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

PERSONNEL AND
READINESS

JAN 24 2018

The Honorable Kay Granger
Chairwoman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report is in response to House Report 114-139, page 278, which accompanies H.R. 2685, the Department of Defense (DoD) Appropriations Bill, 2016, and Senate Report 114-63, page 201, which accompanies S. 1558, the DoD Appropriations Bill, 2016, concerning the Joint Warfighter Medical Research Program (JWMRP). The Assistant Secretary of Defense for Health Affairs is requested to provide a list of projects that received funding, the amount of funding provided to each project, a thorough description of each of these research efforts, and the benefit these projects will provide the DoD.

The fiscal year (FY) 2016 JWMRP-funded projects across five Defense Health Program core research areas include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine. A total of 34 projects were funded, to include 22 science and technology efforts ($28,251,351.00) and 12 advanced development efforts ($18,851,111.00). The FY 2016 JWMRP total funds directed towards scientific awards is $47,102,462.00.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

Robert L. Wilkie

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

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

PERSONNEL AND
READINESS

JAN 24 2018

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

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

PERSONNEL AND
READINESS

JAN 24 2018

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

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

PERSONNEL AND
READINESS

JAN 24 2018

The Honorable Thad Cochran
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to House Report 114-139, page 278, which accompanies H.R. 2685, the Department of Defense (DoD) Appropriations Bill, 2016, and Senate Report 114-63, page 201, which accompanies S. 1558, the DoD Appropriations Bill, 2016, concerning the Joint Warfighter Medical Research Program (JWMRP). The Assistant Secretary of Defense for Health Affairs is requested to provide a list of projects that received funding, the amount of funding provided to each project, a thorough description of each of these research efforts, and the benefit these projects will provide the DoD.

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Sincerely,

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

REPORT IN RESPONSE TO THE HOUSE REPORT 114-139, PAGE 278, TO ACCOMPANY H.R. 2685, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2016 AND SENATE REPORT 114-63, PAGE 201 TO ACCOMPANY S. 1558, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2016

"JOINT WARFIGHTER MEDICAL RESEARCH PROGRAM"

SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

The estimated cost of this report or study for the Department of Defense (DoD) is approximately $9,450 in Fiscal Years 2016 - 2017. This includes $9,150 in expenses and $290 in DoD labor.

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BACKGROUND AND PURPOSE

The House Report 114-139, page 278, which accompanies H.R. 2685, the Department of Defense (DoD) Appropriations Bill, 2016, and Senate Report 114-63, page 201, which accompanies S. 1558, the DoD Appropriations Bill, 2016, requested the Assistant Secretary of Defense for Health Affairs provide a report, not later than 180 days after the enactment of the Act, to the Congressional Defense Committees on the status of the Joint Warfighter Medical Research Program (JWMRP). The House and Senate reports requested a list of projects that received funding, the amount of funding provided to each project, a thorough description of each of these research efforts, and the benefit these projects will provide the DoD.

In Fiscal Year (FY) 2016, Congress appropriated $50 million for the JWMRP. The FY 2016 JWMRP funded projects across five Defense Health Program core research areas to include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine. In FY 2016, a total of 34 projects were funded, to include 22 science and technology efforts costing $28,251,351.00, and 12 advanced development efforts costing $18,851,111.00. The FY 2016 JWMRP total funds directed towards scientific awards are $47,102,462.00. The prominent selection criteria in determining which projects to fund included: (1) whether the project was close to achieving its objectives; and (2) whether it had a clear benefit to military medicine. All of the projects selected have discrete deliverables, which will move the anticipated research outcomes or products forward to the next phase of development, result in the initiation of a clinical trial, or contribute to requirements to facilitate U.S. Food and Drug Administration (FDA) approval.

CONCLUSION

Table 1 is a summary of the projects funded by the FY 2016 JWMRP, including the award recipients, descriptions of the projects and potential military benefit, and amounts funded. The Department remains committed to investing in research to benefit its Service members and their families.

