OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND READINESS

JAN 19 2017

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 113-473, page 284-285 and Senate Report 113-211, page 253, which accompanies H.R. 4870, the Department of Defense (DoD) Appropriations Bill, 2015, concerning the Joint Warfighter Medical Research Program. This report provides details of the $50M provided to augment and accelerate high priority DoD and Service medical requirements and to continue prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine.

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

Sincerely,

for Peter Levine
Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

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

JAN 19 2017

Dear Mr. Chairman:

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Peter Levine
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 19 2017

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

Dear Mr. Chairman:

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Sincerely,

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Peter Levine
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 19 2017

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 113-473, page 284-285 and Senate Report 113-211, page 253, which accompanies H.R. 4870, the Department of Defense (DoD) Appropriations Bill, 2015, concerning the Joint Warfighter Medical Research Program. This report provides details of the $50M provided to augment and accelerate high priority DoD and Service medical requirements and to continue prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine.

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for S Barna

Peter Levine
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

REPORT TO CONGRESS

Fiscal Year 2015 Joint Warfighter Medical Research Program

December 2016

The estimated cost of this report or study for the Department of Defense is approximately $9,410 in Fiscal Years 2015 - 2016. This includes $8,570 in expenses and $850 in DoD labor.

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1. BACKGROUND AND PURPOSE

The Assistant Secretary of Defense for Health Affairs (ASD(HA)), in Fiscal Year (FY) 2015, was requested by the House Appropriations Committee, Sub-committee on Defense, House Report 113-473, pages 284-285, and Senate Appropriations Committee, Subcommittee on Defense, Senate Report 113-211, page 253, to provide a report, not later than 180 days after the enactment of the Act, to the Congressional Defense Committees on the status of the FY15 Joint Warfighter Medical Research Program (JWMRP). As required by the House and Senate reports, the JWMRP funding was not used for new projects, and a review of medical research and development gaps, to include unfinanced medical requirements by the Services, were taken into consideration. The House and Senate reports specified the requirement to list 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 Department of Defense (DoD).

The Defense Health Agency (DHA), established under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, through the ASD(HA), supports policy execution, exercises management responsibility, and provides shared services to consolidate common services and to further integrate operational missions and capabilities in the Military Health System (MHS). The DHA J9, Research and Development Directorate, manages MHS operations in the area of medical research and development and oversees the execution of the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) appropriation.

The US Army Medical Research and Materiel Command (USAMRMC), a major subordinate Command of the US Army Medical Command, is responsible for the execution management of several Congressional Special Interest (CSI) research appropriations across a wide range of diseases and injuries applicable to the general population as well as the military.

The JWMRP, a DHP RDT&E CSI appropriation, is managed by the USAMRMC Congressionally Directed Medical Research Programs in support of the ASD(HA) and DHA J9, Research and Development Directorate. In FY15, Congress appropriated $50 million for the JWMRP that "...shall be used to augment and accelerate high priority Department of Defense and Service medical requirements and to continue 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 for basic research."

The FY15 JWMRP funded projects across six DHP core research areas to include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. After deducting research management support costs, $46,761,423 was available for project funding. In FY15, a total of 30 projects were

funded to include 19 science and technology efforts ($27,966,786) and 11 advanced development efforts ($18,794,637). 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 that will move the project 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.

Table 1 is a summary of the projects funded by the FY15 JWMRP, including the award recipient, a description of the project and potential military benefit, and amount funded.

Table 1 – FY15 JWMRP Research Projects

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
1.	Improvement and User Testing of Modular Enhancements for Mannequin-Based Medical Simulators	Center for Integration of Medicine and Innovative Technology, Massachusetts General Hospital Boston, MA	This project has the potential to enhance medical training of healthcare providers in the MHS. This research is focused on development of a series of modular enhancements, systems that can be mounted to a basic mannequin providing the sense of presence generated by seeing eyes open/close/move, feeling the chest rise during breathing, and hearing the patient voice with a controller linked to the modules, displaying vital signs, and providing a learning management system. This effort will create a SimSuit that integrates all modular enhancements in a unified form that can be worn by a mannequin or standardized patient.	$671,199

