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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Defense Health Agency										Date: February 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	397.066	91.814	112.754	82.883	-	82.883	84.408	86.096	87.818	89.574	Continuing	Continuing
200A: Congressional Special Interests	135.390	12.700	23.100	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
246A: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	6.029	2.082	1.857	1.949	-	1.949	1.989	2.029	2.070	2.111	Continuing	Continuing
306B: Advanced Diagnostics & Therapeutics Research & Development (AF)	12.958	3.830	4.051	4.132	-	4.132	4.215	4.299	4.385	4.472	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	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
372A: GDF Applied Biomedical Technology	208.151	65.629	74.724	67.148	-	67.148	68.357	69.724	71.119	72.542	Continuing	Continuing
447A: Military HIV Research Program (Army)	31.082	7.573	9.022	9.654	-	9.654	9.847	10.044	10.244	10.449	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

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

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

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

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

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

Project: 200A: *Congressional Special Interests*

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

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

FY 2018	FY 2019
12.700	23.100
0.000	0.000

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Appropriation/Budget Activity 0130: <i>Defense Health Program / BA 2: RDT&E</i>		R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	
Congressional Add Details (\$ in Millions, and Includes General Reductions)		FY 2018	FY 2019
Congressional Add Subtotals for Project: 200A		12.700	23.100
Congressional Add Totals for all Projects		12.700	23.100
<u>Change Summary Explanation</u> FY 2018: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-\$1.420 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$1.420 million).			

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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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
200A: <i>Congressional Special Interests</i>	135.390	12.700	23.100	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
A. Mission Description and Budget Item Justification												
In FY 2018, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.												
B. Accomplishments/Planned Programs (\$ in Millions)								FY 2018	FY 2019			
Congressional Add: 426 – CSI - Peer Reviewed Traumatic Brian Injury / Psychological Health (TBI/PH) (PE 0602115) (Army)								12.700	23.100			
FY 2018 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program supported studies to inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on the function, wellness, and overall quality of life for military Service members and veterans, as well as their family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing DoD efforts to ensure the health and readiness of our military forces by promoting a better standard of care for psychological health disorders and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. FY 2018 funds supported research in the areas of diagnosis and treatment of mental health disorders, optimization of psychological health and resilience for readiness, and suicide prevention and reduction.												
FY 2019 Plans:												
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (GDF)								0.000	0.000			
FY 2018 Accomplishments: This Congressional Special Interest initiative was directed toward FY 2018 DHP core research initiatives in PE 0602115. Funds supported applied research in the areas of military operational medicine, combat casualty care, military infectious diseases, clinical and rehabilitative medicine, medical simulation and information sciences, and radiation health effects. (Project 372A).												
FY 2019 Plans:												
Congressional Adds Subtotals								12.700	23.100			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 200A / <i>Congressional Special Interests</i>
C. Other Program Funding Summary (\$ in Millions) N/A Remarks D. Acquisition Strategy N/A E. Performance Metrics Individual efforts are monitored through a quarterly project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives), key performance parameters, and resolution of Force Health Protection gaps. Variances, deviations, and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of Science and Technology governance. Annual reviews are also conducted in person for all of the projects within a specific program area.		

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 246A / <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
246A: <i>Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)</i>	6.029	2.082	1.857	1.949	-	1.949	1.989	2.029	2.070	2.111	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	2.142	1.857	1.949
Description: Focus on continued establishment of in-house capabilities for an antibacterial drug discovery program directed toward military relevant drug-resistant bacteria that a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, b) opens active intramural based discovery efforts of new potential products/candidates/leads for development, and c) fosters partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.			
FY 2019 Plans: CARB program continues its research efforts to evaluate viable small molecule candidate antibacterial agents for planned development for the DoD and Public Health benefit. In addition, the program continues its market analysis efforts of established, non-DoD antibiotic programs to identify other promising compounds that could potentially treat military relevant resistant bacteria, establishing partnership and intellectual property rights agreements where necessary. These promising compounds are screened against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) in order to select compounds for continued development. Specifically designed novel drugs are then synthesized to support lead optimization efforts, exploiting established in vivo (living organism) model standards to treat military relevant resistant bacteria.			
FY 2020 Plans:			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
FY2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement: Pricing adjustment.			
Accomplishments/Planned Programs Subtotals		2.142	1.857
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
D. Acquisition Strategy An Acquisition Strategy will be developed to support future Milestone B when a clinical development candidate is identified and reaches Technology Readiness Level (TRL)-6.			
E. Performance Metrics Performance metrics of the CARB drug discovery program will be provided through semi-annual status reports, periodic reviews by the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR). The performance metric benchmark is progression of research projects to TRL 5 and their schedule to transition.			

