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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 0605145DHA I <i>Medical Products and Support Systems Development</i>
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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	160.599	21.589	21.068	21.489	-	21.489	-	-	-	-	Continuing	Continuing
399A: <i>Hyperbaric Oxygen Therapy Clinical Trial (Army)</i>	28.619	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
500A: <i>CSI - Congressional Special Interests</i>	18.382	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
375: <i>GDF - Medical Products and Support System Development</i>	113.598	21.589	21.068	0.000	-	0.000	-	-	-	-	Continuing	Continuing
375A: <i>GDF - Medical Simulation and Training</i>	0.000	0.000	0.000	2.000	-	2.000	-	-	-	-	Continuing	Continuing
375B: <i>GDF - Medical Readiness</i>	-	0.000	0.000	8.536	-	8.536	-	-	-	-	Continuing	Continuing
375C: <i>GDF - Medical Combat Support</i>	0.000	0.000	0.000	10.953	-	10.953	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force – Medical Products and Support Systems Development: This program element (PE) provides funding for system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping Department of Defense (DoD) Components that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials for products that require US Food and Drug Administration approval.

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

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

UNCLASSIFIED

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B. Program Change Summary (\$ in Millions)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total
Previous President's Budget	21.589	21.068	21.489	-	21.489
Current President's Budget	21.589	21.068	21.489	-	21.489
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	0.000	0.000			

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

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

Congressional Add: *CSI - Congressional Speical Interest*

	FY 2020	FY 2021
	0.000	0.000
Congressional Add Subtotals for Project: 500A	0.000	0.000
Congressional Add Totals for all Projects	0.000	0.000

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 0605145DHA / Medical Products and Support Systems Development	Project (Number/Name) 399A / Hyperbaric Oxygen Therapy Clinical Trial (Army)
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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
399A: Hyperbaric Oxygen Therapy Clinical Trial (Army)	28.619	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials focus on research related to the development of treatment modalities using HBO2 for chronic post-concussion syndrome after mild traumatic brain injury (mTBI). Three HBO2 human clinical trials were designed to evaluate the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments: 1- A pilot phase II (narrow population safety and effectiveness) study of hyperbaric oxygen for persistent post-concussive symptoms after mild traumatic brain injury (HOPPS), 2- Brain Injury and Mechanisms of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (BIMA), and 3- Development of Normative Datasets for Assessments Planned for Use in Patients with Mild Traumatic Brain Injury (Normal). A fourth retrospective study, Long Term Follow-up (LTFU), is focused on the lessons learned from long-term follow-up of subjects enrolled in the Department of Defense (DoD) primary HBO2 trials. To support these protocols, four HBO2 study sites were established within the Military Health System. Each of the research sites consisted of a hyperbaric oxygen chamber enclosed in a mobile trailer, a second mobile trailer for testing and evaluation of the subjects, and a third subject staging trailer. This information is intended to inform DoD policy decisions regarding the use of HBO2 therapy as a treatment for mTBI.

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

	FY 2020	FY 2021	FY 2022
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	0.000	-	-
Description: The Hyperbaric Oxygen (HBO2) clinical trials are designed to test the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments.			
Accomplishments/Planned Programs Subtotals	0.000	-	-

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

N/A

Remarks

D. Acquisition Strategy

The acquisition outcome of this effort is a knowledge product, with the results intended to inform DoD mTBI treatment and reimbursement policies. The decision to pursue FDA registration/off-label application of an existing drug-device combination product will be made as part of a formal decision by leadership after the DoD HBO2 trial results are reviewed. If future work using HBO2 proves beneficial in the treatment of PTSD this knowledge product would inform DoD treatment and reimbursement policies.

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 0605145DHA / Medical Products and Support Systems Development				Project (Number/Name) 500A / CSI - Congressional Special Interests			
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
500A: CSI - Congressional Special Interests	18.382	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

In FY 2019, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

	FY 2020	FY 2021
Congressional Add: CSI - Congressional Speical Interest	0.000	0.000
FY 2020 Accomplishments: No CSI		
FY 2021 Plans: No CSI		
Congressional Adds Subtotals	0.000	0.000

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

N/A

Remarks

D. Acquisition Strategy

N/A

UNCLASSIFIED

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

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / Medical Products and Support Systems Development	Project (Number/Name) 375 / GDF - Medical Products and Support System Development
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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
375: GDF - Medical Products and Support System Development	113.598	21.589	21.068	0.000	-	0.000	-	-	-	-	Continuing	Continuing

Note

Starting in FY2022 Project 375 is being realigned into Projects 375A, 375B, and 375C.

A. Mission Description and Budget Item Justification

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

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

Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)

Description: GDF-Medical Products and Support Systems Development: This funding supports activities to support system development and demonstration prior to initial full rate production and fielding of medical commodities delivered from 0604110HP (Medical Products Support and Advanced Concept Development). Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical training systems technologies.

FY 2021 Plans:

Medical Simulation and Training: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. Medical Simulation Training Systems will begin to develop standardized training capabilities for point of injury, trauma simulation, hospital training, along with a common platform architecture that improves medical care across the DoD.

