

UNCLASSIFIED

| Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
|---|-------------|---------|---------|--------------|--|---------------|---------|---------|---------|----------------|------------------|------------|
| Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD) | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| Total Program Element | - | 82.256 | 94.669 | 43.804 | - | 43.804 | - | - | - | - | - | - |
| 814: NEUROFIBROMATOSIS (CA) | - | 15.000 | 20.000 | - | - | - | - | - | - | - | - | - |
| 945: BREAST CANCER STAMP PROCEEDS | - | 0.454 | - | - | - | - | - | - | - | - | - | - |
| 97T: NEUROTOXIN EXPOSURE TREATMENT (CA) | - | 16.000 | 16.000 | - | - | - | - | - | - | - | - | - |
| CJ3: Prophylactic for Endemic Diarrheal Diseases | - | - | - | 4.009 | - | 4.009 | - | - | - | - | - | - |
| MG4: Tech Base/Enabling Res in Mil Occup Med Adv Tech | - | 7.984 | - | - | - | - | - | - | - | - | - | - |
| MM2: MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA) | - | 10.000 | 21.000 | - | - | - | - | - | - | - | - | - |
| MM5: Tech Base/Enabling Res Combat Cas Care Adv Tech | - | 2.328 | - | - | - | - | - | - | - | - | - | - |
| MM7: Enabling Med Cap to Support Dispersed OPS Adv Tech | - | 1.744 | 2.913 | 3.232 | - | 3.232 | - | - | - | - | - | - |
| MM9: Tech Base/Enabling Rsrch for Infect Dis Adv Tech | - | 2.961 | - | - | - | - | - | - | - | - | - | - |
| MN3: Immediate Cardiopulmonary Stabilization Adv Tech | - | 1.864 | 2.071 | 1.727 | - | 1.727 | - | - | - | - | - | - |
| MN4: Advanced Life Support Advanced Technology | - | 3.710 | 3.615 | 3.927 | - | 3.927 | - | - | - | - | - | - |
| MN5: Next Generation Blood Products Advanced Technology | - | 5.725 | 6.610 | 9.394 | - | 9.394 | - | - | - | - | - | - |

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army **Date:** May 2021

| Appropriation/Budget Activity | R-1 Program Element (Number/Name) | | | | | | | | | | | | |
|---|--|-------|-------|--------|---|--------|---|---|---|---|---|---|---|
| <i>2040: Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)</i> | <i>PE 0603002A / Medical Advanced Technology</i> | | | | | | | | | | | | |
| <i>MN6: Blast & Head Impact Exposure Monitor Advanced Tech</i> | - | 1.354 | 1.878 | 1.546 | - | 1.546 | - | - | - | - | - | - | - |
| <i>MN7: Musculoskeletal Injury Screening Tool Adv Tech</i> | - | 0.287 | 3.274 | 1.664 | - | 1.664 | - | - | - | - | - | - | - |
| <i>MN8: Drugs to Prevent and Treat Malaria Advanced Tech</i> | - | 2.057 | - | - | - | - | - | - | - | - | - | - | - |
| <i>MN9: Far Forward Behavioral Health Care Advanced Tech</i> | - | 0.255 | 1.080 | 0.283 | - | 0.283 | - | - | - | - | - | - | - |
| <i>MO2: Traumatic Brain Injury (TBI) Treatment Adv Tech</i> | - | 4.108 | 4.649 | 10.667 | - | 10.667 | - | - | - | - | - | - | - |
| <i>MO3: Military Occupational Fitness Standards Adv Tech</i> | - | 0.240 | - | - | - | - | - | - | - | - | - | - | - |
| <i>MO4: Burn Recovery Optimization Advanced Technology</i> | - | 2.044 | 3.326 | 2.059 | - | 2.059 | - | - | - | - | - | - | - |
| <i>MO7: Improved Bone Repair Advanced Technology</i> | - | 1.475 | 1.564 | 1.069 | - | 1.069 | - | - | - | - | - | - | - |
| <i>MO8: Expeditionary Performance Nutrition Advanced Techn</i> | - | 0.192 | 2.062 | 1.936 | - | 1.936 | - | - | - | - | - | - | - |
| <i>MO9: Vaccines to Prevent Dengue Fever Advanced Tech</i> | - | 2.474 | 2.037 | - | - | - | - | - | - | - | - | - | - |
| <i>MP3: Phys Chem Toxicity Assessment Sys Adv Tech</i> | - | - | 2.590 | 2.291 | - | 2.291 | - | - | - | - | - | - | - |

A. Mission Description and Budget Item Justification

This Program Element (PE) matures and demonstrates advanced medical technologies including drugs, vaccines, medical diagnostic devices, measures for identification and vector control, and developing medical practices and procedures to effectively protect and improve the survivability of United States Forces across the entire spectrum of military operations. Tri-Service coordination and cooperative efforts are focused in four principal medical areas: Combat Casualty Care, Military Operational Medicine, Militarily Relevant Infectious Diseases, and Clinical and Rehabilitative Medicine. Starting in Fiscal Year 2020 (FY20), the principal area of Clinical and Rehabilitative Medicine is replaced with the area of Medical Assist Support Technologies.

UNCLASSIFIED

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)</i> | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | |
| <p>Promising medical technologies are refined and validated through extensive testing, which is conducted in compliance with Food and Drug Administration (FDA) regulations for human medical products, and environmental protection agency (EPA) regulations for insect-control products that impact humans or the environment (e.g., repellents and insecticides). The FDA requires medical products to undergo extensive preclinical testing in animals and/or other models to obtain preliminary effectiveness and safety information before they can be tested in human clinical trials. Clinical trials are conducted stepwise: first to prove the product is safe in humans, second to demonstrate the desired effectiveness and optimal dosage (amount to be administered) in a small group human study, and third to demonstrate effectiveness in large, diverse human populations. Each successive phase includes larger numbers of human subjects and requires FDA cognizance prior to proceeding. Work conducted in this PE primarily focuses on late stages of technology maturation activities required to conduct safety and effectiveness clinical trials. Some high-risk technologies may require additional maturation with FDA guidance prior to initiating these clinical trials. Such things as proof of product stability and purity are necessary to meet FDA standards before entering later stages of testing and prior to transitioning into a formal acquisition program where large pivotal trials in diverse populations will be conducted for licensure. Activities in this PE may include completion of preclinical animal studies and small safety and effectiveness studies involving humans according to FDA and EPA requirements. Promising medical technologies that are not regulated by the FDA or EPA are modeled, prototyped, and tested in relevant environments.</p> <p>Blast research and research into maturing field rations in this PE are fully coordinated with the United States Army Combat Capabilities Development Command Soldier Center. This coordination enables improved body armor design and rations for Soldiers. Additionally, the activities funded in this PE are externally peer reviewed and fully coordinated with all Services as well as other agencies through the Joint Technology Coordinating Groups of the Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (COI). The ASBREM COI, formed under the authority of the Assistant Secretary of Defense for Research and Engineering, serves to facilitate coordination and prevent unnecessary duplication of effort within the Department of Defense's biomedical research and development community, as well as its associated enabling research areas.</p> <p>The cited work is consistent with the Under Secretary of Defense (Research and Engineering) Science and Technology (S&T) focus areas and the Army Modernization Strategy.</p> <p>Work in this PE is performed by: the U.S. Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.</p> | | |

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army **Date:** May 2021

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| Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)</i> | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> |
|---|--|

| B. Program Change Summary (\$ in Millions) | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 83.030 | 38.896 | 41.136 | - | 41.136 |
| Current President's Budget | 82.256 | 94.669 | 43.804 | - | 43.804 |
| Total Adjustments | -0.774 | 55.773 | 2.668 | - | 2.668 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | 41.000 | 57.000 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | -40.546 | - | | | |
| • SBIR/STTR Transfer | -1.228 | -1.227 | | | |
| • Adjustments to Budget Years | - | - | 2.668 | - | 2.668 |

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

Project: 814: NEUROFIBROMATOSIS (CA)

Congressional Add: *Peer-reviewed Neurofibromatosis Research*

Congressional Add Subtotals for Project: 814

| | FY 2020 | FY 2021 |
|--|---------|---------|
| | 15.000 | 20.000 |
| Congressional Add Subtotals for Project: 814 | 15.000 | 20.000 |

