

4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

JAN 2 9 2016

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

Dear Mr. Chairman:

The enclosed final report responds to Senate Report 113-85, page 189, accompanying S. 1429, the Department of Defense Appropriations Bill, 2014, 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 \$60 million (M) in funding added by Congress above the fiscal year 2014 budget request for research into treatment and prevention of traumatic brain injuries (TBI) and improved psychological health (PH), including information on agreements made with other government agencies. Because the additional \$60M was embedded in the TBI/PH medical research appropriation, this report provides information on all TBI/PH medical research funding.

The total fiscal year (FY) 2014 Defense Health Program PH/TBI Congressional Special Interest expenditure is \$119,102,567 (intramural and extramural). Research projects focused on understudied PH research (e.g., military-related grief and guilt), pilot programs under section 704 of the National Defense Authorization Act (NDAA) for FY 2014 (P.L. 113-66) and section 706 of NDAA for FY 2013 (P.L. 112-239), and neurosensory effect of TBI.

In addition, this report addresses Section 5 of the President's August 31, 2012, Executive Order 13625; "Improving Access to Mental Health Services for Veterans, Service Members, and Military Families," which called for the development of a National Research Action Plan to improve coordination among agency efforts working toward improving prevention and treatment of posttraumatic stress disorder, TBI, and related PH issues. This section responds to the Senate report's request for information on agreements made with other government agencies.

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,

Brad Carson

Acting Principal Deputy

Enclosure: As stated

cc:

The Honorable Jack Reed Ranking Member



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

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cc:

The Honorable Adam Smith Ranking Member



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

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Acting Principal Deputy

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cc:

The Honorable Richard J. Durbin Vice Chairman



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JAN 2 9 2016

The Honorable Rodney P. Frelinghuysen Chairman Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

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**Brad Carson** 

Acting Principal Deputy

Enclosure: As stated

cc:

The Honorable Peter J. Visclosky Ranking Member

# REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO SENATE REPORT 113-85, PAGES 189-190, ACCOMPANYING S. 1429, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2014

"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, CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

The estimated cost of this report or study for the Department of Defense is approximately \$4,290 for the 2014 Fiscal Year. This includes \$3,750 in expenses and \$540 in DoD labor.

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	BACKGROUND  FY 2014 DEFENSE HEALTH PROGRAM (DHP) PH/TBI CONGRESSIONAL SPECIAL INTEREST (CSI) EXPENDITURES

#### 1.0 PURPOSE

In January 2014, the Department of Defense (DoD) Appropriations Act, 2014 (Public Law 113-76), with further detail in the House explanatory statement printed on Congressional Record, 113<sup>th</sup> Congress, page H782, appropriated \$125 million (M) for the Peer-Reviewed Traumatic Brain Injury (TBI) and Psychological Health (PH) Research Program.

This report is in response to the Senate Report 113-85, page 189, accompanying S. 1429, the DoD Appropriations Bill, 2014, which request the Assistant Secretary of Defense for Health Affairs to provide a report to the congressional defense committees on expenditure and obligation data of the \$60,000,000 in congressional special interest (CSI) funding added by Congress above the fiscal year (FY) 2014 budget request for research into treatment and prevention of TBIs and improved PH, including information on agreements made with other government agencies.

In addition, this report addresses Section 5 of the President's August 31, 2012, Executive Order (EO); "Improving Access to Mental Health Services for Veterans, Service Members, and Military Families," which called for the development of a National Research Action Plan (NRAP) to improve coordination among agency efforts working toward improving prevention and treatment of posttraumatic stress disorder (PTSD), TBI, and related PH issues.

#### 2.0 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. Toward the goal of developing improved preventive 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.

As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA), the Defense Health Agency, Research, Development and Acquisition (DHA RDA) Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs provides execution management support aligned with specific DHA RDA Directorate research program areas, including the Military Operational Medicine Research Program (MOMRP)/Joint Program Committee (JPC)-5, Combat Casualty Care Research Program/JPC-6, and the Clinical and Rehabilitative Medicine Research Program (CRMRP)/JPC-8.