Medical Readiness: Programs will focus on prevention of illness and injury along with optimization of human performance. The Health Readiness and Performance System will continue to refine technologies including wearable sensors to monitor nondiagnostic physiologic data in real-time to improve Warfighter health, readiness and performance, reduce casualties, and increase situational awareness.

	FY 2020	FY 2021	FY 2022
	21.589	21.068	-

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 0605145DHA / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 375 / <i>GDF - Medical Products and Support System Development</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
Medical Combat Support: Programs will focus on operational support. The Next Generation Diagnostic System-Infectious Disease Panel program obtained FDA Approval. FY 2021 to FY 2022 Increase/Decrease Statement: Starting in FY 2022, Project 375 is being realigned into Projects 375A, 375B, and 375C.				
Accomplishments/Planned Programs Subtotals		21.589	21.068	-
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 0605145DHA / Medical Products and Support Systems Development	Project (Number/Name) 375A / GDF - Medical Simulation and Training
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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
375A: GDF - Medical Simulation and Training	0.000	0.000	0.000	2.000	-	2.000	-	-	-	-	Continuing	Continuing

Note
Starting in FY 2022, Project 375A was realigned from Project 375. This Project is not a new start.

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Simulation and Training: This funding supports material development activities that enhance system development and demonstration prior to initial full rate production and fielding of capabilities.

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

	FY 2020	FY 2021	FY 2022
Title: GDF - Medical Simulation and Training	-	-	2.000
Description: GDF-Medical Products and Support Systems Development: This funding enhances activities to support system development and demonstration prior to initial full rate production and fielding of medical simulation delivered from 0604110HP (Medical Simulation and Training, Advanced Concept Development). Materiel development may include accelerated transition of Medical Simulation products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical training systems technologies.			
FY 2022 Plans: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. Medical Simulation Training Systems will begin to develop standardized training capabilities for point of injury, trauma simulation, hospital training, along with a common platform architecture that improves medical care across the DoD.			
FY 2021 to FY 2022 Increase/Decrease Statement: Starting in FY 2022, Project 375A was realigned from Project 375.			
Accomplishments/Planned Programs Subtotals	-	-	2.000

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 0605145DHA / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 375A / <i>GDF - Medical Simulation and Training</i>

D. Acquisition Strategy

This program will test and evaluate medical simulation products and platforms developed in order to review data for operational and clinical use prior to production and fielding.

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 0605145DHA / <i>Medical Products and Support Systems Development</i>	Project (Number/Name) 375B / <i>GDF - Medical Readiness</i>
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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
375B: <i>GDF - Medical Readiness</i>	-	0.000	0.000	8.536	-	8.536	-	-	-	-	Continuing	Continuing

Note
Starting in FY 2022, Project 375B was realigned from Project 375. This Project is not a new start.

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Readiness: This funding supports material development activities that enhance system development and demonstration prior to initial full rate production and fielding of capabilities.

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

	FY 2020	FY 2021	FY 2022
Title: GDF - Medical Readiness	-	-	8.536
Description: GDF-Medical Readiness: This funding enhances activities to support system development and demonstration prior to initial full rate production and fielding of medical readiness capability delivered from 0604110HP (Medical Readiness, Advanced Concept Development). Materiel development may include accelerated transition of Medical Readiness products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical readiness systems technologies.			
FY 2022 Plans: Programs will focus on prevention of illness and injury along with optimization of human performance. The Health Readiness and Performance System will continue to refine technologies including wearable sensors to monitor non diagnostic physiologic data in real-time to improve Warfighter health, readiness and performance, reduce casualties, and increase situational awareness.			
FY 2021 to FY 2022 Increase/Decrease Statement: Starting in FY 2022, Project 375B was realigned from Project 375.			
Accomplishments/Planned Programs Subtotals	-	-	8.536

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

N/A

Remarks

D. Acquisition Strategy

This program will test and evaluate medical products in government-managed clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.

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 0605145DHA / Medical Products and Support Systems Development	Project (Number/Name) 375C / GDF - Medical Combat Support
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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
375C: GDF - Medical Combat Support	0.000	0.000	0.000	10.953	-	10.953	-	-	-	-	Continuing	Continuing

Note
Starting in FY 2022, Project 375C was realigned from Project 375. This Project is not a new start.

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Combat Support: This funding supports material development activities that enhance system development and demonstration prior to initial full rate production and fielding of capabilities.

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

Title: GDF - Medical Combat Support	FY 2020	FY 2021	FY 2022
Description: GDF-Medical Combat Support: This funding enhances activities to support system development and demonstration prior to initial full rate production and fielding of medical readiness capability delivered from 0604110HP (Medical Combat Support, Advanced Concept Development). Materiel development may include accelerated transition of Medical Combat Support products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical combat support systems technologies.	-	-	10.953
FY 2022 Plans: Programs will focus on the continued operational support of Cold Stored Platelets and Battlefield Pain Management clinical trials.			
FY 2021 to FY 2022 Increase/Decrease Statement: Starting in FY 2022, Project 375C was realigned from Project 375.			
Accomplishments/Planned Programs Subtotals	-	-	10.953

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

N/A

Remarks

D. Acquisition Strategy

This program will test and evaluate medical products in government-managed clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.