

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG - 8 2022

The Honorable Jon Tester Chairman Subcommittee on Defense Committee on Appropriations United States Senate Washington, DC 20510

Dear Mr. Chairman:

The Department's response to the Joint Explanatory Statement, page 91, accompanying H.R. 1158, the Consolidated Appropriations Act, 2020 (Public Law 116–93), on the Joint Warfighter Medical Research Program (JWMRP), is enclosed.

The final report summarizes the projects selected for Fiscal Year (FY) 2020 JWMRP funding, and covers the total congressional appropriations for the JWMRP during this period (\$40 million). The FY 2020 JWMRP funded 21 projects, aligned under the Science and Technology or Advanced Development project domains, which collectively address the following six Defense Health Program core JWMRP research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; radiation health effects; and clinical and rehabilitative medicine. These projects reflect a diverse set of JWMRP topics of scientific inquiry intended to enhance and accelerate high-priority Department of Defense and Military Department medical requirements, with potential to provide significant benefits to military medicine.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and families. I am sending similar letters to the other congressional defense committees.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:

As stated

cc:

The Honorable Richard C. Shelby Vice Chairman



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG - 8 2022

The Honorable Betty McCollum Chair Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

Dear Madam Chair:

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The Honorable Ken Calvert Ranking Member



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AUG - 8 2022

The Honorable Jack Reed Chairman Committee on Armed Services United States Senate Washington, DC 20510

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The Honorable James M. Inhofe Ranking Member



4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG - 8 2022

The Honorable Adam Smith Chairman Committee on Armed Services U.S. House of Representatives Washington, DC 20515

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Enclosure: As stated

cc:

The Honorable Mike D. Rogers Ranking Member

Report to the Congressional Defense Committees



In Response to: The Joint Explanatory Statement, Page 91, Accompanying H.R. 1158, the Consolidated Appropriations Act, 2020 (Public Law 116–93), on the Joint Warfighter Medical Research Program

August 2022

The estimated cost of this report for the Department of Defense (DoD) is approximately \$1,400.00 for Fiscal Years 2020–2021. This includes \$100.00 in expenses and \$1,300.00 in DoD labor.

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BACKGROUND AND PURPOSE

This report is in response to the Joint Explanatory Statement, page 91, accompanying H.R. 1158, the Consolidated Appropriations Act, 2020 (Public Law 116–93), which requests that the Assistant Secretary of Defense for Health Affairs provide a report to the congressional defense committees on the Joint Warfighter Medical Research Program (JWMRP). The Joint Explanatory Statement specifies this report should list the projects that receive funding, including the funding amount awarded to each project, a thorough description of each project's research, and the benefit this research will provide to the Department of Defense (DoD).

As requested by the Office of the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) provides execution management for the DHP RDT&E JWMRP Congressional Special Interest (CSI) funds.

FISCAL YEAR 2020 JWMRP RESEARCH

Congress appropriated \$40 million (M) for the JWMRP in Fiscal Year (FY) 2020, stipulating that these funds "shall be used to augment and accelerate high priority Department of Defense and Service medical requirements and to continue both core and congressionally-directed prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine. These funds shall not be used for new projects or basic research." The FY 2020 JWMRP Programmatic Panel reviewed medical research and development gaps and unfinanced medical requirements of the Military Departments, and identified focus areas for the FY 2020 JWMRP funding opportunity announcement to address those needs. Applications for the FY 2020 JWMRP were required to address at least one of these high priority focus areas. The FY 2020 JWMRP funding supports projects across the following six DHP core research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; radiation health effects; and clinical and rehabilitative medicine.

Table 1 provides the total number of FY 2020 JWMRP funded projects, including the investment amount per the two project domains: science and technology, and advanced development. The Department allocated the remaining \$4,780,639 of the FY 2020 appropriation to Small Business Innovative Research (SBIR)/Small Business Technology Transfer Program (STTR) withholds, as well as program management costs for the USAMRDC and Congressionally Directed Medical Research Programs (CDMRP).

