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Exhibit R-2, RDT&E Budget Item Justification: PB 2024 Defense Health Agency **Date:** March 2023

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0605502DHA I <i>Small Business Innovation Research</i>
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
Total Program Element	66.784	76.540	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
470: <i>Small Business Innovation Research</i>	58.549	67.106	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
471: <i>Small Business Technology Transfer</i>	8.235	9.434	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

The Small Business Innovation Research (SBIR) program was established in the Defense Health Program (DHP), Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2001, and is funded in the year of execution. The objective of the DHA SBIR Program includes stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The program funds small business proposals chosen to enhance military medical research and information technology research.

The Small Business Technology Transfer (STTR) program was established in the Defense Health Program (DHP), Research, Development, Test and Evaluation (RDT&E) appropriation during FY 2015, and is funded in the year of execution. The STTR Program, although modeled substantially on the SBIR Program, is a separate program and is separately financed. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations. The mission of the STTR program is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy. The program's goals are to stimulate technological innovation, foster technology transfer through cooperative research and development between small businesses and research institutions, and increase private sector commercialization of innovations derived from federal research and development.

B. Program Change Summary (\$ in Millions)	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024 Base</u>	<u>FY 2024 OCO</u>	<u>FY 2024 Total</u>
Previous President's Budget	0.000	0.000	0.000	0.000	0.000
Current President's Budget	76.540	0.000	0.000	0.000	0.000
Total Adjustments	76.540	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	76.540	-			

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency										Date: March 2023		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0605502DHA / <i>Small Business Innovation Research</i>				Project (Number/Name) 470 / <i>Small Business Innovation Research</i>			
COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
470: <i>Small Business Innovation Research</i>	58.549	67.106	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

The Defense Health Agency (DHA) Small Business Innovation Research (SBIR) Program can participate in any of the three (FY.1, FY.2, and FY.3) Department of Defense (DoD) SBIR Broad Agency Announcements (BAA) as well as Out-of-Cycle BAAs (FY.4). The process begins with a call for topics to the Joint Program Committees (JPCs), multi-Service committees established to manage research, development, test and evaluation for DHA sponsored research. DHA SBIR topics are submitted directly to the US Army Medical Research and Development Command (USAMRDC) and then forwarded to the JPCs for review and internal ranking. Topic Authors brief their topics at a Topic Review Meeting attended by the DHA SBIR Program Director (PD) and personnel from the supporting USAMRDC offices. Approved DHA SBIR topics are published in DoD SBIR BAAs. Small businesses submit proposals against topics which are then evaluated by a Technical Evaluation Team (TET) made up of a Team Chief and Technical Evaluators. TETs recommend proposals for selection. All recommended proposals are reviewed by the JPCs and the DHA SBIR PD. Phase I proposal selections are announced and contract negotiations begin. Phase I contracts are awarded up to \$250K for 6 months. Follow-on Phase II projects can be awarded up to \$1.1M for 24 months. This process ensures the SBIR program addresses the multi-agency science and technology priorities.

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: Small Business Innovation Research (SBIR) Program	67.106	0.000	0.000	0.000	0.000
Description: The program funds small business proposals chosen to enhance military medical research and information technology research. The following reflects the FY 2022 research area topics sought for proposals.					
FY 2022 Accomplishments:					
For FY 2022, nine DHA SBIR topics were developed for the 2022.1, 2022.2, and 2022.4 DoD SBIR Broad Agency Announcement (BAA). Funding for each topic is based on the technical merits of the proposals submitted. Topics included:					
2022.1 DHA SBIR Topic DHA221-001 - Prolonged Care: To Demonstrate a Medicated Combat Tourniquet Capable of Wound Infection Treatment Delivery. This DHA SBIR initiative funded research to assemble a system of systems to prevent the development of infection in an austere environment when the provision of surgical intervention is delayed over 72 hours. This effort solicited a total of fifteen SBIR Phase I proposals. Proposals were accepted through the 2022.1 DoD SBIR BAA pre-released in December 2021. Proposals were received in February 2022 followed by Technical Evaluation Team evaluations in March 2022. Phase I proposal selections					

