



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE

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

OCT 10 2013

The Honorable Richard J. Durbin
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:


The enclosed report responds to the requirements of House Report 112-493, page 269, and Senate Report 112-196, page 231, which accompany H.R. 5856, Department of Defense (DoD) Appropriations Act, 2013, encouraging the Secretary of Defense to support multi-disciplinary research toward translational medicine that may provide better diagnostic tools and treatment outcomes for Service members who suffer from posttraumatic stress disorder (PTSD), traumatic brain injury (TBI), and other neurotrauma.

Our proposed program is consistent with the provisions of Executive Order (EO) 13625, "Improving Access to Mental Health Services for Veterans, Service Members, and Military Families." The EO directed the establishment of National Research Action Plan (NRAP) to provide an opportunity for DoD, to address the complex issues of PTSD, TBI, suicide prevention, and related comorbidities. The NRAP is instrumental in achieving the translational medicine capabilities necessary to produce positive mental health outcomes for our Service members who suffer from these issues.

The vision for the multi-disciplinary research described in this report will be achieved through close, continued collaboration across state and federal agencies as well as throughout the scientific community. Agency collaborations will occur formally through joint portfolio review and analyses of efforts aligned with the NRAP. All of the activities discussed in this report will support the research goals that include preventing suicide; reducing the number of individuals affected by PTSD, TBI, and substance-related and other comorbidities; and improving the quality of life of those who do experience these conditions through better coordinated and synchronized efforts to accelerate progress in prevention, diagnosis, and treatment.

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 congressional defense committees.

Sincerely,


Jessica L. Wright
Acting

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Vice Chairman



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

PERSONNEL AND
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OCT 10 2013

The Honorable Carl Levin
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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Jessica L. Wright
Acting

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As stated

cc:
The Honorable James M. Inhofe
Ranking Member



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WASHINGTON, D.C. 20301-4000

OCT 10 2013

The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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Sincerely,


Jessica L. Wright
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member



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

PERSONNEL AND
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OCT 10 2013

The Honorable C.W. Bill Young
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

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Sincerely,


Jessica L. Wright
Acting

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member



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

PERSONNEL AND
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OCT 10 2013

The Honorable Barbara A. Mikulski
Chairwoman
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Madam Chairwoman:

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Vice Chairman



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The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

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Sincerely,


Jessica L. Wright
Acting

Enclosure:
As stated

cc:
The Honorable Nita M. Lowey
Ranking Member

REPORT TO CONGRESS

Multi-Disciplinary Brain Research and Data Sharing Efforts



September 2013

The estimated cost of report or study for the Department of Defense is approximately \$2,540 for the 2013 Fiscal Year. This includes \$2,000 in expenses and \$540 in DoD labor.
Generated on August 30, 2013; RefID: 2-6233CC9

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1.0 PURPOSE

The House Report 112-493, Page 269, and Senate Report 112-196, Page 231, which accompany H.R. 5856, the Department of Defense Appropriations Act, 2013, request the Secretary of Defense to provide a report to the congressional defense committees on Multidisciplinary Brain Research. The report addresses support of multi-disciplinary research toward translational medicine intended to provide better diagnostic tools and treatment outcomes for Service members who suffer from traumatic brain injury, posttraumatic stress disorder, and other neurotrauma/neurological conditions, and on efforts made for the provision of capabilities necessary for researchers, scientists, surgeons, physicians, healthcare professionals, and patients to effectively communicate their findings and outcomes in near real-time.

2.0 EXECUTIVE SUMMARY

On August 31, 2012, President Obama issued Executive Order (EO) 13625 directing the Departments of Defense (DoD), Veterans Affairs (VA), Health and Human Services (HHS), and Education (henceforth referred to as “the agencies”), to develop a National Research Action Plan (NRAP) on posttraumatic stress disorder (PTSD), other mental health conditions, and traumatic brain injury (TBI) “to improve the coordination of agency research into these conditions and reduce the number of affected men and women through better prevention, diagnosis, and treatment.” The agencies called upon in Section 5 of the EO will fund multi-disciplinary research programs devoted to scientific discovery to advance health in civilian and/or military populations. Collectively, the agencies support multi-disciplinary research that will lead to a better understanding, prevention, and treatment of the physical injuries and mental health and substance abuse problems related to stress and trauma experienced by Service members, veterans, and their family members.

