

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Defense Health Agency											Date: May 2021	
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 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	596.717	175.032	72.573	74.024	-	74.024	0.000	0.000	0.000	0.000	Continuing	Continuing
200A: Congressional Special Interests	186.116	90.914	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
246A: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	9.924	1.900	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
306B: Advanced Diagnostics & Therapeutics Research & Development (AF)	19.397	0.716	0.151	0.000	-	0.000	-	-	-	-	Continuing	Continuing
306C: Core Adv Diagnostics & Epigenomics Applied Research (AF)	1.728	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
306D: Biomedical Impact and Readiness Optimization of Air & Space Operations (AF)	1.728	3.265	4.064	4.299	-	4.299	-	-	-	-	Continuing	Continuing
447A: Military HIV Research Program (Army)	47.463	9.435	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
372: GDF - Applied Biomedical Technology	330.361	68.802	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
372A: GDF - ABT (Combat Casualty Care)	0.000	0.000	14.855	15.151	-	15.151	-	-	-	-	Continuing	Continuing
372B: GDF - ABT (Military Operational Medicine)	0.000	0.000	26.255	26.779	-	26.779	-	-	-	-	Continuing	Continuing
372C: GDF - ABT (Medical Simulation & Training/Health Informatics)	0.000	0.000	10.611	10.826	-	10.826	-	-	-	-	Continuing	Continuing
372D: GDF - ABT (Clinical and Rehabilitation Medicine)	0.000	0.000	7.064	7.204	-	7.204	-	-	-	-	Continuing	Continuing

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Defense Health Agency										Date: May 2021			
Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0602115DHA I <i>Applied Biomedical Technology</i>								
372E: <i>GDF - ABT (Military Infectious Disease)</i>	0.000	0.000	8.607	8.779	-	8.779	-	-	-	-	Continuing	Continuing	
372F: <i>GDF - ABT (Radiological Health Effects)</i>	0.000	0.000	0.966	0.986	-	0.986	-	-	-	-	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.

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Defense Health Agency	Date: May 2021
--	-----------------------

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

B. Program Change Summary (\$ in Millions)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total
Previous President's Budget	175.032	72.573	74.024	-	74.024
Current President's Budget	175.032	72.573	74.024	-	74.024
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

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 2020	FY 2021
Congressional Add: <i>PC426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)</i>	58.203	-
Congressional Add: <i>PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)</i>	32.711	-
Congressional Add Subtotals for Project: 200A	90.914	-
Congressional Add Totals for all Projects	90.914	-

UNCLASSIFIED

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

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 200A / <i>Congressional Special Interests</i>			
COST (\$ in Millions)	Prior Years	FY 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
200A: <i>Congressional Special Interests</i>	186.116	90.914	0.000	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 2020	FY 2021
<i>Congressional Add:</i> PC426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)	58.203	-
<i>FY 2020 Accomplishments:</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)	32.711	-
<i>FY 2020 Accomplishments:</i> PC462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)		
Congressional Adds Subtotals	90.914	-

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 Defense Health Agency **Date:** May 2021

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 246A / <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>
--	--	---

COST (\$ in Millions)	Prior Years	FY 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
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	9.924	1.900	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 2020	FY 2021	FY 2022
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	1.900	-	-
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.			
Accomplishments/Planned Programs Subtotals	1.900	-	-

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.

UNCLASSIFIED

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

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 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
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	19.397	0.716	0.151	0.000	-	0.000	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project provides applied research funding needed to increase efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements to improve and enhance clinical Diagnosis, Identification, Quantification and Mitigation (DIQM) methods, technique protocols, guidelines and practices for all Department of Defense (DoD) wounded, ill, and/or injured beneficiaries.

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

	FY 2020	FY 2021	FY 2022
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	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. Project funds seek 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.			
FY 2021 Plans: Research will continue examining stem cell therapies for peripheral nerve regeneration and repair as well as radiofrequency-induced injuries.			
FY 2021 to FY 2022 Increase/Decrease Statement: Reduced funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115DHA, Project Codes 306B and 306D reflect deliberate focus on future readiness mission.			
Accomplishments/Planned Programs Subtotals	0.716	0.151	-

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

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
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>

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

Remarks

Accomplishments: Mesenchymal Stem Cell (MSC)-derived exosomes were examined as modulators of 1) peripheral nerve regeneration and 2) repair from radiofrequency-induced auditory dysfunction. Raman microscopy was evaluated for the rapid detection of microbial water contamination.

