UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR - 7 2023

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 Explanatory Statement accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116–260), on the Joint Warfighter Medical Research Program (JWMRP), is enclosed.

The report summarizes the projects selected for Fiscal Year (FY) 2021 JWMRP funding and covers the total congressional appropriations for the JWMRP during this period ($40 million). The FY 2021 JWMRP funded 19 projects, aligned under the Science and Technology or Advanced Development project domains, which collectively address the following five Defense Health Program core JWMRP research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; and radiation health effects. 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 their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Susan Collins
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR - 7 2023

The Honorable Ken Calvert
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Department's response to the Explanatory Statement accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116–260), on the Joint Warfighter Medical Research Program (JWMRP), is enclosed.

The report summarizes the projects selected for Fiscal Year (FY) 2021 JWMRP funding and covers the total congressional appropriations for the JWMRP during this period ($40 million). The FY 2021 JWMRP funded 19 projects, aligned under the Science and Technology or Advanced Development project domains, which collectively address the following five Defense Health Program core JWMRP research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; and radiation health effects. 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 their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Betty McCollum
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR - 7 2023

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

Dear Mr. Chairman:

The Department's response to the Explanatory Statement accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116–260), on the Joint Warfighter Medical Research Program (JWMRP), is enclosed.

The report summarizes the projects selected for Fiscal Year (FY) 2021 JWMRP funding and covers the total congressional appropriations for the JWMRP during this period ($40 million). The FY 2021 JWMRP funded 19 projects, aligned under the Science and Technology or Advanced Development project domains, which collectively address the following five Defense Health Program core JWMRP research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; and radiation health effects. 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 their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Roger F. Wicker
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

MAR - 7 2023

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Department's response to the Explanatory Statement accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116–260), on the Joint Warfighter Medical Research Program (JWMRP), is enclosed.

The report summarizes the projects selected for Fiscal Year (FY) 2021 JWMRP funding and covers the total congressional appropriations for the JWMRP during this period ($40 million). The FY 2021 JWMRP funded 19 projects, aligned under the Science and Technology or Advanced Development project domains, which collectively address the following five Defense Health Program core JWMRP research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; and radiation health effects. 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 their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Congressional Defense Committees

Joint Warfighter Medical Research Program

February 2023

The estimated cost of this report for the Department of Defense (DoD) is approximately $2,000.00 for Fiscal Years 2022–2023. This includes $400.00 in expenses and $1,600.00 in DoD labor.

Generated on November 2, 2022

Ref ID: 2-29810B1

BACKGROUND AND PURPOSE

This report is in response to the Explanatory Statement accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116–260), 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 Explanatory Statement requests that this report list the projects that receive funding, including the funding amount awarded to each project, a thorough description of the 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 funds.

FISCAL YEAR 2021 JWMRP RESEARCH

Congress appropriated $40 million (M) for the JWMRP in Fiscal Year (FY) 2021, stipulating these funds "shall be used to augment and accelerate high priority DoD and Service medical requirements and to continue core and congressionally directed prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine. The funds shall not be used for new projects or basic research." The FY 2021 JWMRP Programmatic Panel reviewed medical research and development gaps and unfinanced medical requirements of the Military Departments and identified focus areas for the FY 2021 JWMRP funding opportunity announcement to address those needs. Applications for the FY 2021 JWMRP were required to address at least one of these high priority focus areas. The FY 2021 JWMRP funding supports projects across the following five DHP core research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; and radiation health effects.

Table 1 provides the total number of FY 2021 JWMRP funded projects, including the investment amount per the two project domains: Science and Technology, and Advanced Development. The Department allocated the remaining $5,330,491 of the FY 2021 appropriation to Small Business Innovative Research (SBIR)/Small Business Technology Transfer Program (STTR) withholds ($1,335,000) and USAMRDC withholds ($773,300), as well as program management costs ($3,222,191) for the Congressionally Directed Medical Research Programs (CDMRP).