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
2.	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 development of a product that will reduce the incidence of Travelers' diarrhea (TD) will directly impact the operational readiness of our deployed forces. Travelers' diarrhea is one of the principal causes of non-combat-related disease morbidity among U.S. military forces deployed overseas. Enterotoxigenic *Escherichia coli* (ETEC) causes 30% to 50% of TD in most developing countries. Previous studies found protective efficacy from TD using oral bovine colostrum-derived immunoglobulins (BIgG). This effort will assess the protective efficacy of BIgG against one of the most common strains of ETEC. 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 ETEC.	$172,000 Sent to Naval Medical Research Center in support of this effort
3.	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 if untreated can lead to the lethal Dengue Hemorrhagic Fever. 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 priming or boosting 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.	$985,362 Sent to HMJF $108,000 Sent to Naval Medical Research Center in support of this effort

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
4.	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 that are protective against *Plasmodium falciparum*. Animal studies will be conducted to determine that 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.	$2,866,105
5.	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	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 forces worldwide. Malaria remains a serious disease threat across the globe. This proposal 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 to be used in a human clinical trial. The objective of the proposal is to conduct a Phase 1/2a clinical trial of a nanoparticle Malaria vaccine formulated in a liposome-based adjuvant.	$853,074 Sent to HMJF $447,359.00 Sent to Walter Reed Army Institute of Research in support of this effort

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
6.	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 our Service members and their families.	$1,384,342
7.	Improving Cognitive and Functional Deficits after TBI Using Virtual Technology	Center for Brain Health, The University of Texas at Dallas Dallas, TX	Chronic Traumatic Brain Injury (TBI) 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, inhibitory control, and planning and a context-matched control condition lacking these challenges. The potential to remediate deficits in memory, attention and planning can be a key step toward improving the lives of Veterans who frequently suffer long after the initial brain injury. 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.	$1,123,069

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
8.	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 in 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 assesses the development of mental health problems, including post-traumatic stress, hazardous use of alcohol, depression, suicidality, military sexual trauma, anxiety, and other risk-taking behavior. It measures resilience, social adjustment, military culture and support, coping factors, and health issues including traumatic brain injury. Finally, it will evaluate the biological underpinnings of these mental health problems and resilience, with genetic and brain imaging studies conducted on the survey platform population.	$1,576,534
9.	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, on 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.	$416,049

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
10.	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 uses 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 training could be a valuable tool for PCP in caring for patients with PTS, improve access to quality care, and potentially improve patient outcomes.	$412,852
11.	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 in a group working together as a team. It will also explore if administration of the neuropeptide oxytocin enhances the development of team cohesion. If the results are positive, oxytocin may become a powerful performance enhancing and therapeutic intervention.	$436,515

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
12.	Advancing Clinical Outcomes, Biomarkers and Treatments for Severe TBI	Chicago Association for Research and Education in Science Hines, IL	The treatment and rehabilitation of Service members with TBI is a major thrust area in the MHS. This study seeks to improve severe TBI clinical assessments in order to (1) more accurately determine if patients have improved as a result of treatment, (2) identify meaningful amounts of change in function to enable clinicians and researchers to select TBI outcomes that are best suited to the patients, and (3) identify changes in biomarkers as a result of repetitive Transcranial Magnetic Stimulation (rTMS). Advanced understanding of the true neurobehavioral effects of rTMS treatment will provide data on how the underlying neurobiology of the brain may be altered as a result of this treatment.	$3,014,629
13.	The Effect of Hypobaria on Muscle Inflammation and Regeneration After Injury and Hemorrhagic Shock	University of Nevada, Las Vegas Las Vegas, NV	All injured Service members must be 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, interventional clinical practices could be implemented.	$4,681,860

