | - | - |
| Description: Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. | | | |
| Accomplishments/Planned Programs Subtotals | 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 2021 Defense Health Agency **Date:** February 2020

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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) 378B / <i>CoE-Breast Cancer Center of Excellence (USU)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 378B: <i>CoE-Breast Cancer Center of Excellence (USU)</i> | 19.640 | 9.916 | 10.475 | 10.685 | - | 10.685 | 10.898 | 11.116 | 11.339 | 11.566 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Breast Cancer Center of Excellence | 9.916 | 10.475 | 10.685 |
| Description: Breast Cancer CoE provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. | | | |
| FY19 Accomplishments: - Accrued hundreds of breast patients to Breast CoE core protocols - Accrued hundreds of breast patients to the ORIEN research protocol - Acquired over 5,000 new biospecimens at our Breast COE sites to the core tissue protocol - Utilized our biospecimens and data base in support of over 20 research studies - Performed critical research on young women with breast cancer, and the demographic of African-American women with breast cancer, key cohorts affecting cancer as a readiness issue for the DoD - Advanced our Immunome project to analysis and prediction model phase - Near completion of our tumor microenvironment component of APOLLO 4 (breast) proteogenomics - Developed additional research work with NCI regarding young women with breast cancer in relation to the active duty component | | | |
| FY 2020 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- | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>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 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>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 9.916 | 10.475 | 10.685 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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 2021 Defense Health Agency **Date:** February 2020

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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) 379A / <i>CoE-Gynecological Cancer Center of Excellence (Army)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 379A: <i>CoE-Gynecological Cancer Center of Excellence (Army)</i> | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Gynecological Cancer Center of Excellence (Army) | 0.000 | - | - |
| 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. | | | |
| Accomplishments/Planned Programs Subtotals | 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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 379B: <i>CoE-Gynecological Cancer Center of Excellence (USU)</i> | 17.169 | 8.668 | 9.158 | 9.341 | - | 9.341 | 9.528 | 9.719 | 9.913 | 10.111 | 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.

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 2019 | FY 2020 | FY 2021 |
| | 8.668 | 9.158 | 9.341 |
| 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. | | | |
| FY19 Accomplishments: | | | |
| - 34 Peer-Reviewed Publications | | | |
| - 16 Invited Lectures / Presentations | | | |
| - 2 Book Chapters | | | |
| - 24 Abstracts presented: | | | |
| SGO 49th Annual Meeting on Women's Cancer® in New Orleans, LA from March 23-27, 2018 (6); American Association for Cancer Research Annual Meeting in Chicago IL from April 14-18, 2018 (2); 66th ASMS Conference, San Diego, CA, June 4-8, 2018 (1); 2018 Military Health System Research Symposium at the Gaylord Convention Center in Kissimmee FL on August 20-23, | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 2018 (5); 2018 American College of Obstetricians and Gynecologists Armed Forces District Meeting in Honolulu, HI in September 2018 (3); SGO 49th Annual Meeting on Women’s Cancer® in Honolulu, HI in March 16-19, 2019 (7). | | | |
| <p><i>FY 2020 Plans:</i> The FY2020 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 of 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 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 2021 Plans:</i> FY 2021 plans continue efforts as outlined in FY 2020.</p> <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Pricing Adjustment.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 8.668 | 9.158 | 9.341 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 381A: <i>CoE-Integrative Cardiac Health Care Center of Excellence (Army)</i> | 20.780 | 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 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.

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.

No funding programmed. Beginning in FY19, the ICHP funding line is transferred from the Army to USUHS Project 381.

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

N/A

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

N/A

Remarks

N/A

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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
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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) 382A / <i>CoE-Pain Center of Excellence (Army)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Pain Center of Excellence (Army) | 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. | | | |
| Accomplishments/Planned Programs Subtotals | 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 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 382B: CoE-Pain Center of Excellence (USUHS) | 10.901 | 3.202 | 3.376 | 1.945 | - | 1.945 | 2.014 | 2.084 | 2.156 | 2.229 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>Title: Pain Center of Excellence (USUHS)</p> <p>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.</p> <p>FY19 Accomplishments: Obtained approval for the DVCIPM Pain BioBank. The Pain Registry Biobank is a clinical data registry and tissue biobank for the advancement of pain-related research. This Biobank contains PASTOR survey data, the Defense and Veterans Pain Rating Scale (DVPRS), electronic health record data, and biospecimens, (blood and saliva) on targeted individuals eligible for care within the Military Health System. Specimens are being processed in collaboration with the Center for Neuroscience and Regenerative Medicine (CNRM) laboratory.</p> <p>In addition to the DVCIPM site at Madigan Army Medical Center, additional study sites were established at Naval Medical Center San Diego and Joint Base San Antonio. Staff at these locations are seeking approval for the Pain Biobank Registry project.</p> <p>Set up Cooperative Research and Development Agreement's (CRADA) with the University of Washington, Virginia Tech, University of New Mexico and facilitated the development and implementation of PASTOR, through a CRADA at West Virginia University Medical Center. Additionally, the Defense & Veterans Pain Rating Scale (DVPRS) has been integrated into clinical practice and research outside of the DoD. Examples include the Durham VA, and West Virginia University and American Society of Acupuncturists, who rebranded the DVPRS with their own logos.</p> | 3.202 | 3.376 | 1.945 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Obtained several grants including a CDMRP Peer-Reviewed Medical Research Program grant targeting biomarkers of chronic pain maintenance and recovery, and one examining integration of massage therapy services into primary care.</p> <p>Obtained funding to execute and evaluate a pilot program, adapting the Joint Pain Education Program (JPEP) for online continuing medical education, across the National Capital Region.</p> <p>Developed and piloted a Opioid Overdose Education & Naloxone Distribution (OEND), which is now included, in part, in the Stepped Care Model training and is currently being planned for a scaled-up, enterprise-wide roll-out.</p> <p>Established a Memorandum of Agreement with the Defense Health Agency to collaborate on education, training, and research related to pain management and opioid risk reduction in the DoD. Established and maintained collaborations in DHA, providing on-going subject matter expertise and analytics. Facilitated the expansion of PASTOR to include new users and military treatment facilities and the roll-out of the Stepped Care Model for Pain. DVCIPM became a voting member on the DHA Pain Clinical Support Service.</p> <p>Published the Acute Pain Medicine Text Book which was written and edited under the auspices of Oxford Press and the American Academy of Pain Medicine’s Shared Interest Group. Acute Pain Medicine is the first comprehensive, case-based text of its kind that explores the essential topics of acute pain medicine, including interventional, pharmacologic, and diagnostic considerations</p> <p>FY 2020 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.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. Efforts will be scaled back as funds were adjusted to higher priority programs.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| As a result of internal decisions, \$10M of PE 0603115 (\$1.5M in Project Code 382B) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery. | | | |
| Accomplishments/Planned Programs Subtotals | 3.202 | 3.376 | 1.945 |

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 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 383A: <i>CoE-Prostate Cancer Center of Excellence (USUHS)</i> | 49.072 | 7.921 | 8.359 | 8.526 | - | 8.526 | 8.696 | 8.870 | 9.047 | 9.228 | 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 2019 | FY 2020 | FY 2021 |
| Title: CoE-Prostate Cancer Center of Excellence (USUHS) | 7.921 | 8.359 | 8.526 |
| <p>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.</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>Accomplishments (FY19):</p> <ul style="list-style-type: none"> Renewed infrastructure (research laboratory and CAP-certified biospecimen bank) to enhance translational research within the equal access healthcare of the DoD Introduced new and continued successful immunotherapy clinical trials, such as, ProstAtak vaccine trial as adjuvant for localized disease and for intermediate risk prostate cancer and began autologous cellular immunotherapy for active surveillance patients Continued the TRUMPET clinical trial for castration-resistant prostate cancers which assesses the effectiveness of treatment sequencing. Evaluated Rucaparib therapy of metastatic castration-resistant prostate cancers with BRCA 1 / 2, ATM, or CHEK mutations Continued the Multi-disciplinary Prostate Cancer CoE/NCI clinics to determine treatment strategies based on cutting-edge clinical trials Evaluated the predisposing germline mutation BRCA1/2 for aggressive prostate cancer for improved therapeutic stratification to enhance therapy (Petrovics et al., PCPD 2018) Completed the assessment of new and more potent derivatives of the small molecule inhibitor ERGi-USU with potential impact on precision medicine/targeted therapy for ERG positive cancers (Mohamed, Xavier et al., Cancer Research 2018) Provided new insights into the tumor suppressor function of LSAMP gene, frequently deleted in prostate cancers of African American men (Babcock et al., AACR 2019) Continued focus on racial differences in prostate cancer to develop more precise urine-based biomarkers Assessed predictors of disease progression, including: intensity of PSA screening history, comorbidity, and race-treatment interactions Conducted multiple studies to improve clinical risk stratification and better tailored treatment by complementing pathologic patient features with molecular data <p>Knowledge Products (FY19 - 9 Publications); Podium Presentations (FY19 - 7 Presentations); Poster Presentations (FY19 – 11 Presentations)</p> <p>Material Products (FY19) U.S. Issued Patent No.: US 10,238,639 B2, date of patent: March 26, 2019. Azophenols as ERG Oncogene Inhibitors U.S. Published Patent Application No.: US 2018/0024132 A1, date: January 25, 2018. Lipid, Protein, and Metabolite Markers for the Diagnosis and Treatment of Prostate Cancer U.S. Provisional Applications No.: 62/867/029 filed on June 26, 2019: Markers for the Diagnosis of Prostate Cancer</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>No.: 62/779,035 filed on December 13, 2018: Genomic Rearrangements Associated with Prostate Cancer and Methods of Using the Same</p> <p>FY 2020 Plans: Precision Medicine Focus: 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. 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. 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. 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. Enhance pre/post-operative follow-up for cancer diagnosis, progression, pain, mobility deficits and restoration of function through the CoE's long-term database. 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. 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: 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. 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. Develop innovative experimental models for establishing the mechanisms of newly discovered race/ethnicity associated prostate cancer genes towards ethnicity-informed therapeutic strategies. 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:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>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:</p> <p>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> <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:</p> <p>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 2021 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| FY 2021 plans continue efforts as outlined in FY 2020. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | | |
| Accomplishments/Planned Programs Subtotals | | 7.921 | 8.359 | 8.526 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| N/A | | | | |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 398A / <i>CoE-Neuroscience Center of Excellence (USUHS)</i> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 398A: <i>CoE-Neuroscience Center of Excellence (USUHS)</i> | 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).

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.