Table 1. FY 2021 JWMRP Funding Summary

PROJECT DOMAINS*	PROJECTS FUNDED	JWMRP INVESTMENT
Science and Technology	14	$28,994,126
Advanced Development	5	$5,675,383
Less: SBIR/STTR	N/A	$1,335,000
Less: USAMRDC Withholds	N/A	$773,300
Less: CDMRP Management Costs	N/A	$3,222,191
Totals	**19**	**$34,669,509**

*Science and Technology focuses on the development and maturation of technologies to enable transformational capabilities and accelerate transition into Advanced Development. Advanced Development centers on advanced component and prototype development for technologies with demonstrated proof of concept and an established transition pathway.

Primary criteria for selection of the FY 2021 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 beneficiaries; and 4) whether the proposed research had high scientific merit as determined by the evaluations and ratings of peer reviewers. All selected projects have discrete deliverables to advance anticipated research outcomes or products to the next development phase.

Table 2 summarizes the projects funded by the FY 2021 JWMRP, including the research award recipients, project descriptions with explanations of their potential benefits to the DoD, and funding amounts. The JWMRP funding amount was provided to the prime recipient organization or foundation, unless otherwise noted.

Table 2. FY 2021 JWMRP Project Summaries

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
1.	GMP[1] Production and Clinical Trial of a Self-Assembling Protein Nanoparticle and Toll-Like Receptor Liposomal MPL[2] Adjuvanted Malaria Vaccine 1. GMP-Good Manufacturing Practice 2. MPL-Monophosphoryl Lipid A	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Project Description: *Science and Technology* / Malaria persists as a serious disease threat worldwide. This ongoing project carried out by the Walter Reed Army Institute of Research focuses on conducting a Phase 1/2a clinical trial of a nanoparticle malaria vaccine formulated in a liposome-based adjuvant. This project outlines the steps needed to secure the protein and adjuvant components of the proposed vaccine. This effort will combine these two components to form the vaccine FMP-014 for use in a human clinical trial. DoD Benefit: This effort could lead to a better vaccine that will be more effective in protecting people against malaria and improve the health readiness of our Armed Forces worldwide.	$28,100 (Sent to the Walter Reed Army Institute of Research in support of this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
2.	Advanced Development of Gamma-Tocotrienol as a Radiation Countermeasure	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Project Description: *Science and Technology* / The threat of a radiological attack on American cities or a nuclear accident requires the development of a radiation countermeasure capable of protecting military personnel who might have to enter a contaminated area, or capable of mitigating lethality in the general population. There is currently no safe and effective U.S. Food and Drug Administration (FDA)-approved radiation countermeasure for acute radiation syndrome. In previous studies, Gamma-tocotrienol (GT3), an antioxidant, protected almost 100 percent of mice against a lethal dose of radiation when administered subcutaneously 24 hours before exposure. This ongoing study conducted by the Armed Forces Radiobiology Research Institute examines different formulations of GT3 to improve its tolerability when administered subcutaneously and evaluate GT3 soft gel capsules for oral efficacy. It also assesses the efficacy of GT3 in nonhuman primates (NHPs) using different doses of radiation for whole body exposure and investigates hematopoietic and gastrointestinal injury, accelerated recovery, and efficacy biomarkers in NHPs. DoD Benefit: These studies will serve as the foundation for human safety clinical trials toward FDA licensure of GT3 and advance development of GT3 for field use and inclusion in the Strategic National Stockpile/Vendor Managed Inventory. With the deployment of GT3, forces exposed to moderate to high doses of ionizing radiation will demonstrate enhanced survivability, expanding the range of operable threat environments.	$225,627

