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

PERSONNEL AND
READINESS

OCT - 9 2018

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Please find enclosed the Department of Defense's (DoD) fifth annual report submitted in response to section 704 of the National Defense Authorization Act for Fiscal Year 2014 (Public Law 113–66), "Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD)." Section 704 requires the Secretary of Defense to carry out a pilot program to establish a process for randomized, placebo-controlled, clinical trials of investigational treatments of TBI or PTSD. The program must be available for members of the Armed Forces in health care facilities other than military medical treatment facilities.

While DoD is supporting a significant portfolio of research studies for TBI and PTSD, this report describes the details and progress of only two projects responsive to this legislative request following a 2014 program announcement for clinical trials and database development related to TBI and PTSD. After conducting a programmatic review of the proposals submitted in response to the program announcement, two proposals were recommended, with current funding totaling $4.95 million. The two projects encountered slow recruitment and enrollment, but DoD successfully implemented mitigation plans to address this issue. We will submit the next annual update in October 2019, and the final report in October 2020.

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 House Armed Services Committee.

Sincerely,

Stephanie Barna
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
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WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

OCT - 9 2018

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

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While DoD is supporting a significant portfolio of research studies for TBI and PTSD, this report describes the details and progress of only two projects responsive to this legislative request following a 2014 program announcement for clinical trials and database development related to TBI and PTSD. After conducting a programmatic review of the proposals submitted in response to the program announcement, two proposals were recommended, with current funding totaling $4.95 million. The two projects encountered slow recruitment and enrollment, but DoD successfully implemented mitigation plans to address this issue. We will submit the next annual update in October 2019, and the final report in October 2020.

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 Senate Armed Services Committee.

Sincerely,

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

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

REPORT TO THE COMMITTEES ON ARMED SERVICES OF THE SENATE AND HOUSE OF REPRESENTATIVES

The National Defense Authorization Act for Fiscal Year 2014, Section 704, (P.L. 113–66)

Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury and Post-Traumatic Stress Disorder

Fifth Annual Report

The estimated cost of this report or study for the Department of Defense is approximately $660 in Fiscal Years 2014 - 2015. This includes $150 in expenses and $510 in DoD labor.

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Summary:

Section 704 of the National Defense Authorization Act for Fiscal Year (FY) 2014 (Public Law 113–66), Pilot Program on Investigational Treatment of Members of the Armed Forces for Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD), states:

> "*The Secretary of Defense shall carry out a pilot program under which the Secretary shall establish a process for randomized placebo-controlled clinical trials of investigational treatments (including diagnostic testing) of traumatic brain injury or post-traumatic stress disorder received by members of the Armed Forces in health care facilities other than military treatment facilities,"*

and:

> "*The Secretary shall develop and maintain a database containing data from each patient case involving the use of a treatment under this section. The Secretary shall ensure that the database preserves confidentiality and that any use of the database or disclosures of such data are limited to such use and disclosures permitted by law and applicable regulations."*

In addition, section 704 directs the Secretary of Defense to provide to the Committees on Armed Services of the Senate and the House of Representatives a report, not later than 30 days after the last day of each FY, on the implementation of this section and any available results on investigational treatment clinical trials authorized under this section during the FY.

This fifth annual report describes the details and progress, to date, by the Department of Defense (DoD) following development and publication of a 2014 program announcement requesting proposals for clinical trials and database development related to TBI and PTSD. After programmatic review, two proposals were recommended for funding. The total awarded funding for both projects was initially $4.76 million (M), with current funding totaling $4.95M. Applicants received notification in June 2015, and awards were made in September 2015. From each study, a database including data from each patient receiving treatment will be developed and maintained. The DoD will submit the next annual update in October 2019 and final report in October 2020.

Implementation Status:

In response to the requirements of section 704, the Department directed the development of a clinical trial research program announcement to be executed through the military medical research community.