Project: 945: BREAST CANCER STAMP PROCEEDS

Congressional Add: *Breast Cancer Stamp Proceeds*

Congressional Add Subtotals for Project: 945

| | | |
|--|-------|---|
| | 0.454 | - |
| Congressional Add Subtotals for Project: 945 | 0.454 | - |

Project: 97T: NEUROTOXIN EXPOSURE TREATMENT (CA)

Congressional Add: *Peer-reviewed Neurotoxin Exposure Treatment Parkinson's Research*

Congressional Add Subtotals for Project: 97T

| | | |
|--|--------|--------|
| | 16.000 | 16.000 |
| Congressional Add Subtotals for Project: 97T | 16.000 | 16.000 |

Project: MM2: MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)

Congressional Add: *Peer-reviewed Military Burn Research Program*

Congressional Add: *Program increase: Burn care training curriculum*

Congressional Add: *Program increase - peer-reviewed military burn research*

Congressional Add: *Program increase: Advanced hemostat products*

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|--|--------|--------|
| | 10.000 | - |
| | - | 5.000 |
| | - | 10.000 |
| | - | 6.000 |

UNCLASSIFIED

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|---|-----------------------|
| Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army | Date: May 2021 |
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| Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)</i> | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> |
|---|--|

| Congressional Add Details (\$ in Millions, and Includes General Reductions) | FY 2020 | FY 2021 |
|--|----------------|----------------|
| Congressional Add Subtotals for Project: MM2 | 10.000 | 21.000 |
| Congressional Add Totals for all Projects | 41.454 | 57.000 |

Change Summary Explanation

Funding was decrease by \$61.000 million to provide core support to U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) and U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) to maintain the core capability in those two Labs.

\$4.000 million of FY22 will be realigned into APE 611102AB1, Basic Research in Infect Dis, Oper Med and Combat Care;

\$7.000 million of FY22 will be realigned into APE 622787MM4, Cbt Casualty Care Applied Rsch Technology

\$18.200 million of FY22-26 will be realigned into APE 622787MM8, Infectious Diseases and Applied Rsch Technology

\$31.800 million of FY22-26 will be realigned into APE 633002MO2, Traumatic Brain Injury (TBI) Treatment Adv Tech

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army **Date:** May 2021

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|--|---|--|
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | Project (Number/Name) 814 / NEUROFIBROMATOSIS (CA) |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|-----------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 814: NEUROFIBROMATOSIS (CA) | - | 15.000 | 20.000 | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | - | - |

Note

Congressional increase for Neurofibromatosis Research Program.

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurofibromatosis research.

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

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

| | FY 2020 | FY 2021 |
|--|---------|---------|
| Congressional Add: Peer-reviewed Neurofibromatosis Research | 15.000 | 20.000 |
| FY 2020 Accomplishments: Program Increase supported advanced research on Neurofibromatosis. Work executed by Army Futures Command. | | |
| FY 2021 Plans: Program Increase supported advanced research on Neurofibromatosis. Work executed by Army Futures Command. | | |
| Congressional Adds Subtotals | 15.000 | 20.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army **Date:** May 2021

| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) 945 / <i>BREAST CANCER STAMP PROCEEDS</i> | | | |
|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------|-------------------------|-------------------|
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| 945: <i>BREAST CANCER STAMP PROCEEDS</i> | - | 0.454 | - | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

This Project receives funds as proceeds from the sale of Breast Cancer Stamps.

A. Mission Description and Budget Item Justification

This Project receives funds as proceeds from the sale of Breast Cancer Stamps.

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

| | FY 2020 | FY 2021 |
|---|----------------|----------------|
| Congressional Add: Breast Cancer Stamp Proceeds | 0.454 | - |
| FY 2020 Accomplishments: Breast Cancer Stamp Proceeds. | | |
| Congressional Adds Subtotals | 0.454 | - |

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

N/A

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

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|--|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|-----------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) 97T / NEUROTOXIN EXPOSURE TREATMENT (CA) | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| 97T: NEUROTOXIN EXPOSURE TREATMENT (CA) | - | 16.000 | 16.000 | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

Congressional increase for Peer-Reviewed Neurotoxin Exposure Treatment Parkinson's Research Program.

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurotoxin Exposure Treatment.

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

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

| | FY 2020 | FY 2021 |
|---|----------------|----------------|
| Congressional Add: Peer-reviewed Neurotoxin Exposure Treatment Parkinson's Research | 16.000 | 16.000 |
| FY 2020 Accomplishments: Program Increase supported advanced research on Neurotoxin Exposure Treatment Parkinson's Research. Work executed by Army Futures Command. | | |
| FY 2021 Plans: Program Increase supported advanced research on Neurotoxin Exposure Treatment Parkinson's Research. Work executed by Army Futures Command. | | |
| Congressional Adds Subtotals | 16.000 | 16.000 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) CJ3 / Prophylactic for Endemic Diarrheal Diseases | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| CJ3: Prophylactic for Endemic Diarrheal Diseases | - | - | - | 4.009 | - | 4.009 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

In Fiscal Year 2022 this Project was realigned from:
 PE 0602787A (Medical Technology)
 * Project MM8 (Infectious Diseases and Applied Rsch Technology)
 PE 0603002A (Medical Advanced Technology)
 * Project MO9 (Vaccines to Prevent Dengue Fever Advanced Tech)

A. Mission Description and Budget Item Justification

Demonstrate bacterial diarrheal prophylactic candidate safety, effectiveness, and pharmacokinetics through clinical trials in humans. Transition the prophylactic candidate to product developer in support of future FDA licensure.

Research is conducted in compliance with FDA regulations for medical products for human use.

Work is managed by the United States Army Medical Research and Development Command (USAMRDC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

Work in this Project is performed by the USAMRDC, Fort Detrick, MD.

Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Prophylactic for Endemic Diarrheal Diseases | - | - | 4.009 |
| Description: Demonstrate bacterial diarrheal prophylactic candidate safety, effectiveness, and pharmacokinetics through clinical trials in humans. Transition the prophylactic candidate to product developer in support of future FDA licensure. | | | |

UNCLASSIFIED

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) CJ3 / <i>Prophylactic for Endemic Diarrheal Diseases</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| <p><i>FY 2022 Plans:</i> Will mature oral prophylactic candidates for the prevention of bacterial diarrheal diseases; validate commercial off the shelf (COTS) products for prevention of bacterial diarrheal diseases; provide data packages for the FDA to test suitable candidates in humans for safety and effectiveness; demonstrate the candidates in human clinical trials for safety and effectiveness against bacterial diarrheal diseases.</p> <p><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Funds realigned from other efforts in Project MM8 (Prevention and Treatment of Viral Diseases) and Project MO9 (Demonstrate Safety and Perform Limited Efficacy in Humans of a Vaccine to Prevent Dengue Fever).</p> | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 4.009 |

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

N/A

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

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|--|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|-----------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MG4 / Tech Base/Enabling Res in Mil Occup Med Adv Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MG4: Tech Base/Enabling Res in Mil Occup Med Adv Tech | - | 7.984 | - | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

Medical efforts support laboratory studies and field demonstrations of biomedical products designed to counteract diverse environmental, physiological and psychological stressors, as well as reduce the impacts of hazards encountered in training and operational environments. Initiatives will demonstrate and transition medical technologies to support Soldier/squad survivability under demanding operational tempo in order to protect, optimize and enhance Soldier performance and sustain lethality across the diverse range of military operations.

The four main thrust areas are:

- (1) Physiological Health,
- (2) Environmental Protection,
- (3) Injury Prevention and Reduction,
- (4) Psychological (mental) Health and Resilience.