Table 1. FY 2020 JWMRP Funding Summary

PROJECT DOMAINS	PROJECTS FUNDED	JWMRP INVESTMENT
Science and Technology	14	\$27,363,757
Advanced Development	7	\$7,855,604
Totals	21	\$35,219,361

Primary criteria for selection of the FY 2020 JWMRP project award recipients included:

1) whether the proposed research was a logical continuation of a core or congressionally-directed prior year initiative; 2) whether the project had a clear benefit to military medicine by aligning with high-priority DoD and Service medical needs and requirements; 3) whether the project was close to achieving its objectives and poised to augment and/or accelerate a product development effort that would directly benefit Service members, veterans, and other Military Health System (MHS) beneficiaries; and 4) whether the proposed research had high scientific merit as determined by the evaluations and ratings of peer reviewers. All selected projects had discrete deliverables to advance anticipated research outcomes or products to the next development phase.

Table 2 summarizes the projects funded by the FY 2020 JWMRP, including the research award recipients, project descriptions with explanations of their potential benefits to the DoD, and funded amounts.

Table 2. FY 2020 JW12MRP Project Summaries

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
1.	Good	Henry M.	Project Description: Science and Technology /	\$321,900
	Manufacturin	Jackson	Malaria persists as a serious disease threat	
	g Practice	Foundation	worldwide. This project's objective is to	(Sent to the
	(GMP)	for the	conduct a Phase 1/2a clinical trial of a	Walter Reed
	Production	Advancement	nanoparticle malaria vaccine formulated in a	Army
	and Clinical	of Military	liposome-based adjuvant. This project	Institute of
	Trial of a Self-	Medicine,	outlines the steps needed to secure the protein	Research in
	Assembling	Inc.	and adjuvant components of the proposed	support of
	Protein	Bethesda,	vaccine. This effort will combine these two	this effort).
	Nanoparticle	MD	components to form the vaccine FMP-014 for	
	and Toll-Like		use in a human clinical trial.	
	Receptor			
	Liposomal		DoD Benefit: This effort could lead to a better	
	MPL		vaccine that will be more effective in	
	Adjuvanted		protecting people against malaria and improve	
	Malaria		the health readiness of our Armed Forces	
	Vaccine		worldwide.	

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
2.	Integrating Clinical Technology for Military Health: Automating Physiologic Controllers in an Animal ICU as a Platform to Achieve Autonomous Support During Evacuation	DocBox, Inc. Newton, MA	Project Description: Advanced Development / The DocBox platform is a standards-based, secure, point-of-care integrated clinical environment (ICE) that interconnects disparate information technology systems and devices via a shared communications structure. In this product development effort, the developer will work directly with a DoD medical research facility to create applications for the ICE platform and to extend ICE platform functionality to meet the performance, safety, and security requirements for optimal use in the military environment. The effort focuses on remote monitoring and control on the platform during medical evacuation. These applications will undergo testing to determine how the ICE platform may improve safety and efficiency in patient care management. DoD Benefit: The ability to remotely monitor and control medical devices will allow experts in the management of critically ill personnel to adjust lifesaving medications and assist medics in the field who do not have the same level of expertise, thus providing advanced care to military personnel when they need it.	\$196,261 (Sent to the U.S. Army Institute of Surgical Research in support of this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
3.	Interoperable and Compact Infusion Pump Module for the Delivery of Drugs, Fluids, and Blood Products at the Point of Injury and for En Route	NeuroWave Systems, Inc. Cleveland Heights, OH	Project Description: Advanced Development / This project entails continued development of a volumetric infusion pump, AccuPump, for en route care. The project's specific aims are to (1) demonstrate the hemocompatibility/biocompatibility of the administration set; (2) develop user interface software following the U.S. Food and Drug Administration (FDA) Major Level of Concern requirements; (3) demonstrate that user errors do not lead to unacceptable risks; and (4) submit and support a 510(k) application to the FDA containing all evidence data supporting a safety claim. The pump will enable remote operators and automated algorithms to control the rate of delivery of fluids, drugs, or blood/blood products without the need for human intervention/interaction DoD Benefit: This project fills an important gap in current tactical combat casualty care capabilities by making available to third-party developers an off-the-shelf infusion module with proper regulatory clearance for use in humans, and will facilitate and expedite the transition of new related smart technologies to fieldable products.	\$153,000 (Sent to the Naval Medical Research Center, Naval Advanced Development for support of this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
4.	Multicenter Implementatio n Trial of Targeted Normoxia Strategy to Define Oxygen Requirements for Combat Casualty Care	University of Colorado at Denver Aurora, CO	Project Description: Science and Technology / Oxygen therapy has undisputed importance in combat casualty care for the treatment and prevention of hypoxia-associated morbidity. However, generous supplemental oxygen, although routine, often results in hyperoxia, which can increase morbidity and mortality. This effort focuses on determining the feasibility, safety, and clinical effectiveness of a targeted normoxia approach in comparison to conventional oxygenation, through a multicenter, randomized trial among adult emergency department trauma patients. DoD Benefit: Study findings will provide immediately actionable data to define oxygenation practices for critically injured Warfighters and civilians, and will aid in clinical practice guideline development, as well as optimization of patient outcomes, while conserving oxygen supplies in deployed combat settings.	\$9,840 (Sent to the U.S. Army Institute of Surgical Research in support of this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
5.	Preclinical Development of a Novel Medical Device for Total Meniscus Reconstructio n	Rutgers University New Brunswick, NJ	Project Description: Science and Technology / Military Health System providers perform an estimated 20,000 meniscectomies annually, with an additional 800,000 performed in the general population. Meniscal tears occur approximately ten times more frequently in the military than in the civilian population, which negatively affects readiness and resilience, and increases the cost of care. The goal of this project is to accelerate FDA approval and commercialization of MeniscoFix TM , a total meniscus replacement device that gradually resorbs and promotes neo-meniscus formation, potentially restoring the mobility of active military personnel and preventing onset of degenerative post-traumatic osteoarthritis (PTOA) associated with meniscus injuries. This study will focus on creating a repeatable process for the manufacture of MeniscoFix TM devices for subsequent pre-clinical testing; performing safety and efficacy testing; and submitting an Investigational Device Exemption application to the FDA to enable first-in-human clinical trials. DoD Benefit: Commercialization of MeniscoFix TM has potential to accelerate return to duty and, in the long-term, prevent development of PTOA associated with meniscectomy, resulting in improved quality of life and significant health cost savings.	\$2,245,998