The agencies developed a multi-disciplinary translational medicine framework for research using an “Interagency Research Continuum Approach” model that describes the research spectrum from foundational (basic) science through prevention, treatment, follow-up care, and services research. This translational framework highlights the areas where the agencies are supporting studies and areas where more research is needed. New or planned initiatives in the form of Requests for Applications are being developed and released, and research findings generated from funded projects will continue to be reviewed and integrated into patient care when the scientific evidence supports it.

The agencies have begun discussions related to determining how to enhance research data-sharing efforts. Data-sharing efforts will require close and continued collaboration among federal agencies dedicated to addressing challenges specific to research, to meet the overall goal to increase access to study level data. The agencies will leverage government plans to increase access to the results of scientific research as they emerge.

The vision for multi-disciplinary PTSD, TBI, and suicide prevention translational medicine research will be achieved through close, continued collaborations across agencies and throughout the scientific community. Agency collaborations will occur formally through joint portfolio review and analyses of efforts aligned with the NRAP. All of these activities will support the research goals that include preventing suicide; reducing the number of individuals affected by TBI, PTSD, and substance-related and other comorbidities; and improving the

quality of life of those who do experience these conditions through better coordinated and synchronized efforts to accelerate progress in prevention, diagnosis, and treatment.

3.0 BACKGROUND

On August 31, 2012, President Obama issued Executive Order (EO) 13625 directing the Departments of Defense (DoD), Veterans Affairs (VA), Health and Human Services (HHS), and Education (henceforth referred to as “the agencies”), to develop a National Research Action Plan (NRAP) on posttraumatic stress disorder (PTSD), other mental health conditions, and traumatic brain injury (TBI) “to improve the coordination of agency research into these conditions and reduce the number of affected men and women through better prevention, diagnosis, and treatment.” The agencies called upon in Section 5 of the EO will fund multi-disciplinary research programs devoted to scientific discovery to advance health in civilian and/or military populations. Collectively, the agencies support multi-disciplinary research that will lead to a better understanding, prevention, and treatment of the physical injuries and mental health and substance abuse problems related to stress and trauma experienced by Service members, veterans, and their family members. The EO directed the establishment of a NRAP to provide an opportunity for the agencies to collaborate in moving the multi-disciplinary scientific translational medicine research agenda forward to address the complex issues of PTSD, TBI, suicide, and related comorbidities (defined herein as “mental health disorders”), including depression; substance abuse related to alcohol, tobacco and other drugs, including the misuse and abuse of prescription drugs; and chronic pain, each of which can complicate the prevention and treatment of PTSD, TBI, and suicidal behaviors. The NRAP, released in August 2013, is instrumental in achieving the translational medicine capabilities necessary to produce positive mental health outcomes for our Service members who suffer from traumatic brain injury, posttraumatic stress disorder, and other neurotrauma/neurological conditions.

There is limited evidence of the effectiveness of both pharmacological and nonpharmacological interventions, including rehabilitation treatments, due in part to underpowered studies and the limited validated assessment tools that are sensitive enough to detect treatment effects. Research on treatment efficacy and effectiveness has also been hampered by difficulties in defining the active ingredient of many experience-based treatments that are commonly used in rehabilitation. The concurrent application of multiple treatments, including pharmacological and nonpharmacological interventions, poses another challenge. Rigorous definitions of rehabilitation treatments are needed, as well as research regarding the customization of therapies to an individual’s injury, predisposing factors, and co-occurring conditions.

Scientific progress is incremental and takes time, but military Service members, veterans, and their family members need more effective treatments immediately. This must be balanced with a commitment to provide the highest quality evidence-based care. In the NRAP, the agencies plan to capitalize on current research efforts and emerging scientific findings as well as explore and support new opportunities to increase scientific knowledge and accelerate its translation to evidence-based clinical care. These new activities will begin immediately.