The cited work is fully coordinated with Combat Capabilities Development command Soldier Center and with other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by: the U.S. Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Injury Prevention & Reduction | 0.754 | - | - |
| Description: This effort supports and validates injury prediction tools and return-to-duty assessments for brain, spine, and chest injury from blast, blunt, and ballistic impact. These are all priorities for Program Executive Office (PEO)-Soldier and support various Maneuver Center of Excellence programs including Soldier Protection Systems (e.g., Integrated Head Protection Systems and Vital Torso Protection Systems). This effort also addresses need for validated aeromedical standards and strategies to enable aircrew to effectively fight, navigate, and land under a range of degraded visual environments and provide aeromedical return to duty guidelines after neurosensory injury (deficits in the nervous system control of vision, hearing, taste, smell, and touch). This supports Cross Functional Team (CFT) Future Vertical Lift. | | | |

UNCLASSIFIED

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| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MG4 / <i>Tech Base/Enabling Res in Mil Occup Med Adv Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| Title: Physiological Health & Performance Description: This effort supports and matures laboratory prototypes, evaluates nutritional formulations and interventions, and validates decision aids for the prediction of Soldier performance in high operational tempo military environments. | | 2.675 | - | - |
| Title: Psychological Health & Resilience Description: This effort supports and validates neurocognitive (relating to or involving the central nervous system and cognitive abilities) assessment and brain injury detection methods, and validates tools and preclinical methods to treat post-traumatic stress disorder in a military population. This effort also supports validation of interventions in Warfighters for PTSD, validation of biomarkers of individual PTSD symptoms, validation of methods to follow effectiveness of PTSD treatments, validation of neuroprotective (protection of nerves and nervous system) interventions and validation of strategies to prevent neurocognitive deficits (reduced ability to learn and comprehend) and symptomatology associated with brain injury. This effort matures and validates early interventions to prevent and reduce military stressor and combat-related behavioral health problems, including symptoms of PTSD, depression, anger problems, anxiety, substance abuse, suicide, and other health risk behaviors. This effort matures and validates tools and interventions to enhance and sustain psychological resilience throughout Soldiers' careers. | | 0.586 | - | - |
| Title: Environmental Health & Protection Description: This effort supports and matures non-invasive technologies, decision-aid tools, and models to enhance Soldier protection and sustainment across the operational spectrum. The aim is to provide the scientific basis for developing focused heating and cooling solutions to maintain fine motor dexterity, core temperature, and optimized physical and cognitive performance during cold-weather and hot-humid operations. This effort tests a computational algorithm for identifying latent hepatic, renal, and cardiac injury after toxic metal and/or toxic industrial chemical exposure during training and operations. This effort tests models to predict likelihood of neurologic and/or physical injury as a result of hazardous exposure(s) in the operational environment. | | 3.969 | - | - |
| Accomplishments/Planned Programs Subtotals | | 7.984 | - | - |
| C. Other Program Funding Summary (\$ in Millions) N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy N/A | | | | |

UNCLASSIFIED

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MM2 / MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA) | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MM2: MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA) | - | 10.000 | 21.000 | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

Congressional increase for Peer-reviewed military burn research.

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Medical Advanced Technology Initiatives.

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

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

| | FY 2020 | FY 2021 |
|---|----------------|----------------|
| Congressional Add: Peer-reviewed Military Burn Research Program | 10.000 | - |
| FY 2020 Accomplishments: Program Increase supported advanced research on Military Burn Research Program. Work executed by Army Futures Command. | | |
| Congressional Add: Program increase: Burn care training curriculum | - | 5.000 |
| FY 2021 Plans: Program Increase supported advanced research on Burn Care Training Curriculum. Work executed by Army Futures Command. | | |
| Congressional Add: Program increase - peer-reviewed military burn research | - | 10.000 |
| FY 2021 Plans: Program Increase supported advanced research on Peer-reviewed Military Burn Research. Work executed by Army Futures Command. | | |
| Congressional Add: Program increase: Advanced hemostat products | - | 6.000 |
| FY 2021 Plans: Program Increase supported advanced research on Advanced Hemostat Products. | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | Date: May 2021 |
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| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MM2 / <i>MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)</i> |
|--|--|--|

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2020 | FY 2021 |
|---|----------------|----------------|
| Work executed by Army Futures Command. | | |
| Congressional Adds Subtotals | 10.000 | 21.000 |

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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MM5 / <i>Tech Base/Enabling Res Combat Cas Care Adv Tech</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MM5: <i>Tech Base/Enabling Res Combat Cas Care Adv Tech</i> | - | 2.328 | - | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

Preclinical and early clinical development, demonstration, and transition of new combat casualty care technologies that save lives and minimize permanent injury following combat-related traumatic injuries. Focus is identifying more effective critical care technologies and clinical practice guidelines to treat severe bleeding, traumatic brain injury, burns and other combat related traumatic injuries.

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through applied research conducted under PE 0602787A (Medical Technology) Project 874 (Cbt Casualty Care Tech) are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development) Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by: the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| Title: Combat Trauma Therapies | 1.040 | - | - |
| Description: This effort focuses on work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries. | | | |
| Title: Pre-Hospital Tactical Combat Casualty Care | 0.457 | - | - |
| Description: This effort supports demonstration and validation of materiel and knowledge products to advance the level of care that can be provided given the tactical, environmental, and patient factors inherent in the prehospital combat setting. Successful translation of research to the field will augment combat medic capabilities, thereby reducing death and serious injury in the battlefield space where the majority of preventable casualty deaths occur. | | | |
| Title: Traumatic Brain Injury | 0.831 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MM5 / <i>Tech Base/Enabling Res Combat Cas Care Adv Tech</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Description: This effort supports work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from TBI. | | | |
| Accomplishments/Planned Programs Subtotals | 2.328 | - | - |

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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MM7 / Enabling Med Cap to Support Dispersed OPS Adv Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MM7: Enabling Med Cap to Support Dispersed OPS Adv Tech | - | 1.744 | 2.913 | 3.232 | - | 3.232 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project supports advanced technology research to develop tools and prototype medical intelligent systems for Soldiers operating in resource-constrained, hazardous or denied entry environments and for denied, interrupted, or low communications (DIL) characteristic of Multi-Domain Operations: 1) actionable decision support tools that use machine learning and predictive analytic techniques to produce treatment recommendations for "non-expert" providers (such as combat lifesavers and combat medics), infer the patient's condition based on diverse sources of information (e.g. sensor data, medic observations, etc.) , and provide recommendations based on established care guidelines. 2) secure remote patient tele-monitoring, provider telementoring, and medical device teleoperation, and 3) modular, self-contained, platform agnostic, "roll-on, roll-off" robotic and autonomous unmanned system payloads to support medical resupply, casualty evacuation and treatment via man-machine teaming.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Combat Evacuation Mission Module | 1.744 | - | - |
| Description: Research, design and develop a tele-monitored and remote-controlled Combat Evacuation Mission Module to support medical resupply and casualty evacuation using future multi-purpose vertical takeoff and landing (VTOL) UAS. Provides a self-contained medical module capability adaptable to various future multi-purpose VTOL UAS. | | | |
| Title: Medical Robotic and Autonomous Systems | - | 2.913 | - |
| Description: This Task now incorporates the previous Combat Evacuation Mission Module Task. Research, design and develop a tele-monitored and remote-controlled Combat Evacuation Mission Module to support medical resupply and casualty evacuation using future multi-purpose VTOL UAS. Provides a self-contained medical module capability adaptable to various future multi-purpose VTOL UAS. Research, design, and prototype an intelligent decision-support capability that can be operated on an Army or Navy provided End User Device (EUD), such as the NETT Warrior system, to assist medics with patient assessment, triage, treatment, and disposition in a Prolonged Field Care (PFC) environment by assessing patient conditions to provide adaptive care guidelines. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MM7 / <i>Enabling Med Cap to Support Dispersed OPS Adv Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| <p>FY 2021 Plans: Validate conceptual designs and physical prototypes for a Multi-Mission Vehicle Interface (MMVI) system for both manned and unmanned air and ground platforms. This MMVI consists of a common vehicle floor and rail system for rapid configuration of the cabin space and installation of both autonomous and attended en route care systems and innovative patient handling systems. Optimizes design of the MMVI, targeting integration with an Army Future Vertical Lift (FVL) prototype or technology demonstrator vehicle and conduct final integration and demonstration of MMVI prototype. Demonstrate vehicle options that may include 1) a FVL prototype or technology demonstrator vehicle, 2) the ?optionally-manned? variant of the UH-72 Lakota, or 3) the Squad Multipurpose Equipment Transport (SMET) Unmanned Ground Vehicle (UGV). Based on the previous applied research, and in collaboration with US Army Aeromedical Research Laboratory (USAARL) and Combat Capabilities Development Command Aviation and Missile Center, prototype and demonstrate a mission-based flight control interface system integrating with a relevant (optionally-manned FVL variant or similar) UAS flight control system. Demonstrate a proof-of-concept prototype implementation of a rule-based Decision Support System (DSS) knowledge base using published Tactical Combat Casualty Care (TCCC) guidelines for one or more typical use cases. Demonstrate clinical knowledge authoring and knowledge base development techniques. Based on previous applied research, demonstrate sensor fusion, signal processing, and analysis on acquired patient data to understand the context of the data and provide inputs to the Decision Support System. Integrate the DSS with prototype closed loop technologies such as the Navy?s Autonomous Critical Care System (ACCS).</p> | | | | |
| <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funds realigned to other efforts within Project MM7 (Develop Prototype Medical Robotic and Autonomous System).</p> | | | | |
| <p>Title: Develop Prototype Medical Robotic and Autonomous System (Med-RAS)</p> <p>Description: Matures and demonstrates a tele-monitored and remote-controlled Combat Evacuation Mission Module to support medical resupply and casualty evacuation using future multi-purpose Vertical Take-Off and Landing (VTOL) UAS. Provides a self-contained medical module capability adaptable to various future multi- purpose VTOL UAS. Matures and demonstrates an intelligent decision-support capability that can be operated on an Army or Navy provided End User Device (EUD), such as the NETT Warrior system, to assist medics with patient assessment, triage, treatment, and disposition in a Prolonged Field Care (PFC) environment by assessing patient conditions to provide adaptive care guidelines.</p> <p>FY 2022 Plans: Will mature a self-contained Semi-Autonomous Casualty Management Module (SACM2) for integration of medical capability components to move from human to semi-autonomous, and fully automate interfaces for both tele-operated and closed-loop controlled remote patient monitoring and management systems and in-flight interventions; provide communication infrastructure and cyber security solutions for remote patient monitoring, remote supervision and control of semi-autonomous patient management systems, and Virtual Health support for attending medics; demonstrate a Safe Transport and Evacuation Protocol</p> | | - | - | 3.232 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MM7 / <i>Enabling Med Cap to Support Dispersed OPS Adv Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| System (STEPS) to implement the flight control constraints necessary to ensure patient safety and protect sensitive medical materiel during flight onboard unmanned or ?optionally-piloted? vehicles; optimize a Multi-Mission Vehicle Interface which includes an innovative patient handling system and a common vehicle interface (physical, electrical, and data links), providing a means to rapidly reconfigure future vehicle platforms for MEDEVAC or CASEVAC missions; mature a hardware system to enable video and audio data collection for integrating Computer Vision and Natural Language Processing technologies to automate documentation of patient encounter and medic interventions. | | | | |
| FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned from other efforts within Project MM7 (Medical Robotic and Autonomous System). | | | | |
| Accomplishments/Planned Programs Subtotals | | 1.744 | 2.913 | 3.232 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MM9 / Tech Base/Enabling Rsrch for Infect Dis Adv Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MM9: Tech Base/Enabling Rsrch for Infect Dis Adv Tech | - | 2.961 | - | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

