

#### **UNDER SECRETARY OF DEFENSE**

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

JAN 29 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 Research for Traumatic Brain Injury (TBI) and Psychological Health (PH) report is in response to Senate Report 114–63, page 200, to accompany S. 1558, the Department of Defense Appropriations Bill, 2016. The Senate Report requested a report on expenditure and obligation data of the additional funding for PH and TBI, including information on agreements made with other government agencies.

The fiscal year (FY) 2016 PH/TBI Defense Health Program (DHP) Congressional Special Interest (CSI) funds aligned with the following DHP core research areas: Military Operational Medicine Research Program, Combat Casualty Care Research Program, and Clinical and Rehabilitative Medicine Research Program. A total of 57 projects were funded by FY 2016 DHP TBI/PH CSI. The total FY 2016 DHP TBI/PH CSI expenditure for research is \$117,019,086.00.

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

ALTL. Willie

Enclosure: As stated

cc:

The Honorable Peter J. Visclosky Ranking Member



#### **UNDER SECRETARY OF DEFENSE**

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

JAN 29 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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Enclosure: As stated

cc:

The Honorable Adam Smith Ranking Member



#### **UNDER SECRETARY OF DEFENSE**

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JAN 29 2018

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

Dear Mr. Chairman:

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Sincerely

Robert L. Wilkie

Robert Willie

Enclosure: As stated

cc:

The Honorable Jack Reed Ranking Member

# PERSONNEL AND READINESS

#### **UNDER SECRETARY OF DEFENSE**

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

JAN 29 2018

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

Dear Mr. Chairman:

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cc:

The Honorable Richard J. Durbin Vice Chairman

## REPORT IN RESPONSE TO SENATE REPORT 114-63, PAGE 200, TO ACCOMPANY S. 1558, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2016

### "TRAUMATIC BRAIN INJURY/PSYCHOLOGICAL HEALTH"



## 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 \$900 in Fiscal Years 2016–2017. This includes \$700 in expenses and \$200 in DoD labor.

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#### I. PURPOSE

This report is in response to Senate Report 114–63, page 200, to accompany S. 1558, the Department of Defense (DoD) Appropriations Bill, 2016, which requests the Assistant Secretary of Defense for Health Affairs to provide a report to the congressional defense committees on expenditure and obligation data of the additional funding added by Congress for psychological health (PH) and traumatic brain injury (TBI), including information on agreements made with other government agencies.

This report also addresses section 5 of former President Obama's August 31, 2012, Executive Order (EO), "Improving Access to Mental Health Services for Veterans, Service Members, and Military Families," which calls for the development of a National Research Action Plan to improve coordination among agency efforts working toward improving prevention and treatment of post-traumatic stress disorder (PTSD), TBI, and related PH issues.

#### II. BACKGROUND

Although TBI has been described as the signature injury of the Iraq and Afghanistan wars, its relationships with PH issues and other long-term health consequences are largely unknown. Toward the goal of developing improved preventative and management strategies for TBI and associated PH issues in both the military and civilian populations, the DoD currently supports research projects that are relevant to the prevention, detection, diagnosis, treatment, and rehabilitation of TBI and PH issues.

The Defense Health Program (DHP) Research, Development, Test and Evaluation TBI/PH Congressional Special Interest (CSI) funds are aligned with the following DHP core research areas:

- Joint Program Committee-5 (JPC-5)/Military Operational Medicine Research Program (MOMRP)
- JPC-6/Combat Casualty Care Research Program (CCCRP)
- JPC-8/Clinical and Rehabilitative Medicine Research Program (CRMRP)

#### III. FISCAL YEAR (FY) 2016 DHP TBI/PH CSI EXPENDITURES

The total FY 2016 DHP TBI/PH CSI expenditure for research is \$117,019,086.00.

#### A. JPC-5/MOMRP

The JPC-5/MOMRP seeks to develop effective medical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, readiness, and performance of Service members and their families, in support of the Army Human Performance Optimization, Human Dimension, Multi-Domain Battle, and the DoD Total Force Fitness concepts. The JPC-5/MOMRP psychological health and resilience research portfolio is focused on the prevention, treatment, and recovery of Service member and military family behavioral health, which is critical to force health and readiness.

With the FY 2016 DHP TBI/PH CSI funds, the JPC-5/MOMRP invested in research in the following areas: (1) Cognitive Health and Performance; (2) Diagnosis and Treatment of PTSD; (3) Early Assessment and Interventions to Support Service Member Psychological Health; (4) Military, Family, and Community Psychological Health and Resilience; (5) Operational Exposure Standards for Cumulative Mild Traumatic Brain Injury (mTBI); and (6) Suicide Prevention and Reduction (see Table 1).