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)

N/A

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|---|
| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Hard Body Armor | 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. | | | |
| Accomplishments/Planned Programs Subtotals | 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 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 431A / Underbody Blast Testing (Army) | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|---|---------|------------------|------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 431A: Underbody Blast Testing (Army) | 48.611 | 10.800 | 9.200 | 0.000 | - | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Underbody Blast Testing | 10.800 | 9.200 | 0.000 |
| 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 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 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. | | | |
| FY 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 10.800 | 9.200 | 0.000 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 448A: Military HIV Research Program (Army) | 31.454 | 7.185 | 7.877 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Military HIV Research Program | 7.185 | 7.877 | 0.000 |
| 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 2020 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 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | | |
| Accomplishments/Planned Programs Subtotals | | 7.185 | 7.877 | 0.000 |
| 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. | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 830A / Deployed Warfighter Protection (Army) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 830A: <i>Deployed Warfighter Protection (Army)</i> | 34.106 | 5.713 | 6.345 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Deployed Warfighter Protection | 5.713 | 6.345 | 0.000 |
| Description: The Deployed Warfighter Protection project will develop new or improved protection for ground forces from disease-carrying insects. | | | |
| FY 2020 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 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 5.713 | 6.345 | 0.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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)

N/A

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 478: <i>Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS)</i> | 14.766 | 14.237 | 18.556 | 18.640 | - | 18.640 | 18.724 | 19.098 | 19.480 | 19.870 | 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 2019 | FY 2020 | FY 2021 |
| Title: DoD Cancer Moonshot - Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium (USUHS) | 14.237 | 18.556 | 18.640 |
| 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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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <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>FY19 Accomplishments:</p> <ul style="list-style-type: none"> - Through APOLLO 1, 2, 3, and 4 ran nearly 1,000 total cancer specimens through the DNA, RNA, and protein molecular platforms per plan. - Final data analytics completed on APOLLO 1 (lung cancer) molecular platforms, and novel findings identified. Presented at various national scientific forums including MHSRS 2019. Publications in process. - Successfully opened all of our tissue source sites and biobank for APOLLO 5 in FY19, including a total of nine military treatment facilities across DHA. - Successfully began accruing APOLLO 5 prospective samples from one of our sites, and achieved IRB approval of APOLLO 5 at two additional sites (WR Bethesda and NMCS D). <p>FY 2020 Plans: Identify serum specimens and run them through the serum protein analysis lab platform, and perform initial data analytics on the results.</p> <p>FY 2021 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | Date: February 2020 |
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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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| FY 2021 Plans continue efforts as outlined in FY 2020 | | | |
| <i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 14.237 | 18.556 | 18.640 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 479: Framingham Longitudinal Study (USUHS) | 4.920 | 4.746 | 4.920 | 4.920 | - | 4.920 | 4.920 | 5.018 | 5.118 | 5.220 | 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.

FY19 Accomplishments:

- Completed all mass spectrometry proteomic analysis of Framingham 1 specimens (approximately 900)
- Analyzed Framingham 1 data, identified important novel scientific findings, and presented these findings at four national and international meetings in FY19 including MHSRS 2019.
- Working on Framingham 1 publication manuscript
- Identified Framingham 2 and 3 serum specimens and began process of mass spectrometry workflow
- Identified Framingham 4 organ site (pancreatic cancer) and began scientific protocol development with combined DoD / NCI team

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: DoD Cancer Moonshot Program - DoD Framingham Longitudinal Study | 4.746 | 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 | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 479 / Framingham Longitudinal Study (USUHS) |

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>after their successful cancer treatment. Four different serum specimens (two before, one during, and one after cancer diagnosis and treatment) from every ADASM 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 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 ADASM 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 ADASM 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 2020 Plans: Continue to identify Framingham serum specimens and conduct serum protein analysis lab platform, and perform initial data analytics on the results.</p> <p>FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding remains the same.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 4.746 | 4.920 | 4.920 |

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

| | | | |
|-----|--|--|--|
| N/A | | | |
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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 499 / MHS Financial System Acquisition (DHA) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 499: MHS Financial System Acquisition (DHA) | 15.222 | 20.358 | 15.373 | 1.971 | - | 1.971 | 6.011 | 6.051 | 6.092 | 6.143 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: MHS Financial System Acquisition | 20.358 | 15.373 | 1.971 |
| 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 2020 Plans: Additional research funding necessary to continue the consolidation all DHP appropriations into a single Financial Management System (FMS) system to provide the following capabilities: | | | |
| FY 2021 Plans: Deployment requirements for the Navy go down and shift towards the operation and maintenance. This program may increase in later years pending potential GFEBS deployment to AF and acceleration in existing acquisitions. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Deployment requirements for the Navy go down and shift towards the operation and maintenance. This program may increase in later years pending potential GFEBS deployment to AF and acceleration in existing acquisitions. | | | |
| Accomplishments/Planned Programs Subtotals | 20.358 | 15.373 | 1.971 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 (DHA)</i> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|---|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA 3: <i>PE 0807721</i> <i>Replacement & Modernization</i> | 10.409 | 22.611 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |

Remarks

D. Acquisition Strategy

Acquisition Strategy is to be determined.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
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| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 381: CoE - Integrative Cardiac Health Care (USUHS) | 0.000 | 2.811 | 3.118 | 1.680 | - | 1.680 | 1.744 | 1.809 | 1.875 | 1.943 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Integrative Cardiac Health Center of Excellence | 2.811 | 3.118 | 1.680 |
| 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. | | | |
| FY 2020 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. | | | |
| FY 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| FY 2021 Plans continue efforts as outlined in FY 2020. Efforts will be scaled back as funds were adjusted to higher priority programs. | | | |
| <i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> As a result of internal decisions, \$10M of PE 0603115 (\$1.5M in Project Code 381) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery. | | | |
| Accomplishments/Planned Programs Subtotals | 2.811 | 3.118 | 1.680 |

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

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 (Army) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 504: WRAIR Vaccine Production Facility Research (Army) | 0.000 | 8.000 | 8.152 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: WRAIR Vaccine Production Facility | 8.000 | 8.152 | 0.000 |
| 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 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 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 8.000 | 8.152 | 0.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 (Army)</i> |

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

Remarks

D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 506: Health Research for Improved Medical Readiness and Healthcare Delivery (USUHS) | 0.000 | 0.000 | 11.904 | 11.141 | - | 11.141 | 11.385 | 11.631 | 11.883 | 12.141 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>Title: Health Research for Improved Medical Readiness and Healthcare Delivery</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> | 0.000 | 11.904 | 11.141 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <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 2020 Plans: Health Services Research: - 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.</p> <p>Global Health Engagement: - 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</p> <p>Precision Medicine: - 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.</p> <p>Women's Health research: - 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.</p> <p>Infectious Disease Research: - Execute multisite research through a robust sustainable MHS research network, with capability to execute FDA-regulated clinical trials.</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <p>- 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.</p> <p><i>FY 2021 Plans:</i> FY 2021 Plans continue efforts as outlined in FY 2020. Efforts will be scaled back as funds were adjusted to higher priority programs.</p> <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> As a result of internal decisions, \$10M of PE 0603115 (\$1.0M in Project Code 506) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 11.904 | 11.141 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|---|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 507: Brain Injury and Disease Prevention, Treatment and Research (USUHS) | 0.000 | 0.000 | 13.317 | 13.583 | - | 13.583 | 13.855 | 14.132 | 14.415 | 14.703 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Brain Injury and Disease Prevention, Treatment and Research | 0.000 | 13.317 | 13.583 |
| 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. | | | |
| FY 2020 Plans: The USUHS plans for FY 2020 are to: - 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. | | | |
| FY 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Annual price adjustment. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 13.317 | 13.583 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|---|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 508: Psychological Health and Resilience (USUHS) | 0.000 | 0.000 | 7.000 | 7.140 | - | 7.140 | 7.283 | 7.428 | 7.577 | 7.729 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Psychological Health and Resilience | 0.000 | 7.000 | 7.140 |
| 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 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 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 7.000 | 7.140 |

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

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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)

Remarks

D. Acquisition Strategy

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 509 / Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 509: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness (USUHS) | 0.000 | 0.000 | 19.323 | 13.710 | - | 13.710 | 14.104 | 14.505 | 14.916 | 15.334 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Innovative Technologies for Improved Medical Diagnoses, Rehabilitation and Warfighter Readiness | 0.000 | 19.323 | 13.710 |
| <p>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.</p> <p>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.</p> <p>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</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <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 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 2021 Plans: FY 2021 Plans continue efforts as outlined in FY 2020. The Technology Research Program efforts will be scaled back as funds were adjusted to higher priority programs.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| As a result of internal decisions, \$10M of PE 0603115 (\$6.0M in Project Code 509) was re-prioritized which reduced research funding in the areas of health services delivery improvement, pain management and alternatives to opioids, cardiac health, and the development of technologies supporting warfighter health and recovery. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 19.323 | 13.710 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 373 / GDF - Medical Technology Development | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 373: GDF - Medical Technology Development | 1,006.232 | 123.885 | 78.868 | 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 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 2019 | FY 2020 | FY 2021 |
| Title: GDF – Medical Technology Development | 123.885 | 78.868 | 0.000 |
| 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 2020 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 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 373 / <i>GDF - Medical Technology Development</i> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <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 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 373 / <i>GDF - Medical Technology Development</i> |

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <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.</p> <p>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 2021 Plans: Efforts realigned to PE 0603115DHA Project Codes 373A-G.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 373 / <i>GDF - Medical Technology Development</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Efforts realigned to PE 06031115DHA Project Codes 373A-G. | | | |
| Accomplishments/Planned Programs Subtotals | 123.885 | 78.868 | 0.000 |

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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) 373A / <i>GDF - MTD (Combat Casualty Care)</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373A: <i>GDF - MTD (Combat Casualty Care)</i> | - | 0.000 | 0.000 | 11.168 | - | 11.168 | 15.736 | 16.756 | 19.649 | 20.114 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Medical Technology Development provides funds for the development of promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or human clinical trials regulated by the U. S. Food and Drug Administration prior to licensing for human use. Joint Battlefield Healthcare research is optimizing survival, recovery and rehabilitation in injured Service members across the spectrum of care from point of injury through enroute care and facilities care.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care) | 0.000 | - | 11.168 |
| Description: Joint Battlefield Healthcare medical technology development will continue to focus on investigating new diagnostic tools and treatments for prolonged battlefield hemorrhage control, how to best diagnose and treat severe neurotrauma from the point of injury to evacuation/enroute care and long term hospital and rehabilitative care, and research into optimizing the system wide movement of patients to different levels of care to ensure positive clinical outcomes. | | | |
| FY 2021 Plans: Joint Battlefield Healthcare medical technology development will continue to focus on investigating new diagnostic tools and treatments for prolonged battlefield hemorrhage control, how to best diagnose and treat severe neurotrauma from the point of injury to evacuation/enroute care and long term hospital and rehabilitative care, and research into optimizing the system wide movement of patients to different levels of care to ensure positive clinical outcomes. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | 11.168 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 373B / GDF - MTD (Military Operational Medicine) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373B: GDF - MTD (Military Operational Medicine) | - | 0.000 | 0.000 | 23.255 | - | 23.255 | 19.046 | 19.116 | 18.151 | 18.557 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Conduct proof of technological feasibility studies and experiments and/or assessment of operability and producibility to address a military medical need identified through the Joint Capabilities Integration and Development System. Efforts are directed towards prototypes for field experiments and/or tests in a simulated environment, assessment/proof of feasibility or demonstration of utility/cost reduction that support medical countermeasures against operational stressors, or that prevent musculoskeletal, neurosensory, and psychological injuries during training and from point of injury through role of care four.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Military Health and Recovery (Formerly Military Operational Medicine) | 0.000 | - | 23.255 |
| Description: Efforts focus on: Injury prevention and recovery; Optimized cognition and fatigue management; Psychological health and resilience; and, Performance in extreme environments. Activities will continue to focus on: injury prevention and recovery related to musculoskeletal injury; fatigue, cognitive health and performance; human operator health and performance in complex systems; operational systems toxicology for environmental health hazards; protection and performance sustainment in extreme environments; optimization of psychological health and resilience; and diagnosis & treatment of mental health disorders. | | | |
| FY 2021 Plans: Efforts focus on: Injury prevention and recovery; Optimized cognition and fatigue management; Psychological health and resilience; and, Performance in extreme environments. Activities will continue to focus on: injury prevention and recovery related to musculoskeletal injury; fatigue, cognitive health and performance; human operator health and performance in complex systems; operational systems toxicology for environmental health hazards; protection and performance sustainment in extreme environments; optimization of psychological health and resilience; and diagnosis & treatment of mental health disorders. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | 23.255 |