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<p>were announced in April 2022. A total of three Phase I proposals were selected under this topic. Awards were made in June 2022.</p> <p>2022.1 DHA SBIR Topic DHA221-002 - Scalable Multi-person Hearing Protection Device Fit-testing System. This DHA SBIR initiative funded research to develop a system that can simultaneously fit-test multiple people with hearing protection devices (HPDs). This effort solicited a total of nine SBIR Phase I proposals. Proposals were accepted through the 2022.1 DoD SBIR BAA pre-released in December 2021. Proposals were received in February 2022 followed by Technical Evaluation Team evaluations in March 2022. Phase I proposal selections were announced in April 2022. A total of three Phase I proposals were selected under this topic. Awards were made in May and June 2022.</p> <p>2022.1 DHA SBIR Topic DHA221-003 - Olfactory Neuroepithelium Functional Diagnostic Tool. This DHA SBIR initiative funded research to develop a device to determine thickness of mucus on top of the mucosa and then be able characterize important properties of the cellular layers of the olfactory cleft mucosa as has been demonstrated with optical coherence tomography (OCT) and confocal laser endomicroscopy (CLE) in the pulmonary tract. This effort solicited a total of four SBIR Phase I proposals. Proposals were accepted through the 2022.1 DoD SBIR BAA pre-released in December 2021. Proposals were received in February 2022 followed by Technical Evaluation Team evaluations in March 2022. Phase I proposal selections were announced in April 2022. A total of two Phase I proposals were selected under this topic. Awards were made in May and June 2022.</p> <p>2022.1 DHA SBIR Topic DHA221-004 - Blind 3D Kinematic Measurement of High-Rate Complex Surface Deformation. This DHA SBIR initiative funded research to develop and demonstrate technologies capable of measuring complex surface response kinematics at the interface between the torso and body armor system. This effort solicited a total of eight SBIR Phase I proposals. Proposals were accepted through the 2022.1 DoD SBIR BAA pre-released in December 2021. Proposals were received in February 2022 followed by Technical Evaluation Team evaluations in March 2022. Phase I proposal selections were announced in April 2022. A total of three Phase I proposals were selected under this topic. Awards were made in July 2022.</p> <p>2022.2 DHA SBIR Topic DHA222-001 - Developing a Hardened Portable EEG System for Aircrew Physiological. This DHA SBIR initiative funded research to design, build, and demonstrate a portable, dry EEG system that is integrated into the HGU-68/P flight helmet and capable of producing reliable and interpretable data in the flight environment which presents considerable sources of noise such as electronic noise, vibration from mechanical components, acceleration forces, changes in temperature and pressure, and non- neurological signals (e.g.,</p>					

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
muscle activity). This effort solicited a total of thirty two SBIR Phase I proposals. Proposals were accepted through the 2022.2 DoD SBIR BAA pre-released in April 2022. Proposals were received in June 2022 followed by Technical Evaluation Team evaluations in July 2022. Phase I proposal selections were announced in July 2022. A total of three Phase I proposals were selected under this topic. Awards were made in August 2022.					
2022.2 DHA SBIR Topic DHA222-002 - To Demonstrate a Technology for Early Detection and Monitoring of Wound. This DHA SBIR initiative funded research to develop and validate a technology solution for the early detection and monitoring of wound infections in a prolonged care setting. This effort solicited a total of twenty five SBIR Phase I proposals. Proposals were accepted through the 2022.2 DoD SBIR BAA pre-released in April 2022. Proposals were received in June 2022 followed by Technical Evaluation Team evaluations in July 2022. Phase I proposal selections were announced in July 2022. A total of three Phase I proposals were selected under this topic. Awards were made in August 2022.					
2022.4 DHA SBIR Topic DHA224-D001 - Remote Frostbite Prevention System. This DHA SBIR initiative funded research to develop a wireless, readily-scalable, real-time skin temperature sensing system that end-users can use to identify cold stressed workers with hands, feet, and other extremities that are at risk of freezing cold injury. This effort solicited a total of fourteen SBIR Phase II proposals. Proposals were accepted through the 2022.4 DoD SBIR BAA pre-released in March 2022. Proposals were received in April 2022 followed by Technical Evaluation Team evaluations in May 2022. Phase II proposal selections were announced in June 2022. A total of three Phase II proposals were selected under this topic. Awards were made in September 2022.					
2022.4 DHA SBIR Topic DHA224-D002 - Therapeutic Modalities for the Mitigation of Neck/Back Pain during Flight Operations. This DHA SBIR initiative funded research to design, build, and demonstrate a portable, ergonomically appropriate, and powered device for the relief of neck/back pain during long-haul flight operations. This effort solicited a total of seven SBIR Phase II proposals. Proposals were accepted through the 2022.4 DoD SBIR BAA pre-released in March 2022. Proposals were received in April 2022 followed by Technical Evaluation Team evaluations in May 2022. Phase II proposal selections were announced in June 2022. A total of three Phase II proposals were selected under this topic. Awards were made in September 2022.					
2022.4 DHA SBIR Topic DHA224-D003 - Adaptive Technology to Optimize Rehabilitation of Lower Extremity Musculoskeletal Injuries throughout Recovery. This DHA SBIR initiative funded research to develop a technology (e.g. brace, exoskeleton) that adapts to facilitate recovery throughout rehabilitation of service members with lower extremity musculoskeletal injury to enable return to duty throughout rehabilitation of service members with					