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
6.	Anticeramide Single-Chain Variable Fragment (scFv) as Prophylaxis of the Radiation GI Syndrome	Holding, LLC New York, NY	Project Description: Science and Technology / The purpose of this effort is to further develop Ceramedix LLC's anti-ceramide humanized 6B5 (h6B5) single-chain variable fragment antibody as a radiation protector. Specific aims include cGMP manufacturing of the antibody, optimizing antibody scheduling and dosing in a mouse model of gastrointestinal-acute radiation syndrome (GI-ARS), testing the efficacy of the antibody in a non-human primate model of GI-ARS, conducting safety/toxicity assessments of the antibody, and conducting a Phase 1a clinical trial of the antibody in normal healthy volunteers. DoD Benefit: This effort will enable the DoD and Department of Health and Human Services to acquire this preventative for the Strategic National Stockpile/Vendor Managed Inventory for prophylactic use by military and first responders.	\$1,301,609

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
7.	OPUS-C: Open Source Universal Simulated Casualty with a Scalable Weapons Effect and Injury Model for Virtual Medical Training	University of Southern California Los Angeles, CA	Project Description: Science and Technology / Tactical military simulations lack a medical component, while medical simulations are typically standalone experiences. The DoD is moving to larger scale integrated live and virtual training, yet these efforts lack a medical element. This project advances prior physiologic simulation prototypes and focuses on the development of the Open Source Universal Simulated Casualty (OPUS-C), which will provide realistic weapons injury effect determinations along with medical behaviors, detailed casualty reporting, and interactive medical scenarios. Any character in a military simulation will now be capable of becoming a medical patient or casualty using the OPUS-C tool. DoD Benefit: The effort will produce a capability that is integration-ready, well documented, and tested for common tactical scenarios. OPUS-C will provide a complete, easily integrated medical effects and simulation logic capability, resulting in a highly cost-efficient pathway to create tactical trauma simulations.	\$1,999,120