Table 1 – FY 2016 JWMRP Research Projects

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
1.	An Interoperable Platform for Real-Time In-Theater Caregiver Decision Support	Massachusetts General Hospital Boston, MA	This research effort is focused on developing a software system that integrates data from different medical devices used with critically injured patients to enhance clinical decision-making in real time. The product of the effort is several prototype applications, including clinical applications that have the potential to make clinical assessment more efficient, and help the medical provider more easily maintain patient situational awareness while in the critical care treatment paradigm. This research will build on the efforts to increase medical device interoperability, which is a vital component in the critical care environment. If successful, this initiative could improve care efficiency and enhance survivability of wounded or injured Warfighters.	$1,444,737
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	The DocBox platform is a standards-based, secure, point-of-care integrated clinical environment (ICE), which 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 that are hosted and run on the ICE platform and extend the platform functionality to meet the performance, safety, and security requirements to optimize use in the military environment. The effort will focus on remote monitoring and remote control on the platform during medical evacuation. The applications will be tested to determine if improvements in safety and efficiency were achieved using the ICE platform.	$1,498,653
3.	Development of a Bovine Immunoglobulin Supplement that Prevents Travelers' Diarrhea by Blocking Pathogen Adherence	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	The overarching purpose of this effort is to lay the scientific foundation for development of a multivalent, food-based anti-diarrheal supplement that confers protection against Enterotoxigenic *Escherichia coli* (ETEC). ETEC causes 30% to 50% of travelers' diarrhea (TD) in most developing countries. TD is one of the principal causes of non-combat-related disease morbidity among U.S. military forces deployed overseas. The development of a product that will reduce the incidence of TD will directly impact the operational readiness of deployed forces.	$136,000 sent to Naval Medical Research Center in support of this effort

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
4.	Enhancing the Immunogenicity of a Tetravalent Dengue DNA Vaccine	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Dengue virus infections rank second for infectious diseases in our deployed Service members, and can lead to the lethal Dengue Hemorrhagic Fever if untreated. Currently, there are no licensed vaccines to prevent dengue infections. The Naval Medical Research Center developed a Dengue vaccine based on plasmid DNA. This project will test an enhanced vaccine using different combinations of live attenuated virus or inactivated virus in either the prime or boost mode. If successful, this strategy will provide a promising vaccination strategy for further clinical trials. At the end of this project, the product will be ready for the manufacturing and safety studies required by the FDA.	$226,458 sent to HMJF $108,000 sent to Naval Medical Research Center in support of this effort
5.	Development and Validation of the DRAG Humanized Mouse Model for Dengue Virus Infection and Vaccine Evaluation	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Dengue virus infections rank second for infectious diseases in our deployed Service members and, if untreated, can lead to the lethal Dengue Hemorrhagic Fever. The objective of this study is to further understand the complex immune response that humans have to dengue viral infections and to understand what kind of immune response would protect an individual from this infection. The research will be conducted in a small animal model that has a human immune response system. The results of this research will provide a novel animal model that can be used for assessing dengue vaccine candidates pre-clinically. The knowledge gained from this research effort will contribute to the development of dengue vaccines by laying the foundation for testing future dengue vaccine candidates. This effort is critical to the DoD in developing a vaccine that can protect U.S. forces across the globe.	$869,949

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
6.	Preclinical and Clinical Development of the Next Generation Anti-Malaria Prophylactic Agent	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	This effort could directly impact operational readiness through a more effective preventive measure against malaria. Malaria remains the number one infectious disease threat to deployed U.S. forces. Current medications to protect against malaria must be taken every day, may cause stomach upset or sun sensitivity, and may lead to drug resistance. The focus of this effort is to develop a safe and effective drug that can be taken weekly to prevent malaria. This program is advancing a new class of anti-malarial medicine called triazines which are protective against *Plasmodium falciparum*. Animal studies will be conducted to determine which triazine compound is absorbed, distributed, and metabolized through the body most quickly with the least toxicity at various dose levels. The best product will then be manufactured for use in further animal toxicity studies required by the FDA. Results will support an Investigational New Drug submission to the FDA for a Phase 1 clinical trial.	$695,559 sent to Walter Reed Army Institute of Research in support of this effort
7.	GMP Production and Clinical Trial of a Self-Assembling Protein Nanoparticle and Toll-Like Receptor Liposomal MPL Adjuvanted Malaria Vaccine	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Malaria remains a serious disease threat across the globe. The objective of this project is to conduct 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 both the protein and adjuvant components of the proposed vaccine. These two components will be combined to form the vaccine FMP-014, which will be used in a human clinical trial. This effort could lead to a better vaccine that will be more effective in protecting people against malaria and improve the health readiness of U.S. forces worldwide.	$571,258 $660,507 sent to Walter Reed Army Institute of Research in support of this effort