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

N/A

Remarks

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|---|---|---|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 373B / <i>GDF - MTD (Military Operational Medicine)</i> |

D. Acquisition Strategy
N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 373C / GDF - MTD (Medical Simulation & Training/Health Informatics) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 373C: GDF - MTD (Medical Simulation & Training/Health Informatics) | - | 0.000 | 0.000 | 12.613 | - | 12.613 | 13.044 | 13.339 | 13.637 | 13.942 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Conduct proof of technological feasibility studies and experiments and/or assessment of operability and producibility to address a military medical need identified through the Joint Capabilities Integration and Development System. Efforts are directed towards prototypes for field experiments and/or tests in a simulated environment, assessment/proof of feasibility or demonstration of utility/cost reduction that support medical simulation to increase military medical personnel's knowledge, skills and abilities to deliver combat casualty care support to manage patient injury and illness and to conduct patient movement from point of injury through role of care four.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics) | 0.000 | - | 12.613 |
| Description: Studies, investigations, and non-system specific technology effort focus on prototyping tissue models, technologies that simulate medical condition progress over time, technologies that simulate injury, technologies that replicate warfighter bio-physiology, and, technologies that simulate high-fidelity combat casualty care scenarios. Activities will continue to focus on tissue models that accurately simulate the feel, pliability, flexibility, and responsiveness of live tissue; technologies that simulate the degradation or worsening of a medical condition over time, as well as simulate the improvement of a medical condition over time; technologies that simulate injury, especially hemorrhage, fractures, and ocular damage; technologies that accurately reflect warfighter bodily characteristics and are rugged enough to simulate patient care and movement throughout the entire continuum of care; technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care. | | | |
| FY 2021 Plans: Studies, investigations, and non-system specific technology effort focus on prototyping tissue models, technologies that simulate medical condition progress over time, technologies that simulate injury, technologies that replicate warfighter bio-physiology, and, technologies that simulate high-fidelity combat casualty care scenarios. Activities will continue to focus on tissue models that accurately simulate the feel, pliability, flexibility, and responsiveness of live tissue; technologies that simulate the degradation or worsening of a medical condition over time, as well as simulate the improvement of a medical condition over time; technologies that simulate injury, especially hemorrhage, fractures, and ocular damage; technologies that accurately reflect warfighter bodily characteristics and are rugged enough to simulate patient care and movement throughout the entire continuum of care; | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 373C / <i>GDF - MTD (Medical Simulation & Training/Health Informatics)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | | |
| Accomplishments/Planned Programs Subtotals | | 0.000 | - | 12.613 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| N/A | | | | |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|---|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 373D / GDF - MTD (Clinical and Rehabilitation Medicine) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373D: GDF - MTD (Clinical and Rehabilitation Medicine) | - | 0.000 | 0.000 | 13.040 | - | 13.040 | 14.980 | 15.034 | 14.275 | 14.595 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Clinical and rehabilitative medicine activities continue to develop knowledge and materiel products to reconstruct, rehabilitate, and provide care for injured Service member in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and sensory systems.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Clinical and Rehabilitation Medicine | - | - | 13.040 |
| Description: Clinical and rehabilitation medicine efforts will continue to support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment, and rehabilitation outcomes for Service-related injuries. Develop solutions (knowledge and materiel) for the diagnosis and alleviation of pain, restoration or regeneration of neuromusculoskeletal tissues, and sensory system (ocular) rehabilitation and treatment. | | | |
| FY 2021 Plans: Clinical and rehabilitation medicine efforts will continue to support clinical trials in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment, and rehabilitation outcomes for Service-related injuries. Develop solutions (knowledge and materiel) for the diagnosis and alleviation of pain, restoration or regeneration of neuromusculoskeletal tissues, and sensory system (ocular) rehabilitation and treatment. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 13.040 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 373E / GDF - MTD (Military Infectious Disease) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373E: GDF - MTD (Military Infectious Disease) | - | 0.000 | 0.000 | 6.409 | - | 6.409 | 6.630 | 6.779 | 6.932 | 7.087 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Military infectious disease efforts continue to focus on the development of protection and treatment products for military relevant infectious diseases.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Military Infectious Disease | - | - | 6.409 |
| Description: Military infectious disease activities to support efforts (including clinical) to develop innovative therapeutics and delivery technologies for combat wound infections. These efforts include Combating Antibiotic Resistant bacteria as well as accelerating promising drug and vaccine solutions to emerging infectious diseases (e.g. chikungunya, MERS, and Zika). | | | |
| FY 2021 Plans: Military infectious disease activities to support efforts (including clinical) to develop innovative therapeutics and delivery technologies for combat wound infections. These efforts include Combating Antibiotic Resistant bacteria as well as accelerating promising drug and vaccine solutions to emerging infectious diseases (e.g. chikungunya, MERS, and Zika). | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 6.409 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | Project (Number/Name) 373F / GDF - MTD (Radiological Health Effects) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 373F: GDF - MTD (Radiological Health Effects) | - | 0.000 | 0.000 | 0.501 | - | 0.501 | 0.518 | 0.531 | 0.542 | 0.554 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Research and development in countermeasures for acute radiation exposure leading toward identification of post-exposure treatment of radiation injury. Developing an FDA-approved countermeasure for both pre-exposure prophylaxes and post-exposure treatments of acute radiation syndrome (ARS) will help improve health outcomes for radiation exposure injuries.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Radiological Health Effects | - | - | 0.501 |
| Description: Develop in vivo models, assays, and other enabling technologies to support transition of candidate MCM(s) and to reduce risk during advanced development. This efforts will include the identification and characterization of biomarkers to establish novel druggable targets, understanding differences in species sensitivity to radiation, evaluating direct and indirect mechanisms of actions of high and low linear energy transfer (LET) radiation sources (e.g., neutrons, gamma), and, determining radiosensitivity and radioresistance of various systems/organs. | | | |
| FY 2021 Plans: Develop in vivo models, assays, and other enabling technologies to support transition of candidate MCM(s) and to reduce risk during advanced development. This efforts will include the identification and characterization of biomarkers to establish novel druggable targets, understanding differences in species sensitivity to radiation, evaluating direct and indirect mechanisms of actions of high and low linear energy transfer (LET) radiation sources (e.g., neutrons, gamma), and, determining radiosensitivity and radioresistance of various systems/organs. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 0.501 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0603115DHA / Medical Technology Development | | | | Project (Number/Name) 373G / GDF - MTD (Military Medical Photonics) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 373G: GDF - MTD (Military Medical Photonics) | - | 0.000 | 0.000 | 10.000 | - | 10.000 | 10.200 | 10.404 | 10.612 | 10.824 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Conduct proof of technological feasibility studies and experiments and/or assessment of operability and producibility to address military medical needs identified through the Joint Capabilities Integration and Development System. Efforts are directed towards prototypes for field experiments and/or tests in a simulated environment, assessment/proof of feasibility or demonstration of utility/cost reduction that support development and utilization of optical science and technology for diagnostic, imaging, and therapeutic solutions in support of combat casualty care.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Military Medical Photonics | - | - | 10.000 |
| Description: The Military Medical Photonics Program is an interdisciplinary program of physical and biological scientists, engineers, and physicians addressing diagnostic and therapeutic needs to support combat casualty care. Activities will continue to focus on diagnostic, imaging, and therapeutic studies. Specific efforts include: Photochemical tissue bonding for wound repair, passivation, and vein stiffening for abnormal connections between an artery and a vein; Optical applications for treatment and prevention of wound contamination and scarring, and to support wound healing and cartilage regeneration; Photonics-based diagnostics, including early detection of airway inhalation injury and implantable biomarker sensors; Investigations of photonics technologies to support the prolonged shelf life of human platelets; and Photobiomodulation to affect cognitive function. | | | |
| FY 2021 Plans: The Military Medical Photonics Program is an interdisciplinary program of physical and biological scientists, engineers, and physicians addressing diagnostic and therapeutic needs to support combat casualty care. Activities will continue to focus on diagnostic, imaging, and therapeutic studies. Specific efforts include: Photochemical tissue bonding for wound repair, passivation, and vein stiffening for abnormal connections between an artery and a vein; Optical applications for treatment and prevention of wound contamination and scarring, and to support wound healing and cartilage regeneration; Photonics-based diagnostics, including early detection of airway inhalation injury and implantable biomarker sensors; Investigations of photonics technologies to support the prolonged shelf life of human platelets; and Photobiomodulation to affect cognitive function. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned from Project Code 373. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 10.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0603115DHA / <i>Medical Technology Development</i> | Project (Number/Name) 373G / <i>GDF - MTD (Military Medical Photonics)</i> |

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

Remarks

D. Acquisition Strategy
N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i> |
|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 1,264.357 | 158.933 | 138.055 | 132.331 | - | 132.331 | 142.252 | 145.097 | 147.999 | 150.959 | Continuing | Continuing |
| 400Z: <i>CSI - Congressional Special Interests</i> | 354.527 | 46.816 | 10.000 | 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> | 18.617 | 4.000 | 4.000 | 4.080 | - | 4.080 | 4.162 | 4.245 | 4.330 | 4.417 | Continuing | Continuing |
| 374: <i>GDF - Medical Products Support and Advanced Concept Development</i> | 891.213 | 108.117 | 124.055 | 128.251 | - | 128.251 | 138.090 | 140.852 | 143.669 | 146.542 | Continuing | Continuing |
| 374A: <i>GDF - MPSAACD (Medical Modeling and Simulation)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 374B: <i>GDF - MPSAACD (Medical Readiness)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 374C: <i>GDF - MPSAACD (Medical Combat Support)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 374D: <i>GDF - MPSAACD (Restoration and Healthcare Systems)</i> | - | 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 Support and Advanced Concept Development: This program element (PE) provides funding to support: advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record; and medical simulation and training system technologies.

Development, test, and evaluation in this PE is designed to address requirements identified through the Joint Capabilities Integration and Development System and other Department of Defense operational needs. Medical development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the National Defense Strategy, the Joint Staff Surgeon's Joint Concept for Health Services, and other overarching DoD strategic framework documents.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i> |
|---|--|

Program development and execution is coordinated with all of the Military Services and Special Operations Command, 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 Defense Health Agency Component Acquisition Executive (DHA CAE) as the Milestone Decision Authority for medical materiel development efforts. As technologies mature, the most promising efforts will transition to medical products and support systems development funding, PE 0605145.