4.0 MULTIDISCIPLINARY RESEARCH TOWARD TRANSLATIONAL MEDICINE

The agencies developed a multi-disciplinary translational medicine framework for research using an “Interagency Research Continuum Approach” model that describes the research spectrum from foundational (basic) science through prevention, treatment, follow-up care, and services research. This translational framework highlights the areas where the agencies are supporting studies and areas where more research is needed. New or planned initiatives in the form of Requests for Applications (RFAs) are being developed and released, and research findings generated from funded projects will be reviewed and integrated into patient care when the scientific evidence supports it. Notably, coordination with, and leveraging of, results from the President’s Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative are expected to result in useful diagnostic and monitoring tools applicable to brain injury and mental health.

A variety of multi-disciplinary activities are under way in support of the NRAP, including funded research projects within the agencies’ complementary portfolios in TBI, PTSD, and suicide prevention research that also address comorbidities such as substance abuse. The DoD’s Systems Biology Initiative and the Millennium Cohort and Family Cohort Studies, the VA’s Million Veteran Program, and the NIH’s biomarker and mechanistic research programs all hold promise to inform advancement of prevention and treatment interventions. Notably, the DoD has invested more than \$100 million in TBI biomarker discovery and development since 2007; other agencies have supported this increased focus. The DoD and the Centers for Disease Control and Prevention (CDC) are partnering with the Brain Trauma Foundation to develop a clinically meaningful classification system of mild TBI/concussion that will enable improved clinical assessment of current status and prognosis. Suicide prevention research includes the DoD’s Military Suicide Research Consortium (MSRC) and the National Institute of Mental Health and Department of the Army’s Study to Assess Risk and Resilience in Servicemembers (Army STARRS) program. The agencies support research that contributes to a better understanding of the mental health needs of military/veteran families and the best ways to prevent, treat, and provide them services.

All initiatives supported by the NRAP action plan will address comorbidities, when they exist, including substance abuse disorders, through coordination, goal setting, and common efforts. The agencies are independently and jointly funding studies focused on substance abuse research in Service members, veterans, and their family members. There have been collaborations that include joint reviews and analyses of portfolios and joint funding opportunities (e.g., 2010 NIH-VA RFA and 2013 NIH-DoD RFA). Substance abuse research funded by the agencies spans the research continuum from basic science through implementation research.

The DoD and the VA have joined efforts in the Consortium to Alleviate PTSD (CAP). The CAP is a new research effort focused on biomarker discovery and development with the aim of identifying biomarkers for subacute and chronic PTSD that can be used for therapeutic and outcome assessment. With funding from the DoD and the VA, this represents a major investment to advance knowledge related to biomarkers and clinical utility. A CAP award is expected to be finalized by the end of September 2013.

The DoD and CDC, in partnership with the Brain Trauma Foundation, have funded an effort to develop a clinically meaningful classification system of mild TBI/concussion that will

enable improved clinical assessment of current status and prognosis. The International TBI Common Data Elements (CDEs) project has recommended a battery of instruments to be used in TBI epidemiological and interventions research, but evidence demonstrating the utility or superiority of the recommended instruments over other measures is limited. The National Institute of Neurological Disorders and Stroke (NINDS) has funded Transforming Research and Clinical Knowledge in TBI (TRACK – TBI), a pilot project to evaluate the utility and feasibility of the CDEs; the DoD funded the data analysis component of TRACK – TBI. These three successful interagency collaborations underscore the value and need for additional research to create more precise classifications of injury type and severity and more sensitive diagnostic tools to ultimately enable personalized medicine for TBI. There is also the opportunity for leveraging emerging imaging modalities and body fluid-derived biomarkers for improved diagnostics, but validation will be required before they are ready for clinical use.