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
8.	Optimization of Pyrimidinylguanidines as Malaria Prophylaxis Drugs	The Geneva Foundation Tacoma, WA	This research seeks to identify a safe and effective drug to prevent and/or treat malaria. Many of the drugs used today will become ineffective as malaria strains become resistant to current therapeutic interventions. The focus of this effort is to discover a drug candidate from a molecular class of compounds that does not show cross-resistance with known anti-malarials. This compound class, known as pyrimidinyguanidines, was tested in four human clinical trials in the mid-1940's, resulting in relief of malaria symptoms with no serious side effects. This initiative will target improving the potency of this class of compounds that has been shown safe in human clinical trials but has not been used extensively in people. The desired outcome is to develop a drug that is safe, not resistant to current malaria strains, and will prevent and treat malaria. This is an important research effort in the race to develop and improve current treatment and prevention regimens for malaria.	$1,324,853 $515,173 sent to Walter Reed Army Institute of Research in support of this effort
9.	Refinement and Validation of a Military Emotional Intelligence Training Program	University of Arizona	This research effort is focused on further development of a web-based training program designed to bolster emotional resilience skills through the enhancement of emotional intelligence (EI). It will focus on identifying the key training components that lead to the greatest improvements, identify the neural mechanisms underlying the changes in EI abilities and determine the effectiveness of the EI training program for enhancing military performance and sustaining psychological health during stressful military operations, activities, and deployments. Research in this area has the potential to impact the overall psychological health of Service members and their families.	$1,659,395
10.	Does Evidence-Based PTS Treatment Reduce PTS Symptoms and Suicide in Iraq and Afghanistan Veterans Seeking VA Care?	Northern California Institute for Research and Education San Francisco, CA	The goals of this study are to determine: (1) if Prolonged Exposure Therapy and Cognitive Processing Therapy improve post-traumatic stress (PTS) and suicidality symptoms; (2) what factors make it more likely for Veterans to complete the therapy; and (3) the impact on when the therapy began, if at all, for PTS and suicidality symptoms. Information from this research will benefit Service members, Veterans, and their families as they deal with PTS, suicide symptoms and other mental health problems.	$377,075

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
11.	Pre-, Peri-, and Post-deployment Trajectories and Mechanisms of Psychopathology, Psychological Health and Resilience over Nine Years of Follow-up in the Reserves	University Hospitals, Case Medical Center Cleveland, OH	This is an unprecedented study on DoD Reserve component personnel that will provide data to shape future policy and programs to support this population. Over the past five years, the Ohio Army National Guard Mental Health Initiative has evaluated relationships between resilience and risk factors before, during, and after deployment. This effort will extend the research to a nine-year effort, the first longitudinal study of its kind. This study will assess the development of mental health problems, including post-traumatic stress, depression, suicidality, military sexual trauma, anxiety, and hazardous use of alcohol and other risk-taking behavior. It will measure resilience, social adjustment, military culture and support, coping factors, and health issues including traumatic brain injury. Finally, it will evaluate the biological underpinnings of mental health problems and resilience by conducting genetic and brain imaging studies in this population.	$1,578,549
12.	Improving Access to Care for Warfighters: Virtual Worlds Technology To Enhance Primary Care Training in Posttraumatic Stress and Motivational Interviewing	Northern California Institute for Research and Education San Francisco, CA	In previous research, a pilot web-based PTS training program for primary care providers (PCP) was evaluated and found to improve PTS-related knowledge and clinical skills. This follow-on effort will use Virtual World technology to create a training that is more interactive, engaging, and effective, and uses gold standard evaluation methods including provider and patient outcomes. This Virtual World training will be compared to the traditional web-based training to evaluate the effectiveness of educational outcomes. If shown that it significantly improves educational outcomes, Virtual World technology could be a valuable training tool for PCPs in caring for patients with PTS, improving access to quality care, and potentially improving patient outcomes.	$874,727
13.	Psychobiological Assessment and Enhancement of Unit Cohesion and Psychological Resilience in ROTC Cadets Using a Virtual-Reality Team Cohesion Test	Northern California Institute for Research and Education San Francisco, CA	High military unit cohesion is a critical factor that enhances unit performance and promotes individual resilience to combat related trauma. This study will identify the psychological, behavioral, physiological, and hormonal predictors and mechanisms of an individual's ability to develop cohesion within a team in a virtual reality setting. It will also explore if administration of the neuropeptide oxytocin enhances the development of team cohesion. Positive results may support oxytocin as a potential performance enhancing intervention for improving military unit cohesion.	$438,527

