



PERSONNEL AND
READINESS

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

APR - 1 2025

The Honorable Roger F. Wicker
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

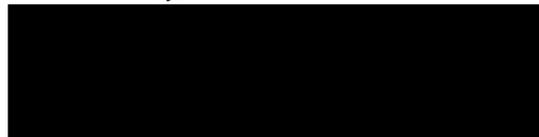
The Department's response to section 723 of the National Defense Authorization Act for Fiscal Year (FY) 2024 (Public Law 118-31), "Program of the Department of Defense to Study Treatment of Certain Conditions Using Certain Psychedelic Substances," is enclosed.

This report provides a status of funding opportunities to conduct research using psychedelic substances to treat post-traumatic stress disorder (PTSD) and/or traumatic brain injury (TBI). Congress identified the study and treatment of certain conditions using certain psychedelic substances as a research priority and appropriated \$10 million for funding of Department of Defense (DoD)-wide psychedelic medical clinical trials. In response, the Department established a process for funding eligible entities to conduct research on treatment of eligible members of the Armed Forces with PTSD and/or TBI using psychedelic substances by leveraging the Congressionally Directed Medical Research Programs program cycle. As directed, the Department identified the Defense Health Agency as the lead administrator.

The following institutions have been recommended for funding and awards are under negotiation: Henry M. Jackson Foundation/Walter Reed National Military Medical Center and the University of Texas Health Science Center at San Antonio. The Department has not finalized the awards and the studies have not begun; therefore, DoD is not able to report on the following: all participating clinics and the number of active duty participants. The Department anticipates providing this information in the report required in FY 2025.

Thank you for your continued strong support for the health and well-being of our Service members. I am sending a similar letter to the Committee on Armed Services of the House of Representatives.

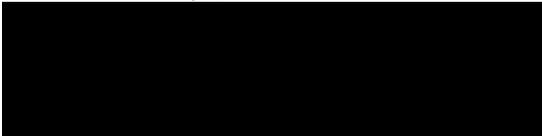
Sincerely,



Jules W. Hurst III
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:





PERSONNEL AND
READINESS

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

APR - 1 2025

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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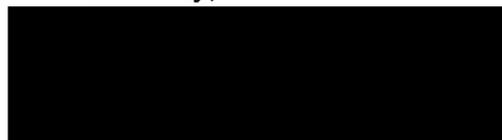
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Sincerely,



Jules W. Hurst III
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith



Report to the Committees on Armed Services of the Senate and the House of Representatives



Program of the Department of Defense to Study Treatment of Certain Conditions Using Certain Psychedelic Substances

April 2025

The estimated cost of this report for the Department of Defense (DoD) is approximately \$1,100 for Fiscal Years 2023-2024. This includes \$900 in expenses and \$200 in DoD labor.

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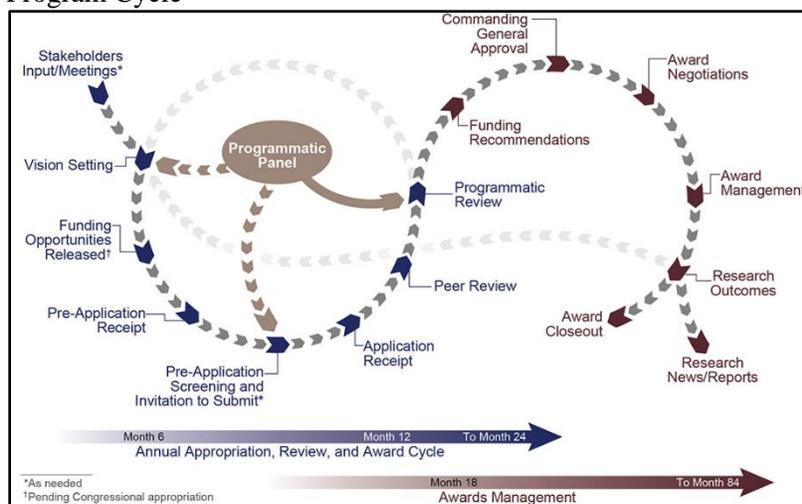
PURPOSE

This report is in response to section 723 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Public Law 118–31), “Program of the Department of Defense to Study Treatment of Certain Conditions Using Certain Psychedelic Substances.” Section 723 requires the Secretary to establish a process to conduct research on the treatment of eligible members of the Armed Forces with a covered condition (post-traumatic stress disorder (PTSD) or traumatic brain injury (TBI)) using covered psychedelic substances (that is, 3,4-Methylenedioxymethamphetamine, psilocybin, ibogaine, 5-Methoxy-N,N-dimethyltryptamine (commonly known as “5-MeO-DMT”), and qualified plant-based alternative therapies). The Secretary is to designate a lead administrator within the Department to execute this program. This report provides a status of funding opportunities to conduct research using psychedelic substances to treat PTSD and/or TBI. The following institutions have been recommended for funding and awards are under negotiation: Henry M. Jackson Foundation/Walter Reed National Military Medical Center and the University of Texas Health Science Center at San Antonio. The Department of Defense (DoD) has not finalized the awards and the studies have not begun therefore, DoD is not able to report on the following: all participating clinics and the number of active-duty participants.¹ The Department anticipates providing this information in the report required in FY 2025.