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 161.094 | 128.055 | 132.331 | - | 132.331 |
| Current President's Budget | 158.933 | 138.055 | 132.331 | - | 132.331 |
| Total Adjustments | -2.161 | 10.000 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 10.000 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -2.161 | - | | | |

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 – *CSI - 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 2019 | FY 2020 |
|---|----------------|----------------|
| | 2.540 | 0.000 |
| | 21.785 | 10.000 |
| | 22.491 | 0.000 |
| | 0.000 | 0.000 |
| Congressional Add Subtotals for Project: 400Z | 46.816 | 10.000 |
| Congressional Add Totals for all Projects | 46.816 | 10.000 |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development | Project (Number/Name) 400Z / CSI - Congressional Special Interests |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 400Z: CSI - Congressional Special Interests | 354.527 | 46.816 | 10.000 | 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 2019 | FY 2020 |
|---|---------|---------|
| Congressional Add: 427A - Traumatic Brain Injury / Psychological Health <i>FY 2019 Accomplishments:</i> CSI Add <i>FY 2020 Plans:</i> N/A | 2.540 | 0.000 |
| Congressional Add: 441A - Joint Warfighter Medical Research Program <i>FY 2019 Accomplishments:</i> CSI Add <i>FY 2020 Plans:</i> CSI Add | 21.785 | 10.000 |
| Congressional Add: 464A – CSI - Program Increase: Restore Core Research Funding Reduction (GDF) <i>FY 2019 Accomplishments:</i> CSI Restoral Add <i>FY 2020 Plans:</i> N/A | 22.491 | 0.000 |
| Congressional Add: PC 540 - CSI HIV/AIDS Prevention Program <i>FY 2019 Accomplishments:</i> CSI Add <i>FY 2020 Plans:</i> N/A | 0.000 | 0.000 |
| Congressional Adds Subtotals | 46.816 | 10.000 |

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

N/A

Remarks

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|---|--|---|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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.

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 434A: <i>Medical Products Support and Advanced Concept Development (AF)</i> | 18.617 | 4.000 | 4.000 | 4.080 | - | 4.080 | 4.162 | 4.245 | 4.330 | 4.417 | 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 AF/SG's aerospace & operational medicine and medical readiness, enabling AF/SG key mission areas and major programs (e.g. Critical Care Air Transport Teams, Operational Support Teams, Operational Medical Readiness Squadrons) to deliver and sustain medical warfighting capabilities. 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 2019 | FY 2020 | FY 2021 |
| Title: Medical Products Support and Advanced Concept Development (AF) | 4.000 | 4.000 | 4.080 |
| 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 2020 Plans: | | | |
| Continue 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. Begin 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| 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; Continue development of patient loading and transport products. FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020. FY 2020 to FY 2021 Increase/Decrease Statement: Inflationary price increases. | | | |
| Accomplishments/Planned Programs Subtotals | 4.000 | 4.000 | 4.080 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development | | | | | Project (Number/Name) 374 / GDF - Medical Products Support and Advanced Concept Development | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost | |
| 374: GDF - Medical Products Support and Advanced Concept Development | 891.213 | 108.117 | 124.055 | 128.251 | - | 128.251 | 138.090 | 140.852 | 143.669 | 146.542 | 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 materiel development of products that provide solutions for the most pressing medical needs of the Warfighter through advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record; and medical simulation and training system technologies.

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: GDF – Medical Product Support and Advanced Concept Development | 108.117 | 124.055 | 128.251 |
| Description: This funding provides product support and advanced concept development of materiel products that meet the medical needs of the warfighter. Materiel development may include accelerated transition of US Food and Drug Administration (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 2020 Plans: | | | |
| Medical Modeling and Simulation: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. The Point-of-Injury and Trauma Simulation program will continue capability development tying together individual, collective, service and Joint training to Warfighters and Medical Professionals across the Department of Defense. The Hospital Training Simulation Systems and Evacuation and Transportation Simulation Systems programs will continue to develop, standardize and baseline the Medical Treatment Facility, Theater Hospital training (care and procedures), and en-route patient care training for interoperability. The Learning, Tactics and Technology Systems program will continue to develop the training courses, hands-on training, and exercises to develop and maintain military medical skills that enhance and maximize the training simulations, manikins and healthcare across the Department of Defense. | | | |
| Medical Readiness: Programs will focus on prevention of illness and injury along with optimization of human performance. The Pharmaceutical Intervention for Noise-Induced Hearing Loss-Acute Exposure Treatment program will continue development of the | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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) 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Capability Development Document with Key Performance Parameters and continue progress with an on-going clinical trial with a promising drug treatment candidate.</p> <p>Medical Combat Support: Programs will focus on operational support. The Hemorrhage Detection program will continue development of the Capability Development Document with Key Performance Parameters along with a laboratory-based technology analysis study to inform ability for the capability to be deployed to Roles 1-3. The Traumatic Brain Injury (TBI) Point of Injury Triage Device program will continue to integrate information from end user feedback, field evaluations in the deployed environment, and market research to identify a solution to aid the medical provider in the ability to triage and monitor a moderate/severe TBI. The Non-Compressible Hemorrhage Control program will continue to expand as a family of systems approach to identify potential solutions that would fulfill this gap. Efficacy of developmental items will be evaluated in clinical studies. The Joint Medical Exchange and Documentation of Information for Combat Casualty Care program will continue to conduct prototype demonstrations in operational and simulated field environments.</p> <p>Restoration and Healthcare Systems: Programs will focus on treatments to be used to restore form and function to warfighters as well as improve healthcare. The Traumatic Brain Injury-Drug Treatment program will continue to evaluate market research to identify possible TBI drug candidates that are ready for focused Phase II clinical trials and conduct clinical trial planning. The Post Traumatic Stress Disorder-Drug Treatment program will continue to explore options for simultaneous testing of multiple drugs using an innovative testing design.</p> <p>FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 108.117 | 124.055 | 128.251 |

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| C. Other Program Funding Summary (\$ in Millions) |
| N/A |
| Remarks |
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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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) 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i> |

D. Acquisition Strategy

This program will test and evaluate pharmaceuticals, devices, medical support systems, and medical information technologies in government-managed clinical trials and user assessments to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval, Environmental Protection Agency registration, and safe-to-fly evaluation.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 - MPSAACD (Medical Modeling and Simulation)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 374A: <i>GDF - MPSAACD (Medical Modeling and Simulation)</i> | - | 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

J4 CAE will update for FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: GDF - Medical Modeling and Simulation | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|---|
| 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) 374B / <i>GDF - MPSAACD (Medical Readiness)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 374B: <i>GDF - MPSAACD (Medical Readiness)</i> | - | 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

J4 CAE will update for FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: GDF - Medical Readiness | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--|--|
| 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) 374C / <i>GDF - MPSAACD (Medical Combat Support)</i> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 374C: <i>GDF - MPSAACD (Medical Combat Support)</i> | - | 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

J4 CAE will update for FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: GDF - Medical Combat Support | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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) 374D / <i>GDF - MPSAACD (Restoration and Healthcare Systems)</i> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 374D: <i>GDF - MPSAACD (Restoration and Healthcare Systems)</i> | - | 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

J4 CAE will update for FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: GDF - Restoration and Healthcare Systems | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 0605013DHA / <i>Information Technology Development</i> |
|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 348.226 | 24.306 | 23.780 | 16.344 | - | 16.344 | 16.492 | 16.174 | 16.498 | 16.829 | 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> | 4.187 | 1.407 | 0.000 | 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> | 3.910 | 2.588 | 2.740 | 2.796 | - | 2.796 | 2.851 | 2.908 | 2.966 | 3.026 | Continuing | Continuing |
| 283C: <i>Medical Operational Data System (MODS) (Army)</i> | 10.999 | 2.632 | 2.759 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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> | 0.202 | 0.077 | 0.000 | 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> | 1.361 | 0.337 | 0.350 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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> | 1.064 | 0.319 | 0.473 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2021 Defense Health Agency | | | | | | | | | | | Date: February 2020 | | |
|---|--------|-------|-------|-------|--|-------|-------|-------|-------|-------|---------------------|------------|------------|
| 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) | 2.662 | 1.370 | 1.450 | 0.465 | - | 0.465 | 0.465 | 0.427 | 0.427 | 0.427 | 0.427 | 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) | 20.010 | 0.000 | 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) | 19.772 | 5.357 | 3.868 | 8.714 | - | 8.714 | 8.719 | 8.293 | 8.468 | 8.646 | 8.646 | 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 2021 Defense Health Agency | | | | | | | | | | | Date: February 2020 | | |
|--|--------|-------|-------|-------|--|-------|-------|-------|-------|-------|---------------------|------------|------------|
| 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) | 8.178 | 0.000 | 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) | 16.761 | 4.047 | 4.284 | 4.369 | - | 4.369 | 4.457 | 4.546 | 4.637 | 4.730 | | 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) | 1.317 | 0.000 | 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) | 0.995 | 0.641 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 485: Legacy Data Repository (DHA-C) | 0.000 | 5.531 | 5.856 | 0.000 | - | 0.000 | 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 | 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 | | | | | | | | | | | | | |

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency Date: February 2020

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

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 2021 Defense Health Agency | Date: February 2020 |
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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 0605013DHA I <i>Information Technology Development</i> |
|---|---|

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 25.228 | 23.780 | 19.844 | - | 19.844 |
| Current President's Budget | 24.306 | 23.780 | 16.344 | - | 16.344 |
| Total Adjustments | -0.922 | 0.000 | -3.500 | - | -3.500 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.922 | - | | | |
| • Departmental decision to transfer Army Medical to Army Line as a readiness initiative. | - | - | -3.500 | - | -3.500 |

Change Summary Explanation

FY 2021: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------|-------------------------|-------------------|
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | | | | Project (Number/Name) 239B / Health Services Data Warehouse (Air Force) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 239B: Health Services Data Warehouse (Air Force) | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-1, 0807781HP: Non-Central Information Management/Information Technology | 0.000 | 0.000 | 0.000 | - | 0.000 | - | - | - | - | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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| | | | | | | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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)

| | | | | | |
|--|----------------|----------------|----------------|---|---|
| | FY 2019 | FY 2020 | FY 2021 | | |
| Title: 239F IM/IT Test Bed (Air Force) | 0.000 | - | - | | |
| 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. | | | | | |
| Accomplishments/Planned Programs Subtotals | | | 0.000 | - | - |

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

| | | | | | | | | | | | |
|------------------|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| • N/A: N/A | - | - | - | - | - | - | - | - | - | | |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | | | | | | | | | | | |
|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------|-------------------------|-------------------|
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | | | | Project (Number/Name) 239G / MHS Information Portal (MIP) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 239G: MHS Information Portal (MIP) | 4.187 | 1.407 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: MHS Information Portal | 1.407 | - | - |
| 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 | | | |
| Accomplishments/Planned Programs Subtotals | 1.407 | - | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-1, 0807793DHA: MHS Tri-Service Information | 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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 239H: <i>IM/IT Test Bed (Air Force) at DHA</i> | 3.910 | 2.588 | 2.740 | 2.796 | - | 2.796 | 2.851 | 2.908 | 2.966 | 3.026 | 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 2019 | FY 2020 | FY 2021 |
| Title: Operational Testing Service | 2.588 | 2.740 | 2.796 |
| 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 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 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 2021 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| 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 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 2.588 | 2.740 | 2.796 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 283C: <i>Medical Operational Data System (MODS) (Army)</i> | 10.999 | 2.632 | 2.759 | 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 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Medical Operational Data System (MODS) | 2.632 | 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 2020 Plans: 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 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 2.632 | 2.759 | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| • BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i> | 13.628 | 13.878 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |
| • BA-3, 0807721HP: <i>Replacement/Modernization</i> | 0.400 | 0.200 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
|------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|