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
8.	Antibacterial Peptide Development and Non-GLP In Vivo Demonstratio n of Activity and Efficacy Against Multidrug- Resistant Biofilm- Forming Wound Pathogens (ESKAPE)	George Mason University Fairfax, VA	Project Description: Science and Technology / This research effort is based on the development of two novel peptides with the ability to kill wound-infecting multi-drug resistant bacteria, prevent and inhibit biofilm formation, and promote wound healing. Previous work demonstrated antibacterial activity of one peptide against gram-positive Pseudomonas aeruginosa and Staphylococcus aureus bacteria in animal models and led to the discovery of another peptide effective against gram-negative Acinetobacter baumannii bacteria. The current objectives focus on demonstrating in vivo efficacy in a non-Good Laboratory Practice (GLP) animal model consistent with its intended use, conducting initial non-GLP toxicity and pharmacokinetic studies, as well as the immune response to the peptides, and determining assays and endpoints to use for future non-clinical and clinical studies. In the short-term, this work will provide a new approach and a new class of compounds in antimicrobial peptides in the medical countermeasures development pipeline to help ensure success in combatting multi-drug resistant organisms in combat wound infections. DoD Benefit: In the long term, this work will benefit wounded Service members, Veterans, military family members, and the American public through its application to chronic, nonhealing infected wounds such as those seen in diabetes patients.	\$2,006,584

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
9.	Phase 1 Clinical Trial for Therapeutic Intervention Particles (TIPs)	J. David Gladstone Institutes San Francisco, CA	Project Description: Science and Technology / Despite the success of antiretroviral therapy for human immunodeficiency virus (HIV)-1, 1.7 million people acquired HIV in 2019. The Department of Veterans Affairs (VA) is the largest single provider of HIV-1 care in the United States with approximately 31,000 HIV-infected veterans (1 in 250 veterans living with HIV as of 2019) and the cost of providing lifelong continuous antiviral therapy is projected to increase to approximately \$31 billion per year before 2030. There is a need for new therapeutic approaches that do not rely on continuous administration, particularly for resource-limited settings and in at-risk populations facing adherence challenges. This project will accelerate the development of a first-in-class biologic therapeutic candidate for HIV-1 termed TIPs by focusing on testing the safety (i.e., tolerability and immunogenicity) of these TIPs. If successful, these studies will lead to a follow-on Phase Ib/IIa clinical intervention trial to test the efficacy of TIPs in sustainably lowering HIV-1 viral loads in HIV positive healthy individuals. DoD Benefit: As a single-administration therapeutic for HIV-1, TIPs would substantially improve the quality of life for HIV-infected Veterans and their caregivers, reduce the burden of treatments that need administered by the VA and MHS, and significantly reduce the overall incidence of new HIV infections in the United States.	\$2,345,195

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10.	A Wearable Spine Health System for Military Readiness Assessment		Project Description: Science and Technology / Musculoskeletal injuries in the form of neck and low back disorders are the leading cause of disability worldwide with annual treatment costs exceeding \$88 billion in the U.S. alone. Within the U.S. military, these disorders are highly prevalent, debilitating, and one of the most common reasons for seeking a medical consult. Current measures used to assess initial presentation of the ailment, monitor treatments, and determine safe reintegration are subjective, lack quantitative functional objectivity, and are often ineffective. This project aims to enhance clinical decision-making for rehabilitation of spine disorders by advancing the development of a wearable spine health system that utilizes motion-based metrics via motion sensors along with a host of patient reported outcomes to quantify function, track treatment response, predict long-term outcomes, and inform optimal personalized treatments. DoD Benefit: This technology will be a scientifically based disruptive technology utilizing wearable sensors that can provide the clinician with objective, biomechanically meaningful information about the functional impairment status of the Warfighter for the first time.	\$3,383,035