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
3.	Development of PfSPZ Vaccine to Protect the Warfighter from Malaria: Determining Protective Efficacy Under Four Deployment Scenarios (Warfighter 3)	Sanaria, Inc. Rockville, MD	Project Description: *Advanced Development* / Malaria is the most significant infectious disease threat for military personnel. In 2016, malaria caused 216 million illnesses and killed nearly a half million people. This follow-on Phase 3 clinical trial (CT) is one facet in a comprehensive clinical development plan intended to lead to FDA licensure of the PfSPZ Vaccine. The CT aims to determine the safety, tolerability, and efficacy against heterologous Controlled Human Malaria Infection, more specifically to define the minimum time threshold for the immune response to be fully established and protective following immunization. The data derived will help health care providers to advise Service members on when they first achieve protection by the PfSPZ Vaccine after immunization and accelerate product development efforts. DoD Benefit: This augmentation funding of an existing Navy contract with the awardee further supports this project to produce the world's first FDA-approved malaria vaccine. Sanaria anticipates that subsequently licensed second-generation vaccines will provide even greater potency in the future. Licensure of the PfSPZ Vaccine would make a safe/effective malaria vaccine rapidly available to at-risk U.S. military personnel, U.S. travelers, and residents of endemic areas.	$300,000 (Sent to the Naval Medical Research Center, Naval Advanced Development to add to an existing contract for this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
4.	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 ongoing 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 FDA Major Level of Concern requirements; (3) demonstrate 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 augmentation funding of an existing Navy contract with the awardee further supports this project to fill 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. This funding will facilitate and expedite the transition of new related smart technologies to fieldable products.	$426,000 (Sent to the Naval Medical Research Center, Naval Advanced Development to add to an existing contract for this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
5.	Multicenter Implementation 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. In collaboration with the U.S. Army Institute of Surgical Research, this ongoing effort focuses on determining the feasibility, safety, and clinical effectiveness of a targeted normoxia approach in comparison to conventional oxygenation, through a multi-center, 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
6.	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 ongoing 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 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.	$81,000

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
7.	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* / Post-traumatic knee osteoarthritis (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. In collaboration with Womack Army Medical Center, this ongoing 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 cost-effective, the portable nature of the prototype LMV device could have substantial implications for military personnel and U.S. civilians, particularly those with limited access to rehabilitation facilities.	$14,000 (Sent to Womack Army Medical Center in support of this effort).

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
8.	Endovascular Variable Aortic Control (EVAC) Automated Controller Verification and Validation Testing for 510(k) Clearance	Certus Critical Care, Inc. 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 Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) to salvage casualties exsanguinating from their injuries. However, REBOA limits the duration of therapy to 30 minutes before distal ischemia becomes so profound, 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 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.	$500,000

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
9.	Augmenting Capabilities and Accelerating Access to Behavioral Sleep Care for Service Members in "CBTI Deserts"	Rehat, LLC Pittsburgh, PA	Project Description: *Science and Technology* / Insomnia affects approximately 40 percent of active duty Service members. Cognitive-behavioral treatment of insomnia (CBTI) is the treatment recommended by DoD/Department of Veterans Affairs (VA) guidelines, the American College of Physicians, and the American Academy of Sleep Medicine. There are many barriers for CBTI, such as the lack of trained providers, long wait lists, rigid structures of protocols, and lack of professional supervision of online programs and applications, which shifts the burden onto patients and disrupts continuity of care. Prior work highlighted disparities in access to CBTI at military medical treatment facilities (MTFs) and local sleep clinics that typically focus on sleep disordered breathing. This project will survey the resources and needs in behavioral sleep medicine across multiple MTFs and pilot the effectiveness of the Clinician Operated Assistive Sleep Technology (COAST™) digital platform to deliver asynchronous, remote, and personalized CBTI to Service members to improve access to and quality of care. DoD Benefit: Overall CTBI can mitigate the adverse effects of insomnia, thus improving performance, readiness, and psychological health and resilience. The COAST™ platform offers a cost-efficient way to augment existing sleep and behavioral health clinician capability to offer recommended insomnia treatments. Study findings will inform decision makers and resource allocations for insomnia care across the Defense Health Agency.	$1,231,185

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
10.	Effects of Military Noise Exposure on Auditory Function in Service Members and Recently Discharged Veterans	Oregon Health and Science University Portland, OR	Project Description: *Science and Technology* / Noise-induced hearing loss is a significant occupational health risk for Service members routinely exposed to many types of loud noise in their duties. In partnership with the DoD Hearing Center of Excellence, the Portland VA Medical Center's National Center for Rehabilitative Auditory Research Noise Outcomes in Service Members Epidemiology (NOISE) study examines the prevalence, incidence, etiology, and short and long-term effects of hearing loss and tinnitus among Service members. This funding will support the addition of a testing site at Southern California to increase enrollment of Service members from the Navy and Marine Corps. The project aims to determine if early patterns of hearing loss and tinnitus among Service members and recently separated veterans persist, and whether new cases of hearing loss and tinnitus develop in the decade following separation from military service. Additionally, the project will identify military and post-military exposures associated with the onset and progression of hearing loss, tinnitus, and other auditory complaints during military service and in the decade following service separation. DoD Benefit: This NOISE study is producing an unprecedented epidemiologic dataset revealing cross-sectional and longitudinal associations between a wide range of exposures, physical and mental health conditions, auditory function, and tinnitus. It will offer unparalleled insight into the hearing health of Service members, informing the prevention of hearing loss and tinnitus, reducing their effects, and ultimately enhancing Service member readiness.	$3,123,590