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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|----------------|-------------------------|-------------------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
| 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 | - |
| FY 2020 Plans: No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: N/A | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| • BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i> | 8.705 | 3.936 | 5.626 | - | 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 | - | - | Continuing | Continuing |
| • BA-1, 0807798HP: <i>Management Headquarters</i> | 2.830 | 2.880 | 2.879 | - | 2.879 | 2.882 | 2.884 | - | - | Continuing | Continuing |

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|---|---|---|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</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>FY 2025</u> | <u>Cost To</u> | |
|--|----------------|----------------|----------------|------------|--------------|----------------|----------------|----------------|----------------|-----------------|-------------------|
| | | | <u>Base</u> | <u>OCO</u> | <u>Total</u> | | | | | <u>Complete</u> | <u>Total Cost</u> |
| • BA-1, 0807796HP: <i>Base Operations</i> | 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | Project (Number/Name) 283H / Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 283H: <i>Psychological and Behavioral Health - Tools for Evaluation, Risk, and Management (PBH-TERM)</i> | 0.202 | 0.077 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Psychological and Behavioral Health – Tools for Evaluation, Risk, and Management (PBH-TERM) | 0.077 | 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 2020 Plans: No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: End of program. | | | |
| Accomplishments/Planned Programs Subtotals | 0.077 | 0.000 | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 | - | - | Continuing | Continuing |

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|---|---|---|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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)

| <u>Line Item</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>FY 2025</u> | <u>Cost To</u> | |
|---|----------------|----------------|----------------|------------|--------------|----------------|----------------|----------------|----------------|-----------------|-------------------|
| | | | <u>Base</u> | <u>OCO</u> | <u>Total</u> | | | | | <u>Complete</u> | <u>Total Cost</u> |
| • BA-1, 0807714HP: <i>other health Activities</i> | 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 | - | - | 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|---|---|
| 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> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Antibiotic Resistance Monitoring and Research (ARMoR-D) | 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 2020 Plans: No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: N/A. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i> | 0.684 | 0.700 | 0.719 | - | 0.719 | 0.735 | 0.829 | - | - | Continuing | Continuing |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
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Remarks

D. Acquisition Strategy

Evaluate and use the most appropriate business, technical, contract and support strategies and acquisition approach to minimize costs, reduce program risks, and remain within schedule while meeting 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 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 283L: <i>Pharmacovigilance Defense Application System</i> | 1.361 | 0.337 | 0.350 | 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 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Pharmacovigilance Defense Application System (PVDAS) | 0.337 | 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 2020 Plans: Funding will be used to implement the testing of the drug surveillance and data visualization capabilities that were developed during fiscal year. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 0.337 | 0.350 | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 | - | - | Continuing | Continuing |
| • BA-1, 0807714HP: <i>Other Health Activities</i> | 1.036 | 2.048 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |
| • BA-1, 0807798HP: <i>Management Headquarters</i> | 1.600 | 1.650 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
|------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|

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 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Business Intelligence Competency Center (BICC) | 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 2020 Plans: No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: N/A. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | - |

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

| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| • BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i> | 0.000 | 0.000 | - | - | - | - | - | - | - | Continuing | Continuing |
| • BA-3, 0807721HP: <i>Replacement/Modernization</i> | 0.000 | 0.000 | - | - | - | - | - | - | - | Continuing | Continuing |

Remarks

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-1, 0807781HP: <i>Non-Central Information Management/Information Technology</i> | 0.114 | 0.115 | 0.117 | - | 0.117 | - | - | - | - | Continuing | Continuing |
| • BA-1, 0807715HP: <i>Dental Care Activities</i> | 13.386 | 13.656 | 13.851 | - | 13.851 | - | - | - | - | Continuing | Continuing |
| • BA-3, 0807721HP: <i>Replacement/Modernization</i> | 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 283P: <i>Mobile HealthCare Environment (MHCE)</i> | 1.064 | 0.319 | 0.473 | 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 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Mobile HealthCare Environment (MHCE) | 0.319 | 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 2020 Plans: Funding will be utilized to finalize the expansion of the MHCE functionality deployed 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 to FY 2021 Increase/Decrease Statement: Programmed effort and funding transferred to the Department of the Army (PE 0603115A Project EB3) as part of the Readiness Transfer for FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 0.319 | 0.473 | - |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021 Base</u> | <u>FY 2021 OCO</u> | <u>FY 2021 Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| • BA-1, 0807781HP: <i>Non-Central Information Management/ Information Technology</i> | 1.477 | 1.551 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |

Remarks

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 | | |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | Project (Number/Name) 423B / Defense Center of Excellence (Army) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Defense Center of Excellence (Army) | 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 2020 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
| No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: N/A | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | - |

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|---|----------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| • 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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 423C: <i>Defense Center of Excellence (T2T/PBH TERM) (DHA)</i> | 2.662 | 1.370 | 1.450 | 0.465 | - | 0.465 | 0.465 | 0.427 | 0.427 | 0.427 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Defense Center of Excellence (DHA) T2T and PBH TERM | 1.370 | 1.450 | 0.465 |
| <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 2020 Plans: Develop six mobile applications, three websites, 2 3D applications and one data warehouse (T2T). Further develop microservices for the web/mobile platform.</p> <p>FY 2021 Plans: Support for web services development software.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Decrease between FY 2020 to FY 2021 is due to larger development efforts and support contracts awarded in FY 2020 as compared to FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 1.370 | 1.450 | 0.465 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

- 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|----------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| • 4187 807783: <i>NCMT</i> | - | - | - | - | - | - | - | - | - | | |
| • 4187 807781: <i>NCMT</i> | - | - | - | - | - | - | - | - | - | | |
| • 1690 807781: <i>HEIS</i> | - | - | - | - | - | - | - | - | - | | |
| • 4859 807781: <i>JMED</i> | - | - | - | - | - | - | - | - | - | | |
| • 4940 807781: <i>JTFCEM</i> | - | - | - | - | - | - | - | - | - | | |
| • 4940 807720: <i>JTFCEM</i> | - | - | - | - | - | - | - | - | - | | |
| • 4273 807781: <i>Engineering and Deployment</i> | - | - | - | - | - | - | - | - | - | | |
| • 4280 807721: <i>Engineering and Deployment</i> | - | - | - | - | - | - | - | - | - | | |
| • 4361 807781: <i>IA Operational Resiliency</i> | - | - | - | - | - | - | - | - | - | | |
| • 4126 807781: <i>Computer Network Defense</i> | - | - | - | - | - | - | - | - | - | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • 4111 807781: <i>Computer Network Defense</i> | - | - | - | - | - | - | - | - | - | - | |
| • 4165 807781: <i>Computer Network Defense</i> | - | - | - | - | - | - | - | - | - | - | |
| • 4177 807781: <i>Computer Network Defense</i> | - | - | - | - | - | - | - | - | - | - | |
| • 4364 807781: <i>Workforce Development</i> | - | - | - | - | - | - | - | - | - | - | |

Remarks

D. Acquisition Strategy

This requirement is currently contracted through the USA Medical Research Activity. The vender is Evolvent Technologies Inc.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 446A: <i>Disability Mediation Service (DMS)</i> | 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 2019 | FY 2020 | FY 2021 |
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | Project (Number/Name) 480B / Defense Medical Human Resources System (Internet) (DMHRSi) (Tri-Service) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 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 | 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 2019 | FY 2020 | FY 2021 |
| 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

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | | | | | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | | | | Project (Number/Name) 480C / Defense Medical Logistics Standard Support (DMLSS) (Tri-Service) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 480C: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service) | 20.010 | 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

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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Defense Medical Logistics Standard Support (DMLSS) (Tri-Service) | 0.000 | - | - |
| 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 | 0.000 | - | - |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA-1, 0807793DHA: <i>MHS Tri-Service Information</i> | 36.143 | 35.494 | 35.206 | - | 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605013DHA / Information Technology Development | Project (Number/Name) 480D / Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 480D: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service) | 19.772 | 5.357 | 3.868 | 8.714 | - | 8.714 | 8.719 | 8.293 | 8.468 | 8.646 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Defense Occupational and Environmental Health Readiness System - Industrial Hygiene (DOEHRS-IH) (Tri-Service) | 5.357 | 3.868 | 8.714 |
| Description: Configure, enhance, and interface DOEHRS-IH modules. | | | |
| FY 2020 Plans: Will be used for priority development initiatives to include implementation of a DOEHRS-IH HAZMAT/SDS capability, DOEHRS-IH to DOEHRS-HC Interface, DOEHRS-IH Interface Design/Development to the Defense Medical Logistics – Enterprise Solution (DML-ES), Thermal Stress Design/Development, Confined Spaces Design/Development and Critical User Enhancements. | | | |
| FY 2021 Plans: Will be used for software development and significant enhancements to existing software to include implementation of a DOEHRS-IH HAZMAT/SDS capability, DOEHRS-IH to DOEHRS-HC Interface, DOEHRS-IH Interface Design/Development to the Defense Medical Logistics – Enterprise Solution (DML-ES), Thermal Stress Design/Development, Confined Spaces Design/Development and Critical User Enhancements. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Funding was increased to accomplish the development schedule. | | | |
| Accomplishments/Planned Programs Subtotals | 5.357 | 3.868 | 8.714 |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| 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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
| 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 2021 Defense Health Agency | Date: February 2020 |
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| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 480P: <i>Other Related Technical Activities (Tri-Service)</i> | 8.178 | 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

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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Other Related Technical Activities (Tri-Service) | 0.000 | - | - |
| 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 | 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|---|--|
| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|---|--|
| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 482A: <i>E-Commerce (DHA)</i> | 16.761 | 4.047 | 4.284 | 4.369 | - | 4.369 | 4.457 | 4.546 | 4.637 | 4.730 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: E-Commerce (DHA) | 4.047 | 4.284 | 4.369 |
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| 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 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 2021 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 2020 to FY 2021 Increase/Decrease Statement:</i> Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 4.047 | 4.284 | 4.369 |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|-------------------------------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| Line Item | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| • BA-1, 0807752HP: | 0.132 | 0.132 | 0.132 | - | 0.132 | 0.135 | 0.138 | - | - | Continuing | Continuing |
| <i>Miscellaneous Support Activities</i> | | | | | | | | | | | |
| • BA-3, 0807721HP: | 0.550 | 0.561 | 0.571 | - | 0.571 | 0.583 | 0.595 | - | - | Continuing | Continuing |
| <i>Replacement/Modernization</i> | | | | | | | | | | | |
| Remarks | Program transfer from project 480R. | | | | | | | | | | |

D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|--|
| 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 |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-1, 0807781HP: Non-Central Information Management/Information Technology | 68.129 | 71.102 | 72.458 | - | 72.458 | - | - | - | - | Continuing | Continuing |
| • BA-1, PE 0807795HP: Base Communications - CONUS | 17.793 | 18.151 | 18.505 | - | 18.505 | - | - | - | - | Continuing | Continuing |
| • BA-1, PE 0807995HP: Base Communications - OCONUS | 2.646 | 2.696 | 2.750 | - | 2.750 | - | - | - | - | Continuing | Continuing |
| • BA-3, PE 0807721HP: Replacement/Modernization | 0.000 | 0.000 | 0.000 | - | 0.000 | - | - | - | - | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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| | | | | | | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|---|
| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-1: 0807793DHA: MHS Tri-Service Information | 6.711 | 6.769 | 6.874 | - | 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 2021 Defense Health Agency **Date:** February 2020

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|--|--|---|
| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 480Z: Patient Reported Outcomes Clinical Record (Previous known as PASTOR) (Tri-Service) | 1.317 | 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 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: Patient Reported Outcomes Clinical Record (PROCR) | 0.000 | - | - |
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <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 | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|---|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605013DHA / <i>Information Technology Development</i> | Project (Number/Name) 480R / <i>Joint Disability Evaluation System IT (DHA)</i> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 480R: <i>Joint Disability Evaluation System IT (DHA)</i> | 0.995 | 0.641 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Joint Disability Evaluation System IT (JDES-IT) | 0.641 | - | - |
| 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. | | | |
| Accomplishments/Planned Programs Subtotals | 0.641 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

Not applicable.