Table 1. JPC-5/MOMRP FY 2016 DHP TBI/PH CSI Investments

JPC-5 Research Area	Title	Organization(s)	FY 2016 Investment
Cognitive Health and Performance	Characterization of Psychological Resilience and Readiness: Cross-Validation of Cognitive and Behavioral Metrics During Acute Military Operational Stress	University of Pittsburgh	\$2,243,842
Diagnosis and Treatment of PTSD	Adaptive Disclosure: A Combat-Specific PTSD Treatment	Boston VA Research Institute	\$499,732
Diagnosis and Treatment of PTSD	Brief Treatment for PTSD: Enhancing Treatment Engagement and Retention	Boston VA Research Institute	\$184,903
Diagnosis and Treatment of PTSD	Improving Voluntary Engagement for PTSD Treatment among Soldiers	University of Washington	\$2,648,171
Diagnosis and Treatment of PTSD	Massed Cognitive Processing Therapy for Combat-Related PTSD	Boston VA Research Institute	\$3,282,395
Diagnosis and Treatment of PTSD	National Institutes of Health/Department of Veterans Affairs/DoD Collaboration on Analysis of Combined Data Sets	National Institutes of Health	\$1,875,648
Diagnosis and Treatment of PTSD	Nicotine to Reduce the Psychological Impact of Stress	McLean Hospital	\$511,915
Diagnosis and Treatment of PTSD	Systems Biology	US Army Center for Environmental Health Research	\$1,870,256
Diagnosis and Treatment of PTSD	Validating Biomarkers for PTSD	New York University School of Medicine	\$350,000
Diagnosis and Treatment of PTSD	Variable-Length Cognitive Processing Therapy for Combat-Related PTSD	University of Texas Health Science Center	\$814,367
Diagnosis and Treatment of PTSD	Dissemination and Implementation Science to Optimize Select Evidence-Based Post Traumatic Stress Disorder Treatment	Palo Alto Veterans Institute for Research	\$8,265,060
Early Assessment and Interventions to Support Service Member Psychological Health	Sex Differences in the Ability to Predict and Treat Opiate Abuse	McLean Hospital	\$732,587
Military, Family, and Community Psychological Health and Resilience	Evaluation of a Work-Family and Sleep Leadership Intervention in the Oregon National Guard: A Behavioral Health Leadership Approach	Oregon Health & Science University	\$793,983

JPC-5 Research Area	Title	Organization(s)	FY 2016 Investment
Military, Family, and Community Psychological Health and Resilience	Interventions for Parent Caregivers of Injured Military/Veterans Personnel	Memphis VA Medical Center	\$1,258,621
Military, Family, and Community Psychological Health and Resilience	Understanding the Impact of Having a Military Father on Adolescent Children	King's College, London	\$185,104
Operational Exposure Standards for Cumulative mTBI	Development of a Predictive Multiscale Traumatic Brain Injury Model	Office of Naval Research	\$2,390,000
Operational Exposure Standards for Cumulative mTBI	Environmental Sensors in Training Blast Gauge Data Collection and Analysis	Applied Research Associates	\$95,429
Operational Exposure Standards for Cumulative mTBI	Human Head Impact Dose Concussion Risk Functions and Sensor Based Military Specific Environmental Monitoring System	Cleveland Clinic Foundation	\$2,886,201
Operational Exposure Standards for Cumulative mTBI	Prediction Algorithm Software Application for mTBI	L-3 Applied Technologies, Inc.	\$679,192
Suicide Prevention and Reduction	Military Suicide Research Consortium	Florida State University  Denver Research Institute, Inc.	\$9,820,808
Suicide Prevention and Reduction	Peer-Led Suicide Prevention: Promoting Healthy Family Role Transitions for Military Personnel	University of Rochester	\$15,097
Suicide Prevention and Reduction	Study to Assess Risk and Resilience in Service members (STARRS) Longitudinal Study (LS) Program-Focused Analysis Support Project	Office of the Deputy Under Secretary of the Army US Army Public Health Center	\$850,000

#### B. JPC-6/CCCRP

The JPC-6/CCCRP neurotrauma portfolio is focused on closing military relevant gaps across a broad range of research areas to improve the acute diagnosis, management, and treatment of TBI and related neurotrauma from point-of-injury through transport and hospitalization. Table 2 provides a summary of the JPC-6/CCCRP FY 2016 DHP TBI/PH CSI investments.