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
11.	Further Development of 5-AED (Androstenediol, Neumune) for the Protection from Acute Radiation Syndrome (ARS)	University of Nebraska Medical Center Omaha, NE	Project Description: *Science and Technology* / Our understanding of how to protect individuals from the effects of radiation exposure is limited despite growing concerns of exposure from terrorist events, military actions, or nuclear disasters. Treatment options for radiation exposure are typically restricted to supportive care and highly dependent on early intervention. 5-Androstene-3β-17β-diol (5-AED), a naturally occurring steroid, is a promising, underdeveloped post-exposure radiomitigator that reduces deoxyribonucleic acid damage and proapoptotic factors. In collaboration with the Armed Forces Radiobiology Research Institute, this project aims to optimize 5-AED formulations with demonstrated efficacy in murine and NHP models of ARS, assess 5-AED toxicity, characterize 5-AED pharmacokinetics, and develop protocols for large-scale synthesis of 5-AED. DoD Benefit: Upon successful completion of this project, 5-AED will be well-positioned for the Investigational New Drug (IND) pathway to FDA approval and for manufacture to supply the Strategic National Stockpile/Vendor Managed Inventory. Development of this countermeasure will provide military personnel and first responders with ready access to an effective treatment of ARS to mitigate the damaging effects of exposure to dangerous levels of radiation that may occur during military action or nuclear disaster.	$4,500,000

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
12.	Partially Automated Critical Care Management (PACC-MAN) - Refinement of the Closed-Loop Critical Care Delivery Platform for Prolonged Field Care	Military Health Research Foundation Laurel, MD	Project Description: *Science and Technology* / To address the needs of critically injured Warfighters during multi-domain operations, Wake Forest University Health Sciences has developed and is refining a platform of autonomous critical care termed PACC-MAN. PACC-MAN delivers fluids, drugs, and blood products based on physiologic data streams; utilizes adaptive algorithms to optimize resuscitation efforts; and minimizes periods of hypo/hypertension. The objective of this project is to develop purpose-built pumps and blood pressure sensors to work in tandem with the PACC-MAN software algorithms. Implementation of software upgrades, beyond current lab-grade versions, will facilitate clinical end-user experience. The study will compare PACC-MAN performance with standard best practices utilized by experienced clinicians delivering manual resuscitative care, paving the way for rapid transition to human trials. DoD Benefit: Results of this effort will directly impact the care of Soldiers with multiple types of severe shock in the austere environment. The PACC-MAN platform will enhance combat casualty care by providing clinical decision support and automated control of cardiovascular support, medication administration, and intravenous fluid delivery, enabling a single medic in a resource-limited environment to act as an entire intensive care unit team.	$4,489,088

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
13.	Integrating Isoagglutinin Reduction for a Universal Dried Plasma Product for Battlefield and First Responder Use	CytoSorbents, Inc. Princeton, NJ	Project Description: *Science and Technology* / Uncontrolled hemorrhage, secondary to traumatic injury, is the leading cause of potentially survivable deaths within 24 hours of injury. Rapid implementation of early and aggressive transfusion protocols improves survival. Plasma from blood type AB individuals (universal plasma) is in great demand during emergency transfusions as it does not contain the anti-A and anti-B antibodies found in other blood types. These Blood Group Antibodies (BGAs) can induce fatal hemolytic reactions when they bind to a recipient's red blood cells, a critical issue in severe hemorrhage where time and resources for blood typing and plasma thawing are severely constrained. The objective of this project is to develop a BGA filtration device (adsorber), which will involve scale up production of blood group A and B ligands used in the adsorber and integrate the device with freeze-dried plasma (FDP) preparation for the ultimate deployment-ready blood product. DoD Benefit: With the availability of antibody-depleted, universal FDP, military blood product depots will no longer have to stock specific blood type units that expire within a short time, making storage and distribution easier. The simplified storage and distribution logistics will allow military and civilian blood banks to meet widespread demand for emergency and point-of-injury plasma transfusions to resuscitate hemorrhaging trauma or surgical patients without straining donor resources.	$4,292,641

