

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

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

JAN 3 1 2017

Dear Mr. Chairman:

The enclosed report is in response to Senate Report 113–211, page 252, which accompanies H.R. 4870, the Department of Defense Appropriations Bill, 2015, requesting a report on expenditure and obligation data of the additional funding added by Congress for psychological health (PH) and traumatic brain injuries (TBIs), including information on agreements made with other government agencies.

The Fiscal Year 2015 Defense Health Program TBI/PH Congressional Special Interest funds were invested in research areas to develop effective countermeasures against stressors to maximize the health, performance, and well-being of the warfighter throughout the deployment cycle. Efforts 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 neuro-trauma from point-of-injury through transport and hospitalization. The Department also is investing in research areas to implement long-term strategies to develop knowledge and material products to reconstruct, rehabilitate, and provide definitive care for injured Service members.

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,

A. M. Kurta

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

Enclosure: As stated

cc:

The Honorable Richard J. Durbin Vice Chairman



OFFICE OF THE UNDER SECRETARY OF DEFENSE

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

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cc:

The Honorable Jack Reed Ranking Member



OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

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

JAN 3 1 2017

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Enclosure: As stated

cc:

The Honorable Adam Smith Ranking Member

PERSONNEL AND READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

JAN 3 1 2017

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

Dear Madam Chairwoman:

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

Enclosure: As stated

cc:

The Honorable Peter J. Visclosky Ranking Member

REPORT IN RESPONSE TO SENATE REPORT 113-211, PAGE 252, ACCOMPANYING H.R. 4870, DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 2015

"TRAUMATIC BRAIN INJURY [TBI]/PSYCHOLOGICAL HEALTH [PH]"



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

SUPPORTED BY THE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

The estimated cost of this report or study for the Department of Defense is approximately \$1,940 in Fiscal Years 2015 - 2016. This includes \$1,500 in expenses and \$450 in DoD labor.

Generated on 2016Oct14 RefID: 9-32CD006

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I. PURPOSE

This report is in response to the Senate Report 113-211, page 252, accompanying H.R. 4870, Department of Defense Appropriations Act, 2015, which requests 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.

To address the requirement to include information on agreements made with other government agencies, this report includes information on collaborative efforts in support of the National Research Action Plan (NRAP) for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families. The National Research Action Plan was developed 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.

II. BACKGROUND

Although TBI has been described as the signature injury of the Iraq and Afghanistan wars, its relationship with PH issues and long-term health consequences are largely unknown. The Department of Defense (DoD) currently supports research projects that are relevant to prevention, detection, diagnosis, treatment, and rehabilitation of TBI and PH issues, aiming to develop improved preventative and management strategies for both military and civilian populations.

As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), the Defense Health Agency (DHA) J9, Research and Development Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) provides execution management support for the DHP RDT&E TBI/PH Congressional Special Interest (CSI) funds 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. FY15 DHP TBI/PH CSI EXPENDITURES

After deducting research management support costs, the total FY15 DHP TBI/PH CSI available for research is \$117,668,870.

A. JPC-5/MOMRP

The JPC-5/MOMRP seeks to develop effective countermeasures against stressors to maximize the health, performance, and well-being of the Warfighter throughout the deployment cycle. 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 FY15 DHP TBI/PH CSI funds, the JPC-5/MOMRP invested in research in the following areas: (1) Diagnosis and Treatment of PTSD; (2) Military, Family, and Community Psychological Health and Resilience; (3) Early Assessment & Interventions to Support Service Member Psychological Health; (4) Suicide Prevention and Reduction; (5) Occupational Exposure Standards for Cumulative Mild Traumatic Brain Injury (mTBI); and (6) Military Operational Computational Modeling (see Table 1).

Table 1. JPC-5/MOMRP FY15 DHP TBI/PH CSI Investments

JPC-5 Research Area	Title	Organization	FY15 Investment
Diagnosis and Treatment of PTSD	A POC Clinical Trial for PTSD with a First-in-Class Vasopressin 1a Receptor Antagonist	Azevan Pharmaceuticals, Inc.	\$577,905
Diagnosis and Treatment of PTSD	Cannabinoid Induced Upregulation of Neurosteroid Levels Improves Fear Responses	University of Illinois, Chicago	\$945,211
Diagnosis and Treatment of PTSD	Effects of Dose-Dependent Sleep Disruption on Fear Responses and Reward Processing	University of Pittsburgh	\$374,456
Diagnosis and Treatment of PTSD	In-Home Exposure Therapy for Veterans with PTSD	VA Medical Center, San Diego	\$301,258
Diagnosis and Treatment of PTSD	Intranasal Neuropeptide Y for PTSD and Other Stress Triggered Neuropsychiatric Disorders	New York Medical College	\$1,250,000
Diagnosis and Treatment of PTSD	Novel Ryanodine Receptor Calcium Release Stabilizer Compounds for the Treatment of PTSD	ARMGO Pharma, Inc.	\$415,121
Diagnosis and Treatment of PTSD	Pilot Trial of Inpatient Cognitive Therapy for the Prevention of Suicide in Military Personnel with Acute Stress Disorder or Post Traumatic Stress	Uniformed Services University of the Health Sciences	\$221,741
Diagnosis and Treatment of PTSD	Randomized Controlled Trial of Sertraline, Prolonged Exposure Therapy and Their Combination in OEF/OIF with PTSD	VA Medical Center, Ann Arbor, Michigan	\$403,802