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
14.	A Closed-Loop Neural Prosthesis for Restoration of Function after Traumatic Brain Injury	Case Western Reserve University Cleveland, OH	This effort could provide a gateway for transforming treatment for patients with TBI. The goal of this project is to use an implantable brain-machine-brain interface in an animal model to enhance recovery after TBI. This effort will record neuronal activity in one part of the brain, and transfer these signals in another part of the brain to stimulate new functional connections. While this novel approach is still in its infancy, if successful this initiative will provide data to support follow-on animal studies to support the ultimate goal of human testing and FDA approval of the device.	$1,654,757
15.	Advanced Development of Gamma-Tocotrienol as a Radiation Countermeasure	Armed Forces Radiobiology Research Institute, Uniformed Services University of the Health Sciences	Treatment of radiation exposure was specifically highlighted in the congressional language in FY14 and is a national defense priority. In previous studies, Gamma-tocotrienol (GT3), an antioxidant, protected almost 100% of mice against a lethal dose of radiation when administered subcutaneously 24 hours before exposure. This study will look at different formulations of GT3 to improve its tolerability when administered subcutaneously, and evaluate GT3 soft gel capsules for oral efficacy. Also, it will study the efficacy of GT3 in nonhuman primates (NHP) using different doses of radiation for whole body exposure and investigate hematopoietic and gastrointestinal injury, accelerated recovery, and efficacy biomarkers in NHPs. These efforts are the foundation for a safety clinical trial in humans.	$1,687,897

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
16.	Thermoresponsive Reversible Attachable Patch for Temporary Intervention in Ocular Trauma - II	University of Southern California Los Angeles, CA	This technology for treating ocular trauma may improve vision outcomes for combat casualties and result in greater return to duty statistics or increase quality of life for our Veteran population. In this research effort a novel adhesive polymer (hydrogel) materiel will be synthesized and tested for its ability to temporarily seal penetrating injuries to the eye. If successful, the data will be used to support a submission to the FDA to begin clinical safety trials.	$1,599,999
17.	Development of an Implantable Pudendal Nerve Stimulator to Restore Bladder Function in Human after Spinal Cord Injury	University of Pittsburgh Pittsburgh, PA	Currently there is no medication that can treat both incontinence and the ability of the bladder to empty completely after spinal cord injury (SCI). It is believed that bladder functions can be normalized by electrical stimulation and/or blockade of pudendal nerves after chronic SCI using an implantable neuroprosthetic device. This research effort will design and develop an implantable nerve stimulation system and test it for safety and efficacy in a chronic SCI animal model. The goal is submission of this device for FDA Investigational Device Exemption approval. This technology has potential high payoff by providing the ability for SCI patients to function without daily catheterization.	$2,581,782
18.	Accelerate Applications to Transhumeral and Higher Levels of Limb Loss	Motion Control, Inc. Salt Lake City, UT	This development effort will complete a new high-level and ultra-rugged prosthetic elbow system. This project will provide injured Service members with a ruggedized, water resistant, high performance prosthesis. If successful, the product should be available 2 years after this effort commences and meets a critical focus area need in rehabilitation technologies for DoD beneficiaries.	$450,000

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
19.	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 preclinically. 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.	$843,402
20.	Multiaxial Multi-Instrument Tracking System for Endovascular Interventional Radiology Simulator	Center for Integration of Medicine and Innovative Technology, Massachusetts General Hospital Boston, MA	Endovascular interventional radiology is a familiar minimally invasive method for procedures ranging from stenting vessels to treating brain aneurysms. The objective of this project is to create a new series of interfaces, based on earlier prototype systems, which will provide better tracking characteristics and haptic feedback. This effort will create wired force-feedback tracking devices; wireless tracking-only devices and a prototype simulator. This effort is focused for use in the military medical training arena.	$1,349,522

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
21.	Phase 2 Clinical Development of the PfSPZ Vaccine to Protect the Warfighter from Malaria	Sanaria, Inc. Rockville, MD	This effort fulfills a critical DoD requirement for vaccines for the prevention of malaria. In initial clinical trials, the PfSPZ malaria vaccine development initiative has been demonstrated to be safe and well tolerated. This effort is focused on improving the manufacturing process for the PfSPZ vaccine in preparation for licensure and commercialization. Further, knowledge gained from six ongoing trials with this product will be used to design and conduct a pivotal late Phase 2 study. This will provide the foundation for Phase 3 studies and licensure of the PfSPZ vaccine.	$2,174,394 Sent to Sanaria $112,287 Sent to Walter Reed Army Institute of Research in support of this effort
22.	Treatment of Adult Severe Traumatic Brain Injury Using Autologous Bone Marrow Mononuclear Cells	The University of Texas Health Science Center at Houston Houston, TX	Currently there are no effective reparative/restorative treatments for 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 and later after injury. 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.	$3,770,038