Advanced technology development, demonstration, and integration of model systems required for Food and Drug Administration (FDA) approval or licensure of medical countermeasures, such as drugs, vaccines, and devices, against military health threats for which human effectiveness studies are not feasible or ethical.

Research is conducted in compliance with FDA regulations and guidance.

Work is managed by the United States Army Medical Research and Development Command (USAMRDC).

Technologies developed in this Project are integrated with specific countermeasures under PE 0603807A (Medical Systems Advanced Development) to conduct pivotal demonstrations of effectiveness required for FDA approval.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the USAMRDC, Fort Detrick, MD including USAMRIID (Fort Detrick, MD) and USAMRICD (Aberdeen Proving Ground, MD).

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Advanced Technology Research on drugs and vaccines against parasitic diseases | 1.980 | - | - |
| Description: Test lead drug candidates in healthy volunteers to determine drug pharmacology, safety, and effectiveness against malaria. Transition the lead anti-malarial drug with improved safety, effectiveness and less frequent dosing to advanced development. Perform small studies in healthy volunteers to test vaccine safety, effectiveness and immunogenicity against malaria with down-selection and transition of the vaccines to advanced development. | | | |
| Title: Viral Disease Threats | 0.981 | - | - |
| Description: Perform small studies in healthy volunteers to test vaccine safety, effectiveness, and immunogenicity against Dengue and Hantaviruses infections so as to down-select and transition lead vaccine candidates to advanced development. | | | |
| Accomplishments/Planned Programs Subtotals | 2.961 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technol ogy</i> | Project (Number/Name) MM9 / <i>Tech Base/Enabling Rsrch for Infect Dis Adv Tech</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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MN3 / Immediate Cardiopulmonary Stabilization Adv Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MN3: Immediate Cardiopulmonary Stabilization Adv Tech | - | 1.864 | 2.071 | 1.727 | - | 1.727 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project covers development, pre-clinical and early-clinical demonstration, and transition of technologies for immediate pre-hospital hemorrhage detection and control and airway management. These technologies facilitate autonomous intubation and airway management in combat casualties with obstructed airways. This Project also demonstrates advanced technologies for use in forward areas to detect and control non-compressible internal bleeding, and demonstration of pain-relieving drugs that are safe for use during bleeding.

Promising efforts identified through Applied Research conducted under PE 0602787A (Medical Technology) Project MM4 (Cbt Casualty Care Applied Rsch Technology) are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development) Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy. Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| Title: Immediate Cardiopulmonary Stabilization Advanced Technology | 1.864 | 2.071 | - |
| Description: Development, preclinical and early-clinical demonstration, and transition of technologies that facilitate autonomous intubation and airway management in combat casualties with obstructed airways, as well as advanced hemostatic bandage candidates that augment the patient's blood clotting system and new tourniquet technologies suitable for prolonged use. | | | |
| FY 2021 Plans: Perform preclinical demonstration and clinical validation of sensor technology to aid medics performing endotracheal intubation (placement of a flexible plastic tube into the windpipe to maintain an open airway) and airway management; validate currently available pain relieving drugs in an animal model of hemorrhage with orthopedic trauma; demonstrate preclinical and clinical minimally invasive interventional technologies for control of non-compressible truncal hemorrhage; clinically demonstrate new technology to detect hemorrhage in trauma casualties through computer analysis of standard vital signs. | | | |
| FY 2021 to FY 2022 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN3 / <i>Immediate Cardiopulmonary Stabilization Adv Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| Funds realigned to Project MN3 (Tactical Combat Casualty Care Pharmaceuticals and Devices Cap Set 1). | | | | |
| Title: Tactical Combat Casualty Care Pharmaceuticals and Devices Cap Set 1 | | - | - | 1.727 |
| Description: Development, preclinical and early-clinical demonstration, and transition of technologies that facilitate autonomous intubation and airway management in combat casualties with obstructed airways, as well as advanced hemostatic (arrest of bleeding) bandage candidates that correct the patient's blood clotting system and new tourniquet technologies suitable for prolonged use. | | | | |
| FY 2022 Plans: Demonstrate most promising bleeding control intervention candidates for limb and junctional bleeding (bleeding from a junction of the torso to the extremities, i.e., the base of the neck, shoulder, axilla, perineum, buttocks, gluteal area and the groin) through mechanical testing, and provide best practices for bleeding control; engineer battlefield-relevant manikin and employ large animal injury models for demonstration of airway management technologies and devices. | | | | |
| FY 2021 to FY 2022 Increase/Decrease Statement: Funds realigned from other efforts within Project MN3 (Immediate Cardiopulmonary Stabilization Advanced Technology). | | | | |
| Accomplishments/Planned Programs Subtotals | | 1.864 | 2.071 | 1.727 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MN4 / <i>Advanced Life Support Advanced Technology</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MN4: <i>Advanced Life Support Advanced Technology</i> | - | 3.710 | 3.615 | 3.927 | - | 3.927 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project covers development, demonstration, and transition of technologies that enable advanced life support under prolonged care scenarios, including life-support devices that provide lung and kidney functions in casualties with severe injuries and devices and clinical guidelines for the prevention of irreversible organ damage resulting from prolonged lack of blood circulation.