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
306B: <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	12.958	3.830	4.051	4.132	-	4.132	4.215	4.299	4.385	4.472	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

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

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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. FY 2019 Plans: Provide further analysis of genetic, epigenetic, proteomic and pharmacogenetic testing to advance force health protection measures within the AFMS. Implement genomic data into secure DoD Digital BioBank. FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		3.975	4.051
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) 306B / <i>Advanced Diagnostics & Therapeutics Research & Development (AF)</i>
<u>E. Performance Metrics</u> Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.		

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 306C / <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
306C: <i>Core Adv Diagnostics & Epigenomics Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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

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

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

Remarks

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

E. Performance Metrics
 Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

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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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
306D: <i>Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)</i>	1.728	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

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

N/A

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

N/A

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.***

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
372A: <i>GDF Applied Biomedical Technology</i>	208.151	65.629	74.724	67.148	-	67.148	68.357	69.724	71.119	72.542	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

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

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

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 372A / <i>GDF Applied Biomedical Technology</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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). 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. Combat casualty care hemorrhage research is investigating new diagnostic tools and continuing the development of treatments for severe hemorrhage following injury. Research is focusing on the pathophysiological impacts of using advanced hemorrhage control and resuscitation approaches in prolonged field care scenarios where evacuation may be delayed. Research is focusing on novel oxygen carriers for use in severe casualties where blood transfusions are not available. Inflammatory modulation and other research focused on the time period from 4 to 72 hours post-injury (related to prolonged field care scenarios) are ongoing. Tactical Combat Casualty Care (TCCC) is investigating novel approaches to enable field care of casualties when evacuation is delayed. Neurotrauma research is focusing on precision medicine capabilities. This research is anticipated to improve the characterization of traumatic brain injury (TBI), and lead to the development of targeted therapies, devices and clinical guidelines to improve the care provided to TBI casualties. Treatments for extremity trauma to advance wound stabilization for prolonged			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency		Date: February 2019	
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
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. 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). 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. FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019. FY 2019 to FY 2020 Increase/Decrease Statement: Increasing focus to refine potential military medical solutions to increase advanced technology development efforts.			
Accomplishments/Planned Programs Subtotals		49.639	58.724
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) 372A / <i>GDF Applied Biomedical Technology</i>
<u>D. Acquisition Strategy</u> 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. <u>E. Performance Metrics</u> Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports to include information on publications, intellectual property, additional funding support, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with applied research funding is the attainment of a maturity level that is at least Technology Readiness Level (TRL) 4, and typically TRL 5, or the equivalent for knowledge products. Products nearing attainment of TRL 5 will be considered for transition.		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Defense Health Agency										Date: February 2019		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>				Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
447A: <i>Military HIV Research Program (Army)</i>	31.082	7.573	9.022	9.654	-	9.654	9.847	10.044	10.244	10.449	Continuing	Continuing

A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Title: Military HIV Research Program	7.794	9.022	9.654
Description: This project conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
FY 2019 Plans: The Military HIV Research Program is producing and characterizing new vaccine candidates for use in pre-clinical and clinical testing. Vaccine candidates will be evaluated to assess their ability to invoke an immune response in non-human primates by using novel delivery systems containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, B, C, D and E. The program is developing and optimizing methods of large scale production of new vaccine candidates for testing in Africa and Asia to assess candidate vaccines against diverse HIV subtypes. Efforts to identify and develop new clinical trial sites in Europe, Southeast Africa Asia and the US are ongoing in order to allow scientists the opportunity to test future vaccine candidates against predominant HIV subtypes circulating around the world.			
FY 2020 Plans: FY 2020 plans continue efforts as outlined in FY 2019.			
FY 2019 to FY 2020 Increase/Decrease Statement:			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115DHA / <i>Applied Biomedical Technology</i>	Project (Number/Name) 447A / <i>Military HIV Research Program (Army)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
Pricing Adjustment.			
Accomplishments/Planned Programs Subtotals		7.794	9.022
			9.654
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
The program receives periodic funding from Division of AIDS of NIAID ranging from \$10-20 million per year through an Interagency Agreement with USAMRMC.			
D. Acquisition Strategy			
N/A			
E. Performance Metrics			
Performance of the HIV research program is monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Product Team and in-process reviews.			