This report conveys the FY 2014 DHP PH/TBI CSI funding expenditures as well as information on collaborative efforts initiated by the DoD, Department of Veterans Affairs (VA), and Department of Health and Human Services (HHS) in FY 2014.

#### 3.0 FY 2014 DHP PH/TBI CSI EXPENDITURES

The total FY 2014 DHP PH/TBI CSI expenditure is \$119,102,567 (intramural and extramural).

# 3.1 Support for Ongoing Research

Table 1 summarizes the ongoing research efforts that were funded with FY 2014 DHP PH/TBI CSI funds.

Table 1. Ongoing efforts funded with FY 2014 DHP PH/TBI CSI

Alignment	Title	Organization	FY 2014 Funding
JPC-5	Evaluation of the Safety and Efficacy of the Fatty Acid Amide Hydrolase Inhibitor in Patients with PTSD	Uniformed Services University of the Health Sciences (USUHS)	\$1,956,000
JPC-5	Spin, Unit Climate and Aggression, New Term, Long Term and Reciprocal Predictors of Violence among Workers in Military Settings	University of Texas, San Antonio	\$49,110
JPC-5	STRONG STAR Assessment Core Infrastructure	VA Boston Healthcare System	\$250,000
JPC-5	Under Body Blast/Warrior Injury Assessment Manikin Project	Army Research Laboratory/Research, Development and Engineering Command	\$328,000
JPC-5	Changing Family Roles Across the Deployment Cycle	Purdue University	\$631,737
JPC-5	Biomechanical Modeling and Measurement of Blast Injury and Hearing Protection Mechanisms	University of Oklahoma	\$361,531
JPC-5	HomeFront Strong: Building Resiliency in Military Families	University of Michigan	\$959,372
JPC-5	Comparing Web, Group and Telehealth Formats of a Military Parenting Program	University of Minnesota	\$812,030
JPC-5	Intervening to Reduce Suicide Risk in Veterans with Substance Abuse Disorders	University of Michigan	\$3,054,208

Alignment	Title	Organization	FY 2014 Funding
JPC-5	The STRONG STAR  Multidisciplinary PTSD Research  Consortium	Duke University	\$261,645
JPC-5	Military Suicide Research Consortium (MSRC)	Florida State University	\$306,218
JPC-5	Millennium Cohort Study	Naval Health Research Center (NHRC)	\$1,100,000
JPC-5	Occupational Standard Development for Multiple Exposures to Blast	USUHS	\$30,000
JPC-5	The PTSD Practitioner Registry: An Innovative Tracking, Dissemination, and Support Tool for Providers in Military and Nonmilitary Settings	Walter Reed Army Institute of Research (WRAIR)	\$48,462
JPC-5	Biomarkers for PTSD Through Systems Biology	U.S. Army Center for Environmental Health Research Institute of Systems Biology	\$1,383,182
JPC-6	High Definition Fiber Tracking Biological Diagnosis of TBI	University of Pittsburgh	\$3,000,000
JPC-6	Portable Neuromodulation Stimulator, University of Wisconsin IGCE Support	University of Wisconsin	\$500,000
JPC-6	The Major Extremity Trauma Research Consortium	Johns Hopkins University	\$3,926,245
JPC-6	Role of micro RNA in mTBI and PTSD: Identification of Biomarkers and Therapeutic Strategies	USUHS	\$2,274,000
JPC-6	Concussion Definition	Brain Trauma Foundation	\$279,000
JPC-6	Mission Connect Mild TBI Translational Research Consortium	Virginia Polytechnic Institute and State University	\$155,724
JPC-6	Uncovering Latent Deficiencies due to mTBI by Using Normobaric	U.S. Army Aeromedical Research Laboratory	\$521,000
	Hypoxic Stress	National Intrepid Center of Excellence	\$522,000
JPC-6	Enhancing the Detection and Management of mTBI in Military Personnel using the Combat Casualty Care App	Cleveland Clinic	\$70,042