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<p>lower extremity musculoskeletal injury to enable return to duty. This effort solicited a total of twenty one SBIR Phase II proposals. Proposals were accepted through the 2022.4 DoD SBIR BAA pre-released in March 2022. Proposals were received in April 2022 followed by Technical Evaluation Team evaluations in May 2022. Phase II proposal selections were announced in June 2022. A total of three Phase II proposals were selected under this topic. Awards were made in August 2022.</p> <p>FY 2023 Plans: FY 2023 Plans:</p> <p>For FY 2023, four DHA SBIR topics are being developed for the 2023.1 DoD SBIR Broad Agency Announcement (BAA). Additional topics will be developed throughout FY 2023. Funding for each topic is based on the technical merits of the proposals submitted. Topics included:</p> <p>2023.1 DHA SBIR Topic DHA231-001 - Wireless Core Temperature Measurement during Extreme Environmental Exposure. This DHA SBIR initiative will fund research to develop a wireless technical solution and data logging system for measuring real-time core temperatures in humans during hot and cold exposure, to include water immersion, for up to 24 hours in resting and exercising individuals. This topic will be pre-released on 11 January 2023. The 2023.1 DoD BAA will open on 8 February 2023 and close on 8 March 2023. Proposals submitted against topic DHA231-001 will be evaluated in March 2023. Phase I proposal selections will be announced in April 2023. A total of 3 Phase I proposals are estimated to be awarded. Phase I contracts should be awarded by July 2023.</p> <p>2023.1 DHA SBIR Topic DHA231-002 - Portable Technology to Assess Ankle Instability. This DHA SBIR initiative will fund research to improve service member readiness by objectively assessing ankle instability with technology that is portable and can be used by minimally trained personnel in the area of lower limb movement and ankle injuries. This topic will be pre-released on 11 January 2023. The 2023.1 DoD BAA will open on 8 February 2023 and close on 8 March 2023. Proposals submitted against topic DHA231-001 will be evaluated in March 2023. Phase I proposal selections will be announced in April 2023. A total of 3 Phase I proposals are estimated to be awarded. Phase I contracts should be awarded by July 2023.</p> <p>2023.1 DHA SBIR Topic DHA231-003 - Development and Testing of Dual-lumen Femoral Cannula with Echogenic Material for Faster, Safer, and More Reliable Delivery of Extracorporeal Life Support during Prolonged Field Care. This DHA SBIR initiative will fund research to design, build, and demonstrate a femoral</p>					

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<p>dual-lumen cannula that will allow for the initiation of lifesaving extracorporeal life support (ECLS) treatment in a prolonged-field-care environment. The end goal is to save the lives of warfighters with severe lung failure. This will be accomplished by (1) limiting the risks associated with two separate cannula placements; (2) enabling confirmation of cannula placement by means of handheld ultrasound in the field; and (3) making cannulation easy to perform by non-subspecialist providers. This topic will be pre-released on 11 January 2023. The 2023.1 DoD BAA will open on 8 February 2023 and close on 8 March 2023. Proposals submitted against topic DHA231-001 will be evaluated in March 2023. Phase I proposal selections will be announced in April 2023. A total of 3 Phase I proposals are estimated to be awarded. Phase I contracts should be awarded by July 2023.</p> <p>2023.1 DHA SBIR Topic DHA231-004 - Minimally or Non-invasive Systemic Oxygen Delivery and Carbon Dioxide Removal. This DHA SBIR initiative will fund research to develop a drug, biologic, or device that is capable of facilitating transport of oxygen (O2) into the body and carbon dioxide (CO2) out of the body in a minimally-invasive or non-invasive manner without the need for oxygen generating systems. The proposed product must be usable in an austere environment with minimal clinical staff operation requirements. The ideal product will be usable by medical first responders such as combat medics (or equivalent). The final product will be low size, low weight, low power, stable at temperature extremes, with a prolonged shelf life. This topic will be pre-released on 11 January 2023. The 2023.1 DoD BAA will open on 8 February 2023 and close on 8 March 2023. Proposals submitted against topic DHA231-001 will be evaluated in March 2023. Phase I proposal selections will be announced in April 2023. A total of 4 Phase I proposals are estimated to be awarded. Phase I contracts should be awarded by July 2023.</p> <p>FY 2024 Base Plans: N/A</p> <p>FY 2024 OCO Plans: N/A</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: No funding programmed. The DHA SBIR program is funded in the year of execution.</p>					
Accomplishments/Planned Programs Subtotals	67.106	0.000	0.000	0.000	0.000