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
14.	Collaborative Research to Optimize Warrior Nutrition III	Pennington Biomedical Research Center Baton Rouge, LA	This effort continues a partnership of 28 years with the DoD to extend and build on research discoveries in nutrition, metabolism, and human physiology. The objective of the research is to discover nutritional interventions, field feeding programs, and food products that promote Warfighter resilience and improve combat readiness and performance. The specific aims are: (1) determine the role of testosterone in the loss of lean mass during energy deficit; (2) evaluate whether added dietary protein can sustain lean body mass when underfed and operating at high altitude; (3) determine the interaction of gender and physiological strain on inflammation; (4) quantify the effectiveness of the military dining facility intervention "Go For Green" on Soldier food choices; and (5) develop a valid and militarily appropriate survey tool for assessment of Warfighter eating behaviors. The data derived from this effort may result in better models to predict dietary requirements which will enhance operational readiness.	$1,500,000
15.	Effects of Military Noise Exposure on Auditory Function in Service Members and Recently Discharged Veterans	Oregon Health and Science University Portland, OR	The primary objective of this research effort is to examine the prevalence, incidence, etiology, and short- and long- term effects of tinnitus and hearing loss among Service members. The study will provide data revealing estimates of: (1) the prevalence of tinnitus and hearing loss in Service members and recently discharged Veterans; (2) the effects of military noise exposure verses the potential causes of early-onset tinnitus and hearing loss; (3) the perceived functional limitations associated with these conditions; (4) common mental and physical comorbidities; (5) disability and clinical care burden to the DoD and the Department of Veterans Affairs; and (6) factors affecting the severity of these conditions. The algorithms developed by the study will help predict the risk for acquiring tinnitus and/or hearing loss for military populations.	$1,204,749
16.	The Effect of Hypobaria on Muscle Inflammation and Regeneration After Injury and Hemorrhagic Shock	University of Nevada, Las Vegas Las Vegas, NV	Injured Service members are air evacuated from the theater of operations to acute care medical facilities, which may involve a flight time of 8-16 hours from the battlefield. The objective of this research is to understand the effect of long distance flying on recovery after muscle injury and significant bleeding. If it is shown that air transport slows recovery for these types of patients, mitigating clinical practices could be developed and implemented.	$876,941

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
17.	Light-Activated Sealing to Improve Outcomes Following Penetrating Bowel Trauma	Massachusetts General Hospital Boston, MA	This study will investigate if photochemical tissue bonding (PTB), a light-activated sealing technology, can provide more secure wound closure and reduce complications, leading to improved outcomes for penetrating bowel trauma. Specifically, the effort will utilize animal models of penetrating bowel trauma to identify lead PTB colon patch/wound closure materials based on seal strength and resistance to biodegradation, and compare the efficacy of using an optimized PTB approach verses standard repair in preventing infections. If successful, the PTB product could be deployed in resource-limited military treatment facilities for use by non-specialist surgeons to enhance survivability from penetrating bowel trauma. Additionally, it would increase the potential for return to duty, reduce long-term rehabilitation costs, and improve quality of life for our wounded Warfighters.	$639,404
18.	Treatment of Adult Severe Traumatic Brain Injury Using Autologous Bone Marrow Mononuclear Cells	Center for Brain Health, The University of Texas at Dallas Dallas, TX	Currently there are no effective reparative/restorative treatments for traumatic brain injury (TBI). Pre-clinical studies in animals have shown that bone marrow-derived cells improve memory and cognitive function. This study will determine if cells harvested and isolated from a patient's own bone marrow can be infused to control the brain swelling after TBI. Functional outcomes will be measured using cognitive testing and skills testing early (initial week of injury) and later (six months post injury) time points. Success will be measured by clear improvement in structural biomarkers in the brain. If successful, this effort will be the foundation for a Phase 3 multi-center clinical trial. Cellular therapy may provide the first restorative/reparative treatment for TBI.	$1,737,556