D. Acquisition Strategy

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

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
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 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
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	1.728	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.)

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency										Date: May 2021		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306D / <i>Biomedical Impact and Readiness Optimization of Air & Space Operations (AF)</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
306D: <i>Biomedical Impact and Readiness Optimization of Air & Space Operations (AF)</i>	1.728	3.265	4.064	4.299	-	4.299	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project provides applied research to define and develop medical attribute-linked solutions to better address Air Force operational readiness and mission effectiveness. This research develops approaches aimed at increasing the understanding of full spectrum factors impacting health and performance across Air Force operating environments, to include critical Air Force-supported mission areas of air and space superiority, aeromedical evacuation, communications and intelligence systems, global information operations, reconnaissance and electronic-combat aircraft. Focus areas include Biomedical Impact of Flight and Airman Readiness Optimization.

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

	FY 2020	FY 2021	FY 2022
Title: Biomedical Impact and Readiness Optimization of Air & Space Operations (AF)	3.265	4.064	4.299
Description: Applied research to develop approaches to increase the understanding of the underlying medical and biological mechanisms of health in operating environments that link to optimizing mission performance and readiness. Research will identify metrics of cognitive, behavioral, physiological, sensory and motor attributes. This will shape medically relevant screening, risk-assessment, retention and return-to-duty criteria through data driven risk analysis and mitigation actions, and enhance the delivery of Air Force operational care.			
FY 2021 Plans: Assess relevant biomarkers, chemical, environmental and medical attributes that impact high performing Airmen. Characterize Aircrew physiologic response to aerospace stressors. Understand the exposure-based pathophysiology behind the high-rates of neck and back pain and injury amongst United State Air Force (USAF) pilots. Study effects of enroute care transport exposure on high-incidence rate clinical presentations and patient outcomes.			
FY 2022 Plans: Develop models of health and performance relevant to Air Force operational environments using attribute-linked data to assess and mitigate risks impacting mission readiness. Continue to characterize relevant biomarkers, chemical, environmental and medical attributes that optimize mission performance. Continue to evaluate enroute care relevant safety issues and patient outcomes.			
FY 2021 to FY 2022 Increase/Decrease Statement:			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306D / <i>Biomedical Impact and Readiness Optimization of Air & Space Operations (AF)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
Increased funding due to realignment within Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115DHA, Project Codes 306B and 306D reflect deliberate focus on future readiness mission.				
Accomplishments/Planned Programs Subtotals		3.265	4.064	4.299
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
Accomplishments: Discovery of microRNA (miRNA) biomarkers for specific injury mechanisms, novel therapeutics that enhance recovery and resiliency, characterizing neurovascular effects of acceleration and altitude exposures, modeling operational impact of Mission Oriented Protective Posture (MOPP) gear on aircrew and medical operations, physiologic-based pharmacokinetic models of multi-contaminant exposures, modeling ocular health and performance risk criteria for aircrew.				
D. Acquisition Strategy				
Air Force Contracting, Interagency Agreements, and Inter-service Support Agreements with the U.S. Army, U.S. 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 Announcements (BAA) and Intramural calls for proposals, which are used to award initiatives in this project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and / or regulatory approvals (IRB, etc.).				

UNCLASSIFIED

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

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 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
447A: <i>Military HIV Research Program (Army)</i>	47.463	9.435	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)

Title: Military HIV Research Program	FY 2020	FY 2021	FY 2022
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.	9.435	-	-
Accomplishments/Planned Programs Subtotals	9.435	-	-

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

UNCLASSIFIED

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

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 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
<i>372: GDF - Applied Biomedical Technology</i>	330.361	68.802	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

	FY 2020	FY 2021	FY 2022
Title: GDF Applied Biomedical Technology	68.802	-	-
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.			
Accomplishments/Planned Programs Subtotals	68.802	-	-

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

N/A

Remarks

D. Acquisition Strategy

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

UNCLASSIFIED

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

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 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
372A: <i>GDF - ABT (Combat Casualty Care)</i>	0.000	0.000	14.855	15.151	-	15.151	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Joint Battlefield Healthcare (Formerly Combat Casualty Care)	-	14.855	15.151
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 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 2022 Plans: Conduct Joint Battlefield Healthcare applied research activities focused on establishing preclinical and clinical effects of prolonged care technologies, early interventions for acute traumatic brain injury, and innovative products for resuscitation and immediate stabilization of combat casualties in a scenario of multi-domain operations.			
FY 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.			
Accomplishments/Planned Programs Subtotals	-	14.855	15.151