Table 2. JPC-6/CCCRP FY 2016 DHP TBI/PH CSI Investments

JPC-6 Research Area	Title	Organization(s)	FY 2016 Investment
Neurotrauma, Neuroprotection, and Neurodiagnostics	A Novel Advanced Resuscitation Fluid for Traumatic Brain Injury with Hemorrhagic Shock	University of New Mexico Health Sciences Center	\$1,416,397
Neurotrauma, Neuroprotection, and Neurodiagnostics	Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database	National Intrepid Center of Excellence	\$208,000

JPC-6 Research Area	Title	Organization(s)	FY 2016 Investment
Neurotrauma, Neuroprotection, and Neurodiagnostics	Digitization and Analysis of Non-Contact Inertial Loadings Related to Neurological Injury within the Biodynamics Data Resource	US Army Aeromedical Research Laboratory	\$2,000,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	Clinical Implications of Pharmacologic Alterations of Thrombosis Following Moderate-to-Severe and Penetrating Traumatic Brain Injury	Henry M. Jackson Foundation	\$632,413
Neurotrauma, Neuroprotection, and Neurodiagnostics	Development and Validation of Spreading Depolarization Monitoring for TBI Management	University of Cincinnati	\$1,614,993
Neurotrauma, Neuroprotection, and Neurodiagnostics	Dose Optimization of Valproic Acid in a Swine Model of Traumatic Brain Injury, Hemorrhage, and Polytrauma, with the Initiation of a Clinical Trial	University of Michigan	\$2,831,873
Neurotrauma, Neuroprotection, and Neurodiagnostics	Federal Interagency Traumatic Brain Injury Research (FITBIR) Operation and Management Costs	National Institute of Neurological Disorders and Stroke	\$3,277,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	FITBIR Repository and Advanced Analytics Development	National Institute of Neurological Disorders and Stroke	\$1,000,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	Functional and Structural Changes in Cerebral Vasculature Following Exposure to Blast Overpressures Associated with TBI in Military Personnel	Naval Medical Research Center	\$1,359,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	Hypothermia for Patients Requiring Evacuation of Subdural Hematoma: Effects on Spreading Depolarization	University of Cincinnati	\$822
Neurotrauma, Neuroprotection, and Neurodiagnostics	Increasing Survival Rate Following Hemorrhagic Shock and Traumatic Brain Injury in Austere Environments	The Mind Research Network	\$2,395,040
Neurotrauma, Neuroprotection, and Neurodiagnostics	Isobolic Combination Drug Therapy Development for TBI	Walter Reed Army Institute of Research	\$56,270
Neurotrauma, Neuroprotection, and Neurodiagnostics	Mitochondria-Focused Diagnostic and Treatment Strategies for Combined Blast Traumatic Brain Injury and Hemorrhagic Shock in Rats	Uniformed Services University of the Health Sciences	\$250,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	Non-Invasive Neuroassessment Device Assessment	Uniformed Services University of the Health Sciences	\$1,677,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	Oculomotor Assessment of TBI	National Intrepid Center of Excellence	\$163,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	Pharmacotherapy of Traumatic Brain Injury Accompanied by Hemorrhagic Shock	University of Oklahoma Health Sciences Center	\$1,471,461
Neurotrauma, Neuroprotection, and Neurodiagnostics	Point of Injury Device to Assess/Monitor/Maintain Stability of Severe TBI Casualties During Prolonged Field Care	Neural Analytics, Inc. InfraScan, Inc.	\$9,406,510

JPC-6 Research Area	Title	Organization(s)	FY 2016 Investment
Neurotrauma, Neuroprotection, and Neurodiagnostics	Relationship Between TBI Management and Short- and Long-Term Outcomes	US Army Institute of Surgical Research Joint Trauma Registry	\$771,123
Neurotrauma, Neuroprotection, and Neurodiagnostics	Severe TBI Triage and Monitoring with Advanced Cerebral Hemodynamics	Neural Analytics, Inc.	\$1,482,841
Neurotrauma, Neuroprotection, and Neurodiagnostics	Sustained V1A Receptor Activation for Prolonged Hemodynamic Support and Neurological Protection After Noncompressible Hemorrhage and Traumatic Brain Injury	Rosalind Franklin University of Medicine and Science	\$1,991,466
Neurotrauma, Neuroprotection, and Neurodiagnostics	TBI Endpoints Development	University of California, San Francisco	\$4,109,805
Neurotrauma, Neuroprotection, and Neurodiagnostics	Team Approach to the Prevention and Treatment of Post-Traumatic Epilepsy	CURE (Citizens United for Research in Epilepsy)	\$850,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	The Effect of Head Impacts on Cerebral Vascular and Autonomic Function	US Army Institute of Surgical Research	\$310,503
Neurotrauma, Neuroprotection, and Neurodiagnostics	Uncovering Latent Deficiencies Due to mTBI by Using Normobaric Hypoxic Stress	National Intrepid Center of Excellence US Army Aeromedical Research Laboratory	\$724,623
Neurotrauma, Neuroprotection, and Neurodiagnostics	Tau Prion Therapeutics for Chronic Traumatic Encephalopathy	Uniformed Services University of the Health Sciences University of California, San Francisco	\$10,000,00 0
Neurotrauma, Neuroprotection, and Neurodiagnostics	Protocol to Expand Access to Brain Specimens	Uniformed Services University of the Health Sciences	\$3,180,000
Neurotrauma, Neuroprotection, and Neurodiagnostics	TBI Consensus Conference	Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury	\$1,935,000