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
14.	IND-Enabling Studies of Novel A. baumannii Therapeutics in Combat-Relevant Animal Models	Walter Reed Army Institute of Research Silver Spring, MD	Project Description: *Science and Technology / Acinetobacter baumannii* is an opportunistic pathogen that targets immunocompromised individuals and is responsible for thousands of deaths and enormous financial burden in civilian and military healthcare systems. This pathogen was always among the most frequently isolated species from combat wounds in recent conflicts. *A. baumannii's* intrinsic resistance to antibiotics combined with genomic flexibility to increase its fitness makes it extremely difficult to treat. Walter Reed Army Institute of Research has identified Outer Membrane Protein OmpW as a druggable conserved key transport protein among clinical isolates of *A. baumannii* and other Gram-negative bacteria and has developed small molecule candidates against OmpW that have demonstrated efficacy in vitro and in a murine wound infection model. This project will involve in vivo safety and efficacy studies of lead therapeutic candidates in combat relevant animal models involving blast and polytrauma. Clearly identifiable "go-no-go" checkpoints will identify the top lead compound and support pre-IND meetings with the FDA. DoD Benefit: The development and availability of novel antibacterials for the treatment of *A. baumannii* will maximize Warfighter health and combat effectiveness.	$311,455

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
15.	Preclinical Development of a Balanced, Tetravalent, Live-Attenuated Vaccine Against the 4 Dengue Virus Serotypes	Codagenix, Inc. Farmingdale, NY	Project Description: *Science and Technology* / The mosquito-borne dengue virus (DENV) is a major international health concern and was ranked as the top viral threat to U.S. military personnel and the third most significant infectious disease threat overall by a military prioritization panel in 2019. This project is a critical step in the development of CodaVax-DENV, a tetravalent live attenuated vaccine to prevent dengue fever for which the only current prevention strategy is the avoidance of mosquito bites. Aims primarily focus on administering CodaVax-DENV to NHPs and monitoring animals for reduced viremia in response to DENV challenge and development of a neutralizing antibody response that persists for at least 24 weeks. This remaining pre-clinical work, along with required manufacturing tasks, will allow for the preparation and submission of an IND package to the FDA to enable first-in-human clinical trials. DoD Benefit: Successful development of CodaVax-DENV would address a critical unmet need in protecting active duty and retired Service members and the public against DENV. It would also be a tremendous benefit to the billions of people living in DENV endemic regions.	$4,443,544

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
16.	Network-Enabled Tactical Combat Casualty Care (NETC3) Scale-Up	Vcom3D, Inc. Orlando, FL	Project Description: *Science and Technology* / The objective of the NETC3 scale-up is to advance this technology from an early prototype developed under a SBIR award to a system for integrating combat casualty care into the tactical training of squads before they are deployed to fight. NETC3 reinforces and augments the treatment criteria established in Tactical Combat Casualty Care, the current leading guidelines for treating the most common causes of death on the battlefield. This project will incorporate a virtual patient into an Augmented Reality display that can graphically represent various traumatic injuries. This approach will provide an effective form of stress inoculation training to prepare Soldiers for the life-threatening conditions they will face on the battlefield. DoD Benefit: By using emerging gaming and simulation technology, NETC3 will provide more cost-effective training with greater flexibility than training dependent upon expensive medical manikins, thereby reducing taxpayer burden. NETC3 simulation-based training can significantly improve Soldiers' ability to make the critical decisions necessary for saving the lives of those injured in battle while also enhancing survivability.	$2,634,246