The DoD and the VA are jointly sponsoring the Chronic Effects of Neurotrauma Consortium (CENC) award, which will fund a large consortium to: a.) establish the association of the chronic effects of mild TBI and common comorbidities; b.) determine whether there is a causative effect of chronic mild TBI/concussion on neurodegenerative disease and other comorbidities; c.) identify diagnostic and prognostic indicators of neurodegenerative disease and other comorbidities associated with mild TBI/concussion; and d.) develop and advance methods to treat and rehabilitate chronic neurodegenerative disease and comorbid effects of mild TBI/concussion.

5.0 RESEARCH DATA SHARING EFFORTS

Research data sharing, ideally, would be collaborative and promote team science to rapidly and effectively fill gaps in knowledge that will ultimately improve health care and outcomes. The scientific community would be able to submit and access research data in a participatory manner in order to test new hypotheses, combine data sets for meta-analyses, and compare and contrast findings across disorders, the lifespan, and the continuum of care. Research data elements would be standardized to the greatest extent possible, and also aligned with clinical data elements to enable greater integration of research and clinical practice.

The ability to leverage existing and emerging information technology will be a key factor in successfully coordinating and accelerating research under the NRAP. Transparent and accessible information about the agencies' ongoing and planned efforts will guide the agencies and researchers alike to reduce overlap, eliminate redundancies, identify gaps, and focus new research questions. Publicly accessible databases that contain information about funded grants (e.g., the NIH Research Portfolio Online Reporting Tools (RePORTER), which is used by VA and the NIH) act as repositories for government-sponsored research.

The DoD has committed to move its medical research information onto the NIH RePORTER via Electronic Research Administration Commons, thus promoting a higher level of transparency and analysis across agencies and for the public. Beyond the transparent sharing of data about funded studies, a commitment has been made to promote the standardization and sharing of study-level (raw) data. Many smaller sized studies are able to involve only a modest number of participants; therefore, the ability to share study data when appropriate will increase the power for analyses and potentially accelerate research progress. In addition, large-scale studies supported by each agency provide a platform for rich secondary data analyses when

study-level data are shared. Central repositories such as the Federal Interagency TBI Research (FITBIR) Informatics System can be leveraged in these data-sharing efforts. The agencies have begun discussions relating to determining how to more efficiently share data describing funded research studies as well as study-level data; details can be found in the NRAP, along with proposed strategies and plans for utilizing electronic health records for research.

Access to study-level data for the purpose of secondary data analysis is important for research in general. Data sharing allows for an increase in the amount of data that can be combined or compared by the community of scientists. Many smaller studies involve only a modest number of participants; therefore the ability to share data when appropriate will increase the power for analyses and potentially accelerate research progress. In addition, large-scale studies supported by each agency provide a platform for rich secondary data analyses when data are shared.

Examples of data-sharing efforts include:

- The FITBIR Informatics System has been established to provide a central repository for TBI-related clinical research data. The FITBIR was funded by the DoD, and subsequently developed and managed by the NIH. Clinical data are entered into FITBIR utilizing the TBI CDEs, which were developed to allow more precise comparisons of TBI research data. Research data from newly funded NINDS and Defense Health Program TBI clinical research projects will be entered into FITBIR. Although not required, clinical research data from previously funded projects can be entered into the FITBIR. Additionally, the TBI CDE project is developing data standards to allow expansion of the FITBIR to preclinical work, enabling advancement of preclinical knowledge and improved modeling of TBI. This data repository decreases costs to the researcher, standardizes the collection of research data, and allows access to researchers outside the original research studies to re-analyze and compare data across studies.
- The National Institute on Disability and Rehabilitation Research (NIDRR) established the Traumatic Brain Injury Model System National Database (TBIMS-NDB) to provide a data repository for clinical data from individuals with moderate and severe TBI who are within the Model Systems network of centers. This database offers decades of information on the clinical progress and outcomes of individuals with moderate to severe TBI. The NIDRR and the VA have partnered to create a VA Polytrauma Rehabilitation Centers TBI Database that includes the same data elements found in the TBIMS-NDB.
- The VA computing infrastructure allows for de-identified data to be accessible to VA researchers. While not limited to PTSD or TBI, this environment allows sharing of research data within the VA.

