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

Appropriation/Budget Activity 1319: <i>Research, Development, Test & Evaluation, Navy / BA 5: System Development & Demonstration (SDD)</i>	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical 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	213.775	32.036	39.612	3.967	-	3.967	-	-	-	-	-	-
0933: <i>Medical/Dental Equipment Dev</i>	25.474	7.902	2.112	3.967	-	3.967	-	-	-	-	-	-
9999: <i>Congressional Adds</i>	188.301	24.134	37.500	0.000	-	0.000	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

The purpose of this program is to develop biomedical equipment and related techniques to reduce morbidity; to enhance the logistic feasibility of modern medical care for combat casualties; to sustain casualties for evacuation to fixed medical facilities for definitive care; and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firm/industry participation in the projects.

B. Program Change Summary (\$ in Millions)

	<u>FY 2020</u>	<u>FY 2021</u>	<u>FY 2022 Base</u>	<u>FY 2022 OCO</u>	<u>FY 2022 Total</u>
Previous President's Budget	33.181	2.120	5.152	-	5.152
Current President's Budget	32.036	39.612	3.967	-	3.967
Total Adjustments	-1.145	37.492	-1.185	-	-1.185
• Congressional General Reductions	-	-0.008			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	37.500			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.145	0.000			
• Program Adjustments	0.000	0.000	-1.047	-	-1.047
• Rate/Misc Adjustments	0.000	0.000	-0.138	-	-0.138

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

Project: 9999: *Congressional Adds*

Congressional Add: *Military Dental Research*

Congressional Add: *Wound Care Research*

Congressional Add: *Physiological episodes research*

Congressional Add: *Autonomous Aerial Technology for Distributed Logistics*

FY 2020	FY 2021
9.653	10.000
9.654	10.000
4.827	0.000
0.000	7.500

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

Congressional Add: *ETEC Enteric Disease Research*

Congressional Add Subtotals for Project: 9999

Congressional Add Totals for all Projects

	FY 2020	FY 2021
	0.000	10.000
	24.134	37.500
	24.134	37.500

Change Summary Explanation

The FY 2022 funding request was reduced by \$0.778 million for higher Navy Priority

The FY 2022 funding request was reduced by \$0.407 million to account for the availability of prior year execution balances.

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Navy										Date: May 2021		
Appropriation/Budget Activity 1319 / 5					R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>				Project (Number/Name) 0933 / <i>Medical/Dental Equipment Dev</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
0933: <i>Medical/Dental Equipment Dev</i>	25.474	7.902	2.112	3.967	-	3.967	-	-	-	-	-	-
Quantity of RDT&E Articles		-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

The purpose of this program is to develop biomedical equipment and related techniques to reduce morbidity; to enhance the logistic feasibility of modern medical care for combat casualties; to sustain casualties for evacuation to fixed medical facilities for definitive care; and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms/industry participation in the projects.

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)

	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total
Title: Medical/Dental Equipment Development	7.902	2.112	3.967	0.000	3.967
Articles:	-	-	-	-	-
FY 2021 Plans:					
-Complete Individual Fatigue-Based Scheduling and Countermeasure System that predicts, prevents, detects, and mitigates periods of high risk associated with fatigue.					
-Continue fatigue mitigation and validation of scheduling tools to include validation of an alternative watchstanding schedule on Naval Surface Combatants.					
-Complete support for mitigating adverse physiological episodes to enhance safety and warfighter readiness in tactical aircraft.					
-Continue Human Performance/Crew Endurance effort: Controlled Light Exposure and Fatigue Mitigation.					
-Complete innovative medical technologies and enhanced medical logistics: Autonomous system for field delivery of critical medical supplies.					
-Continue cabin-pressure/decompression sickness (DCS) test and evaluation capability.					
-Continue evaluation of physiological monitoring sensor system in relevant military environments.					
-Continue Human Performance/Crew Endurance effort: Navy specific Stress Inoculation Study.					
FY 2022 Base Plans:					
-Continue fatigue mitigation and validation of scheduling tools to include validation of an alternative watchstanding schedule on Naval Surface Combatants.					
-Continue Human Performance/Crew Endurance effort: Controlled Light Exposure and Fatigue Mitigation.					
-Continue cabin-pressure/decompression sickness (DCS) test and evaluation capability.					
-Continue evaluation of physiological monitoring sensor system in relevant military environments.					