The Office of the Assistant Secretary of Defense for Health Affairs, through the Defense Health Agency (DHA), requested Joint Program Committee-5 (Military Operational Medicine Research Program) and Joint Program Committee-6 (Combat Casualty Care Research Program) to work with the Congressionally Directed Medical Research Programs (CDMRP) at the United States Army Medical Research and Materiel Command (USAMRMC) to publish a program announcement to address section 704. This solicitation requested proposals for clinical trials and database development related to TBI and PTSD. DHA allocated $5M from the Defense Health

Program Research, Development, Test, and Evaluation appropriation for this effort. The FY 2014 Investigational Treatments for TBI and PTSD Clinical Trial Award program announcement was released on September 18, 2014.

A total of 56 pre-applications were received in November 2014 and reviewed by a programmatic panel of scientific and military research subject matter experts. Based on the pre-application selection criteria published in the program announcement, 11 investigators were invited to submit applications. Nine compliant applications were received by the January 23, 2015 deadline. The applications underwent a scientific peer review in March 2015, conducted by an external panel of expert scientists, clinicians, and specific research topic area advocates. In May 2015, the programmatic panel conducted a programmatic review of the nine applications according to the published application evaluation criteria. The panel recommended funding two of the nine applications for a total of $4,761,697. The Commanding General, USAMRMC, and the Director of the DHA J9, Research & Development Directorate approved funding for the applications recommended during programmatic review. Applicants received notification of their funding recommendation status in June 2015 and awards were made in September 2015. From each study, a database including data from each patient receiving treatment is being developed and maintained. A summary of the funded projects follows.

Brief Treatment for PTSD: Enhancing Treatment Engagement and Retention:

- **Awardee:** Boston VA Research Institute, Inc.
  (CDMRP Log # PT140164; Award # W81XWH-15-1-0391)
- **Awarded Amount:** $2,268,872 (initial); $2,453,775 (current)
- **Description:** This study will examine whether a brief, five-session narrative therapy approach, called Written Exposure Therapy (WET), is efficacious in the treatment of military-related PTSD. If proven effective, WET could provide an alternative to existing evidence-based forms of PTSD treatment. It would require less time and potentially be more appealing and more accessible to many Service members who have avoided or discontinued other treatments.
- **Current Status:** The WET project has completed early study activities, including finalizing study materials and protocols, obtaining regulatory approvals from all required organizations, as well as hiring and training of study staff. To alleviate slow recruitment and enrollment, a supplement of $184,903 was provided in June 2017 to support a second clinical site located outside of Fort Hood in Killeen, Texas. Consequently, recruitment, screening, and consent of study subjects for the study have increased. However, the study timeline is delayed, and the recruitment rate remains lower than projected. The WET project is leveraging resources with three additional clinical trials to pre-screen potential participants. So far, 69 individuals have consented to the study, and of those, 45 have been randomized into treatment toward a target of 132. Pre-screening and consenting will continue along with randomization, treatment, and follow-up over the coming year. Due to the delayed study timeline, it is anticipated that this study will receive a one-year no-cost extension.

The Efficacy of 90-Minute vs 60-Minute Sessions of Prolonged Exposure for PTSD: A Randomized Control Trial in Active Duty Military Personnel:

- **Awardee:** University of Pennsylvania

(CDMRP Log # PT140178; Award # W81XWH-15-1-0555)

- **Awarded Amount:** $2,492,825
- **Description:** This study will test the efficacy and efficiency of 90-minute versus 60-minute prolonged exposure therapy for combat-related PTSD in active duty military personnel. The results will inform dissemination efforts of evidence-based treatment in the military, as well as in the public sector, and help identify mechanisms for how prolonged exposure therapy might be improved to better reduce PTSD symptoms.
- **Current Status:** The prolonged exposure therapy project team implemented a mitigation plan to alleviate slow recruitment and enrollment into the study. A modification to the assistance agreement was made in October 2017 to allow the University of Pennsylvania to change subcontractors, and thus, change recruitment sites from the greater San Antonio area to the area surrounding Charleston, SC. As a result, recruitment and enrollment have increased. As of June 2018, 53 individuals have been screened and consented. Of those, 33 have been randomized into the study. No additional funding was provided for this change. Due to the delayed study timeline, it is anticipated that this study will receive a one-year extension.

The DoD will provide progress on both projects in the next status update to the Armed Services Committees by October 2019 and the final report in October 2020.