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
19.	Development and Dissemination of Clinical Practice Guidelines and Appropriate Use Criteria for Treatment of Major Extremity Trauma	Johns Hopkins University Baltimore, MD	The purpose of this research is to develop Clinical Practice Guidelines (CPGs) and Appropriate Use Criteria (AUCs) relevant to the treatment of severe extremity trauma. The CPGs and AUCs will focus on six areas of extremity trauma, including: diagnosis and treatment of acute compartment syndrome; decision-making to pursue limb salvage or early limb amputation following lower limb trauma; early screening for psychosocial risks and protective factors that influence long-term outcomes; use of multimodal pharmacologic pain management in the perioperative period to reduce long-term pain and disability; determining the best techniques for performing a below-the-knee amputation in a young active patient; and prevention and treatment of surgical site infections following major extremity trauma. Development of these CPGs and AUCs will immediately impact the care of patients with severe limb trauma and patients undergoing extremity trauma reconstruction.	$2,889,817
20.	Large Extremity Peripheral Nerve Repair in Nonhuman Primate Models	Massachusetts General Hospital Boston, MA	The goal of this research is to further develop a novel technology to improve recovery for wounded Warfighters that suffer from severe nerve damage in the arms. This effort will evaluate peripheral nerve repair in a nonhuman primate model using a light-activated dye and biocompatible nerve wrap to effectively seal the nerve graft in place without sutures. In preliminary studies with small animals, this approach resulted in significant improvement in nerve regeneration when compared to the standard suture repair. If successful, the patented technology would next be tested in humans and could significantly improve functional outcomes for wounded Warfighters who suffer devastating nerve injury.	$1,071,617

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
21.	Non-Invasive Intracranial Pressure Assessment Using a Compact, Portable Monitor	Vivonics, Inc. Sudbury, MA	This effort will further develop the Intracranial Pressure Assessment and Screening System (IPASS), which is capable of measuring intracranial pressure (ICP) noninvasively. The specific aims are: 1) complete design under International Organization for Standardization standards; 2) manufacture IPASS pre-production prototypes; 3) demonstrate in a pivotal study that the IPASS monitor is substantially equivalent to the measurement of ICP with an external ventricular drain); 4) prepare and submit a complete documentation package to the FDA for investigational device exemption approval. If this effort is successful, the IPASS would provide the capability to triage casualties with closed-head brain injuries for elevated ICP much closer to the time of the trauma, and enable rapid treatment to preclude further injury.	$4,097,422
22.	Joint Warfighter: "The Shelter of the Future"	ROM Development Corporation Bristol, RI	This development effort is focused on the creation of a carbon/fiberglass shelter system to meet the requirements of future medical operations. The objectives are to improve speed of set up and operating room space, and conditions of a rigid wall shelter, lower operating energy costs, lower the maintenance of the shelter through composite construction, creating a cleaner work environment, increase the interior space, and create rigid wall complexes which will be superior to soft wall systems currently used. This effort will directly support far forward care on the battlefield or humanitarian efforts in resource-limited environments.	$655,154

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
23.	NIRS to Reduce the Prophylactic Fasciotomies for and Missed Cases of Acute Compartment Syndrome in Solders Injured in OEF/OIF: Interventional Study	The Geneva Foundation Tacoma, WA	Severely injured limbs can develop acute compartment syndrome (ACS), which occurs when increased swelling due to injury causes poor blood flow to the muscle and tissue in the injured extremity. Untreated ACS leads to permanent muscle and nerve damage and the potential loss of limb function. Currently, there is no objective and reliable means to diagnose ACS. Near Infrared Spectroscopy (NIRS) is a noninvasive, objective way to monitor blood flow in extremities and previous work established guidelines for the use of NIRS in monitoring extremity blood flow. The goal of this study is to examine the sensitivity and specificity of these guidelines in monitoring injured extremity blood flow in a multi-center clinical trial. The investigators hypothesize that NIRS values will be highly correlated to perfusion pressures and more sensitive and specific than a clinical exam. If this is correct, NIRS would revolutionize ACS diagnostic capabilities and enhance the treatment and care of patients with extremity trauma.	$1,706,427
24.	Development of Moisture Management Liner and Active Cooling System for Improving Residual Limb Skin Care	Vivonics, Inc. Sudbury, MA	Heat- and perspiration-related discomfort inside a prosthesis socket is a problem impacting the comfort and effective use of a prosthesis. The objective of this effort is to further develop an Intrasocket Cooling Element (ICE) active cooling system for lower limb prosthetic sockets. The developers will evaluate the effectiveness of ICE on 16 lower limb amputees in a laboratory setting as well as in a real world environment. If this active cooling system removes sufficient heat from inside the socket to reduce sweating thus creating a cooler and dryer environment for the skin, it will improve user comfort, socket fit, and the overall quality of life for the amputee.	$1,398,545