6.0 RESEARCH DATA SHARING FOLLOW-UP PLAN

The overall goal for the NRAP related to data sharing is centered on accelerating research progress. The major emphasis is on sharing data describing funded research studies to facilitate an understanding of what is being supported across agencies, increase transparency in the public domain, and reduce redundancy, should any be identified. Planned compilation of funded research studies and common coding of categories of research across the spectrum from basic to implementation research will allow researchers to search for various topics across agencies to

identify ongoing work (e.g., all studies that examine PTSD and suicide attempts) and facilitate the next generation of research questions. The DoD will pursue utilization of the Electronic Research Administration (eRA) Commons, Information for Management, Planning, Analysis and Coordination II, and related systems for such research study portfolio management.

The agencies have begun discussions related to determining how to enhance research data-sharing efforts. Data-sharing efforts will require close and continued collaboration among federal agencies dedicated to addressing challenges specific to research, to meet the overall goal to increase access to study level data. The agencies will leverage government plans to increase access to the results of scientific research as they emerge.

The action plan for data sharing represents an integrated effort to address the major objectives of sharing funded research information and enhancing research data sharing, with continued communication among partners. Some examples of the type of activities that will meet the requirements of the EO include:

- Continue to convene the joint DoD/VA/HHS/ED strategic portfolio reviews in the areas of TBI, PTSD, suicide prevention, and substance abuse research.
- Explore expansion of the Psychiatric Genomics Consortium (<https://pgc.unc.edu/index.php>) to include PTSD cohorts. Research funded by federal agencies may deposit de-identified genotypic and phenotypic data to facilitate meta-analyses, replication, and extension of early findings.
- Improve the delivery of health care services in the private sector by sharing research findings and data through agencies and policymakers (e.g., Agency for Healthcare Research and Quality), consensus development conferences (e.g., NIH Consensus Development Program), and practice-based research.
- Develop a minimum set of defined demographic CDEs by surveying the demographic elements used across topics and efforts (FITBIR, MSRC, VA information technology environment, etc.) and proposing adoption or expansion of these elements.
- Expand the FITBIR to include preclinical research data. CDEs for preclinical models will be developed. Methods will be developed to enable researchers with existing or even completed research to more easily align their data with the CDEs, which may be expanded to relevant psychological health elements. Entry of data into the FITBIR will be a requirement for all DoD TBI clinical research projects.
- Facilitate the collaboration of the FITBIR with TBIMS-NDB, the International TBI Research Initiative, and other related/relevant data repositories that can be leveraged for research, as permissible.
- Encourage use of the National Addiction and HIV Data Archive Program (NADHAP) (<http://www.icpsr.umich.edu/icpsrweb/NAHDAP/>) for the purpose of archiving data. Researchers can use the NADHAP to upload data sets relevant to substance abuse and military and veteran populations, and use data from the NADHAP for the purpose of secondary data analysis.
- Encourage use of NIH Funding Opportunity Announcement (FOA) PAR-13-080, “Accelerating the Pace of Drug Abuse Research Using Existing Data.” The purpose of this FOA is to invite applications proposing the innovative analysis of existing social

science, behavioral, administrative, and neuroimaging data to study the etiology and epidemiology of drug-using behaviors (defined as alcohol, tobacco, prescription, and other drugs) and related disorders, associated HIV risk behaviors, prevention of drug use and HIV, and health service utilization.

7.0 CONCLUSION

The vision for multi-disciplinary PTSD, TBI, and suicide prevention translational medicine research described here will be achieved through close continued collaborations across agencies and throughout the scientific community. Agency collaborations will occur formally through joint portfolio review and analyses of efforts aligned with the NRAP. All of these activities will support the research goals that include preventing suicide; reducing the number of individuals affected by PTSD, TBI, and substance-related and other comorbidities; and, for those who experience these conditions, improving the quality of life through better coordinated and synchronized efforts to accelerate progress in prevention, diagnosis, and treatment.