#### C. JPC-8/CRMRP

The JPC-8/CRMRP seeks to implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return the Service member to duty and restore their quality of life. With FY 2016 DHP TBI/PH CSI funds, the JPC-8/CRMRP invested in research addressing complex TBI rehabilitation within the following areas: (1) Neuromusculoskeletal Injury Rehabilitation; (2) Pain Management; and (3) Sensory Systems Traumatic Injury (see Table 3).

Table 3. JPC-8/CRMRP FY 2016 DHP TBI/PH CSI Investments

JPC-8 Research Area	Title	Organization(s)	FY 2016 Investmen t
Neuromusculoskeletal Injury Rehabilitation	Portable Warrior Test Of Tactical Agility: POWAR-TOTAL	Womack Army Medical Center	\$947,233
Pain Management	Neuromodulatory Treatments for Pain Management in Complex TBI Using Mobile Technology	Duke University	\$2,598,606
Pain Management	Photosensitivity and Pain in Complex Traumatic Brain Injury	Oregon Health and Science University	\$2,221,422
Sensory Systems Traumatic Injury	Factors Associated With Outcomes in Patients with Vestibular Symptoms Related to Traumatic Brain Injury	Mountain Home VA Medical Center, Tennessee	\$1,499,715
Sensory Systems Traumatic Injury	High-Definition Transcranial Direct Current Stimulation for Sensory Deficits in Complex Traumatic Brain Injury	University of New Mexico Health Sciences Center	\$3,065,451
Sensory Systems Traumatic Injury	Quantitative Evaluation of Visual and Auditory Dysfunction and Multi-Sensory Integration in Complex TBI Patients	Vanderbilt University Medical Center	\$1,832,899
Sensory Systems Traumatic Injury	Randomized Controlled Trial of Closed-Loop Allostatic Neurotechnology to Improve Sensory Function and Pain Management After Traumatic Brain Injury	Uniformed Services University of the Health Sciences	\$2,833,185
Sensory Systems Traumatic Injury	Sensory Integration Balance Deficits in Complex mTBI: Can Early Initiation of Rehabilitation with Wearable Sensor Technology Improve Outcomes?	Oregon Health and Science University	\$4,652,124

# IV. NATIONAL RESEARCH ACTION PLAN FOR IMPROVING ACCESS TO MENTAL HEALTH SERVICES FOR VETERANS, SERVICE MEMBERS, AND MILITARY FAMILIES

On August 31, 2012, former President Obama issued an EO titled "Improving Access to Mental Health Services for Veterans, Service Members, and Military Families," which directed the DoD, Department of Veterans Affairs (VA), Department of Health and Human Services (HHS), and Department of Education (ED), in coordination with the Office of Science and Technology Policy, to establish a National Research Action Plan (NRAP) to improve the coordination of agency research into PTSD, other mental health conditions, and TBI and reduce the number of affected men and women through better prevention, diagnosis, and treatment. To attain these goals, the EO urged research agencies to improve data sharing and harness new tools and technologies.

In response, the DoD, VA, HHS, and ED published the NRAP in August 2013, outlining coordinated research efforts to accelerate discovery of the causes and mechanisms underlying PTSD, TBI, and other co-occurring conditions like suicide, depression, and substance abuse disorders. The NRAP describes research to rapidly translate and implement what is learned into new effective prevention strategies and clinical innovations; biomarkers to detect disorders early and accurately; and efficacious and safe treatments to improve function and quality of life and to promote community participation and reintegration. In addition, the NRAP describes research to accelerate the implementation of proven means of preventing and treating these devastating conditions. A joint DoD/VA/HHS Review and Analysis meeting was conducted for PH (PTSD, Suicide Prevention, and Substance Abuse Prevention) and TBI research portfolios on July 17-18, 2017.

