



PERSONNEL AND
READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE

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

OCT 29 2017

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

Dear Mr. Chairman:

The enclosed report is the Department of Defense's (DoD) fourth 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 the DoD is supporting a significant portfolio of research studies for TBI and PTSD, this report describes the details and progress of 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 have encountered slow recruitment and enrollment. The Department is implementing mitigation plans to address this issue. We will submit annual updates on this pilot program through December 2018.

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 Jack Reed
Ranking Member



PERSONNEL AND
READINESS

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

OCT 29 2017

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

Dear Mr. Chairman:

The enclosed report is the Department of Defense's (DoD) fourth 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 the DoD is supporting a significant portfolio of research studies for TBI and PTSD, this report describes the details and progress of 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 have encountered slow recruitment and enrollment. The Department is implementing mitigation plans to address this issue. We will submit annual updates on this pilot program through December 2018.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

A handwritten signature in blue ink that reads "A M Kurta".

A. M. Kurta
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,
(Public Law 113-66)**

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

Fourth Annual Report

The estimated cost of this report or study for the DoD is approximately \$300 for the 2016 Fiscal Year. This includes \$120 in expenses and \$180 in DoD labor. Generated on 2017 August 22 RefID: 7-EA3751A

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 that:

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,

Also, that:

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 such FY.

This fourth annual report describes the details and progress, to date, by the Department of Defense 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 \$4.76M, 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 annual updates on this pilot program through December 2018.

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.

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 were 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 to support a second clinical site located outside of Fort Hood in Killeen, Texas. Recruitment, screening, and consent of study subjects for the study are ongoing and will continue along with randomization and treatment over the coming year.

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 is in the process of implementing a mitigation plan to address slow recruitment and enrollment into the study. No additional funding will be provided for this change. New, non-military treatment facilities and additional populations of Active Duty Service members have been identified. Enrollment into the study will resume as soon as practical.

The Department will provide progress on both projects in the next status update to Congress by October 31, 2018.