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11.	Quantification of Cervical and Lumbar Spine Kinematics and Muscle Physiology in Swift Boat Combatant Commands	Naval Health Research Center San Diego, CA	Project Description: Science and Technology / Combatant-craft Crewmen operate high-performance watercraft on missions aimed at unconventional warfare, special reconnaissance, direct action, and counter terrorism. Exposure to extreme and varied gravitational forces during these missions affects musculoskeletal structure, increasing risk of injury and reduced physicality. This extension effort aims to apply novel magnetic resonance imaging (MRI) techniques to understand the effect of high-speed maritime transits on both cervical spine (CS) and lumbar spine (LS) structure and supporting musculature. Information gathered could lead to physical training strategies to increase muscular strength and endurance in critical muscle groups that support the spine under the dynamic impact imposed by this operational environment. Relative to operational environment. Relative to operational readiness and injury rates, these data may shed light onto measurable changes in the CS/LS, which may predict injury. DoD Benefit: In the long term, these data may provide information to prevent future injury, either through changes in training practices, gear design, and/or implementation of exercises to strengthen the musculature of the spine.	\$2,091,000 (Sent to the Naval Health Research Center in support of this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
12.	REBOA Physiologic Sensing Catheter for Advanced Control of Non- compressible Torso Hemorrhage	Prytime Medical Devices, Inc. Boerne, TX	Project Description: Science and Technology / Non-compressible Torso Hemorrhage (NCTH) is the leading cause of potentially preventable death on the battlefield. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a life-saving innovation that controls NCTH by advancing a balloon catheter into the aorta through access gained in the common femoral artery. The ER-REBOATM catheter meets the urgent need for hemorrhage control during combat operations and is effective for rapid transport of combat casualties for advanced surgical care. This project accelerates the development of a catheter that combines partial REBOA technology (in which some blood is still allowed to flow past the occlusion balloon) with sensors that measure blood potassium levels (to stabilize cardiac function) and lactate (to balance hemorrhage control and tissue perfusion), which makes this effort unique from another REBOA technology in the program portfolio. DoD Benefit: This advancement addresses the most important limitation of current REBOA technology for use in battlefields of the future (i.e., the limited time during which REBOA can be safely applied without serious risk of lethal injury to the intestines and kidneys due to lack of blood flow).	\$2,625,521

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
13.	Nanostasis Intravenous Agent for Traumatic Hemorrhage Control	Cayuga Biotech, Inc. Santa Barbara, CA	Project Description: Science and Technology / Non-compressible hemorrhage is a serious issue affecting military as well as civilian populations. A review of combat deaths from 2001–2011 revealed that 90 percent of potentially survivable deaths were due to hemorrhage, the majority of which were at non-compressible sites. The traditional strategy for managing non-compressible hemorrhage is to reduce the time from injury until definitive surgical care, however with the majority of U.S. combat deaths occurring in an out-of-hospital environment, there is a need for technologies amenable for rapid administration by users with minimal training. This project accelerates the development of CAY001, a shelf-stable intravenous therapeutic that quickly and safely accelerates clotting near injury sites without inducing potentially dangerous off-target thrombotic events. Proposed GLP toxicology/safety studies in a swine model will pave the way for an Investigational New Drug filing with the FDA, as well as first-in-human trials. DoD Benefit: Ultimate deployment of CAY001 on the battlefield will improve treatment protocols for combat casualty care and will help reduce mortality due to blood loss. It is also possible to infuse CAY001 into currently deployed medical devices, such as bandages, to improve topical treatment of hemorrhage without the risk for unintended thrombotic events.	\$922,870

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
14.	Development of JNJ- 26366821 (TPOm) as a Prophylactic Radiation Countermeasu re as well as a Mitigator (Shortly After Radiation)	Inc. Bethesda,	Project Description: Science and Technology / There is a heightened threat of nuclear exposure either through intentional or accidental means in the current geopolitical climate. Such exposure could be disruptive to military personnel, causing acute illness or death or resulting in long-term health effects, and could impede their ability to execute orders properly. While there are FDA approved mitigators for radiation exposure, there are currently no prophylactics against impending exposure to ionizing radiation. This effort furthers the development of the thrombopoietin mimetic JNJ-26366821 (TPOm) as a safe and effective prophylactic countermeasure for acute radiation syndrome (ARS) that can be used by first responders and military personnel and tests the ability of TPOm to provide protection from gastrointestinal-specific damage in two ARS animal models. Proposed GLP studies will support a New Drug Application filing with the FDA for TPOm, which has demonstrated efficacy over a broad window as a prophylactic countermeasure, as well as a mitigator. DoD Benefit: This prophylactic countermeasure would provide broad coverage for Warfighters and first responders entering a contaminated field, confer greater protection from radiation, increase survival, and have the potential to alleviate possible long-term health effects in these individuals.	\$4,326,872