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|---|
| 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> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 485: <i>Legacy Data Repository (DHA-C)</i> | 0.000 | 5.531 | 5.856 | 0.000 | - | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Legacy Data Repository | 5.531 | 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 2020 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Finalize RMF - Complete RMF Control Packages (1-3) Begin System Development (Phase 1 of 2) <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). | | | |
| <i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> RDT&E decreases due to requirements completion in FY20. | | | |
| Accomplishments/Planned Programs Subtotals | 5.531 | 5.856 | - |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 505: <i>Military Health System Virtual Health Program (MHS VHP)</i> | 0.000 | 0.000 | 2.000 | 0.000 | - | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| 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 2021 Defense Health Agency | Date: February 2020 |
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| 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2020 to FY 2021 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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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> |
|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2021 Defense Health Agency | Date: February 2020 |
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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> |
|---|---|

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) | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021 Base</u> | <u>FY 2021 OCO</u> | <u>FY 2021 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 | 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 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|---|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA-1, PE 0807784DHA: <i>Information Technology Development -</i> | 16.529 | 17.986 | 16.912 | - | 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 | - | - | - | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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> |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|----------------|-------------------------|-------------------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| • BA-1, PE 0807784: <i>Integrated Electronic Health Record (iEHR)</i> | 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 | - | - | - | - | 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-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 0605025DHA / <i>Theater Medical Information Program - Joint (TMIP-J)</i> |
|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019</u> | <u>FY 2020</u> | <u>FY 2021 Base</u> | <u>FY 2021 OCO</u> | <u>FY 2021 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-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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)

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021 Base</u> | <u>FY 2021 OCO</u> | <u>FY 2021 Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|---------------------|--------------------|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| • BA-1, 0807793DHA: MHS Tri-Service Information | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | - | - | Continuing | Continuing |
| • BA-1, 0807744DHA: Theater Medical Information Program - Joint (TMIP-J) | 73.433 | 32.176 | 27.119 | - | 27.119 | 27.663 | 28.218 | - | - | Continuing | Continuing |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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)

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA-3, 0807744DHA: <i>Theater Medical Information Program - Joint (TMIP-J)</i> | 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| • BA-3, 0807744DHA: Theater Medical Information Program - Joint | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | - | - | - | Continuing | Continuing |
| • BA-1, 0807744DHA **: Theater Medical Information Program - Joint | 36.947 | 32.107 | 27.049 | - | 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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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> |
|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 780.251 | 27.293 | 14.478 | 18.336 | - | 18.336 | 15.751 | 6.012 | 6.132 | 0.000 | Continuing | Continuing |
| 483A: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i> | 780.251 | 27.293 | 14.478 | 18.336 | - | 18.336 | 15.751 | 6.012 | 6.132 | 0.000 | 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 28.326 | 38.256 | 18.336 | - | 18.336 |
| Current President's Budget | 27.293 | 14.478 | 18.336 | - | 18.336 |
| Total Adjustments | -1.033 | -23.778 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | -23.778 | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -1.033 | - | | | |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 483A: <i>Information Technology Development - DoD Healthcare Management System Modernization (DHMSM) at DHA</i> | 780.251 | 27.293 | 14.478 | 18.336 | - | 18.336 | 15.751 | 6.012 | 6.132 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: DoD Healthcare Management System Modernization (DHMSM) Program | 27.293 | 14.478 | 18.336 |
| <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 2020 Plans: FY20 RDT&E:</p> <ul style="list-style-type: none"> • Conduct Test Planning of new interfaces, patches, and of semi-annual releases. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| <ul style="list-style-type: none"> Support configuration efforts for approved enhancements. <p>FY20 Procurement:</p> <ul style="list-style-type: none"> Purchase required commercial software licenses and perform multiple deployments of the modernized DHMSM Electronic Health Record (EHR) to Military Treatment Facilities (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. <p>FY 2021 Plans:</p> <p>FY21 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>FY21 Procurement:</p> <ul style="list-style-type: none"> Purchase required commercial software licenses and perform 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>FY21 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>FY 2020 to FY 2021 Increase/Decrease Statement: FY 2021 RDT&E funds decrease in accordance with acquisition schedule.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 27.293 | 14.478 | 18.336 |

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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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 / <i>DoD Medical Information Exchange and Interoperability</i> |
|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2021 Defense Health Agency | Date: February 2020 |
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|---|--|
| Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i> | R-1 Program Element (Number/Name) PE 0605039DHA / PE 0605039HP / DoD Medical Information Exchange and Interoperability |
|---|--|

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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 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 2021 Defense Health Agency **Date:** February 2020

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| 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) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

| <u>Line Item</u> | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021</u> <u>Base</u> | <u>FY 2021</u> <u>OCO</u> | <u>FY 2021</u> <u>Total</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> | <u>FY 2025</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • BA-1, 0807788HP: <i>DoD Medical Information Exchange and Interoperability</i> | 47.047 | 47.613 | 46.901 | - | 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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130: Defense Health Program I BA 2: RDT&E | R-1 Program Element (Number/Name) PE 0605045DHA I Joint Operational Medicine Information System (JOMIS) |
|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 127.961 | 49.084 | 41.902 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 447A: Joint Operational Medicine Information System (JOMIS) | 127.961 | 49.084 | 41.902 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 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) | <u>FY 2019</u> | <u>FY 2020</u> | <u>FY 2021 Base</u> | <u>FY 2021 OCO</u> | <u>FY 2021 Total</u> |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 78.136 | 59.902 | 49.260 | - | 49.260 |
| Current President's Budget | 49.084 | 41.902 | 0.000 | - | 0.000 |
| Total Adjustments | -29.052 | -18.000 | -49.260 | - | -49.260 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | -18.000 | | | |
| • Congressional Rescissions | -26.200 | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -2.852 | - | | | |
| • Programmatic change | - | - | -49.260 | - | -49.260 |

Change Summary Explanation

FY 2021: Realignment of funding to BA 08 (Software and Digital Technology Pilot Program).

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 447A: Joint Operational Medicine Information System (JOMIS) | 127.961 | 49.084 | 41.902 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
| Title: Joint Operational Medicine Information System (JOMIS) | 49.084 | 41.902 | 0.000 |
| 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 2020 Plans: FY 20 RDT&E: | | | |

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|--|--|---|----------------|----------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 |
| <ul style="list-style-type: none"> • Continue software development, configuration, and other activities related to Military Health Systems (MHS) GENESIS and Theater Medical Information Program-Joint (TMIP-J) integration. • Support Department of Defense Healthcare Management System Modernization (DHMSM) Program Management Office (PMO) for Contractor Testing and Development Testing of MHS GENESIS. • Continue Operational Medicine Government Approved Laboratory (OM GAL) efforts to support planning activities, user readiness, user training, and change management activities for the Initial Operating Capability (IOC) sites. • Continue engineering and program management support from the Air Force, Army, Marine Corps, and Navy. • Enhancements to the Medical Situational Awareness in Theater/Theater Medical Data Store (MSAT/TMDS) and AHLTA-T/TC2 projects. • Theater Blood (TBLD) development, system integration and test, Contractor System Engineering, Contractor Program Management and associated training material development. • Transportation Command (TRANSCOM) Regulating and Command and Control Evacuation System (TRAC2ES). <p>FY20 Procurement:</p> <ul style="list-style-type: none"> - 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>FY20 O&M:</p> <ul style="list-style-type: none"> - Prepare analyses and acquisition documentation in support of Test and Evaluation Authority to Proceed (ATP) Milestone Event. - Continue decomposition into Requirements Definition Package (RDP) to inform JOMIS Increment 1 and the delivery of future increments capability. - Continue support of Program Management Office (PMO). - 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 2021 Plans:</p> <p>FY21 RDT&E:</p> <ul style="list-style-type: none"> • Continue software development and other activities related to MHS-GENESIS Segment 2 Build 4 Gold Disk delivery. • Support the Defense Health Management System Modernization (DHMSM) program office for testing of MHS GENESIS Segment 2 Build 4 Gold Disk delivery. • Continue engineering and program management support for the Services. | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | Date: February 2020 |
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| 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) |
|--|--|---|

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| <p>FY21 Procurement:</p> <ul style="list-style-type: none"> • Continue integration activities, software licenses and utilities and tools. • Continue to support maintenance of government-approved laboratory infrastructure, software maintenance, hardware procurement and technical refreshes. <p>FY21 O&M:</p> <ul style="list-style-type: none"> • Prepare analyses and acquisition documentation in support of Test and Evaluation Authority to Proceed (ATP) Milestone Event • Continue decomposition into Requirements Definition Package (RDP) to inform JOMIS Increment 1 and the delivery of future increments capability • Continue support of Program Management Office (PMO) • Operate and maintain OM GAL Testing Facility • Continue engineering and program management support from the Air Force, Army, Marine Corps, and Navy • Fund sustainment of TMIP-J legacy systems prior to delivery of PM JOMIS <p><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Reflects the program's updated strategy and timeline.</p> | | | |
| Accomplishments/Planned Programs Subtotals | 49.084 | 41.902 | 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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i> | | | | | R-1 Program Element (Number/Name) PE 0605145DHA I <i>Medical Products and Support Systems Development</i> | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 135.678 | 24.921 | 21.589 | 21.068 | - | 21.068 | 21.489 | 21.919 | 22.357 | 22.804 | Continuing | Continuing |
| 399A: <i>Hyperbaric Oxygen Therapy Clinical Trial (Army)</i> | 27.762 | 0.857 | 0.935 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 500A: <i>CSI - Congressional Special Interests</i> | 13.031 | 5.351 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 375: <i>GDF - Medical Products and Support System Development</i> | 94.885 | 18.713 | 20.654 | 21.068 | - | 21.068 | 21.489 | 21.919 | 22.357 | 22.804 | Continuing | Continuing |
| 375A: <i>GDF - MPASSD (Medical Modeling and Simulation)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 375B: <i>GDF - MPASSD (Medical Readiness)</i> | - | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 375C: <i>GDF - MPASSD (Medical Combat Support)</i> | - | 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 for products that require US Food and Drug Administration approval.