JPC-5 Research Area	Title	Organization	FY15 Investment
Diagnosis and Treatment of PTSD	RNA Expression in PTSD in Induced Human Neurons and Blood Cells in Basal and Glucocorticoid-Stimulated Conditions	Icahn School of Medicine at Mount Sinai	\$3,363,124
Early Assessment & Interventions to Support Service Member Psychological Health	Preventing Risky Drinking in Veterans Treated with Prescription Opioids	University of Pennsylvania	\$116,978
Early Assessment & Interventions to Support Service Member Psychological Health	Emotional Brain Fitness via Limbic Targeted Neurofeedback	Tel Aviv University	\$ 1,159,139
Military Operational Computational Modeling	Experimental and Computational Studies of Blast and Blunt Traumatic Brain Injury	Biotechnology High Performance Computing Software Applications Institute	\$200,000
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	\$2,750,523
Military, Family, and Community Psychological Health and Resilience	SMART Optimization of a Parenting Program for Active- Duty Families	University of Minnesota, Twin Cities	\$4,304,180
Military, Family, and Community Psychological Health and Resilience	The Impact of Service Member Death on Military Families: A National Study of Bereavement	Uniformed Services University of the Health Sciences	\$1,500,000
Military, Family, and Community Psychological Health and Resilience	Valuation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Military Primary Care	Wright State University	\$878,979
Operational Exposure Standards for Cumulative mTBI	Digitization and Analysis on Non- Contact Inertial Loadings Related to Neurological Injury Within the Biodynamics Data Resource	US Army Aeromedical Research Laboratory	\$631,598
Suicide Prevention and Reduction	Improving Universal Suicide Prevention Screening in Primary Care by Reducing False Negatives	University of Utah	\$366,346
Suicide Prevention and Reduction	Military Suicide Research Consortium	Denver Research Institute Florida State University	\$19,993,468
Suicide Prevention and Reduction	Study to Examine Psychological Process in Suicidal Ideation and Behavior	University of Stirling, UK	\$444,877

JPC-5 Research Area	Title	Organization	FY15 Investment
Suicide Prevention and Reduction	The Study to Assess Risk and Resilience in Servicemembers (Army STARRS)	Office of the Deputy Under Secretary of the Army US Army Public Health Center (Provisional)	\$1,029,000

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 FY15 DHP TBI/PH CSI investments.

Table 2. JPC-6/CCCRP FY15 DHP TBI/PH CSI Investments

JPC-6 Research Area	Title	Organization	FY15 Investment
TBI Neurotrauma and Brain Dysfunction	A Comparative Evaluation of Blood Biomarkers and Automated QEEG from Concussed and Non- Concussed Cohorts in a Combat Zone Protocol M-10216	Walter Reed Army Institute of Research	\$436,149
TBI Neurotrauma and Brain Dysfunction	Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database	National Intrepid Center of Excellence	\$1,795,000
TBI Neurotrauma and Brain Dysfunction	Advanced Longitudinal Diffusion Imaging for TBI Diagnosis of Military Personnel	University of Pittsburgh Naval Health Research Center	\$805,000
TBI Neurotrauma and Brain Dysfunction	Banyan/Philips TBI Assay	US Army Medical Materiel Development Activity Banyan Biomarkers, Inc. Philips Healthcare Naval Health Research Center	\$8,683,595
TBI Neurotrauma and Brain Dysfunction	Biostatistician III Support	US Army Institute of Surgical Research	\$149,141
TBI Neurotrauma and Brain Dysfunction	Brain Trauma Evidence-based Consortium	Stanford University Naval Health Research Center	\$4,338,000
TBI Neurotrauma and Brain Dysfunction	Development and Validation of Spreading Depolarization Monitoring for TBI Management	University of Cincinnati	\$1,196,130
TBI Neurotrauma and Brain Dysfunction	Evaluation of Clinically Relevant Prognostic Indicators in a Model of Mild TBI/Concussion	Geneva Foundation	\$793,729