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
15.	A Portable Virtual Reality (VR) Headset for Detecting Deficits in Balance, Vestibular, and Oculomotor Function Following Traumatic Brain Injury (TBI), Post- Traumatic Stress Disorder (PTSD), and/or Other Disease/Injury		Project Description: Science and Technology / Veteran and military populations suffer from unique pathologies with complex, comorbid sequelae following TBI and combat exposure, which include overlapping physiogenic and psychogenic etiologies. Accurate and expedient assessment and diagnosis significantly increase a clinician's ability to prescribe the most effective treatment plan for full patient recovery to pre-injury functionality and improved probability of community reintegration. This product development effort is for a novel VR head-mounted display (HMD) that is ultraportable, highly adaptable, and easy to use for accurately identifying balance and vestibular/oculomotor deficits and guiding effective treatment plans. Clinical studies on multiple populations at high risk for falls will test the accuracy of the device for assessing balance and oculomotor function in both veterans and civilians, and establish the validity and reliability of the HMD-based assessments in each population. Dod Benefit: With falls considered the leading cause of injuries and death due to injuries in older adults, the implications of this technology are far-reaching for the American public. Because this device requires just a headset and a tablet to operate, it is portable and amenable not only to clinical use at well-equipped, full-sized military treatment facilities, but also for forward resuscitative care.	\$1,201,221

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
16.	The Effects of Vibration on Indicators of Post-Traumatic Knee Osteoarthritis Risk Following Anterior Cruciate Ligament Injury	University of North Carolina at Chapel Hill Chapel Hill, NC	Project Description: Science and Technology / PTOA is a leading cause of medical separation from military service, degrades quality of life, increases the risks of several comorbidities (e.g., obesity, depression, cardiovascular disease), and is a primary contributor to years of life lost due to disability. Improving rehabilitation of knee injuries is paramount for maintaining the combat readiness of our Armed Forces and preserving the health and well-being of Service members, Veterans, and the American public. This study aims to evaluate the effects of a local muscle vibration (LMV) device used for anterior cruciate ligament reconstruction rehabilitation in comparison to standard rehabilitation by assessing quadriceps function, gait biomechanics linked to PTOA development, patient self-report outcomes, and MRI indicators of knee joint health via a Phase 2 treatment, single-blind, randomized controlled clinical trial. These studies are necessary to establish the efficacy of the LMV prototype and accelerate its development as a commercially available device. DoD Benefit: In addition to being costeffective, the portable nature of the prototype LMV device could have substantial implications for military personnel and civilians, particularly those with limited access to rehabilitation facilities.	\$2,582,992

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
17.	Endovascular Variable Aortic Control (EVAC) Automated Controller Verification and Validation Testing for 510(k) Clearance	Sacramento, CA	Project Description: Advanced Development / Non-compressible truncal hemorrhage, which commonly occurs after traumatic injury, is a leading cause of potentially survivable death among Warfighters. Special Operations medical providers and first responders are using REBOA to salvage casualties exsanguinating from their injuries. However, REBOA limits the duration of therapy to 30 minutes before distal ischemia becomes so profound that survival is no longer possible. To overcome the challenges of prolonged field care for combat casualties, this product development effort focuses on development of an automated endovascular variable aortic control (EVAC) system, consisting of a large vessel occlusion catheter and automated controller, as a next-generation REBOA technology. Project specific aims include finalizing the design of a clinical-grade EVAC controller for prolonged weaning to provide partial flow, developing the hardware and software for test fixtures needed for the EVAC controller, manufacturing sterile units in final packaging, verifying and validating the EVAC catheter and controller, and producing regulatory documentation for the EVAC controller. DoD Benefit: This additional research and development, which is complementary and not duplicative of another REBOA technology in the program portfolio, will accelerate the EVAC system toward FDA approval and commercial launch.	\$1,843,815

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
18.	Improving Neurotrauma by Depolarizatio n Inhibition with Combination Therapy (INDICT): A Phase 2 Randomized Trial	University of Cincinnati Cincinnati, OH	Project Description: Advanced Development / This project tests the hypothesis of improving outcomes from severe TBI by targeting intensive care therapies to suppress the pathology of spreading depolarizations (SDs) as a brain marker and mechanism of secondary injury. Specific aims include determining the feasibility of real-time SD monitoring to guide intensive care management of severe TBI, and the effect of SD-guided versus standard care management to reduce secondary brain insults in severe TBI, through first-time implementation of a treatment protocol in a three-site, prospective, randomized Phase 2 clinical trial. The intervention involves placement of an electrode strip on the brain during surgery for subsequent electrocorticography recording followed by treatment protocols upon observation of SDs. Dod Benefit: The projected outcomes are determination of the feasibility of implementing, for the first time, a treatment protocol for intensive care of severe TBI guided by real-time SD monitoring and determination of the effects of this protocol to reduce secondary injury and improve cerebral physiology. If successful, this effort will be the foundation for a Phase 3 efficacy trial.	\$4,427,503