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
25.	Ultrawide-Band, Wearable Ultrasound Probe for Battlefield Use	Sonivate Medical Portland, OR	Ultrasound is a standard of care technology for early diagnosis of hemorrhage and other injuries in trauma situations. Sonivate Medical previously developed finger-worn ultrasound probes. This effort will expand upon extensive product development and technical refinement to transition from a laptop display to a wearable wireless ultrawide-band smart phone display. The first phase will focus on development of the probe and associated electronics to support smart phone display. Combat medics will be trained on the device to demonstrate device utility and develop training procedures. In the second phase, the device will be programmed and wirelessly connected to a smart phone to display real-time ultrasound images. The data captured on the device during this development effort will be used to support a 510(k) clearance from the FDA.	$1,118,645
26.	Predicting Blood Transfusion Using Automated Analysis of Vital Sign Input from All Available Sources	University of Maryland, Baltimore Baltimore, MD	This project builds on a 5-year project that delivered a hospital/center based real-time vital signs data collection system. This effort will build a decision support tool using the vital signs data transmitted when an injured patient is en route to a hospital to predict the need for blood transfusion upon arrival. While blood transfusion is a key in the early care of badly injured, more knowledge is needed on how exactly to differentiate casualties who need blood immediately from those who do not. This project, if successful, will provide a valid, robust, user-friendly, and reliable software application that can be embedded in patient care monitors already widely used on the battlefield and in civilian care. This initiative could save lives, reduce complications, and directly impact clinical practices related to the use of blood with trauma patients.	$1,142,207 $106,735 sent to the US Army Telemedicine and Advanced Technology Research Center in support of this effort

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
27.	Improving Cognitive and Functional Deficits after TBI Using Virtual Technology	Center for Brain Health, The University of Texas at Dallas Dallas, TX	Chronic TBI symptoms may include persistent difficulties with memory, inhibitory control, and the ability to plan, which may impact employment and personal relationships. This research will test and evaluate a virtual reality-based intervention using active condition challenging memory and inhibitory control and planning against a context-matched control condition lacking these challenges. The potential to remediate deficits in memory, attention and planning could be a key step toward improving the lives of Veterans who frequently suffer long after the initial TBI. If successful, this effort could benefit many Service members, Veterans, and families impacted by the residual effects of TBI. This is a vital area of research in the DoD.	$760,516
28.	Adaptive Orthopedic Biologics for Highly Targeted Regeneration	The Geneva Foundation Tacoma, WA	This product may improve outcomes for patients with traumatic bone injuries or spinal disc degeneration, the two most common injuries in Service members. The product, a bone morphogenic protein-2 (BMP-2) compound modified with beta tricalcium phosphate (tBMP-2), will be evaluated pre-clinically. The effort will also establish a scalable recombinant production method for the tBMP-2 and conduct various animal studies to evaluate the product. At the end of this effort, the goal is to file a Request for Designation with the FDA to designate the product as a Class III device, and prepare an Investigational Device Exemption submission to the FDA in order to begin a Phase 1 safety trial.	$742,214

