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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency											Date: February 2020	
Appropriation/Budget Activity 0130: Defense Health Program I BA 2: RDT&E					R-1 Program Element (Number/Name) PE 0602115DHA I Applied Biomedical Technology							
COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
Total Program Element	488.880	107.837	175.032	72.573	-	72.573	74.024	75.505	77.015	78.560	Continuing	Continuing
200A: Congressional Special Interests	148.090	38.026	92.149	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
246A: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	8.111	1.813	1.949	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
306B: Advanced Diagnostics & Therapeutics Research & Development (AF)	16.788	2.609	0.716	0.151	-	0.151	0.000	0.000	0.000	0.000	Continuing	Continuing
306C: Core Adv Diagnostics & Epigenomics Applied Research (AF)	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
306D: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	1.728	0.000	3.416	4.064	-	4.064	4.299	4.385	4.473	4.567	Continuing	Continuing
447A: Military HIV Research Program (Army)	38.655	8.808	9.654	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
372: GDF - Applied Biomedical Technology	273.780	56.581	67.148	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
372A: GDF - ABT (Combat Casualty Care)	-	0.000	0.000	14.855	-	14.855	15.151	15.453	15.763	16.078	Continuing	Continuing
372B: GDF - ABT (Military Operational Medicine)	-	0.000	0.000	26.255	-	26.255	26.779	27.316	27.862	28.419	Continuing	Continuing
372C: GDF - ABT (Medical Simulation & Training/Health Informatics)	-	0.000	0.000	10.611	-	10.611	10.826	11.041	11.263	11.488	Continuing	Continuing
372D: GDF - ABT (Clinical and Rehabilitation Medicine)	-	0.000	0.000	7.064	-	7.064	7.204	7.350	7.495	7.645	Continuing	Continuing

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372E: <i>GDF - ABT (Military Infectious Disease)</i>	-	0.000	0.000	8.607	-	8.607	8.779	8.954	9.133	9.316	Continuing	Continuing	
372F: <i>GDF - ABT (Radiological Health Effects)</i>	-	0.000	0.000	0.966	-	0.966	0.986	1.006	1.026	1.047	Continuing	Continuing	

A. Mission Description and Budget Item Justification

This program element (PE) provides applied research funding to refine concepts and ideas into potential solutions for military health and performance problems, with a view toward evaluating technical feasibility. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation (RDT&E) priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance.

Research will support efforts such as the Precision Medicine Initiative which seeks to increase the use of big data and interdisciplinary approaches to establish a fundamental understanding of military disease and injury to advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research & Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and coordinated with all of the Military Services, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Funds in the PE support studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115) funding.

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

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

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

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

Project: 200A: *Congressional Special Interests*

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

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

Congressional Add Subtotals for Project: 200A

Congressional Add Totals for all Projects

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

Change Summary Explanation

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

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 200A / <i>Congressional Special Interests</i>
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
200A: <i>Congressional Special Interests</i>	148.090	38.026	92.149	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

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

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

	FY 2019	FY 2020
<i>Congressional Add:</i> PC426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	22.318	59.000
<i>FY 2019 Accomplishments:</i> 426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)		
<i>FY 2020 Plans:</i> 426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)		
<i>Congressional Add:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)	15.708	33.149
<i>FY 2019 Accomplishments:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)		
<i>FY 2020 Plans:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)		
Congressional Adds Subtotals	38.026	92.149

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

N/A

Remarks

D. Acquisition Strategy

N/A

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

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 246A / <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	8.111	1.813	1.949	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