To address the objectives outlined in the NRAP, the National Institutes of Health (NIH), VA, and DoD have ongoing and new joint initiatives. Some examples of collaborations include the following:

- The NIH-DoD-VA Pain Management Collaboratory Program leverages research between DoD, NIH, and VA to conduct efficient, large-scale pragmatic clinical trials on non-pharmacological approaches to pain management and other co-morbid conditions in military personnel, Veterans, and their families. Primary outcomes of treatment interventions include assessing pain and pain reduction, ability to function in daily life, quality of life, and medication usage/reduction/discontinuation. Secondary outcomes include assessing impact on comorbid conditions (e.g., PTSD, depression, substance abuse) and enhancing resilience. A total of 11 projects (four DoD projects, six NIH projects, and one VA project) have been selected for funding. Performance progress, including meeting of regulatory milestones and enrollment goals, will be monitored regularly through submitted reports, and managed through tools such as in-progress reviews and site visits where appropriate.
- The DoD is continuing to upload DoD-funded research information to Federal RePORTER to enable transparent flow of information with the public and across federal funding agencies. This enhanced visibility mitigates unnecessary redundancy. The DoD is participating in the National Institute of Mental Health-sponsored Psychiatric Genomics Consortium for PTSD. This collaboration, of unprecedented size and scope within the field of traumatic stress, is expected to identify genetic associations and new insights into the biological underpinnings of PTSD. Recently, this group published the largest Genome-Wide Association Study of PTSD, based upon 20,070 subjects.
- The VA/DoD Third Edition PTSD Clinical Practice Guideline (CPG) for Treatment of PTSD was published in June of 2017. The CPG offers clear and comprehensive evidence-based treatment recommendations for practitioners throughout the DoD and VA health care systems.
- Development of a PTSD Brain Bank, which includes brains from PTSD and Major Depressive Disorder patients and healthy control subjects, continues and currently has

- over 120 brain hemispheres in its collection. Researchers can access this resource through a publically available research application and review process.
- The Consortium to Alleviate PTSD (CAP) is now fully implemented with 10 studies underway. The CAP is a jointly funded VA/DoD initiative, with research projects focused exclusively upon active duty military and Veteran populations.
- Research findings from both VA and DoD researchers have concluded that delivery of
  psychological health care for PTSD via telehealth is equivalent to in-person treatment, a
  finding that should substantially increase access to care.
- The DoD is collaborating with the VA on the Naval Health Research Center (NHRC) Millennium Cohort Study (MCS). Two VA investigators work with the MCS team at the NHRC, and the MCS is working collaboratively with the VA Million Veteran Program (MVP) to assist with referral of MCS participants.
- FY 2016 TBI/PH CSI funding supported the DoD Military Suicide Research Consortium (MSRC), which is co-led by investigators at the VA Rocky Mountain Mental Illness Research Education Clinical Center for Suicide Prevention (VISN 19). The MSRC focus is on conducting research to deliver evidence-based tools and interventions for suicide prevention that are effective for the military population.
- The Targeted Evaluation, Action, and Monitoring of Traumatic Brain Injury (TEAM-TBI) is a collaboration between the DoD, National Intrepid Center of Excellence, Naval Medical Center San Diego, and the University of Pittsburgh. TEAM-TBI brings together TBI patients, advanced evaluation methods, and world class experts in a monitored, multiple interventional trial design to address the heterogeneity of TBI and identify evidence-based treatment protocols.
- The TBI Endpoints Development (TED) is a DoD-led initiative with over 20 universities and hospitals to establish a collaborative, multidisciplinary team to advance the identification and validation of clinical outcome assessments (COAs) and biomarkers for use as potential Food and Drug Administration-qualified drug development tools, and initiate development of Clinical Data Interchange Standards Consortium data standards for clinical trials involving diagnosis and treatment of mild to moderate TBI and to validate candidate COAs and biomarkers.
- The DoD and NIH are collaboratively funding the Transforming Research and Clinical Knowledge in TBI (TRACK-TBI) effort to determine and validate new diagnostic brain imaging modalities, establish clinically-relevant TBI biomarkers, and refine TBI outcome assessments to improve clinical trial design. To date, over 3,000 patients have been enrolled in this study. The TED initiative and TRACK-TBI work together to share data and findings.

#### V. CONCLUSION

The DoD is committed to continued research in TBI and PH to assist Service members and their families.