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Navy	Date: May 2021
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Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 0933 / <i>Medical/Dental Equipment Dev</i>
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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total
<p>-Continue Human Performance/Crew Endurance effort: Navy specific Stress Inoculation Study. -Initiate Human Performance Neurocognitive Tool development and Test & Evaluation.</p> <p>FY 2022 OCO Plans: N/A</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: The increase from FY21 to FY22 supports continuation of the project activities for a Physiological Monitoring Sensors and Systems that will involve integration and T&E activities for diveable biomedical monitoring systems (i.e., Integrated Monitoring System [IMS]) and personnel recovery technology(ies) (e.g.,recovery beacon). In addition, the Physiological Monitoring Sensors and Systems activities in FY22 will include neurocognitive assessment tool suitable for during underwater operations. The increase from FY21 to FY22 accounts for expanded Human Performance activities and the funding will be attributed to the activities noted herein. The increase is not solely for Human Performance Neurocognitive Tool development and Test & Evaluation, rather for all the activities noted here.</p>					
Accomplishments/Planned Programs Subtotals	7.902	2.112	3.967	0.000	3.967

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

N/A

Remarks

D. Acquisition Strategy

The acquisition strategy for product lines and products in the Medical Development Program is designed and implemented consistent with the purpose of the particular product and with the nature and size of the investment.

The major Product Areas in the Medical Development Program are: 1) Equipment, 2) Pharmaceuticals/Biologics, and 3) Operational Knowledge/Concepts. The primary Program Areas of Interest are: 1) Optimize health, performance, and resilience of the ready and forward operating forces; 2) Enhance medical logistics; 3) Reduce mortality and morbidity from battlefield and mission-related injuries in support of Navy Health Services Support in Terrestrial, Maritime Surface, Submarine, and Aviation Operations and USMC in Expeditionary Operations.

For Product Areas 1 and 2, there are two primary acquisition strategies. The first is to test and evaluate for Naval application commercially-developed medical product or candidates in managed trials or test events with the ultimate goal of supporting Food and Drug Administration (FDA) approval, where appropriate. Partnerships with commercial developers promotes developing products of military interest for procurement by the Operating Forces. A second benefit of this strategy is that products are made available across the DoD, Federal Government, and commercial market, thus reducing overall procurement costs. During development, DoD end users are

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

Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (Number/Name)
1319 / 5	PE 0604771N / <i>Medical Development</i>	0933 / <i>Medical/Dental Equipment Dev</i>

included in the process to the extent possible. The second strategy is to drive a collaborative development process with larger DoD program investments. This process involves developing in-house or industrial prototypes in government-managed programs to meet Naval needs while meeting regulatory requirements for production and fielding. Both tactics promote development of procurement plans that align product availability with Service integration strategies.

The Third Product Area (Knowledge/Concepts) is focused on the introduction of technologies, techniques, and procedures that enhance medical practice and standards of care for effective delivery of health care and casualty care in the Naval operating environment. These primarily require early involvement of the senior leadership of military medicine, in that the end product of the program is modification of concepts of operations, policy, and/or doctrine. These acquisitions can impact the care and performance of Sailors and Marines. Medical Development Program examples include Navy Crew Endurance Handbook and associated implementation tools.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Navy **Date:** May 2021

Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 0933 / <i>Medical/Dental Equipment Dev</i>
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Product Development (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Human Factors Individualized Fatigue Based Scheduling	Allot	Naval Submarine Medical Research Laboratory : Groton, CT	2.495	0.044	Feb 2020	0.000		0.000		-		0.000	-	-	-
Fatigue Based Scheduling	WR	Naval Post Graduate School : Monterey, CA	2.017	0.301	Dec 2019	0.301	Dec 2020	0.000		-		0.000	-	-	-
Mitigation of Adverse Physiological Episodes in Tactical Aircraft	Allot	Various : Not Specified	1.267	0.000		0.000		0.000		-		0.000	-	-	-
Crew Endurance and Fatigue Mitigation	WR	Naval Post Graduate School : Monterey, CA	3.065	1.850	Dec 2019	0.400	Dec 2020	0.000		-		0.000	-	-	-
Autonomous System for Field Delivery of Critical Medical Supplies	Various	Various : Not Specified	6.623	0.000		0.000		0.000		-		0.000	-	-	-
Cabin-pressure/ Decompression Sickness Test and Evaluation Capability	Allot	NAVFAC EXWC : Port Hueneme, CA	2.434	0.584	Sep 2020	0.125	Sep 2021	0.000		-		0.000	-	-	-
Physiological Monitoring Sensor Systems	Various	Various : Not Specified	0.000	4.500	Sep 2021	0.600	Sep 2021	2.605	Jun 2022	-		2.605	-	-	-
Navy specific Stress Inoculation Study	WR	Naval Post Graduate School : Monterey, CA	0.300	0.299	Dec 2019	0.306	Dec 2020	0.000		-		0.000	-	-	-
Human Performance Neurocognitive Tool	Various	Various : Not Specified	0.000	0.000		0.000		0.605	Jun 2022	-		0.605	-	-	-
Medical Product Development	Various	Various : Not Specified	5.586	0.000		0.130	Aug 2021	0.115	Aug 2022	-		0.115	-	-	-
Subtotal			23.787	7.578		1.862		3.325		-		3.325	-	-	N/A

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Exhibit R-4, RDT&E Schedule Profile: PB 2022 Navy **Date: May 2021**

Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 0933 / <i>Medical/Dental Equipment Dev</i>
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Proj 0933	FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Optimized Health, Performance, and Resilience: Human Performance/Crew Endurance and Fatigue Mitigation	Evaluate System and Design Integration Methods																											
	Technology Development and Testing																											
Reduced Morbidity and Mortality: Physiological Monitoring Sensor Systems	Technology Development and Testing																											

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Exhibit R-4A, RDT&E Schedule Details: PB 2022 Navy **Date:** May 2021

Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 0933 / <i>Medical/Dental Equipment Dev</i>
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Schedule Details

Events by Sub Project	Start		End	
	Quarter	Year	Quarter	Year
<i>Proj 0933</i>				
Optimized Health, Performance, and Resilience: Human Performance/Crew Endurance and Fatigue Mitigation: Evaluate System and Design Integration Methods	1	2020	4	2022
Reduced Morbidity and Mortality: Physiological Monitoring Sensor Systems: Technology Development and Testing	4	2021	4	2022

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Navy										Date: May 2021		
Appropriation/Budget Activity 1319 / 5					R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>				Project (Number/Name) 9999 / <i>Congressional Adds</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
9999: <i>Congressional Adds</i>	188.301	24.134	37.500	0.000	-	0.000	-	-	-	-	-	-
Quantity of RDT&E Articles		-	-	-	-	-	-	-	-	-		

Note

None

A. Mission Description and Budget Item Justification

Congressional Adds

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

	FY 2020	FY 2021
Congressional Add: Military Dental Research FY 2020 Accomplishments: N/A FY 2021 Plans: Continue efforts in craniofacial injury surveillance; combat dentistry; treatment of maxillofacial injury; dental disease non-battle injuries; and oral/facial disease and infection in military personnel.	9.653	10.000
Congressional Add: Wound Care Research FY 2020 Accomplishments: N/A FY 2021 Plans: Continue to develop novel diagnostics and treatments to enhance the care of the wounded warfighter.	9.654	10.000
Congressional Add: Physiological episodes research FY 2020 Accomplishments: N/A FY 2021 Plans: N/A	4.827	0.000
Congressional Add: Autonomous Aerial Technology for Distributed Logistics FY 2020 Accomplishments: N/A FY 2021 Plans: Initiate Research, Development, Test and Evaluation (RDT&E) on autonomous aerial technologies distribution of medical materials to enhance medical capabilities in the distributed operational environment.	0.000	7.500
Congressional Add: ETEC Enteric Disease Research	0.000	10.000