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
23.	Portable Ultrasound Imaging of the Brain for Use in Forward Battlefield Areas	UltraDiagnostics, Inc. Ponte Vedra Beach, FL	This effort will afford the DoD the potential to quickly and non-invasively assess brain injuries on the most forward areas of the battlefield. A previous project demonstrated the feasibility of noninvasive ultrasound imaging through the skull using shear waves. This effort will build a prototype ultrasound tomographic device capable of assessing critical head trauma with improved imaging hardware, image reconstruction software, and clinical interfaces. At the conclusion of the project, an optimized transcranial ultrasound imager will be ready for human clinical testing.	$316,703
24.	LifeChair for Passive Physiological Monitoring in MEDEVAC	Oceanit Laboratories Honolulu, HI	This device will meet a critical requirement of vital signs monitoring during patient evacuation. The Passive Physiological Monitor and LifeBed provide continual patient vital signs through a passive and unobtrusive sensor array. The sensor requires no physical connection to the patient while it monitors and displays respiratory and heart rates. This project will leverage the existing FDA-approved market ready LifeBed product. In this effort, the hardware will be converted for a chair format, meet wireless communications requirements, and be ruggedized for medical evacuation platforms. The product will be tested in a Blackhawk helicopter. The data will be used to support the submission of the LifeChair device for FDA approval.	$979,152

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
25.	The North American Clinical Trials Network (NACTN) for the Development of Treatments for Spinal Cord Injury	Methodist Hospital, Houston, TX	This project will accelerate development of an effective treatment for acute SCI that could be given on the battlefield. Presently, there are no demonstrated effective treatments for either acute or chronic SCI. This effort is a Phase 2/3 multi-center, randomized, placebo-controlled, double-blinded trial testing the efficacy and safety of Riluzole. Validation of the efficacy of an orally administered agent that could be given on the battlefield or at an accident site would be a major advance in SCI care.	$2,500,000
26.	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 our Service members and Veterans. 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 medical 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.	$1,390,772

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
27.	Prosthetic Knee-Ankle-Foot System With Biomechatronic Sensing, Control, and Power Generation	Massachusetts Institute of Technology Boston, MA	The purpose of this effort is to develop a prototype transfemoral bionic limb that will enable amputees to walk on level surfaces and which inclines with a walking gait that is biomechanically and energetically equivalent to non-amputees. There are two primary development components to this effort: 1) inverse and forward modeling of the reflex-based neuromuscular simulation, and 2) implementation of the forward model in a control system developed for the powered transfemoral prosthesis. The prototype prosthesis and control scheme will be tested in a full biomechanical study with ten transfemoral amputees.	$743,928
28.	Powered Leg Prosthesis for the Restoration of Amputee Balance, Locomotory Metabolism and Speed	Massachusetts Institute of Technology Boston, MA	This effort will further enable ankle-foot amputees to fine-tune the position of their prosthesis by activating their residual limb muscles. It modifies the design and furthers the development of a controller that will predict terrain transitions. The intrinsically-predictive controller will enable amputees to instinctively transition between terrains, such as ramps or stairs, by classifying data from intrinsic sensors and adjusting ankle position in real-time.	$265,485

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	FY15 JWMRP AWARDED AMOUNT
29.	Bioengineered Corneas for Transplantation	Cellular Bioengineering, Inc. Honolulu, HI	If successful, this effort will change the rehabilitation paradigm for patients with ocular injuries. The goal of this research is further development of a bioengineered cornea (BEC), which has the potential to improve or restore sight to people who are blind because of injury or disease to their corneas. The effort includes (1) optimizing the formulation of the BEC, (2) submission of an Investigational Device Exemption to the FDA for approval to conduct human clinical trials to demonstrate safety and efficacy of the BEC, and (3) scale-up manufacturing of the BEC in anticipation of seeking premarket approval from the FDA to market the device.	$2,463,905
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 population. 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.	$2,728,451