Alignment	Title	Organization	FY 2014 Funding
JPC-6	Analysis of Alternatives	Booz Allen Hamilton	\$250,000
JPC-6	Strategic Planning Support	Booz Allen Hamilton	\$750,000
JPC-6	Eye-Sync Clinical Validation	Brain Trauma Foundation	\$2,530,000
JPC-6	Eyetrac Application Clinical Trial	Brain Trauma Foundation	\$59,000
JPC-6	Protocol to Expand Access to Brain Specimens	USUHS	\$2,217,000
JPC-6	Partnership to Develop Tau Prion Therapeutics for Chronic Traumatic Encephalopathy	University of California, San Francisco USUHS	\$2,800,000

#### 3.2 Support for New Research

Research projects addressing military-relevant TBI and PH issues were solicited via the FY 2014 USAMRMC Broad Agency Announcement (BAA) for Extramural Medical Research and by FY 2014 Program Announcements (PAs) for the MOMRP/JPC-5 and the CRMRP/JPC-8.

# 3.2.1 FY 2014 USAMRMC Broad Agency Announcement for Extramural Medical Research

The FY 2014 USAMRMC BAA for Extramural Medical Research solicited research applications relevant to research areas of interest with the potential to benefit and inform both military and civilian medical practice and knowledge. Extramural investigators and DoD investigators collaborating with extramural organizations were eligible to apply. Applications selected for FY 2014 DHP PH/TBI CSI funding are summarized in Table 2, below.

Table 2. FY 2014 USAMRMC BAA for Extramural Medical Research Funded Applications

Alignment	Title	Organization	FY 2014 Funding
JPC-5	Trauma Brain Triage Tool: Multi- modal Early Detection Interactive Classifier	U.S. Army Research Institute of Environmental Medicine	\$500,000

Alignment	Title	Organization	FY 2014 Funding
JPC-5	Inflammation, Oxidative Stress, and Neuroprotective Mechanism in the Pathophysiology of PTSD in an Animal Model: Blueberries and Exercise as Possible Therapeutic Approaches	Louisiana State University and A&M College	\$225,000
JPC-5	Neurogenic Tremors Training for Stress and PTSD: A Controlled Clinical Trial	Phoenix VA Health Care System	\$494,859
JPC-5	Primary Blast Injury Criteria for Animal/Human TBI Models Using Field Validated Shock Tubes	New Jersey Institute of Technology	\$1,065,032
JPC-5	Demonstrating the Efficacy of Group Prolonged Exposure Treatment of PTSD in OEF/OIF/OND Veterans	New Mexico VA Health Care System	\$1,568,196
JPC-5	A Nonpharmacologic Method for Enhancing Sleep in PTSD	McLean Hospital	\$3,823,700
JPC-5	Internet-Delivery of Prolonged Exposure Therapy for Combat- Related PTSD	University of Pennsylvania	\$333,299
JPC-5	Historical Blast Data Recovery and Knowledge Base	L-3 Applied Technologies	\$4,000,008
JPC-5	Investigating Resilience Training in Military Spouses	University of Miami	\$1,253,905
JPC-5	Prevention of Alcohol Related Incidents in the U.S. Air Force	University of Tennessee Health Science Center	\$3,772,062
JPC-5	A POC Clinical Trial for PTSD with a First-in-Class Vasopressin 1a Receptor Antagonist	Azevan Pharmaceuticals, Inc.	\$1,000,000
JPC-6	Brain Trauma Evidence-Based Consortium	Stanford University/ Brain Trauma Foundation	\$2,610,000
JPC-6	Federal Interagency Traumatic Brain Injury Research (FITBIR) Operation and Management Costs	National Institute of Neurological Disorders and Stroke	\$2,100,000
JPC-5/6	Army-Navy Head Acceleration Data Digitization/Entry into FITBIR	US Army Aeromedical Research Laboratory	\$2,200,000