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through Applied Research conducted under PE 0602787A (Medical Technology) Project MM4 (Cbt Casualty Care Applied Rsch Technology) are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development) Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| Title: Battlefield Sustainment of Critical Organ Function Capability Set 1 | 3.710 | 3.615 | 3.927 |
| Description: Develop, demonstrate and transition technologies that enable advanced life support under prolonged field care scenarios: life-support devices that provide lung and kidney functions in casualties with severe injuries, and devices and clinical guidelines for the prevention of irreversible organ damage resulting from prolonged lack of blood circulation. | | | |
| FY 2021 Plans: Demonstrate lead candidate anti-blood clotting technologies for coating of extracorporeal life support (ECLS) circuitry vs standard of care in advanced animal injury models; validate prototype ECLS technologies with and without mechanical ventilation in simulated forward environments under prolonged field care conditions; begin demonstration of ECLS in combination with non-compressible hemorrhage control technologies, and modular ECLS systems for cardiorespiratory, kidney, and liver support. | | | |
| FY 2022 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN4 / <i>Advanced Life Support Advanced Technology</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| <p>Will perform preclinical validation studies of down selected Nitric oxide-release/Non-adhesive coating in extracorporeal life support (ECLS) circuit vs. immobilized heparin standard of care in advanced injury models; mature and demonstrate a single device and pump driven modular platform for lung and renal support that will carry out ECLS without systemic anticoagulation; demonstrate portable ECLS platform designed to improve blood oxygenation through first in human study to inform the US critical care community about the safety, feasibility and efficacy of this system in reducing mechanical ventilator settings, and avoiding use of mechanical ventilation in the critically ill.</p> <p><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Funding change reflects planned lifecycle of this effort.</p> | | | | |
| Accomplishments/Planned Programs Subtotals | | 3.710 | 3.615 | 3.927 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MN5 / <i>Next Generation Blood Products Advanced Technology</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MN5: <i>Next Generation Blood Products Advanced Technology</i> | - | 5.725 | 6.610 | 9.394 | - | 9.394 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project covers technology development, pre-clinical and early-clinical demonstration, and transition of new blood products with increased shelf life and functionality. Cold-stored platelets, fibrinogen replacement technologies, and pharmaceuticals that protect and metabolically stabilize blood-deprived tissues and reverse impaired blood clotting subsequent to severe injury, will improve prompt hemorrhage control, mitigate effects of shock, and minimize sustainment requirements.

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through Applied Research conducted under PE 0602787A (Medical Technology) Project MM4 (Cbt Casualty Care Applied Rsch Technology) are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development) Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Next Generation Human-Derived Blood Replacement | 5.725 | 6.610 | 9.394 |
| Description: Develop, demonstrate in pre-clinical and early-clinical studies, and transition new blood products with increased shelf life and functionality including cold-stored platelets and biopharmaceutical technologies that stop life threatening bleeding, stabilize tissue metabolism, mitigate shock and restore normal blood clotting will improve prompt hemorrhage control and minimize sustainment requirements. | | | |
| FY 2021 Plans: Perform preclinical validation of hypotensive (lower than normal blood pressure) resuscitation parameters in militarily-relevant trauma; optimize and validate low volume resuscitation algorithms; validate therapeutic approaches to inform new clinical practices using synthetic and animal models of acute coagulopathy (impaired blood clotting ability) of trauma; demonstrate candidate drugs in animal hemorrhage models to identify potential candidates with optimal hemostatic (refers to an agent that | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN5 / <i>Next Generation Blood Products Advanced Technology</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| <p>stops bleeding) and metabolic stabilizing effects; validate candidate hemostatic devices to improve hemorrhage control and survival of bleeding casualties under prolonged field care scenarios and during states of inhibited blood clotting ability; conduct preclinical and clinical demonstration of blood clotting capability when platelets are stored under novel conditions to prolong shelf life.</p> <p>FY 2022 Plans: Will perform preclinical studies and early clinical evaluations aimed at extending availability of whole blood, platelets, and plasma to all areas of the battlefield; comparatively demonstrate ability of promising cold-stored platelet additives to extend shelf life and maintain normal platelet function; validate engineered plasma in a small animal polytrauma model for ability to reverse acute traumatic coagulopathy (a condition in which the blood's ability to form clots is impaired), prolong survival, and improve outcomes; validate currently available portable blood storage and transport containers under a variety of environmental conditions for impact on blood function.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Fund realigned from other efforts within PE 0603002 (Medical Advanced Technology).</p> | | | | |
| Accomplishments/Planned Programs Subtotals | | 5.725 | 6.610 | 9.394 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MN6 / Blast & Head Impact Exposure Monitor Advanced Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MN6: Blast & Head Impact Exposure Monitor Advanced Tech | - | 1.354 | 1.878 | 1.546 | - | 1.546 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This project will inform the development of technologies and strategies to detect and provide actionable information to unit leader/Soldier about hazardous exposure to blast and head impact. This capability will help prevent degradation to Soldier cognitive readiness and performance and enhance combat power.

The cited work is fully coordinated with PE 0602143A (Soldier Lethality Technology) and complimentary to PE 0603118A (Soldier Lethality Advanced Technology) and is fully coordinated with other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY21 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy. Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Blast & Head Impact Exposure Monitor | 1.354 | - | - |
| Description: This effort will develop a prototype predictive tool that can provide the unit leader an indication of whether a potential mild traumatic brain injury event has occurred. This capability will provide the unit leader an additional objective tool to determine whether a Soldier can be safely exposed to more impacts without increased risk of injury. | | | |
| Title: Injury Criteria for Informing the Development of New Tactical Head borne Systems. | - | 1.878 | 1.546 |
| Description: This effort validates injury risk assessment/guidance/criteria that will inform the development of technologies (i.e., personal protection equipment, vehicles) and strategies (i.e., health hazard assessments) to protect the Soldier against current and emerging operational threats (i.e., blast, blunt, ballistic, and accelerative). | | | |
| FY 2021 Plans: Expand the collection of field measurements of blast exposure and head impact data from heavy weapons training, breaching, and airborne communities in order to validate a blast and head impact exposure monitoring algorithm for a next generation head protection system. Refine and validate cervical neck injury criteria for next generation head borne and protection systems. | | | |
| FY 2022 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN6 / <i>Blast & Head Impact Exposure Monitor Advanced Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| Finalize the validation and deliver Go/No Go Readiness predictive algorithm that will alert and inform unit leader/Soldier of cognitive status after a potential injurious head impact and blast exposure has occurred. Finalize the validation and deliver head supported mass criteria in dismounted Soldier environments. | | | | |
| FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned to PE 0603002A Project M02 (Traumatic Brain Injury (TBI) Treatment Adv Tech). | | | | |
| Accomplishments/Planned Programs Subtotals | | 1.354 | 1.878 | 1.546 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MN7 / Musculoskeletal Injury Screening Tool Adv Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MN7: Musculoskeletal Injury Screening Tool Adv Tech | - | 0.287 | 3.274 | 1.664 | - | 1.664 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

In Fiscal Year 2022 this Project was realigned from:
 PE 0603002A (Medical Advanced Technology)
 *Project MN1 (Applied Sensory Systems Trauma Technology)

A. Mission Description and Budget Item Justification

This project develops strategies and technologies to reduce musculoskeletal injury (MSKI) rates and improve outcomes following Return to Duty (RTD) in the Army training (i.e., TRADOC), operational (e.g., FORSCOM, USASOC) and medical communities (e.g., OTSG) to improve Soldier readiness.