	FY 2019	FY 2020	FY 2021
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	1.813	1.949	0.000
Description: Focus on continued establishment of in-house capabilities for an antibacterial drug discovery program directed toward military relevant drug-resistant bacteria that a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, b) opens active intramural based discovery efforts of new potential products/candidates/leads for development, and c) fosters partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.			
FY 2020 Plans: CARB program continues its research efforts to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit. In addition, the program continues its market analysis efforts of established, non-DoD antibiotic programs to identify other promising compounds that could potentially treat military relevant resistant bacteria, establishing partnership and intellectual property rights agreements where necessary. These promising compounds are screened against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) in order to select compounds for continued development. Specifically designed novel drugs are then synthesized to support lead optimization efforts, exploiting established in vivo (living organism) model standards to treat military relevant resistant bacteria.			
FY 2021 Plans:			

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2019	FY 2020	FY 2021
Programmed effort and funding transferred to the Department of the Army (PE 0602115A Project EB2) as part of the Readiness Transfer for FY 2021.			
<i>FY 2020 to FY 2021 Increase/Decrease Statement:</i> Programmed effort and funding transferred to the Department of the Army in FY 2021.			
Accomplishments/Planned Programs Subtotals	1.813	1.949	0.000

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

N/A

Remarks

D. Acquisition Strategy

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

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	16.788	2.609	0.716	0.151	-	0.151	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Advanced Diagnostics & Therapeutics Clinical Translational Applied Research (Air Force): This project provides applied research funding needed to increase efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Modernization Thrust Areas to improve and enhance clinical Diagnosis, Identification, Quantification and Mitigation (DIQM) methods, techniques protocols, guidelines and practices for all DoD wounded, ill and/or injured beneficiaries. This project area seeks to manage and support research activities designed to facilitate the clinical integration of genomic-based medicine across the AFMS. Research in genomic medicine seeks to initiate the transition of genomic research discoveries into clinical practice, specifically applying knowledge derived from the study of pharmacogenomics, cancer genomics, gene-environment interactions, and inherited disease genomics in Airmen and beneficiaries. The program funds applied research which seeks to promote 'omic'-informed personalized medicine with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve health in Warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This applied research supports multiple focus areas, each of which represents an identified barrier/gap which must be addressed for successful implementation of 'omic'-informed personalized medicine. Focus areas for applied research include knowledge generation research; ethical legal and social issues/policy research; bioinformatics research; educational research; research for development of advanced genomic diagnostic system. Plans are to utilize patient modeling algorithms to identify pharmacogenomics interventions that can improve patient health and reduce healthcare costs across the AFMS. Program aims to further conduct analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressants and pain medication within the AFMS is also planned. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine data is a key program component.

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

	FY 2019	FY 2020	FY 2021
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	2.609	0.716	0.151
Description: This project provides applied research funding needed to perform research in the area of diagnostic assay development/refinement for diseases of operational significance. This project area seeks to manage and support research activities designed to facilitate the clinical integration of genomic-based medicine across the AFMS. Research in genomic medicine seeks to initiate the transition of genomic research discoveries into clinical practice, specifically applying knowledge derived from the study of pharmacogenomics, cancer genomics, gene-environment interactions, and inherited disease genomics in Airmen and beneficiaries. The program funds seeks to promote 'omic'-informed personalized medicine with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2019	FY 2020	FY 2021
<p>health in Warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This applied research supports multiple focus areas, each of which represents an identified barrier/gap which must be addressed for successful implementation of 'omic-informed personalized medicine. Focus areas for applied research include knowledge generation research; ethical legal and social issues/policy research; bioinformatics research; educational research; research for development of advanced genomic diagnostic system. Analyze genomics survey data to identify gaps in genomic education, and development of educational programs to correct these gaps. Plans are to utilize patient modeling algorithms to identify pharmacogenomics interventions that can improve patient health and reduce healthcare costs across the AFMS. Program aims to further conduct analysis in educational interventions for the proper use of genetic testing within the AFMS. Research for pharmacogenomics for anti-depressants and pain medication within the AFMS is also planned. Analysis of methodologies and challenges associated with the establishment of an AFMS genome data repository for future implementation of genomic medicine is a key program component.</p> <p>FY 2020 Plans: Research will continue examining Mesenchymal Stem Cell (MSC)-derived exosomes as modulators of peripheral nerve regeneration and repair. Studies will continue evaluating portable Raman microscopy and surface-enhanced Raman scattering (SERS) technology for the rapid detection of microbial water contamination. Analyses will continue assessing mitigation strategies of radiofrequency-induced auditory dysfunction using a MSC-derived exosome-based approach.</p> <p>FY 2021 Plans: Mitigation strategies for radiofrequency-induced auditory dysfunction will be demonstrated using a MSC-derived exosome-based approach. FY 2021 plans continue efforts as outlined in FY 2020.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding shifts over the FYDP into Project Code 306D- Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF) reflect deliberate focusing on future readiness mission.</p>			
Accomplishments/Planned Programs Subtotals	2.609	0.716	0.151