Alignment	Title	Organization	FY 2014 Funding
JPC-6	LATBI	Banyan/Philips	\$2,356,958
JPC-6	Transforming Research and Clinical Knowledge in TBI Enhancement	University of Pittsburgh	\$2,500,000
JPC-6	NCAA-DoD Grand Alliance	Indiana University Medical School	\$12,847,755
JPC-6	Omega-3 Fatty Acids - A Neutraceutical Currently in Widespread Use by Our Troops, Achieving Proof of Concept for a Safe Product to Prevent TBI in Our Troops	WRAIR	\$804,000
JPC-6	Team Approach to the Prevention and Treatment of Post-Traumatic Epilepsy	Citizens United for Research in Epilepsy	\$2,000,000

#### 3.2.2 FY 2014 Program Announcements

The following sections describe the PAs and awards supported by the FY 2014 DHP PH/TBI CSI funds by research program areas.

#### 3.2.2.1 **MOMRP/JPC-5**

#### a. Psychological Health Research Award

The FY 2014 MOMRP Psychological Health Research Award PA solicited applications addressing one or more of the following specific PH research topic areas that have been historically understudied: (1) military-related grief, guilt, or loss issues, and/or anger, rage or aggression issues; (2) interdisciplinary and comprehensive prevention and life-skills training strategies to improve brain health; (3) military-related psychosocial/psychological health challenges unique to persons of non-traditional sexual orientation [i.e., lesbian, gay, bisexual, and transgender]; and (4) sexual assault and trauma related issues in a military context.

The MOMRP/JPC-5 allotted \$13,239,878 of the FY 2014 DHP PH/TBI CSI appropriation to fund 6 Psychological Health Research Award applications (Table 3).

Table 3. FY 2014 MOMRP Psychological Health Research Award PA Funded Applications

Title	Organization	FY 2014 Funding
	University of Southern California	\$583,259
Improving Acceptance, Integration, and Health Among LGBT Service Members	University of Southern California	\$857,387
	University of Southern California	\$397,533
Effects of Interpersonal Challenges, Social Support, and Transitions on the Mental Health and Readiness of Lesbian, Gay and Bisexual Military Personnel	Claremont Graduate University	\$987,911
Strength at Home Couples Program to Prevent Military Partner Violence	Boston VA Research Institute, Inc. (BVARI)	\$609,933
Sexual Assault Prevention for Men in the Military	Rhode Island Hospital	\$2,686,278
Trauma-Informed Guilt Reduction Intervention	Veterans Medical Research Foundation, San Diego	\$1,989,869
	Brown University	\$935,978
Great-SF (Grief-focused Resilience	Henry M. Jackson Foundation	\$1,679,814
Activities and Training for Surviving Families) An Online Selective Intervention for Bereaved Military Families	Columbia University	\$2,511,916

# b. Investigational Treatments for TBI and PTSD Clinical Trial Award (ITTPCTA)

The FY 2014 PH/TBIRP ITTPCTA PA solicited applications addressing Section 704 of the National Defense Authorization Act (NDAA) for FY 2014, which directs a pilot program and establishment of a process for randomized placebo-controlled clinical trials of investigational treatments (including diagnostic testing) of TBI and PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities.

The OASD(HA) allotted \$4,766,675 of the FY 2014 DHP PH/TBI CSI appropriation to fund two ITTPCTA applications (Table 4).

Table 4. FY 2014 PH/TBI Research Program ITTPCTA PA Funded Applications

Title	Organization	FY 2014 Funding
Brief Treatment for PTSD: Enhancing Treatment Engagement and Retention	BVARI	\$2,269,882
The Efficacy of 90-Minute vs 60-Minute Sessions of Prolonged Exposure for PTSD: A Randomized Control Trial in Active Duty Military Personnel	University of Pennsylvania	\$2,496,793

#### c. Community Partners in Mental Health Research Award (CPMHRA)

The FY 2014 PH/TBIRP CPMHRA PA solicited applications addressing section 706 of the NDAA for FY 2013 by supporting research on the causes, development, and innovative treatment of mental health, substance use disorders, TBI, and suicide prevention in members of the National Guard and Reserves, their family members, and their caregivers.

The OASD(HA) allotted \$4,685,372 of the FY 2014 DHP PH/TBI CSI appropriation to fund two CPMHRA applications (Table 5).