Development, test, and evaluation in this PE is designed to address requirements identified through the Joint Capabilities Integration and Development System and other Department of Defense operational needs. Medical development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the National Defense Strategy, the Joint Staff Surgeon’s Joint Concept for Health Services, and other overarching DoD strategic framework documents.

Coordination occurs through the planning and execution activities of the Defense Health Agency Component Acquisition Executive (DHA CAE) as the Milestone Decision Authority for medical materiel development efforts. As technologies mature, the most promising efforts will transition to production and deployment.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 25.745 | 21.589 | 22.022 | - | 22.022 |
| Current President's Budget | 24.921 | 21.589 | 21.068 | - | 21.068 |
| Total Adjustments | -0.824 | 0.000 | -0.954 | - | -0.954 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.824 | - | | | |
| • Reprogrammings | - | - | -0.954 | - | -0.954 |

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

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

Congressional Add: *CSI Restoral*

Congressional Add Subtotals for Project: 500A

Congressional Add Totals for all Projects

| | FY 2019 | FY 2020 |
|--|----------------|----------------|
| | 5.351 | - |
| | 5.351 | - |
| | 5.351 | - |

Change Summary Explanation

FY 2021: Programmed funding transferred to the Department of the Army (PE 0605145A Project CD6) as part of the Readiness Transfer for FY 2021.

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 399A: Hyperbaric Oxygen Therapy Clinical Trial (Army) | 27.762 | 0.857 | 0.935 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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)

| | | | |
|---|----------------|----------------|----------------|
| Title: Hyperbaric Oxygen Therapy Clinical Trial (Army) | FY 2019 | FY 2020 | FY 2021 |
| 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. | 0.857 | 0.935 | 0.000 |
| FY 2020 Plans: Concluded the Hyperbaric Oxygen Therapy clinical trial and other associated project effort. The project determined that no clinically statistical significance existed related to the use of hyperbaric oxygen interventions. | | | |
| FY 2021 Plans: Programmed funding transferred to the Department of the Army (PE 0605145A Project CD6) as part of the Readiness Transfer for FY 2021. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Programmed funding transferred to the Department of the Army (PE 0605145A Project CD6) as part of the Readiness Transfer for FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 0.857 | 0.935 | 0.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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.

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 500A: <i>CSI - Congressional Special Interests</i> | 13.031 | 5.351 | 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 2019, 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 2019 | FY 2020 |
|---|----------------|----------------|
| Congressional Add: CSI Restoral | 5.351 | - |
| FY 2019 Accomplishments: In FY 2019, 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. | | |
| Congressional Adds Subtotals | 5.351 | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605145DHA / <i>Medical Products and Support Systems Development</i> | Project (Number/Name) 375 / <i>GDF - Medical Products and Support System Development</i> |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| <i>375: GDF - Medical Products and Support System Development</i> | 94.885 | 18.713 | 20.654 | 21.068 | - | 21.068 | 21.489 | 21.919 | 22.357 | 22.804 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Support Systems Development: This funding supports materiel development activities that further system development and demonstration prior to initial full rate production and fielding of commodities.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD) | 18.713 | 20.654 | 21.068 |
| <p>Description: GDF-Medical Products and Support Systems Development: This funding supports activities 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). Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical training systems technologies.</p> <p>FY 2020 Plans: Medical Modeling and Simulation: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. Medical Simulation Training Systems will begin to develop standardized training capabilities for point of injury, trauma simulation, hospital training, along with a common platform architecture that improves medical care across the DoD.</p> <p>Medical Readiness: Programs will focus on prevention of illness and injury along with optimization of human performance. The Health Readiness and Performance System will continue to refine technologies including wearable sensors to monitor non-diagnostic physiologic data in real-time to improve Warfighter health, readiness and performance, reduce casualties, and increase situational awareness.</p> <p>Medical Combat Support: Programs will focus on operational support. The Next Generation Diagnostic System-Infectious Disease Panel program will continue to refine a diagnostic assay for malaria, dengue fever, chikungunya, and leptospirosis that can be use in the operational setting.</p> <p>FY 2021 Plans:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605145DHA / <i>Medical Products and Support Systems Development</i> | Project (Number/Name) 375 / <i>GDF - Medical Products and Support System Development</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| FY 2021 plans continue efforts as outlined in FY 2020. | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: Pricing adjustment for inflation. | | | | |
| Accomplishments/Planned Programs Subtotals | | 18.713 | 20.654 | 21.068 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| This program will test and evaluate medical products in government-managed clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding. | | | | |

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|---|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605145DHA / Medical Products and Support Systems Development | Project (Number/Name) 375A / GDF - MPASSD (Medical Modeling and Simulation) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 375A: GDF - MPASSD (Medical Modeling and Simulation) | - | 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

J4 CAE will break out in FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: GDF - Medical Modeling and Simulation | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|---|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605145DHA / Medical Products and Support Systems Development | Project (Number/Name) 375B / GDF - MPASSD (Medical Readiness) |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 375B: GDF - MPASSD (Medical Readiness) | - | 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

J4 CAE will break out in FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: GDF - Medical Readiness | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|--|--|
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605145DHA / Medical Products and Support Systems Development | Project (Number/Name) 375C / GDF - MPASSD (Medical Combat Support) |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| <i>375C: GDF - MPASSD (Medical Combat Support)</i> | - | 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

J4 CAE will break out in FY22-26 POM

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: GDF - Medical Combat Support | 0.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | |
|---|--|
| 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> |
|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 355.005 | 66.784 | 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> | 324.552 | 58.549 | 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> | 30.453 | 8.235 | 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 2021 Defense Health Agency **Date:** February 2020

| | |
|---|--|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 0.000 | 0.000 | 0.000 | - | 0.000 |
| Current President's Budget | 66.784 | 0.000 | 0.000 | - | 0.000 |
| Total Adjustments | 66.784 | 0.000 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | 66.784 | - | | | |

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 470A: <i>Small Business Innovation Research (SBIR) (Army)</i> | 324.552 | 58.549 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Small Business Innovation Research (SBIR) Program | 58.549 | 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 2020 Plans: No funding programmed. The DHA SBIR program is funded in the year of execution. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: No funding programmed. The DHA SBIR program is funded in the year of execution. | | | |
| Accomplishments/Planned Programs Subtotals | 58.549 | 0.000 | - |

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

N/A

Remarks

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0605502DHA / Small Business Innovation Research (SBIR) Program | Project (Number/Name) 470A / Small Business Innovation Research (SBIR) (Army) |

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.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 470B: <i>Small Business Technology Transfer (STTR) Program</i> | 30.453 | 8.235 | 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 2019 | FY 2020 | FY 2021 |
| Title: Small Business Technology Transfer (STTR) Program | 8.235 | 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 2020 Plans: No funding programmed. The DHA STTR program is funded in the year of execution. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| No funding programmed. The DHA SBIR program is funded in the year of execution. | | | |
| Accomplishments/Planned Programs Subtotals | 8.235 | 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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | |
|---|--|
| 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> |
|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 394.999 | 70.610 | 69.219 | 48.672 | - | 48.672 | 49.645 | 50.638 | 51.651 | 52.692 | Continuing | Continuing |
| 305T: <i>USAMRIID IO&T (Army)</i> | 109.680 | 0.438 | 0.000 | 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> | 33.693 | 5.253 | 5.358 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 432A: <i>OCONUS Laboratory Infrastructure Support (Army)</i> | 63.186 | 13.217 | 14.144 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 433A: <i>NMRC Biological Defense Research Directorate (BDRD) (Navy)</i> | 17.690 | 3.109 | 5.163 | 3.267 | - | 3.267 | 3.371 | 3.479 | 3.589 | 3.796 | 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 | 6.872 | 2.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 494A: <i>Medical Development (Lab Support) (Navy)</i> | 79.489 | 41.721 | 42.554 | 45.405 | - | 45.405 | 46.274 | 47.159 | 48.062 | 48.896 | Continuing | Continuing |
| 376A: <i>GDF - Medical Program-Wide Activities</i> | 8.666 | 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 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 2021 Defense Health Agency **Date:** February 2020

| | |
|---|--|
| 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> |
|---|--|

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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 70.755 | 67.219 | 68.563 | - | 68.563 |
| Current President's Budget | 70.610 | 69.219 | 48.672 | - | 48.672 |
| Total Adjustments | -0.145 | 2.000 | -19.891 | - | -19.891 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 2.000 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.145 | - | | | |
| • Reprogrammings | - | - | -19.891 | - | -19.891 |

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

Project: 600A: *CSI - Congressional Special Interests*

Congressional Add: *PC 466 - CSI Core Restoral Medical Program-wide Activities*

Congressional Add Subtotals for Project: 600A

Congressional Add Totals for all Projects

| | FY 2019 | FY 2020 |
|--|----------------|----------------|
| | 6.872 | 2.000 |
| | 6.872 | 2.000 |
| | 6.872 | 2.000 |

Change Summary Explanation

FY 2021: Programmed effort and funding transferred to the Department of the Army in FY 2021 (PE 06066105A Project CD7) as part of the Readiness Transfer for FY 2021.

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 305T: USAMRIID IO&T (Army) | 109.680 | 0.438 | 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 Infectious Diseases (USAMRIID), Fort Detrick, Maryland.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: USAMRIID IO&T (Army) | 0.438 | 0.000 | - |
| Description: US Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland, IO&T costs associated with MILCON. | | | |
| FY 2020 Plans: No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: USAMRIID IO&T program completed in FY 2019. | | | |
| Accomplishments/Planned Programs Subtotals | 0.438 | 0.000 | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|---|
| 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) |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| 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

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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) | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: USAMRICD IO&T (Army) | 0.000 | - | - |
| Description: The USAMRICD, Aberdeen Proving Ground, Maryland, IO&T costs associated with MILCON. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | - | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 401A: CONUS Laboratory Support Clinical Infrastructure (Army) | 33.693 | 5.253 | 5.358 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: CONUS Laboratory Support Clinical Infrastructure (Army) | 5.253 | 5.358 | 0.000 |
| 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 2020 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 2021 Plans: Programmed effort and funding transferred to the Department of the Army in FY 2021 (PE 06066105A Project CD7). | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 5.253 | 5.358 | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|--|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 432A: OCONUS Laboratory Infrastructure Support (Army) | 63.186 | 13.217 | 14.144 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: OCONUS Laboratory Infrastructure Support (Army) | 13.217 | 14.144 | 0.000 |
| <p>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.</p> <p>FY 2020 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.</p> <p>FY 2021 Plans: Programmed effort and funding transferred to the Department of the Army in FY 2021 (PE 06066105A Project CD7).</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Programmed effort and funding transferred to the Department of the Army in FY 2021. | | | |
| Accomplishments/Planned Programs Subtotals | 13.217 | 14.144 | 0.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|---|---|
| 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) |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 433A: NMRC Biological Defense Research Directorate (BDRD) (Navy) | 17.690 | 3.109 | 5.163 | 3.267 | - | 3.267 | 3.371 | 3.479 | 3.589 | 3.796 | 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)

| | | | |
|--|---------|---------|---------|
| Title: NMRC Biological Defense Research Directorate (BDRD) (Navy) | FY 2019 | FY 2020 | FY 2021 |
| Description: Funding for this project 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. | 3.109 | 5.163 | 3.267 |
| 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 Biological Weapon (BW) agent detection, analysis, and deployable BW diagnostic lab service. | | | |
| FY 2021 Plans: Continue plans as outlined in FY 2020. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: The adjustment of \$2.0M is due to right-sizing project 433A based on historical execution data. The \$2.0M would be moved to Lab Support project 494A in order to allow for additional investment across all the R&D medical labs to cover increased fixed and recurring base operating costs (BOS), which would allow for a more sustained investment in core S&T capabilities, as well as affording the laboratories flexibility in accommodating increased workloads and surge requirements. | | | |
| Accomplishments/Planned Programs Subtotals | 3.109 | 5.163 | 3.267 |