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

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>

D. Acquisition Strategy

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

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>			Project (Number/Name) 306C / <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>				
COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

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

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306D / <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>	1.728	0.000	3.416	4.064	-	4.064	4.299	4.385	4.473	4.567	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance. Research will assess and analyze the diverse attributes of humans (cognitive, behavioral, physiological) and operational environments (chemical, physical, psychological, biological, radiological stressors) to drive optimal performance and care of our Airmen. Research will focus on identifying environmental hazards associated with unique AF environments, determine the risk of those hazards on AF operations and identify ways to mitigate those negative impacts. Research will investigate how the flight environment affects the processes of life, the ability to maintain homeostasis, the risk for injury or secondary insult, and seek to ameliorate these stressors to optimize Airman health, safety and performance.

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

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

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

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

N/A

Remarks

D. Acquisition Strategy

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

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
447A: <i>Military HIV Research Program (Army)</i>	38.655	8.808	9.654	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

	FY 2019	FY 2020	FY 2021
Title: Military HIV Research Program	8.808	9.654	0.000
Description: This project conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
FY 2020 Plans: The Military HIV Research Program is producing and characterizing new vaccine candidates for use in pre-clinical and clinical testing. Vaccine candidates will be evaluated to assess their ability to invoke an immune response in non-human primates by using novel delivery systems containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, B, C, D and E. The program is developing and optimizing methods of large scale production of new vaccine candidates for testing in Africa and Asia to assess candidate vaccines against diverse HIV subtypes. Efforts to identify and develop new clinical trial sites in Europe, Southeast Africa Asia and the US are ongoing in order to allow scientists the opportunity to test future vaccine candidates against predominant HIV subtypes circulating around the world.			
FY 2021 Plans: Programmed effort and funding transferred to the Department of the Army (PE 0602115A Project EB2) as part of the Readiness Transfer for FY 2021.			
FY 2020 to FY 2021 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency		Date: February 2020
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2019	FY 2020	FY 2021
Programmed effort and funding transferred to the Department of the Army in FY 2021.			
Accomplishments/Planned Programs Subtotals	8.808	9.654	0.000

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

N/A

Remarks

The program receives periodic funding from Division of AIDS of NIAID ranging from \$10-20 million per year through an Interagency Agreement with USAMRMC.

D. Acquisition Strategy

N/A

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

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: Applied biomedical technology research will focus on refining concepts and ideas into potential solutions for military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research is managed by the Joint Program Committees in the following areas: 1- Medical Simulation and Information Sciences applied research is developing informatics-based simulated military medical training. 2- Military Infectious Diseases applied research is developing protection and treatment products for military relevant infectious diseases. 3- Military Operational Medicine applied research goals are to develop medical countermeasures against operational stressors, prevent musculoskeletal, neurosensory, and psychological injuries during training and operations, and to maximize health, performance and fitness of Service members. 4- Combat Casualty Care applied research is focused on optimizing survival and recovery in injured Service members across the spectrum of care from point of injury through en route and facility care. 5- Radiation Health Effects applied research supports tasks for the development of radiation medical countermeasures. 6- Clinical and Rehabilitative Medicine applied research is focused on efforts to reconstruct, rehabilitate, and provide care for injured Service members.