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
29.	A Comprehensive Approach to Whole Eye Transplantation: Building a Scientific Foundation for New Therapies in Vision Restoration	University of Pittsburgh Pittsburgh, PA	Combat ocular trauma and other visual disorders from penetrating wounds affect 16% of all evacuated Service members from the theater of operations. The overarching goal of this research effort is to restore vision following ocular trauma and ischemic or degenerative damage with whole eye transplantation. The effort will define and address immune rejection, improve ganglion cell survival, and integrate the donor eye with the host brain by stimulating optical nerve regeneration in a small animal model. The effort will also optimize a non-human primate whole eye transplant model. The lack of available medical interventions to restore vision leaves blind military Service members with a significant decline in quality of life and reduced capability to return to duty. The knowledge gained from this research has the potential to help wounded Service members suffering from blindness regain independence, enhance their quality of life, and make them feel whole again.	$2,827,377
30.	Automated Control of Volume Management Systems for People with Limb Loss	University of Washington Seattle, WA	This effort has the potential to improve the quality of life for both the Active Duty and retired amputee military populations. Individuals using prostheses often experience socket fit problems that result from changes in the volume of their residual limb. Poor fitting sockets reduce performance and lead to injury. This effort will develop and test an automatic adjusting prosthetic socket system utilizing a wireless controller, which can decrease or increase socket size in response to changes in residual limb volume.	$1,738,891

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
31.	Lyophilized Injectable for Point-of-Care Therapeutic for Post-Traumatic Osteoarthritis	Massachusetts General Hospital Boston, MA	In the military population, acute knee injuries comprise 5% of the reported injuries, and post-traumatic osteoarthritis (OA) is a primary source of disability. J-PRO is an injectable extracellular matrix which is mixed with the patient's blood and injected into an injured joint to minimize the development of arthritis. While this has been completed in an animal model, it has not been tested in humans. The aim of this project is to complete all preclinical testing required to obtain an Investigational Device Exemption from the FDA and conduct a first-in-human clinical study. The investigators will complete pre-clinical studies for a Pre-Market Approval Application and design a pivotal randomized clinical trial of J-PRO. Successful implementation of an injectable therapeutic to restore articular cartilage after joint injury and prevent the development of OA have the potential to maximize joint function, enhance the opportunity to return to duty, and improve injured Service members' quality of life.	$4,257,948
32.	Improving Functional Outcomes of Combat-Injured Warfighters by Relieving Post Amputation Pain Using NerveSpace	SPR Therapeutics, LLC Cleveland, OH	This project addresses a significant health care need for non-narcotic pain relief for post-amputation residual limb pain and phantom limb pain. Previously funded studies have shown the percutaneous peripheral nerve stimulation (PNS) has the potential to reduce post-amputation pain and pain related disability. This Phase 3 randomized controlled trial will determine if active stimulation with PNS therapy results in greater pain relief when compared to sham stimulation. Data from this study will be used to support a FDA 510(k) clearance to market this medical device for pain treatment.	$2,240,829

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY16 JWMRP AWARDED AMOUNT
33.	Development of Highly Functional, Neurally Controlled, Skeletally Attached, and Intelligent Prosthetic Devices	Western Institute for Biomedical Research Salt Lake City, UT	This project meets a critical need in the rehabilitation of Service members and Veterans after neuromusculoskeletal injuries. The goal of this project is to maximize the functional recovery of patients with above elbow amputations (AEA). It is difficult to fit a prosthesis that is comfortable and functional for patients with short residual limbs when shrapnel remains embedded in the residual limb or when additional bone tissue forms. This effort will develop a Percutaneous Osseointegrated Docking System (PODS) prosthesis that is ready for translation to human clinical trials. The deliverables are the AEA PODS prosthesis/device, the instrumentation for development of the PODS, and written surgical procedures required by the FDA in order to conduct human clinical trials with the device.	$1,375,047
34.	Electronic Capture and Seamless Communication of Point-of-Injury Patient Information Utilizing Ultra-Wide-Band Technology Integrated with Nett Warrior Platform	Sierra Nevada Corporation Sparks, NV	This effort proposes to wirelessly connect existing medical devices such as monitors for blood pressure or heart beat to hand-held portable computers used by U.S. Army combat medics via invisible, low power, hard to detect radio waves called ultra wide band (UWB). The project will transmit clinical data from patient care devices using UWB technology to the Nett Warrior Electronic User Device to populate an automated Tactical Combat Casualty Care Card. The focus of the effort is to make patient care and condition information widely visible throughout all phases of evacuation. This information can then be part of the patient's permanent health record, which is an overarching precept in the defense health arena. Funding in FY 2016 will cover an update to a government owned software package developed by the Air Force Research Laboratory that supports this effort.	$35,000