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

N/A

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

Remarks

D. Acquisition Strategy

Test and evaluate commercially developed prototypes funded by the SBIR program to ensure military and regulatory requirements are met prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.

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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
471: <i>Small Business Technology Transfer</i>	8.235	9.434	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

Small Business Technology Transfer (STTR) is a program that expands funding opportunities in the federal innovation research and development arena. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations. The program funds small business proposals that partner with a research institution, are technically meritorious, and enhance Joint Program Committee (JPC) research and development efforts. The DHA STTR Program can participate in any of the three (FY.A, FY.B, and FY.C) Department of Defense (DoD) STTR BAAs as well as Out-of-Cycle BAAs (FY.D). The process begins with a call for topics to the JPCs. DHA STTR topics are submitted directly to US Army Medical Research and Development Command (USAMRDC) and then forwarded to the JPCs for review and internal ranking. Topic Authors brief their topics at a Topic Review Meeting attended by the DHA STTR Program Director (PD) and personnel from the supporting USAMRDC offices. Approved DHA STTR topics are published in the DoD STTR BAA. Small businesses submit proposals against topics which are then evaluated by a Technical Evaluation Team (TET) made up of a Team Chief and Technical Evaluators. TETs recommend proposals for selection. All recommended proposals are reviewed by the JPCs and the DHA STTR PD. Phase I proposal selections are announced and contract negotiations begin. Phase I contracts are awarded up to \$250K for 6 months. Follow-on Phase II projects can be awarded up to \$1.1M for 24 months. This process ensures the STTR program addresses the multi-agency science and technology priorities.

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: Small Business Technology Transfer (STTR) Program	9.434	0.000	0.000	0.000	0.000
<p>Description: STTR Program offers funding opportunities in federal research and development to small businesses. The program aims to stimulate technological innovation in DoD research and development, strengthen the role of small business in meeting DoD research and development needs, foster and encourage participation by minority and disadvantaged persons in technological innovation, and increase the commercial application of DoD-supported research or research and development results. The following reflects the FY 2022 research area topics sought for proposals.</p> <p>FY 2022 Accomplishments:</p> <p>For FY 2022, one DHA STTR topic was developed for the 2022.B DoD STTR Broad Agency Announcement (BAA). Funding for each topic is based on the technical merits of the proposals submitted. Topics included:</p>					

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<p>2022.B DHA STTR Topic DHA22B-001 - Integrated Blast Acquisition Test Surrogate. This DHA STTR initiative funded research to develop an anatomically accurate low cost blast surrogate to test and evaluate current and next-generation personal protective equipment (PPE). This effort solicited a total of twelve STTR Phase I proposals. Proposals were accepted through the 2022.B DoD STTR BAA pre-released in April 2022. Proposals were received in June 2022 followed by Technical Evaluation Team evaluations in July 2022. Phase I proposal selections were announced in July 2022. A total of three Phase I proposals were selected under this topic. Awards were made in September 2022.</p> <p>FY 2023 Plans: FY 2023 Plans:</p> <p>For FY 2023, DHA STTR topics will be solicited for the 2023.B DoD SBIR Broad Agency Announcement (BAA). 2023.B topics will be pre-released in April 2023.</p> <p>FY 2024 Base Plans: N/A</p> <p>FY 2024 OCO Plans: N/A</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: No funding programmed. The DHA STTR program is funded in the year of execution.</p>					
Accomplishments/Planned Programs Subtotals	9.434	0.000	0.000	0.000	0.000

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

Remarks
N/A

D. Acquisition Strategy
Test and evaluate commercially developed prototypes funded by the STTR program to ensure military and regulatory requirements are met prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.