



PERSONNEL AND
READINESS

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

MAR - 5 2018

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

Dear Mr. Chairman:

The enclosed report responds to House Report 115-219, page 286, to accompany H.R. 3219, the Department of Defense (DoD) Appropriations Bill, 2018, concerning the Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD) Pilot Program. The House Report requests that the Assistant Secretary of Defense for Health Affairs provide a report on the status of the pilot program for investigational treatment of members of the Armed Forces for TBI and PTSD. This pilot program was mandated by section 704 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 (Public Law 113-66). The DoD reports annually on this pilot program. The fourth report was submitted on October 31, 2017. Per the requirement, annual reporting will end in 2018.

Through a two-tier review process, DoD awarded a total of \$4,761,697.00 to two institutions to develop clinical trials for innovative PTSD treatments that meet all requirements of Public Law 113-66, including the corresponding databases to record patient cases. Although the two projects have encountered slow recruitment and enrollment, DoD is implementing mitigation plans to address this issue. We will submit the final report in October 2018, as required by the NDAA for FY 2014.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert L. Wilkie".

Robert L. Wilkie

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

MAR - 5 2018

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 responds to House Report 115-219, page 286, to accompany H.R. 3219, the Department of Defense (DoD) Appropriations Bill, 2018, concerning the Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD) Pilot Program. The House Report requests that the Assistant Secretary of Defense for Health Affairs provide a report on the status of the pilot program for investigational treatment of members of the Armed Forces for TBI and PTSD. This pilot program was mandated by section 704 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 (Public Law 113-66). The DoD reports annually on this pilot program. The fourth report was submitted on October 31, 2017. Per the requirement, annual reporting will end in 2018.

Through a two-tier review process, DoD awarded a total of \$4,761,697.00 to two institutions to develop clinical trials for innovative PTSD treatments that meet all requirements of Public Law 113-66, including the corresponding databases to record patient cases. Although the two projects have encountered slow recruitment and enrollment, DoD is implementing mitigation plans to address this issue. We will submit the final report in October 2018, as required by the NDAA for FY 2014.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

A handwritten signature in black ink that reads "Robert L. Wilkie".

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member



PERSONNEL AND
READINESS

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

MAR - 5 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 report responds to House Report 115-219, page 286, to accompany H.R. 3219, the Department of Defense (DoD) Appropriations Bill, 2018, concerning the Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD) Pilot Program. The House Report requests that the Assistant Secretary of Defense for Health Affairs provide a report on the status of the pilot program for investigational treatment of members of the Armed Forces for TBI and PTSD. This pilot program was mandated by section 704 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 (Public Law 113-66). The DoD reports annually on this pilot program. The fourth report was submitted on October 31, 2017. Per the requirement, annual reporting will end in 2018.

Through a two-tier review process, DoD awarded a total of \$4,761,697.00 to two institutions to develop clinical trials for innovative PTSD treatments that meet all requirements of Public Law 113-66, including the corresponding databases to record patient cases. Although the two projects have encountered slow recruitment and enrollment, DoD is implementing mitigation plans to address this issue. We will submit the final report in October 2018, as required by the NDAA for FY 2014.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member



PERSONNEL AND
READINESS

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

MAR - 5 2018

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

Dear Mr. Chairman:

The enclosed report responds to House Report 115-219, page 286, to accompany H.R. 3219, the Department of Defense (DoD) Appropriations Bill, 2018, concerning the Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD) Pilot Program. The House Report requests that the Assistant Secretary of Defense for Health Affairs provide a report on the status of the pilot program for investigational treatment of members of the Armed Forces for TBI and PTSD. This pilot program was mandated by section 704 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 (Public Law 113-66). The DoD reports annually on this pilot program. The fourth report was submitted on October 31, 2017. Per the requirement, annual reporting will end in 2018.

Through a two-tier review process, DoD awarded a total of \$4,761,697.00 to two institutions to develop clinical trials for innovative PTSD treatments that meet all requirements of Public Law 113-66, including the corresponding databases to record patient cases. Although the two projects have encountered slow recruitment and enrollment, DoD is implementing mitigation plans to address this issue. We will submit the final report in October 2018, as required by the NDAA for FY 2014.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

**Report in Response to the House Report 115–219, Page 286, Accompanying
H.R. 3219, the Department of Defense Appropriations Bill, 2018
“Traumatic Brain Injury and Post-Traumatic Stress Disorder Pilot Program”**



**Submitted by the Office of the
Assistant Secretary of Defense for Health Affairs**

February 2018

The estimated cost of this report or study for the Department of Defense (DoD) is approximately \$500.00 for the 2017 Fiscal Year. This includes \$0.00 in expenses and \$500.00 in DoD labor.

Generated on December 12, 2017

RefID: 5-7239247

Summary

The Department of Defense (DoD) submits this report in response to House Report 115–219, page 286, to accompany H.R. 3219, the DoD Appropriations Bill, 2018, concerning the Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD) Pilot Program. The House Report requests that the Assistant Secretary of Defense for Health Affairs provide a report on the status of the pilot program for investigational treatment of members of the Armed Forces for TBI and PTSD.

This pilot program was mandated by section 704 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 (Public Law 113–66). The DoD reports annually on this pilot program. The fourth report was submitted on October 31, 2017. Per the requirement, annual reporting will end in 2018.

This report provides an update on the DoD’s efforts to implement section 704. Through a selective process, DoD awarded a total of \$4,761,697.00 to two institutions to develop clinical trials for innovative PTSD treatments that meet all requirements of the legislation, including the corresponding databases to record patient cases.

Implementation Status Timeline

The DoD immediately began implementing the requirement in section 704. By September 2014, DoD had allocated \$5M from the Defense Health Program Research, Development, Test, and Evaluation appropriation and developed and published a program announcement to solicit proposals for clinical trials with databases for investigational treatments of PTSD and TBI. The proposal selection—a two-tier review process—commenced in November 2014, when the tier one peer review panel of scientific and military research subject matter experts reviewed the 56 pre-applications. Eleven of the 56 pre-applicants met the established pre-selection criteria and were invited to submit applications. By the deadline, January 2015, the DoD received nine compliant applications. In March 2015, the tier two programmatic review panel of expert scientists, clinicians, and specific research topic area advocates reviewed those nine applications. In May 2015, the panel evaluated the applications against the published criteria and selected two of the nine proposals, totaling \$4,761,697.00. Thereafter, DoD leadership approved funding for the panel’s recommendations. Lastly, the DoD notified the investigators of their funding recommendation status in June 2015 and finalized the awards in September 2015.

Funded Project Summaries

Brief Treatment for PTSD: Enhancing Treatment Engagement and Retention

- **Awardee:** Boston VA Research Institute, Inc. (Congressionally Directed Medical Research Program (CDMRP) Log # PT140164; Award # W81XWH-15-1-0391)
- **Awarded Amount:** \$2,268,872.00 (initial); \$2,453,775.00 (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, potentially be more appealing, and accessible to many Service members who 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, and hiring and training study staff. To alleviate slow recruitment and enrollment, the DoD provided a supplement of \$184,903.00 to support a second clinical site located outside of Fort Hood in Killeen, Texas. Over the coming year, recruitment, screening, consent, randomization, and treatment of study subjects for the study are ongoing. Moreover, the WET project has developed and is maintaining a database with information on each patient's treatment.

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:** \$2,492,825.00
- **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 and public sector and will 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 study is also developing and will maintain a database with information on each patient's treatment.

As directed by section 704 of the NDAA for FY 2014, DoD will provide a status update on both projects to the Armed Services Committees by October 31, 2018.