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

Title: GDF Applied Biomedical Technology	FY 2019	FY 2020	FY 2021
Description: Focus is on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development.	56.581	67.148	0.000
FY 2020 Plans: Medical simulation and information sciences applied research is focusing on researching pharmacodynamics (effects of drugs and the mechanism of their action) and pharmacokinetics (movement of drugs within the body) algorithms. This research supports a repository that contains simulated pharmaceuticals and other resuscitative treatments that are the most relevant to point of injury and en route care training. The mathematical algorithms development are focusing on specific pharmacodynamics (effects of drugs and the mechanism of their action.) and pharmacokinetics as well as absorption, distribution, metabolism, and excretion of the pharmaceuticals and resuscitative options. Research is being conducted on high fidelity tactile haptics (recreated sense of touch in simulated settings) to improve tactile sensation and resistance realism of virtual reality systems and mannequin based medical training systems.			
Military infectious diseases research continues to support multi-year studies in bacterial diseases research, and will down-select promising efforts for further development. Multi-year studies in wound infections are being supported to address critical research focus areas such as the ability to predict infection and better treatment options for infections with MDROs and development of biomarker assays for diagnosis of infection. Novel and innovative therapeutics and delivery technologies for combat wound			

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

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

	FY 2019	FY 2020	FY 2021
<p>infections are being developed. Subject matter expertise in acute respiratory diseases is being maintained. These efforts support the National Action Plan for Combating Antibiotic-Resistant Bacteria. Scientific awareness and a capability to respond to emerging infectious diseases are being maintained. Partnerships with other entities are being supported to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, MERS, Zika).</p> <p>Military operational medicine research is collecting experimental data to validate whole-body computational models of the direct and indirect mechanism of blast brain injury. Research also focuses to determine optimal temporal spacing of repeated blast events to prevent cumulative effects and analyze changes in brain injury biomarkers. Additionally, research collecting impulse noise experimental data from volunteer subjects to validate computational models of inner ear injury. Research to inform refinements to comprehensive aircrew performance risk models of fatigue and hypoxia (oxygen deficiency) is ongoing. Efforts to refine models of dietary supplement use patterns by Armed Forces members and determining demographic and lifestyle factors associated with dietary supplement and caffeine use along with risks and benefits of consumption are progressing. Studies to assess the physical, psychosocial and physiological factors affecting overuse injury susceptibility and career success of female Warriors are advancing. Research is ongoing to inform prototype development for Service member and family resilience building interventions. Studies are progressing to deliver an evidence-based substance abuse prevention and training model and screening and compliance tools. Research aimed at developing an evidence-based approach to reduce stigma and a training program to increase provider skill in assessing and treating suicidality is in progress. In addition, novel and evidence-based PTSD interventions investigations are ongoing. Adaptations in delivery of care are being studied to achieve the goal of increased accessibility. Efforts to identify and developing candidate biomarker panels indicative of PTSD treatment-related improvement, and animal/human PTSD model development are progressing. Novel compounds and existing FDA-approved medications are being analyzed for potential use in treatment of PTSD. Candidate biomarkers of exposure to inhaled or ingested toxic substances are being evaluated for utility to establish the probability of adverse health risk outcomes and refine a non-invasive tool for diagnosing pulmonary diseases. Research focuses to refine metrics for optimized operational task performance in extreme environmental conditions.</p> <p>Combat casualty care hemorrhage research is investigating new diagnostic tools and continuing the development of treatments for severe hemorrhage following injury. Research is focusing on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Research is focusing on novel oxygen carriers for use in severe casualties where blood transfusions are not available. Inflammatory modulation and other research focused on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios) are ongoing. Tactical Combat Casualty Care (TCCC) is investigating novel approaches to enable field care of casualties when evacuation is delayed. Neurotrauma research is focusing on precision medicine capabilities. This research is anticipated to improve the characterization of traumatic brain injury (TBI), and lead to the development of targeted therapies, devices and clinical guidelines</p>			