Table 5. FY 2014 PH/TBIRP CPMHRA PA Funded Applications

Title	Organization	FY 2014 Funding
Mental Health Disorders, Suicide Risk, and Treatment Seeking Among Formerly Deployed National Guard and Reserve Service Member Seen in Non-VA Facilities	Geisinger Clinic	\$2,270,953
Technologies for Assessing Behavioral and Cognitive Markers of Suicide Risk	University of Utah	\$2,414,419

#### 3.2.2.2 **CRMRP/JPC-8**

#### a. Neurosensory and Rehabilitation Research Award (NSRRA)

The FY 2014 CRMRP NSRRA PA solicited both applied (preclinical) research and clinical trials addressing TBI within specific focus areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation.

The CRMRP/JPC-8 allotted \$19,715,333 of FY 2014 PH/TBI DHP CSI appropriation to fund 14 NSRRA applications (Table 6).

Table 6. FY 2014 CRMRP NSRRA PA Funded Applications

Title	Organization	FY 2014 Funding
Microglia Contribute to Ongoing Pain Caused by TBI	University of California, Irvine	\$1,498,566
Automated Comprehensive Evaluation of mTBI Visual Dysfunction	Geneva Foundation	\$858,048
Diagnosing Contributions of Sensory and Cognitive Deficits to Hearing Dysfunction in Blast-Exposed/TBI Service Members	Boston University, Charles River Campus	\$1,477,944
Neuromodulation and Neurorehabilitation for Treatment of Functional Deficits after mTBI plus PTSD	Chicago Association for Research and Education in Science	\$2,999,030
Neuroprotective Strategies for the Treatment of Blast-Induced Optic Neuropathy	Vanderbilt University	\$1,500,000
Melanopsin-Specific Contributions to Photophobia in Brain Trauma	University of Pennsylvania	\$1,438,150
Investigation of Notch Signaling during Spontaneous Regeneration of Cochlear Hair Cells	Southern Illinois University School of Medicine	\$1,499,960
Controlling Mitochondrial Dynamics to Mitigate Noise-Induced Hearing Loss	Oregon Health & Science University	\$1,233,279
Assessment and Rehabilitation of Central Sensory Impairments for Balance in mTBI	Oregon Health & Science University	\$1,993,522
Preclinical Validation of Novel Fluorescently Labeled Compounds to Treat Neurodegenerative Hearing Loss	Massachusetts Eye and Ear Infirmary	\$1,500,000
Development of Novel Local Analgesics for Management of Acute Tissue Injury Pain	Children's Hospital, Boston	\$711,000
Vision Restoration with a Collagen Cross- linked Boston Kerato-prosthesis Unit	Massachusetts Eye and Ear Infirmary	\$294
Sensorimotor Assessment and Rehabilitative Apparatus	Johns Hopkins University	\$1,500,000
Automated Assessment of Postural Stability	Temple University	\$1,360,569

#### 4.0 COLLABORATIVE EFFORTS WITH OTHER FEDERAL AGENCIES

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, VA, HHS, and Department of Education, in coordination with the Office of Science and Technology Policy, to establish a 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. In addition, the EO calls for the establishment of a comprehensive longitudinal study of 100,000 Service members focused on PTSD, TBI, and related injuries.

To attain these goals, the EO urged research agencies to improve data sharing and harness new tools and technologies. In the NRAP, the agencies outline coordinated research efforts to accelerate discovery of the causes and mechanisms underlying PTSD, TBI, and other cooccurring outcomes like suicide, depression, and substance abuse disorders. It 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 guidance outlined in the NRAP, the VA and DoD jointly funded two consortiums: (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 comorbid 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-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 collaborating with the NIH to determine the feasibility of using Federal RePORTER to share data with the public and across federal funding agencies on current and past research studies.
- The DoD, VA, and NIH are collaborating to establish a preliminary set of recommendations of high-quality measures for common data elements for research data reporting.
- The DoD is collaborating with the VA on the NHRC Millennium Cohort Study. Two VA investigators work with the MCS team at the NHRC.