BACKGROUND

Currently, the U.S. Food and Drug Administration has not approved a psychedelic for the management of PTSD and/or TBI. Congress identified the study and treatment of certain conditions using certain psychedelic substances as a research priority and appropriated \$10 million (M) for funding of DoD-wide psychedelic medical clinical trials. The Defense Health Agency (DHA) manages the Defense Health Program Research, Development, Test and Evaluation appropriation. The DHA is designated as lead administrator for funding research to study treatment of PTSD and TBI with the Congressionally Directed Medical Research Programs (CDMRP) as the execution manager. Consistent with this mandate, DHA has been designated as the administrator to carry out this program.

Figure. CDMRP Program Cycle



¹ Section 723 of the NDAA for FY 2024 (Public Law 118–31), “Program of the Department of Defense to Study Treatment of Certain Conditions Using Certain Psychedelic Substances.” December 22, 2023.

The CDMRP program cycle includes a two-tier review process to develop funding recommendations that balance the most meritorious science across many disciplines and offer the highest promise to fulfill the programmatic goals set forth in the funding opportunity. The two-tier review process consists of a peer and a programmatic review. The peer review is a criterion-based evaluation of the full proposal which determines its scientific merit. For peer reviews there are no standing panels and reviewers are recruited based on required expertise. In addition, there is no contact between applicants, reviewers, and CDMRP program staff. The programmatic review is a comparison among proposals of high scientific merit, including a determination of adherence to intent, program relevance, and potential for impact. The outcome of the programmatic review is funding recommendations.

APPROACH AND STATUS

In response to section 723 of the NDAA for FY 2024, DHA, with CDMRP execution management support, released a targeted clinical trial award, Psychedelic Treatment Research Clinical Trial Award (PTRCTA). This funding opportunity solicited applications for funding from the \$10M FY 2024 DoD-wide psychedelic medical clinical trials appropriation. CDMRP published a pre-announcement² on July 10, 2024, and the PTRCTA funding opportunity was released August 2024.

The intent of the CDMRP PTRCTA is to support clinical trials with eligible U.S. Service members to evaluate treatments for PTSD and/or TBI involving the use of covered psychedelic substances. Applicants must select at least one of the two covered conditions (PTSD or TBI) and one or more of the covered psychedelic substances noted above. Treatment may involve the use of covered psychedelic substances alone or in conjunction with other evidence-based treatments. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) to demonstrate feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant patient populations.³

In addition, applications from investigators within the Military Departments and applications involving multidisciplinary collaborations among academia, industry, the Department of Veterans Affairs, and other Federal Government Agencies, were highly encouraged. Funding from this award mechanism must support a clinical trial and may not be used for animal or preclinical studies. Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.⁴

The study population is required to consist of active duty Service members or members of the Reserve Components. Study populations other than Service members will not be supported. While veterans are an important population, they are not the focus of this funding opportunity. The outcomes of the study are expected to benefit Service members, veterans, and

² Department of Defense, Congressionally Directed Medical Research Programs (CDMRP), Defense Medical Research and Development Program (DMRDP), Anticipated Funding Opportunities for Fiscal Year 2024 (FY24). <https://cdmrp.health.mil/pubs/press/2024/24dmrdppreann>.

³ Program Announcement. Defense Medical Research and Development Program, "Psychedelic Treatment Research Clinical Trial Award." https://cdmrp.health.mil/funding/pa/HT942524DMRDPTRCTA_GG.pdf.

⁴ Program Announcement. Defense Medical Research and Development Program, "Psychedelic Treatment Research Clinical Trial Award." https://cdmrp.health.mil/funding/pa/HT942524DMRDPTRCTA_GG.pdf.

the public. The application should demonstrate the availability of and access to a suitable population of U.S. Service members that will support a meaningful outcome for the study.⁵

The Department received application for the PTRCTA in October 2024 and they underwent peer review in December 2024. The programmatic review was conducted in January 2025. In response to the PTRCTA program announcement the DoD received 13 letters of intent, received nine compliant applications and recommended funding for two. The following institutions have been recommended for funding and awards are under negotiation: Henry M. Jackson Foundation/Walter Reed National Military Medical Center and the University of Texas Health Science Center at San Antonio.^{6,7}

CONCLUSION

The Department has established the process for funding eligible entities to conduct research on treatment of eligible members of the Armed Forces with PTSD and/or TBI using psychedelic substances noted above by leveraging the CDMRP program cycle. As directed, the Department identified DHA as the lead administrator. The Department will submit an annual report on the status of this Congressional requirement. The initial report will include an overview of the awards funded under the program announcements included in this report.

⁵ Program Announcement. Defense Medical Research and Development Program, “Psychedelic Treatment Research Clinical Trial Award.” https://cdmrp.health.mil/funding/pa/HT942524DMRDPTRCTA_GG.pdf.

⁶ The list of Psychedelic Treatment Research Clinical Trial applications recommended for funding is for informational purposes only. Identification on the list of applications recommended for funding is not intended to either confer a right to funding nor does it guarantee funding. The award of Federal funds to support any of these applications is contingent upon successful negotiations and applicable Federal policy. <https://cdmrp.health.mil/dmrdp/awards/24ptrct>.

⁷ Congressionally Directed Medical Research Programs (CDMRP) Fiscal Year 2024 (FY24) Defense Medical Research and Development Program (DMRDP). Description of Review Procedures. https://cdmrp.health.mil/dmrdp/pdfs/HT94254DMRDPTRCTA_Information%20Paper_Final.pdf.