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

N/A

Remarks

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
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

UNCLASSIFIED

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

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 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
372B: <i>GDF - ABT (Military Operational Medicine)</i>	0.000	0.000	26.255	26.779	-	26.779	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Military Health and Recovery (Formerly Military Operational Medicine)	-	26.255	26.779
<p>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.</p> <p>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.</p> <p>FY 2022 Plans: Efforts will continue to focus on: injury prevention and recovery related to blunt, blast, and accelerative injuries, as well as 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.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement:</p>			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
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>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
Funding change reflects planned lifecycle of this effort.			
Accomplishments/Planned Programs Subtotals	-	26.255	26.779

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 Defense Health Agency										Date: May 2021		
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 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
372C: <i>GDF - ABT (Medical Simulation & Training/Health Informatics)</i>	0.000	0.000	10.611	10.826	-	10.826	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Medical Simulation Technologies (Formerly Medical Simulation Technologies & Training/Health Informatics)	-	10.611	10.826
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.			
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; technologies that simulate combat scenarios to provide realistic environments; and, technologies that simulate patient movement through the continuum of care.			
FY 2022 Plans:			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021		
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 2020	FY 2021	FY 2022
<p>Conduct studies, investigations, and non-system specific technology effort focus on prototyping tissue models, technologies that simulate medical condition progress over time, personalized 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, including the brain and all organ systems of the body; 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 -including those anticipated from future weaponry, 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><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Funding change reflects planned lifecycle of this effort.</p>				
Accomplishments/Planned Programs Subtotals		-	10.611	10.826
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 Defense Health Agency **Date:** May 2021

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 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
372D: <i>GDF - ABT (Clinical and Rehabilitation Medicine)</i>	0.000	0.000	7.064	7.204	-	7.204	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Clinical and Rehabilitation Medicine	-	7.064	7.204
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 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 2022 Plans: Efforts will continue to focus on neuromusculoskeletal injuries to advance the diagnosis, treatment and rehabilitation outcomes after Service-related injuries; targets for therapies to alleviate acute, chronic, and battlefield pain; 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 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.			
Accomplishments/Planned Programs Subtotals	-	7.064	7.204

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

N/A

Remarks

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
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>
D. Acquisition Strategy N/A		

UNCLASSIFIED

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

Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 372E / <i>GDF - ABT (Military Infectious Disease)</i>			
COST (\$ in Millions)	Prior Years	FY 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
372E: <i>GDF - ABT (Military Infectious Disease)</i>	0.000	0.000	8.607	8.779	-	8.779	-	-	-	-	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 2020	FY 2021	FY 2022
<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 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 2022 Plans: Identify and optimize lead drug compounds to identify emerging infectious diseases (EID) countermeasure candidates for human studies. Test lead drug candidates for safety and toxicity in animals. Down-select lead candidates as an EID drug for use in humans. Optimize antigens and platforms for use in animal studies. Evaluate new immunoprophylactic candidates for safety, effectiveness, and immunogenicity in animal models to advance to human clinical trials. Optimize and test of antigens and vaccine platforms for Dengue. Demonstrate efficacy and safety of dengue vaccine candidates in animal models.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.</p>	-	8.607	8.779
Accomplishments/Planned Programs Subtotals	-	8.607	8.779

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

N/A

Remarks

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
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>

D. Acquisition Strategy
N/A

UNCLASSIFIED

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

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

COST (\$ in Millions)	Prior Years	FY 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
372F: <i>GDF - ABT (Radiological Health Effects)</i>	0.000	0.000	0.966	0.986	-	0.986	-	-	-	-	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 2020	FY 2021	FY 2022
Title: Radiological Health Effects	-	0.966	0.986
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 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 2022 Plans: Continue research toward the development of prophylactic medical countermeasures against acute radiation exposures and supporting mechanistic science and animal development.			
FY 2021 to FY 2022 Increase/Decrease Statement: Funding change reflects planned lifecycle of this effort.			
Accomplishments/Planned Programs Subtotals	-	0.966	0.986

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

N/A

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2022 Defense Health Agency		Date: May 2021
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