The cited work is fully coordinated with PE 0602143A (Soldier Lethality Technology) and complimentary to PE 0603118A (Soldier Lethality Advanced Technology), and is fully coordinated with the Army Training and Doctrine Command (TRADOC) and other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY21 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Musculoskeletal Injury Screening Tool | 0.287 | - | - |
| Description: This capability will deliver a prototype unit leader tool that can provide an objective assessment of musculoskeletal tissue integrity and provide fitness or return-to-duty recommendations. | | | |
| Title: Leader and Medical Provider Tools to Prevent and Reduce Musculoskeletal Injury in All Settings | - | 3.274 | 1.067 |
| Description: Project validates in field environment strategies and technologies to reduce musculoskeletal injury (MSKI) rates and improve outcomes following Return to Duty (RTD) in the Army training (i.e., TRADOC), operational (e.g., FORSCOM, USASOC) and medical communities (e.g., OTSG) to improve Soldier readiness. | | | |
| FY 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN7 / <i>Musculoskeletal Injury Screening Tool Adv Tech</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| <p>Complete primary data collection and processing of established biomarkers for stress fracture from 1,500 participants; provide initial bone biomarker and microstructure data for transition to the Training and Doctrine Command's U.S. Army Center for Initial Military Training (TRADOC/USACIMT) to inform strategies for reducing injury risk.</p> <p>FY 2022 Plans: Will provide follow-up data, data processing, and dissemination of Nonsteroidal Anti-inflammatory Drugs (NSAIDs) data to the U.S. Army Training and Doctrine Command/Center for Initial Military Training (TRADOC/CIMT); provide the most important modifiable risk factors from validated field musculoskeletal injury data and begin transition of an injury risk capability to TRADOC/CIMT.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned to PE 0603002A Project MO2 (Traumatic Brain Injury (TBI) Treatment Adv Tech).</p> | | | |
| <p>Title: Forward Neuro-Muscular Skeletal Injury Assessment to Reduce Unnecessary Evacuations</p> <p>Description: This program will validate solutions to accurately assess the severity of acute, non-penetrating soft-tissue injuries in training and operational environments. This capability once transitioned will show proof of concept of a capability that will improve Soldier readiness and return to duty and limit unnecessary evacuations by accurately diagnosing and assessing musculoskeletal injury.</p> <p>FY 2022 Plans: Will validate field expedient bone imaging technologies; validate use of existing handheld ultrasound technologies with limited use providers for use in the field; validate use of real-time handheld ultrasound to assess soft tissue injury in the field by providers with limited training.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funds realigned from PE 06022787A (Medical Technology) Project MN1 (Applied Sensory Systems Trauma Technology).</p> | - | - | 0.597 |
| Accomplishments/Planned Programs Subtotals | 0.287 | 3.274 | 1.664 |

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

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army **Date:** May 2021

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|--|---|--|
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | Project (Number/Name) MN8 / Drugs to Prevent and Treat Malaria Advanced Tech |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| MN8: <i>Drugs to Prevent and Treat Malaria Advanced Tech</i> | - | 2.057 | - | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | - | - |

Note

In Fiscal Year 2021 this Project is realigned to:
 PE 0602787A (Medical Technology)
 * Project MM8 (Infectious Diseases and Applied Rsch Technology)

A. Mission Description and Budget Item Justification

This Project covers technology development, demonstration, and transition of a candidate malaria prevention drug with weekly or less frequent dosing. The candidate drug may also be effective for the treatment of *P. falciparum* and *P. vivax* malaria. Infectious disease prevention sustains individual and unit readiness and reduces health services requirements and cost. Research is conducted in compliance with Food and Drug Administration (FDA) regulations for medical products for human use.

Work is managed by the United States (U.S.) Army Medical Research and Development Command (USAMRDC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.

Promising medical countermeasures identified in this Project are further matured under PE 0603807A (Medical Systems Advanced Development), Project 808 (DoD Drug & Vacc Ad).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by: the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|
| Title: Drugs to Prevent and Treat Malaria Advanced Technology | 2.057 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN8 / <i>Drugs to Prevent and Treat Malaria Advanced Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| Description: Test drugs in healthy volunteers to determine drug pharmacology, safety, and effectiveness against malaria. Transition current lead anti-malarial prophylactic drug (triazine) with improved safety, effectiveness, and requiring less frequent dosing to Program Manager for Pharmaceutical (PM Pharm) in support of future FDA licensure. | | | | |
| Accomplishments/Planned Programs Subtotals | | 2.057 | - | - |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MN9 / <i>Far Forward Behavioral Health Care Advanced Tech</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MN9: <i>Far Forward Behavioral Health Care Advanced Tech</i> | - | 0.255 | 1.080 | 0.283 | - | 0.283 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This effort will deliver a tested delivery system for behavioral health interventions oriented to far forward settings that will ensure the psychological readiness of Soldiers and safeguard their far forward readiness and performance in austere operating environments, under high intensity operational stressors.

The cited work is fully coordinated with PE 0602143A (Soldier Lethality Technology) and complimentary to PE 0603118A (Soldier Lethality Advanced Technology), and is fully coordinated with other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY21 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| Title: Optimal Delivery of Far Forward Behavioral Health Care | 0.255 | - | - |
| Description: The effort will deliver improved psychological treatment interventions to keep Soldiers in the fight under high intensity operational stressors. | | | |
| Title: Far Forward Behavioral Health Care | - | 1.080 | 0.283 |
| Description: This effort will deliver a tested delivery system for behavioral health interventions oriented to far-forward settings that will ensure the psychological readiness of Soldiers and safeguard their far-forward readiness and performance in austere operating environments, under high intensity operational stressors. | | | |
| FY 2021 Plans: Validate interventions and technologies that promote rapid recovery from acute stress and other behavioral health problems in far-forward settings immediately following a traumatic battlefield event; field test content and products to deliver behavioral health stabilization services oriented to far-forward settings; provide team-based training (Team CORE) to boost social connection and | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MN9 / <i>Far Forward Behavioral Health Care Advanced Tech</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| <p>reduce individual isolation, a major risk factor in behavioral health; mature components for enhancing behavioral health leadership skills and deliver new training.</p> <p>FY 2022 Plans: Will complete sleep leadership training data analyses demonstrating efficacy of training for improving sleep leadership and sleep behaviors & transition, a brief sleep leadership training module intended for Behavioral Health Officers (BHOs) or their equivalent to provide to unit leadership teams. The training module will be delivered to the US Army Medical Center of Excellence (MEDCoE) to be incorporated into training courses and to the Office of the Surgeon General (OTSG) Behavioral Health Service Line (BHSL). Will optimize the sleep leadership training by conducting interviews with BHOs and incorporating feedback to increase usability, feasibility, and impact of training.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned to PE 0603002A Project MO2 (Traumatic Brain Injury (TBI) Treatment Adv Tech).</p> | | | |
| Accomplishments/Planned Programs Subtotals | 0.255 | 1.080 | 0.283 |

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| <p>C. Other Program Funding Summary (\$ in Millions) N/A</p> <p>Remarks</p> |
| <p>D. Acquisition Strategy N/A</p> |

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|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|-----------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MO2 / <i>Traumatic Brain Injury (TBI) Treatment Adv Tech</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MO2: <i>Traumatic Brain Injury (TBI) Treatment Adv Tech</i> | - | 4.108 | 4.649 | 10.667 | - | 10.667 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

In FY 2022 funding for this Project was realigned from:

PE 0602787A (Medical Technology)

- *Project MM4 (Cbt Casualty Care Applied Rsch Technology)
- *Project MM6 (Medical Technologies to Support Dispersed Ops Tech)
- *Project MK4 (Warfighter Health Applied Rsch Technology)

PE 0603002A (Medical Advanced Technology)

- *Project MM7 (Enabling Med Cap to Support Dispersed OPS)
- *Project MN3 (Immediate Cardiopulmonary Stabilization Adv Tech)
- *Project MN4 (Advanced Life Support Advanced Technology)
- *Project MN5 (Next Generation Human-Derived Blood Products Advanced Technology)
- *Project MN6 (Blast & Head Impact Exposure Monitor Advanced Tech)
- *Project MN7 (Musculoskeletal Injury Screening Tool)
- *Project MN9 (Far Forward Behavioral Health Care Advanced Tech)
- *Project MO7 (Improved Bone Repair Advanced Technology)
- *Project MO8 (Expeditionary Performance Nutrition Advanced Tech)

A. Mission Description and Budget Item Justification

This Project covers development, demonstration, transition of technologies for acute battlefield management of brain trauma, and maintains laboratory capability to perform these functions. Efforts include pre-clinical demonstration of drug therapy and resuscitation strategies for treatment of acute brain injury in the pre-hospital setting, biomarkers, diagnostics, and devices, as well as novel drug delivery technologies to facilitate administration of pharmaceuticals at or near the point of injury to protect the injured brain from further damage.