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
19.	Transition of a Maturing Battlefield Whole-Blood Logistics Solution	Delta Development Team Inc. Tucson, AZ	Project Description: Advanced Development / Hemorrhage is a leading cause of death on the battlefield, with patients suffering from traumatic coagulopathy having an 80 percent mortality rate. After stopping bleeding, transfusion of fresh whole blood is the most effective way to increase survival rates. Having whole blood close to the point of injury requires reliable and predictable cold storage that operates safely and easily in the battlefield environment. This product development effort aims to reduce the short-term consequences of severe hemorrhage by accelerating safety certification and subsequent fielding of stored whole blood with a portable, battery-powered autonomous portable refrigeration unit (APRU) refrigerator having sufficient and predictable operating duration as well as compatibility with aircraft safety restrictions. Specific aims include determining airworthiness performance gaps; correcting airworthiness performance deficiencies; and certifying airworthiness, Underwriters Laboratories safety, and European Conformity marking. DoD Benefit: When fielded, the APRU will increase the availability of stored whole blood for Special Forces teams in far-forward locations, increasing combat injury survival rates. Civilian emergency medical services will also benefit from the simplified logistics of a vehicle-portable blood storage device that provides temperature recording and portability.	\$397,131

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
20.	Non-Invasive Intracranial Pressure Assessment (IPASS) Using a Compact, Portable Monitor	Bedford, MA	Project Description: Advanced Development / TBI is a common and devastating injury, with approximately 2,500 Service members suffering from moderate/severe TBI each year. Intracranial pressure (ICP) is a critical parameter in the identification and management of TBI. The Vivonics non-invasive intracranial pressure assessment (IPASS) device provides the ability to quickly and non-invasively assess and monitor ICP in far forward military environments, using a simple, hand-held device. Development has proceeded to IPASS testing on hospital patients who have already received a gold-standard invasive device, connected to a patient monitor. This effort will be part of the acquisition strategy for the development of multiple ICP monitor prototypes, expanding a current pilot clinical study to increase statistical power of the data and associated evidence for the clinical success of IPASS in order to proceed with a pivotal study for de novo submission to the FDA. DoD Benefit: This acceleration effort of an existing Army contract with the awardee addresses an Army unfinanced medical requirement. If successful and fielded, the IPASS device will increase casualty survival, improve the standard of care, and serve as a field medical force multiplier.	\$597,894 (Sent to the U.S. Army Medical Materiel Development Activity to put on an existing contract for this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
21.	Commander's Risk Mitigation Dashboard (CRMD)	Northrup Grumman Falls Church, VA	Project Description: Advanced Development / The Commander's Risk Mitigation Dashboard (CRMD) seeks to provide commanders at all echelons with a robust understanding of the risk for destructive behaviors faced by Sailors at their specific commands. The effort aims to create a common operating picture via a dashboard to display the results of risk assessment models to forecast risk of destructive behaviors at the unit level. Tasks supported include updating predictive risk model code and scripts documents, updating dashboard (i.e., graphic user interface) documentation, and updating predictive risk model and associated data dictionaries. DoD Benefit: This acceleration effort of an existing Navy contract with the awardee addresses a Navy unfinanced medical requirement and assists the Sea Warrior Office in progressing the effort towards initial operating capability.	\$240,000 (Sent to the Naval Medical Research Center, Naval Advanced Development to put on an existing contract for this effort).

SUMMARY

Congressional appropriations for the FY 2020 JWMRP totaled \$40M, of which the DHP JWMRP CSI invested approximately \$35.2M in research, after final USAMRDC and CDMRP management costs and SBIR/STTR withholds. The FY 2020 JWMRP funded 21 projects. These projects, each aligned under the Science and Technology or Advanced Development project domains, collectively address the following six DHP core medical research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; radiation health effects; and clinical and rehabilitative medicine. These projects reflect a diverse set of JWMRP topics of scientific inquiry intended to enhance and accelerate high-priority DoD and Military Department medical requirements, with potential to provide significant benefits to military medicine.