JPC-6 Research Area	Title	Organization	FY15 Investment
TBI Neurotrauma and Brain Dysfunction	Evaluation of Defense and Veterans Brain Injury Center (DVBIC) Clinical Recommendation for Management of Headache Following Concussion	Uniformed Services University of the Health Sciences	\$717,000
TBI Neurotrauma and Brain Dysfunction	EYE-SYNC Clinical Validation	Brain Trauma Foundation Naval Health Research Center	\$1,357,000
TBI Neurotrauma and Brain Dysfunction	Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System Legacy Clinical Data from the Mission Connect Mild TBI Translational Research Consortium	University of Texas Health Science Center	\$380,968
TBI Neurotrauma and Brain Dysfunction	FITBIR Repository and Advanced Analytics Development	National Institute of Neurological Disorders and Stroke	\$3,768,000
TBI Neurotrauma and Brain Dysfunction	Focused Task Area Integrated Blast Functional and Structural Changes in Cerebral Vasculature Following Exposure to Blast Overpressures Associated with TBI in Military Personnel	Naval Medical Research Center	\$1,500,000
TBI Neurotrauma and Brain Dysfunction	Focused Task Area Integrated NeuroAssessment	Uniformed Services University of the Health Sciences Naval Medical Research Center	\$1,820,000
TBI Neurotrauma and Brain Dysfunction	HOPES Hypothermia for Patients Requiring Evacuation of Subdural Hematoma: Effect of Spreading Depolarization	University of Cincinnati	\$998,178
TBI Neurotrauma and Brain Dysfunction	Linking Investment in Trauma Emergency Services (LITES) – Multicenter Clinical Research Network Capability	University of Pittsburgh	\$2,029,600
TBI Neurotrauma and Brain Dysfunction	National Collegiate Athletic Association (NCAA)-DoD Grand Alliance – Intramural Service Academy Portion	Uniformed Services University of the Health Sciences National Intrepid Center of Excellence	\$1,623,000
TBI Neurotrauma and Brain Dysfunction	Portable Neuromodulation Stimulator (PONS) – University of Wisconsin Independent Government Cost Estimate (IGCE) Support	US Army Medical Materiel Agency	\$391,707

JPC-6 Research Area	Title	Organization	FY15 Investment
TBI Neurotrauma and Brain Dysfunction	Preclinical Evaluation of FDA- Approved Human Neural Stem Cell Engraftment in a Rat Model of Severe Traumatic Brain Injury	University of Miami	\$3,398,263
TBI Neurotrauma and Brain Dysfunction	Preclinical Evaluation of the Effects of Aeromedical Evacuation on Military-Relevant Casualties	Uniformed Services University of the Health Sciences	\$2,674,000
TBI Neurotrauma and Brain Dysfunction	Ultra-High Performance MRI System for Microstructure & Functional Assessment of TBI	General Electric	\$1,788,784
TBI Neurotrauma and Brain Dysfunction	Tau Prion Therapeutics for Chronic Traumatic Encephalopathy	Uniformed Services University of the Health Sciences University of California, San Francisco	\$10,000,000
TBI Neurotrauma and Brain Dysfunction	Team Approach to the Prevention and Treatment of Post-Traumatic Epilepsy	CURE (Citizens United for Research in Epilepsy)	\$5,500,000

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 FY15 DHP TBI/PH CSI funds, the JPC-8/CRMRP invested in research addressing TBI within the following areas: (1) Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus; (2) Pain Management; (3) Cognitive Rehabilitation; and (4) Vision Dysfunction (see Table 3).

Table 3. JPC-8/CRMRP FY15 DHP TBI/PH CSI Investments

JPC-8 Research Area	Title	Organization	FY15 Investment
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Assessment and Rehabilitation of Blast-Related Auditory Processing Disorders	Walter Reed National Military Medical Center	\$1,263,289
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Central Mechanisms and Treatment of Blast-Induced Auditory and Vestibular Injuries	Walter Reed Army Institute of Research	\$1,484,907
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Chronopharmacological Interventions for the Successful Treatment of Noise-Induced Hearing Loss	Karolinska Institutet, Sweden	\$1,499,582