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | Date: May 2021 |
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| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MO2 / <i>Traumatic Brain Injury (TBI) Treatment Adv Tech</i> |
|--|--|--|

Promising efforts identified through Applied Research conducted under PE 0602787A (Medical Technology) Project MM4 (Cbt Casualty Care Applied Rsch Technology) are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development) Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Medical Research Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| <p>Title: Drugs to Prevent and Treat Brain Injury (TBI)</p> <p>Description: Develop, demonstrate, and transition technologies to treat combat-related brain injury. Technologies include drugs administered at or near the point of injury to treat combat-related brain injury while also stabilizing and protecting non-injured brain tissues, and novel drug delivery platforms that specifically target injured brain cells.</p> <p>FY 2021 Plans: Demonstrate pre-clinically neuroprotective and anti-inflammatory effects of drugs and biologics delivered directly to brain cells via targeting nanoparticles; validate pre-clinical and clinical pre-hospital administered drugs to stabilize the blood clotting system in injured brain tissue; demonstrate pre-clinically drugs for stabilizing metabolic function in injured brain tissue and preserving function of brain cells after injury.</p> <p>FY 2022 Plans: Will evaluate a novel drug-releasing gel material designed for application at point of injury that will safely seal open penetrating brain injuries, protecting exposed brain tissue from further injury while simultaneously releasing potent anti-inflammatory, antibiotic drugs directly to the injured brain; validate prehospital intranasal administration of drugs to preserve brain cell function following traumatic brain injury. Will continue studies to demonstrate effectiveness of new drugs developed to preserve brain cell function following traumatic brain injury; optimize approaches to treating traumatic brain injured casualties, who have also been exposed to nerve agent.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned from PE 0602787A Project MM4 (Cbt Casualty Care Applied Rsch Technology), Project MK4 (Warfighter Health Applied Rsch Technology), and Project MM6 (Medical Technologies to Support Dispersed Ops Tech).</p> | 4.108 | 4.649 | 10.667 |
| Accomplishments/Planned Programs Subtotals | 4.108 | 4.649 | 10.667 |

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

N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technol ogy</i> | Project (Number/Name) MO2 / <i>Traumatic Brain Injury (TBI) Treatment Adv Tech</i> |

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

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army **Date:** May 2021

| | | |
|--|---|--|
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | Project (Number/Name) MO3 / Military Occupational Fitness Standards Adv Tech |
|--|---|--|

| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| MO3: Military Occupational Fitness Standards Adv Tech | - | 0.240 | - | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | - | - |

Note

In Fiscal Year 2021 this Project is realigned to:
 PE 0303002A (Medical Advanced Technology)
 * Project MN7 (Musculoskeletal Injury Screening Tool Adv Tech)

A. Mission Description and Budget Item Justification

This project will develop an integrated set of trainings, portable interventions, tools, and technologies to assist individuals, small-teams, medics, and leaders in recognizing and mitigating reactions to stress, and maintaining readiness, performance and lethality of small groups, with limited medical asset availability. The cited work is fully coordinated with Combat Capabilities Development Command Soldier Center and with other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|
| Title: Military Occupational Fitness Standards | 0.240 | - | - |
| Description: This capability will provide the unit leader a validated toolkit of operationally relevant physical fitness assessments that can supplement clinical criteria to determine whether a Soldier can return to duty after musculoskeletal injury without the risk of re-injury. | | | |
| Accomplishments/Planned Programs Subtotals | 0.240 | - | - |

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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MO4 / <i>Burn Recovery Optimization Advanced Technology</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MO4: <i>Burn Recovery Optimization Advanced Technology</i> | - | 2.044 | 3.326 | 2.059 | - | 2.059 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project covers technology development, demonstration, and transition of burn recovery optimization technologies, including diagnostic technology to predict skin graft success or failure, technologies to measure and predict burn wound healing rate and assess burn treatment effectiveness, and novel dressings that protect severe burn wounds from further injury and prevent inflammation and infection until definitive surgical burn care is available.

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through Applied Research conducted under PE 0602787A (Medical Technology) Project MM4 (Cbt Casualty Care Applied Rsch Technology) are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development), Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Rapid Burn Injury Treatment and Return to Duty Capability Set 1 | 2.044 | 3.326 | 2.059 |
| Description: Mature, demonstrate, and transition burn recovery optimization technologies. These include diagnostic technology to predict skin graft success or failure, and advanced dressings that contain anti-infective and anti-inflammatory agents for prehospital use to protect severe burn wounds from further injury, infection and inflammation for prolonged periods until definitive surgical wound care is provided. | | | |
| FY 2021 Plans: Provide initial development of burn wound healing indices and predictive models by initiating a preclinical severe burn animal model study; demonstrate anti-infective, protective bandage for severe burn wounds in an animal model of delayed surgical burn care as would be experienced under prolonged field care conditions; validate nitric oxide-releasing wound dressing in an animal | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MO4 / <i>Burn Recovery Optimization Advanced Technology</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| <p>model of infected deep partial thickness burn. As part of continuing work on burn wound biomarkers, provide a large animal burn model in which to test burn treatments and grafting.</p> <p>FY 2022 Plans: Validate best approach for giving fluids to burn patients (by mouth or intravenously) through a small clinical study; demonstrate new therapies to be deployed by medics at the point of injury to safely remove dead skin and underlying tissues from burn wounds in order to prevent infection; validate two new anti-bacterial agents to provide data for which is most effective in reducing infections in burn wounds; perform validation studies of a hand-held device designed to assess severity of burn wounds through non-contact measurement of the wound's size and depth.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned to PE 0603002A Project MO2 (Traumatic Brain Injury (TBI) Treatment Adv Tech).</p> | | | | |
| Accomplishments/Planned Programs Subtotals | | 2.044 | 3.326 | 2.059 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | | | | Project (Number/Name) MO7 / <i>Improved Bone Repair Advanced Technology</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MO7: <i>Improved Bone Repair Advanced Technology</i> | - | 1.475 | 1.564 | 1.069 | - | 1.069 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project matures, demonstrates, and validates promising medical technologies and new clinical practices to improve outcomes following severe limb injuries involving complex bone fractures and injured surrounding soft tissues.

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through Applied Research conducted under PE 0602787A (Medical Technology), Project 874 (Cbt Casualty Care Tech), are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A (Medical Systems Advanced Development), Project 836 (Field Medical Systems Advanced Development).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| Title: Limb Function Repair and Return to Combat Duty & Field Stabilization on Bone in Preparation for Evac | 1.475 | 1.564 | - |
| Description: Development, demonstration, and transition of technologies that improve outcomes, mobility and return to duty following severe limb injuries involving complex bone fractures and injured soft tissues. | | | |
| FY 2021 Plans: Provide retrospective epidemiological analysis of extremity compartment syndrome (condition characterized by increased pressure within a confined space, such as a muscle compartment, resulting in reduced blood flow, pain, and, if untreated, tissue death and functional impairment) to identify means to improve monitoring, assessment, and diagnosis of casualties at risk for developing extremity compartment syndrome; validate candidate anti-infective agents in animal infected open fracture model under prolonged field care conditions; demonstrate preclinical efficacy of candidate drugs for restoring normal immune response to injury in order to promote normal healing in severe extremity fractures. | | | |
| FY 2021 to FY 2022 Increase/Decrease Statement: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) M07 / <i>Improved Bone Repair Advanced Technology</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| Funds realigned to other efforts within Project M07 (Limb Function Repair and Return to Combat Duty, Field Stabilization of Bone in Preparation for Evac). | | | | |
| <p>Title: Field Stabilization of Bone in Preparation for Evac</p> <p>Description: Maturation, demonstration, and transition of technologies that improve outcomes, mobility, and return to duty following severe limb injuries involving complex bone fractures and injured soft tissues in casualties treated under multi-domain operations conditions.</p> <p>FY 2022 Plans: Develop and demonstrate prototype noninvasive external fixation device for stabilization of lower extremity fractures with weight bearing support to enhance casualty mobility.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funds realigned from other efforts within Project M07 (Limb Function Repair and Return to Combat Duty & Field Stabilization on Bone in Preparation for Evac).</p> | | - | - | 0.564 |
| <p>Title: Limb Function Repair and Return to Combat Duty</p> <p>Description: Maturation, demonstration, and transition of technologies that improve outcomes, and return to duty following severe limb injuries involving complex bone fractures and injured soft tissues.</p> <p>FY 2022 Plans: Will validate local and regional antibiotic delivery strategies to achieve therapeutic soft tissue antibiotic levels during and after tourniquet induced ischemia (an inadequate blood supply to an extremity) in a large animal model and will validate if intervention reduces level of infection within an open wound distal to the tourniquet; demonstrate alternative portable technologies to aid medics in diagnosing acute extremity compartment syndrome (increased pressure within a confined body space, especially of the leg or forearm. May require surgery and loss tissue or extremity).</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funds realigned from other efforts within Project M07 (Limb Function Repair and Return to Combat Duty & Field Stabilization on Bone in Preparation for Evac).</p> | | - | - | 0.505 |
| Accomplishments/Planned Programs Subtotals | | 1.475 | 1.564 | 1.069 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MO7 / <i>Improved Bone Repair Advanced Technology</i> |

D. Acquisition Strategy
N/A

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MO8 / Expeditionary Performance Nutrition Advanced Techn | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MO8: Expeditionary Performance Nutrition Advanced Techn | - | 0.192 | 2.062 | 1.936 | - | 1.936 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project covers the development of real-time, specific, and individualized interventions to optimize mental acuity and fatigue and manage metabolic and nutritional needs to sustain Soldier physical, mental, and immunological performance.