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

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

	FY 2019	FY 2020	FY 2021
<p>to improve the care provided to TBI casualties. Treatments for extremity trauma to advance wound stabilization for prolonged field care scenarios that might enhance initial treatment and improve longer term outcomes are being studied. Closed loop and decision assist technologies for burns, lung ventilation, organ support, and other complex injuries to include maxillofacial injury are progressing. Pre-hospital Tactical Combat Casualty Care research is studying the effectiveness of acute lifesaving interventions and how to improve survival for those in need of critical care on the battlefield, in acute stages of injury, and for those requiring prolonged times until reaching definitive care in the prolonged field care/pre-hospital/hospital setting. En-route care research continues to study clinically-relevant testing standards for monitors in the transport environment and to develop new non-invasive monitoring technologies.</p> <p>Radiation health effects research will conduct non-clinical research to identify therapeutic candidates for acute radiation exposure and develop data to support preparation of technical data package requirements for investigational new drug applications. Research also focuses on evaluating candidate preventative radioprotectants (drugs) to determine their feasibility and practicality as candidate solutions to military needs. Objectives include identifying mechanisms of action, efficacy and safety data in animal models for medical countermeasures for Acute Radiation Syndrome (ARS).</p> <p>Clinical and rehabilitative medicine research is selecting the most promising candidate products to transition to technology development in the areas of neuromusculoskeletal injury, pain management, and regenerative medicine. Applied research in neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries is progressing. Targets for therapies to alleviate acute, chronic, and battlefield pain and identify strategies for addressing psychosocial aspects of pain management and pain-related substance abuse will be identified. Research to identify biomarkers to implement precision medicine approaches for pain management is ongoing. Regenerative medicine research is focusing efforts on developing solutions to repair, reconstruct or regenerate tissue lost or damaged due to traumatic injury.</p> <p>FY 2021 Plans: Efforts realigned to PE 06021115DHA Project Codes 372A-F.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Efforts realigned to PE 06021115DHA Project Codes 372A-F.</p>			
Accomplishments/Planned Programs Subtotals	56.581	67.148	0.000

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

N/A
Remarks

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

D. Acquisition Strategy

Evaluate technical feasibility of potential solutions to military health issues. Implement models into data or knowledge and test in a laboratory environment. Technology Transition and Milestone A packages will be developed to facilitate product transition.

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

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 372A / <i>GDF - ABT (Combat Casualty Care)</i>			
COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
372A: <i>GDF - ABT (Combat Casualty Care)</i>	-	0.000	0.000	14.855	-	14.855	15.151	15.453	15.763	16.078	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

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

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

N/A

Remarks

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

D. Acquisition Strategy
N/A

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

Remarks

D. Acquisition Strategy
N/A

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

A. Mission Description and Budget Item Justification

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

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

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

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

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

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

A. Mission Description and Budget Item Justification

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

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

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

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

N/A

Remarks

D. Acquisition Strategy

N/A

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

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372E / <i>GDF - ABT (Military Infectious Disease)</i>
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
372E: <i>GDF - ABT (Military Infectious Disease)</i>	-	0.000	0.000	8.607	-	8.607	8.779	8.954	9.133	9.316	Continuing	Continuing

A. Mission Description and Budget Item Justification
 Military infectious diseases activities continue to support studies in bacterial diseases research, and will down-select promising efforts for further development.

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

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

Remarks

D. Acquisition Strategy
N/A

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

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372F / <i>GDF - ABT (Radiological Health Effects)</i>
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
372F: <i>GDF - ABT (Radiological Health Effects)</i>	-	0.000	0.000	0.966	-	0.966	0.986	1.006	1.026	1.047	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

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

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

N/A

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

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

Remarks

D. Acquisition Strategy

N/A