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

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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|--|---|--|
| 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) |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | 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 2019 | FY 2020 | FY 2021 |
| Title: USARIEM Pike's Peak IO&T (Army) | 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 2020 Plans: No funding programmed. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: No funding programmed. | | | |
| Accomplishments/Planned Programs Subtotals | 0.000 | 0.000 | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|--|
| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 600A: <i>CSI - Congressional Special Interests</i> | 27.613 | 6.872 | 2.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

The FY 2019 DHP Congressional Special Interest (CSI) Restoral 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 2019 | FY 2020 |
|--|---------|---------|
| Congressional Add: PC 466 - CSI Core Restoral Medical Program-wide Activities | 6.872 | 2.000 |
| FY 2019 Accomplishments: CSI Restoral | | |
| FY 2020 Plans: CSI Restoral | | |
| Congressional Adds Subtotals | 6.872 | 2.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

| | | |
|--|---|---|
| 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) |
|--|---|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 494A: Medical Development (Lab Support) (Navy) | 79.489 | 41.721 | 42.554 | 45.405 | - | 45.405 | 46.274 | 47.159 | 48.062 | 48.896 | 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 2019 | FY 2020 | FY 2021 |
|---|---------|---------|---------|
| Title: Medical Development (Lab Support) (Navy) | 41.721 | 42.554 | 45.405 |
| Description: Funding in this project 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 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 2021 Plans: Continue plans as outlined in FY 2020. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: An additional \$2 million in order to allow for additional investment across all the R&D medical labs to cover increased fixed and recurring base operating costs (BOS), which would allow for a more sustained investment in core S&T capabilities, as well as affording the laboratories flexibility in accommodating increased workloads and surge requirements. | | | |
| Accomplishments/Planned Programs Subtotals | 41.721 | 42.554 | 45.405 |

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

N/A

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|---|--|--|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

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

Remarks

D. Acquisition Strategy

N/A

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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 | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 376A: GDF - Medical Program-Wide Activities | 8.666 | 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 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 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| 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

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 98.276 | 15.140 | 16.819 | 17.215 | - | 17.215 | 17.619 | 17.971 | 18.330 | 18.697 | Continuing | Continuing |
| 377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i> | 94.558 | 15.140 | 16.819 | 17.215 | - | 17.215 | 17.619 | 17.971 | 18.330 | 18.697 | 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 developmental upgrades to medical systems, training 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. These funds will support testing and evaluation for the enhancement of fielded or procured medical systems/products and medically-related information technology systems, assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and analyses of clinical intervention outcomes to enhance and improve indications for pharmaceutical products. 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, and others as appropriate. Coordination occurs through the planning and execution activities of the Defense Health Agency Component Acquisition Executive (DHA CAE).

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 15.714 | 16.819 | 17.215 | - | 17.215 |
| Current President's Budget | 15.140 | 16.819 | 17.215 | - | 17.215 |
| Total Adjustments | -0.574 | 0.000 | 0.000 | - | 0.000 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -0.574 | - | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| 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> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i> | 94.558 | 15.140 | 16.819 | 17.215 | - | 17.215 | 17.619 | 17.971 | 18.330 | 18.697 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Guidance for Medical Products and Capabilities Enhancement Activity: This funding supports enhancement of existing medical products and medically related information technology systems to further fielding of joint medical materiel capabilities to meet Warfighter needs through support testing and evaluation for the enhancement of fielded or procured medical systems/products and medically-related information technology systems, assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and analyses of clinical intervention outcomes to enhance and improve indications for pharmaceutical products.

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

| | | | |
|--|----------------|----------------|----------------|
| | FY 2019 | FY 2020 | FY 2021 |
| Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities | 15.140 | 16.819 | 17.215 |
| Description: This funding provides 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. These funds will support testing and evaluation for the enhancement of fielded or procured medical systems/products and medically-related information technology systems, assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and analyses of clinical intervention outcomes to enhance and improve indications for pharmaceutical products. | | | |
| FY 2020 Plans: Funding will be used to modernize and upgrade products through joint testing and evaluation to improve fielding and procurement of medical materiel products. Programs for enhancement include: an assessment of a novel video laryngoscope for far-forward endotracheal intubation; evaluation of markerless-based motion capture technology as a screening tool for musculoskeletal injury; evaluation of a longer-acting sleep aid for military operations; expanding the use of a hemostatic device to control bleeding in wounded areas where a tourniquet cannot be utilized; and enhance a burn navigator application for care of burn patients in an operational setting. | | | |
| FY 2021 Plans: FY 2021 plans continue efforts as outlined in FY 2020. | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| 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> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Pricing adjustment for inflation. | | | |
| Accomplishments/Planned Programs Subtotals | 15.140 | 16.819 | 17.215 |

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

N/A

Remarks

D. Acquisition Strategy

This program will integrate product improvements and enhancements resulting from post marketing studies and surveillance in existing medical products and medically related information technology systems to better meet Warfighter needs.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130 / 2 | R-1 Program Element (Number/Name) PE 0607100DHA / Medical Products and Capabilities Enhancement Activities | Project (Number/Name) 457A / AF Advanced Technology Development – Rapid Technology Transition |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 457A: AF Advanced Technology Development – Rapid Technology Transition | 1.336 | 0.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

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

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| 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.

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| 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 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 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
 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

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

| Appropriation/Budget Activity | | | | | R-1 Program Element (Number/Name) | | | | | | | |
|--|-------------|---------|---------|--------------|--|---------------|---------|---------|---------|---------|------------------|------------|
| 0130: <i>Defense Health Program I BA 8: Software and Digital Technology Pilot Programs</i> | | | | | PE 0608045DHA I <i>Software and Digital Technology Pilot Program</i> | | | | | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| Total Program Element | 0.000 | 0.000 | 0.000 | 160.428 | - | 160.428 | 163.542 | 166.811 | 273.426 | 278.893 | Continuing | Continuing |
| 845: <i>Software & Digital Technology Pilot Program</i> | - | 0.000 | 0.000 | 160.428 | - | 160.428 | 163.542 | 166.811 | 273.426 | 278.893 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Issue: The Defense Health Agency's Joint Operational Medicine Information Systems (JOMIS) (BA's 01, 02 and 03) and Theater Medical Information Program - Joint (TMIP-J) (BA 01) will be realigned to the Software and Digital Technology Budget Activity (BA 08).

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).

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.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency **Date:** February 2020

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| Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 8: Software and Digital Technology Pilot Programs</i> | R-1 Program Element (Number/Name) PE 0608045DHA I <i>Software and Digital Technology Pilot Program</i> |
|--|--|

| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 0.000 | 0.000 | 0.000 | - | 0.000 |
| Current President's Budget | 0.000 | 0.000 | 160.428 | - | 160.428 |
| Total Adjustments | 0.000 | 0.000 | 160.428 | - | 160.428 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | - | - | | | |
| • Reprogrammings | - | - | 160.428 | - | 160.428 |

Change Summary Explanation

The Software and Digital Technology Pilot Program (Budget Activity 08) is being stood up this cycle for the Defense Health Program by realigning the following funding streams to Budget Activity 08:

- 1) non-CIVPAY O&M funding (Budget Activity 01) for TMIP-J in the amount of \$87.497M and for JOMIS in the amount of \$21.051M.
- 2) RDT&E funding (Budget Activity 02) for JOMIS in the amount of \$49.260M.
- 3) Procurement funding (BA 03) for JOMIS in the amount of \$2.620M.

The establishment of the Software & Digital Technology PE/Project Code (Budget Activity 08) in the Research, Development, Test & Evaluation (RDT&E) appropriation allows software capability delivery to be funded as a single budget line item, with no separation between RDT&E, production and sustainment.

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 8 | | | | | R-1 Program Element (Number/Name) PE 0608045DHA / <i>Software and Digital Technology Pilot Program</i> | | | | Project (Number/Name) 845 / <i>Software & Digital Technology Pilot Program</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 845: <i>Software & Digital Technology Pilot Program</i> | - | 0.000 | 0.000 | 160.428 | - | 160.428 | 163.542 | 166.811 | 273.426 | 278.893 | Continuing | Continuing |

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.

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. Accomplishments/Planned Programs (\$ in Millions)

| | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Title: Software and Digital Technology Pilot Program | - | - | 160.428 |
| 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 | | | |

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|--|--|--|----------------|----------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 | | |
| Appropriation/Budget Activity 0130 / 8 | R-1 Program Element (Number/Name) PE 0608045DHA / <i>Software and Digital Technology Pilot Program</i> | Project (Number/Name) 845 / <i>Software & Digital Technology Pilot Program</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| <p>system capabilities for Medical Logistics, Patient Movement and Evacuation, Medical Situational Awareness and Medical Command & Control.</p> <p>FY 2021 Plans: Research Activities: • Continue software development and other activities related to MHS-GENESIS Segment 2 Build 4 Gold Disk delivery. • Support the Defense Health Management System Modernization (DHMSM) program office for testing of MHS GENESIS Segment 2 Build 4 Gold Disk delivery. • Continue engineering and program management support for the Services.</p> <p>Procurement Activities: • Continue integration activities, software licenses and utilities and tools. • Continue to support maintenance of government-approved laboratory infrastructure, software maintenance, hardware procurement and technical refreshes.</p> <p>Sustainment Activities: • Prepare analyses and acquisition documentation in support of Test and Evaluation Authority to Proceed (ATP) Milestone Event • Continue decomposition into Requirements Definition Package (RDP) to inform JOMIS Increment 1 and the delivery of future increments capability • Continue support of Program Management Office (PMO) • Operate and maintain OM GAL Testing Facility • Continue engineering and program management support from the Air Force, Army, Marine Corps, and Navy • Fund sustainment of TMIP-J legacy systems prior to delivery of PM JOMIS</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Reflects the program's updated strategy and timeline. New funding in BA 08 starting in FY 2021 reflects the realignment of the funding for JOMIS/TMIP-J from BA's 01, 02 and 03 to BA 08.</p> | | | | |
| Accomplishments/Planned Programs Subtotals | | - | - | 160.428 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency | | Date: February 2020 |
| Appropriation/Budget Activity 0130 / 8 | R-1 Program Element (Number/Name) PE 0608045DHA / <i>Software and Digital Technology Pilot Program</i> | Project (Number/Name) 845 / <i>Software & Digital Technology Pilot Program</i> |

D. Acquisition Strategy
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