The cited work is fully coordinated with PE 0602143A (Soldier Lethality Technology) and complimentary to PE 0603118A (Soldier Lethality Advanced Technology), and is fully coordinated with other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Performance Nutrition for an Expeditionary Force | 0.192 | - | - |
| Description: Development of nutritionally-optimized food products prototypes that will allow Soldiers to eat-on-the-go with minimal logistical footprint while ensuring maximal physiological and cognitive performance. | | | |
| Title: Medical Strategies to Sustain Soldier Alertness and Performance in All Settings | - | 2.062 | 1.936 |
| Description: Develop real-time, specific, and individualized interventions to optimize mental acuity and fatigue and manage metabolic and nutritional needs to sustain Soldier physical, mental, and immunological performance. | | | |
| FY 2021 Plans: Validate interventions to mitigate sleep loss and fatigue and improve individual and team performance in operational settings, including multi-domain battle scenarios; demonstrate the utility and effectiveness of electrical stimulation technologies that provide direct current to the brain as neurocognitive interventions for the enhancement of recuperative sleep and the development of operationally relevant sleep strategies. | | | |
| FY 2022 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MO8 / <i>Expeditionary Performance Nutrition Advanced Techn</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| <p>Will continue validation of interventions to mitigate sleep loss and fatigue and improve individual and team performance in training and operational settings, including multi-domain battle scenarios. Will continue to demonstrate the utility and effectiveness of electrical stimulation technologies that provide direct current to the brain, in addition to acoustic stimulation of brain patterns during sleep, as neurocognitive interventions for the enhancement of recuperative sleep and the development of operationally relevant sleep strategies.</p> <p><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Funding realigned to PE 0603002A Project MO2 (Traumatic Brain Injury (TBI) Treatment Adv Tech).</p> | | | | |
| Accomplishments/Planned Programs Subtotals | | 0.192 | 2.062 | 1.936 |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MO9 / Vaccines to Prevent Dengue Fever Advanced Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MO9: Vaccines to Prevent Dengue Fever Advanced Tech | - | 2.474 | 2.037 | - | - | - | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

In Fiscal Year 2022 this Project was realigned to:
 PE 0603002A (Medical Advanced Technology)
 * Project MM9 (Tech Base/Enabling Rsrch for Infect Dis Adv Tech)
 * Project CJ3 (Prophylactic for Endemic Diarrheal Diseases)

A. Mission Description and Budget Item Justification

This Project covers technology development, demonstration and transition of a candidate vaccine for the prevention of Dengue fever caused by any of the four Dengue virus serotypes. The vaccine is intended to be effective in people with and without a prior history of Dengue infection. Research is conducted in compliance with FDA regulations for medical products for human use.

Promising medical countermeasures identified in this Project are further matured under Program Element 0603807A (Medical Systems Advanced Development), Project 808 (DoD Drug & Vacc Ad).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work is managed by the United States Army Medical Research and Development Command (USAMRDC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.

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

| | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| Title: Vaccines to Prevent Dengue Fever Advanced Technology | 2.474 | 2.037 | - |
| Description: Perform Good Manufacturing Practice (GMP) manufacture of Dengue vaccine candidate. Demonstrate Dengue vaccine candidate safety, effectiveness, and pharmacokinetics in humans. Transition the Dengue vaccine candidate to product developer. | | | |
| FY 2021 Plans: | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MO9 / <i>Vaccines to Prevent Dengue Fever Advanced Tech</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2020 | FY 2021 | FY 2022 |
| Continue clinical trial to determine safety and immune response in humans of the optimized vaccine regimen; continue Dengue fever controlled human infection model clinical trial to determine additional safety, appropriate immune response, and effectiveness against all Dengue strains. <i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Funds realigned to other efforts in Project CJ3 (Prophylactic for Endemic Diarrheal Diseases). Funding realigned to PE 0603002A Project MM9 (USAMRIID/USAMRICD Disease Defeat). | | | | |
| Accomplishments/Planned Programs Subtotals | | 2.474 | 2.037 | - |
| 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 2022 Army | | | | | | | | | | Date: May 2021 | | |
| Appropriation/Budget Activity 2040 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology | | | | Project (Number/Name) MP3 / Phys Chem Toxicity Assessment Sys Adv Tech | | | |
| COST (\$ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
| MP3: Phys Chem Toxicity Assessment Sys Adv Tech | - | - | 2.590 | 2.291 | - | 2.291 | - | - | - | - | - | - |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

This is a new start in FY2021.
This Project is a New Start for Fiscal Year 2021 (FY21).

A. Mission Description and Budget Item Justification

This Project covers the development of products and solutions that will protect and prevent degradation of Soldier health, readiness and performance from environmental stressors (heat, cold, altitude, and chemical toxicants) while conducting prolonged operations in the MDO. Develop algorithms and physiological models to inform unit leaders and Soldiers and provide actionable information and interventions to manage metabolic needs, maintain performance, and avoid non-battle injuries while operating in extreme environments.

This Project contains no duplication with any effort within the Military Departments and includes direct participation by other Services. The cited work is fully coordinated with PE 0602143A (Soldier Lethality Technology) and complimentary to PE 0603118A (Soldier Lethality Advanced Technology).

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

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

| | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|
| Title: Solutions to Sustain Warfighter Performance in Extreme Environments | - | 2.590 | 2.291 |
| Description: Protect and prevent degradation of Soldier health, readiness and performance from environmental stressors (heat, cold, altitude, chemical toxicants) while conducting prolonged operations in the MDO. Develop algorithms and physiological models to inform unit leaders and Soldiers and provide actionable information and interventions to manage metabolic needs, maintain performance, and avoid non-battle injuries while operating in extreme environments. | | | |
| FY 2021 Plans: Provide validated tools that sustain lethality and optimize performance to prevent injuries related to multi-environmental stressors; provide scientific-based evidence of the impact of these stressors on medical readiness by leveraging commercial and emerging technologies for knowledge and materiel solutions that optimize physiological and cognitive performance across the spectrum of multi-domain operations; provide predictive models to prevent injury and illness, validated physiological sensor systems, and | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2022 Army | | Date: May 2021 |
| Appropriation/Budget Activity 2040 / 3 | R-1 Program Element (Number/Name) PE 0603002A / <i>Medical Advanced Technology</i> | Project (Number/Name) MP3 / <i>Phys Chem Toxicity Assessment Sys Adv Tech</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|
| <p>assessment tools to optimize performance and improve lethality; demonstrate a capability for improved performance and thermal comfort in hot environments using cooling technology with skin temperature feedback control; demonstrate a capability to increase finger and toe temperatures for improved manual dexterity and performance in cold weather operations.</p> <p>FY 2022 Plans: Will provide validated tools to sustain lethality and optimize performance and to prevent injuries related to multi-environmental stressors; optimize capability to improve performance and thermal comfort in hot environments using innovative cooling technology; deliver to advanced development mature and validated algorithms for exertional heat injury, acute mountain sickness, and cold-weather clothing selection; complete animal model to demonstrate capability to use real-time physiological data to determine the extent to which an individual has been exposed to a toxic chemical; begin validation of method for cold habituation to improve cold tolerance and comfort when operating in arctic conditions.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding realigned to PE 0603002A Project MO2 (Traumatic Brain Injury (TBI) Treatment Adv Tech).</p> | | | |
| Accomplishments/Planned Programs Subtotals | - | 2.590 | 2.291 |

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

N/A

Remarks

D. Acquisition Strategy

N/A