JPC-8 Research Area	Title	Organization	FY15 Investment
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Diagnosing Contributions of Sensory and Cognitive Deficits to Hearing Dysfunction in Blast- Exposed/TBI Service Members	Walter Reed National Military Medical Center	\$6,000
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Effectiveness of a Vestibular Ocular Motor Screening (VOMS) Tool for Identifying mTBI and Tracking Recovery in Military Personnel	University of Pittsburgh	\$1,354,046
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Patterns of Tinnitus and Hearing Loss Secondary to Blast Injury	Veterans Medical Research Foundation of San Diego	\$1,499,323
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	The Quantification of Visual Function and Postural Stability Under Single-and Dual-Task Conditions Using Mobile Technology	Cleveland Clinic Foundation	\$1,499,987
Hearing Loss/Dysfunction, Balance Disorders, and/or Tinnitus	Effects of Blast Exposure on the Auditory Systems of Deployed Navy and Marine Corps Personnel	Naval Health Research Center	\$967,000
Pain Management	Antilysophosphatidic Acid Antibodies in the Treatment of Post-TBI Neuropathic Pain	LPath Therapeutics, Inc.	\$1,446,655
Pain Management	Development of Novel Local Analgesics for Management of Acute Tissue Injury Pain	Children's Hospital, Boston	\$258,101
Pain Management	Utility of Magnetic Resonance Spectroscopy (MRS) Brain Biomarkers of Pain Phenotypes after TBI	University of Miami, Coral Gables	\$1,499,841
Cognitive Rehabilitation	Development, Reliability, and Equivalence of an Alternative Form of the Charge of Quarters Duty Performance-Based Measure	Allina Health	\$247,961
Vision Dysfunction	Active Confocal Imaging System for Visual Prostheses	Schepens Eye Research Institute	\$2,999,953
Vision Dysfunction	CB2 Receptor Therapy Using the FDA-Approved Drug Raloxifene to Mitigate Visual Deficits after Mild TBI and/or Ocular Trauma	University of Tennessee, Health Science Center	\$1,346,882
Vision Dysfunction	Molecular Control of Optic Nerve Regeneration	Children's Hospital, Boston	\$1,500,000

JPC-8 Research Area	Title	Organization	FY15 Investment
Vision Dysfunction	Preventing and Repairing Combat- Related Proliferative Vitreoretinopathy: Using 3D Engineered Eye Tissue Derived from Human-Induced Pluripotent Stem Cells	National Eye Institute US Army Institute of Surgical Research	\$1,424,393

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

On August 31, 2012, 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, 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 the Department of Education 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 outcomes 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.

To address the objectives outlined in the NRAP, the VA and DoD jointly funded two consortia: (1) the Consortium to Alleviate PTSD (CAP), and (2) the Chronic Effects of Neurotrauma Consortium (CENC). The CAP seeks to improve the psychological and physical health and well-being of Operations Enduring Freedom, Iraqi Freedom, and New Dawn Service members and Veterans by developing and evaluating the most effective preventive, diagnostic, prognostic, treatment, and rehabilitative strategies for combat-related PTSD and co-morbid conditions. The CENC is dedicated to establishing a comprehensive understanding of the chronic sequelae associated with neurotrauma, primarily focused on mTBI. To do so, the objectives of the CENC are to (1) establish the association of the chronic effects of mTBI and common co-morbidities; (2) determine whether there is a causative effect of chronic mTBI on neurodegenerative disease and other co-morbidities; (3) identify diagnostic and prognostic indicators of degenerative disease and other co-morbidities associated with mTBI; and (4) develop and advance methods to treat and rehabilitate chronic neurodegenerative disease and co-morbid effects of mTBI.

In addition to the above, some specific examples of other ongoing collaborations include the following:

- The DoD is participating in the National Institutes of Health (NIH)/National Institute of Mental Health (NIMH)-led National Action Alliance for Suicide Prevention portfolio analysis of federal and non-federal funding agencies and organizations. The joint NIH/DoD Funding Opportunity Announcement (FOA), "Prevention and Health Promotion Interventions to Prevent Alcohol and Other Drug Abuse and Associated Physical and Psychological Health Problems in U.S. Military Personnel, Veterans and their Families," has funded 11 projects (4 DoD projects and 7 NIH projects [3 National Institute on Drug Abuse, 2 National Institute on Alcohol Abuse and Alcoholism, 2 National Center for Complementary and Alternative Medicine]). Applications to the FOA are jointly reviewed through annual In Progress Reviews hosted by the DoD.
- The DoD is in the process of uploading current and past DoD-funded research information to Federal RePORTER to enable transparent flow of information with the public and across federal funding agencies. This enhanced visibility will mitigate duplicative efforts.
- 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.
- The DoD, VA, and NIH are collaborating to establish a preliminary set of recommendations of high-quality measures for common data elements (CDEs) for research data reporting.
 - The agencies met in June 2016 and identified several research projects and consortia that meet the criteria for CDE and data sharing plans, including the following:
 - Longitudinal Assessment of Posttraumatic Syndromes (U01MH110925)
 - CAP (W81XWH-13-2-0065)
 - Zero Suicide Implementation and Evaluation in Mental Health Clinics (R01MH112139)
 - Acute Neurocognitive-affective Predictors of Chronic Post-trauma Outcomes (R01MH10574)
 - The Military Suicide Research Consortium (MSRC) 1 and MSRC 2 (W81XWH-10-2-0178; W81XWH-10-2-0181)
 - o The MSRC implemented CDEs with the first round of MSRC studies that were funded and have continued their use into the second funding period (MSRC 2). To date, the MSRC has uploaded data from over 5,000 participants and more data will be uploaded as the remaining MSRC 1 studies wrap up within the next year.