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Navy	Date: May 2021
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Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 9999 / <i>Congressional Adds</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021
<i>FY 2020 Accomplishments:</i> N/A		
<i>FY 2021 Plans:</i> Initiate Research, Development, Test and Evaluation (RDT&E) efforts on ETEC enteric disease research to treat and/or mitigate the impact of ETEC and ETEC-related illnesses.		
Congressional Adds Subtotals	24.134	37.500

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

N/A

Remarks

D. Acquisition Strategy

None

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Navy **Date:** May 2021

Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 9999 / <i>Congressional Adds</i>
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Product Development (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Congressional Add - Wound Care Research	Various	Various : Not Specified	56.069	9.654	Jun 2020	10.000	Sep 2021	0.000		-		0.000	-	-	-
Congressional Add - Military Dental Research	Allot	Naval Medical Research Unit - San Antonio : San Antonio, TX	18.611	4.827	Jun 2020	5.000	May 2021	0.000		-		0.000	-	-	-
Congressional Add - Military Dental Research	MIPR	USAISR Dental & Craniofacial Trauma Research Dir. : San Antonio, TX	18.293	4.826	Jun 2020	5.000	May 2021	0.000		-		0.000	-	-	-
Congressional Add - Hypoxia Research (C0232)	Various	Various : Not Specified	4.828	0.000		0.000		0.000		-		0.000	-	-	-
Congressional Add - Aircrew Mounted Physiological Sensors (C0233)	Various	Various : Not Specified	2.897	0.000		0.000		0.000		-		0.000	-	-	-
Congressional Add - Hypoxia Research (C471)	Various	Various : Not Specified	4.827	0.000		0.000		0.000		-		0.000	-	-	-
Congressional Add - Physiological Episodes Research (C562)	Various	Various : Not Specified	0.000	4.827	Sep 2020	0.000		0.000		-		0.000	-	-	-
Congressional Add - Autonomous Aerial Technology for Distributed Logistics (C592)	Various	Various : Not Specified	0.000	0.000		7.500	Sep 2021	0.000		-		0.000	-	-	-
Congressional Add - ETEC Enteric Disease Research (C609)	Various	Various : Not Specified	0.000	0.000		10.000	Sep 2021	0.000		-		0.000	-	-	-
Congressional Adds	Various	Various : Not Specified	82.776	0.000		0.000		0.000		-		0.000	-	-	-
Subtotal			188.301	24.134		37.500		0.000		-		0.000	-	-	N/A

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Exhibit R-4, RDT&E Schedule Profile: PB 2022 Navy **Date:** May 2021

Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 9999 / <i>Congressional Adds</i>
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Proj 9999	FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Military Dental Research (2896)																												
Wound Care Research (C210)																												
Physiological Episodes Research (C562)																												
Autonomous Aerial Technology for Distributed Logistics (C592)																												
ETEC Enteric Disease Research (C5609)																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2022 Navy **Date:** May 2021

Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / <i>Medical Development</i>	Project (Number/Name) 9999 / <i>Congressional Adds</i>
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Schedule Details

Events by Sub Project	Start		End	
	Quarter	Year	Quarter	Year
Proj 9999				
Military Dental Research (2896): Schedule Detail	3	2020	4	2022
Wound Care Research (C210): Schedule Detail	3	2020	4	2022
Physiological Episodes Research (C562): Schedule Detail	4	2020	4	2021
Autonomous Aerial Technology for Distributed Logistics (C592): Schedule Detail	4	2021	4	2022
ETEC Enteric Disease Research (C5609): Schedule Detail	4	2021	4	2022