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
17.	Advancement of a Void-Filling Hyaluronic Acid-Based Sponge Form Factor (Volumatrix) for Enhanced Wound Healing of Polytraumatic Volumetric Muscle Loss Injuries	University of Virginia Charlottesville, VA	Project Description: *Science and Technology* / Damage to the extremities accounts for 50–70 percent of injuries sustained by Service members in recent conflicts, with soft tissue injury accounting for 53 percent of combat-related extremity wounds. Explosive devices particularly can result in complex wounds requiring extensive repair. Volumetric muscle loss (VML) injuries involve substantial loss of muscle structure/volume, resulting in permanent cosmetic and functional impairment and lifelong disability. Current VML treatment neither fully replaces nor restores skeletal muscle form and function. To close this high-priority medical gap, the objective of this effort is to further the development of a novel semi-synthetic hyaluronic acid-based hydrogel, called Volumatrix™. This project aims to obtain FDA approval of an Investigational Device Exemption to conduct a regulated clinical trial with Volumatrix™ sponge form factor for the treatment of VML injuries. DoD Benefit: Volumatrix™ has documented potential to encourage more robust muscle regeneration and tissue building at the VML wound site by more fully leveraging endogenous repair mechanisms through an improved cell/tissue microenvironment that better recapitulates the requirements of muscle tissue wound healing, repair, and regeneration. Direct impact on the wounded Warrior should manifest as accelerated tissue maturation and enhanced functional recovery following VML injuries, resulting in increased return to duty/activity. If successful, there is also long-term potential for battlefield deployment, at or near the point of injury, as the technology offers the potential of a freeze-dried form factor for off-the-shelf use.	$3,609,810

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
18.	Phase 1 Clinical Trial Utilizing SN514 for Enzymatic Debridement of Burns	Metis Foundation San Antonio, TX	Project Description: *Advanced Development* / There are limited options for non-surgical debridement in the treatment of burns and other wounds that generate necrotic tissue. SN514 is a novel enzymatic debrider that offers an easy-to-use topical hydrogel formulation, room temperature storage with long-term stability, and more comprehensive reduction of wound eschar in a faster timeframe than the only enzymatic debrider product currently on the U.S. market. Preclinical toxicity studies show an appropriate safety profile. The objective of this effort is to implement a Phase 1 study to explore the safety and tolerability of SN514 in burn patients at the U.S. Army Institute for Surgical Research at Fort Sam Houston, TX in collaboration with SERDA B.V. (Netherlands), which holds an exclusive license for SN514. DoD Benefit: The successful progression of SN514 through subsequent required Phase 2 and Phase 3 trials in support of FDA approval could greatly benefit military personnel injured on the battlefield by allowing for the initiation of burn wound care soon after injury, as well as in the prolonged field care setting. Due to ease of application, untrained providers could use this agent in mass casualty burn events. Non-operative management of burn wounds will help to reduce the morbidity associated with burn injury and the subsequent need for operative intervention.	$649,383

NO.	PROJECT TITLE	RECIPIENT	PROJECT DESCRIPTION AND DOD BENEFIT	JWMRP FUNDING AMOUNT
19.	AUGMED Mobile: Anywhere, Anytime Military Cross-Service Immersive Medical Training	Design Interactive, Inc. Orlando, FL	Project Description: *Advanced Development* / This effort builds upon an existing learning platform designed to deliver high quality, effective simulation technology to the military medical community. The current project extends this simulation technology to develop and prepare for commercialization, anatomically accurate simulation models that reproduce the appearance and feel of military-relevant, time-critical ophthalmic trauma, including ocular chemical injury, orbital compartment syndrome, and open globe injury. These simulation models target non-specialists managing eye trauma and provide them with the clinical skills to recognize these ophthalmic conditions and perform the appropriate first aid steps. DoD Benefit: In the short-term, successful performance of appropriate clinical procedures will reduce morbidity associated with ophthalmic trauma, which had a 13 percent incidence during Operation IRAQI FREEDOM and Operation ENDURING FREEDOM. In the long-term, improved visual outcomes after trauma will improve return to duty, and thus maintain Service member readiness.	$3,800,000

SUMMARY

Congressional appropriations for the FY 2021 JWMRP totaled $40M. The JWMRP invested approximately $34.7M in research, after final CDMRP management costs, USAMRDC withholds, and SBIR/STTR withholds. The FY 2021 JWMRP funded 19 projects. These projects, each aligned under the Science and Technology or Advanced Development project domains, collectively address five DHP core medical research areas: medical simulation and information sciences; military infectious diseases; military operational medicine; combat casualty care; and radiation health effects. 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.