

4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

APR 22 2015

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

Dear Mr. Chairman:

The enclosed report responds to Senate Report 113-211, pages 253-254, to accompany H.R. 4870, the Department of Defense Appropriations Bill, 2015, concerning Collaboration on Medical Research. This final report includes a full description of the pilot program, a timeline of its implementation, and any impediments for the Department in uploading research information into the database.

The pilot program continues to move forward toward the implementation of ongoing data transfers to the National Institutes of Health (NIH) for use in Query View Report and Federal NIH Research Portfolio Online Reporting Tools. The Department of Defense is committed to increasing access to medical research information and improving the coordination of research programs across agencies.

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 other congressional defense committees.

Sincerely,

Brad Carson

Acting

Enclosure:

As stated

cc:

The Honorable Nita M. Lowey Ranking Member



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APR 22 2015

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

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The Honorable Barbara A. Mikulski Vice Chairwoman



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APR 22 2015

The Honorable Rodney P. Frelinghuysen Chairman Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

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The Honorable Peter J. Visclosky Ranking Member



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APR 22 2015

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

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The Honorable Adam Smith Ranking Member



4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

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

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The Honorable Jack Reed Ranking Member



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

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The Honorable Richard J. Durbin Vice Chairman

FINAL REPORT IN RESPONSE TO SENATE REPORT 113-211, PAGES 253-254, WHICH ACCOMPANIED H.R. 4870, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2015

"COLLABORATION ON MEDICAL RESEARCH"



The estimated cost of report for the Department of Defense is approximately \$1,500 in Fiscal Years 2014-2015. This includes \$1,000 in expenses and \$500 in DoD labor.

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1. PURPOSE

This report responds to Senate Report 113-211, pages 253-254, "Collaboration on Medical Research," which accompanied H.R. 4870, the Department of Defense Appropriations Bill, 2015. The following provides the status of the pilot program for sharing DoD medical research data, funded via the Defense Health Program (DHP), into the National Institutes of Health (NIH) Federal Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER). This report includes a full description of the pilot program, timeline of its implementation, and any impediments for the Department in uploading its research information into the database.

2. BACKGROUND

In the February 2012 Government Accountability Office (GAO) Report: "GAO-12-342SP Duplication, Overlap, and Fragmentation," the GAO recommended federal agencies should determine ways to improve access to comprehensive electronic information for funded health research shared among agency officials and improve the ability of agency officials to identify possible duplication.

Several Department of Defense (DoD) medical research partners—National Institutes of Health (NIH), the Department of Veterans Affairs (VA), the Department of Education, and other federal agencies—already use RePORTER and Electronic Research Administration (eRA) applications to find or share federally-funded medical research data. Some of the DoD research portfolio information is in publicly accessible websites; however, the National Research Action Plan (NRAP) 2013 identified the NIH RePORTER and eRA as data management tools for the DoD's medical research information to promote a higher level of transparency and analysis among all federal agencies.

Federal RePORTER is a public, searchable database of scientific awards from several federal agencies. The eRA provides information technology solutions and support for the full life cycle of grants administration functions, from receipt of proposals to closeout of funded projects, and to consolidate reports, data, and analyses of medical research activities, for the NIH as well as the Agency for Healthcare Research and Quality; Centers for Disease Control and Prevention; Food and Drug Administration; the Substance Abuse and Mental Health Services Administration; and the Veterans Health Administration.

There are a number of organizations within the DoD that execute DHP research, development, training, and education (RDT&E) medical research and each has its own specific processes and data management systems. These DoD organizations include, but are not limited to: 1) the U.S. Army Medical Research and Materiel Command (USAMRMC), including the Congressionally Directed Medical Research Programs (CDMRP); 2) the U.S Navy Medical Research Units and Office of Naval Research; 3) the U.S. Air Force's 59 Medical Wing and 711 Human Performance Wing; and 4) the Uniformed Services University of the Health Sciences (USUHS).

DHP RDT&E-funded medical research differs from NIH-funded research in that the funding mechanisms are not only grants but also, if consistent with the Office of the Assistant Secretary of Defense for Health Affairs (HA) and Defense Health Agency (DHA) management controls, any mechanism authorized by law, DoD issuances, and Military Department regulations. These mechanisms include, but are not limited to contracts; grants; cooperative agreements; cooperative research and development agreements (pursuant to section 3710a of Title 15, United States Code); agreements (pursuant to section 2539b of Title 10, United States Code); agreements through USUHS; and interagency and interservice agreements, including support agreements (in accordance with DoD Instruction 4000.19, "Support Agreements," April 25, 2013).

3. PILOT PROGRAM DESCRIPTION

The goals of the CDMRP pilot plan are the following:

- To determine the effectiveness of the "like" function of the Query View Report (QVR) for
 identifying potential duplication of USAMRMC research applications against NIH and other
 organizations whose data are currently stored in the data systems' resources (e.g., VA). The
 QVR is a government-only access system used by approved users for analysis and reporting.
 It offers powerful analysis capabilities of applications and awards as well as a corporate view
 of the entire portfolio;
- To test the effectiveness of the QVR for characterization of the USAMRMC portfolio using the category function based on the unique fingerprinting process of the text analysis application;
- To test the availability of the USAMRMC portfolio by the public through the use of RePORTER; and
- To develop longer-term requirements.

The data shared in this pilot are limited to proposal submission information and award information, not research data produced by the awarded projects.

4. TIMELINE

From July to September 2012, the Assistant Secretary of Defense for Health Affairs (ASD(HA)), CDMRP, NIH, and VA met to address a way to use RePORTER for a pilot program. Through these meetings, they agreed on the following: 1) Data from multiple agencies should be housed in a central repository (NIH Data Systems); 2) Core data sets should be used (Grants.gov application data); 3) Automated tools should be used for comparisons (Research Condition and Disease Categorization, Fingerprinting); and 4) A centralized award data set for public access (NIH RePORTER) and pre-award data should be shared using the QVR.

During this time, NIH developed and tested Federal RePORTER, based on the functionality of NIH RePORTER. Federal RePORTER was designed to host common data from across agencies for public visibility of award data. The QVR was considered by NIH as the mid-term solution between Federal RePORTER and eRA.

In 2013, the ASD(HA) identified the CDMRP as a suitable organization to administer a pilot project to enable public visibility of DHP RDT&E-funded medical research via Federal RePORTER.

From September 2012 to March 2013, the CDMRP staff was provided access to the QVR and developed pilot plans using CDMRP's specific electronic data system. CDMRP's electronic data system has a Defense Business Certification (DBC) as well as interdependencies with other USAMRMC-specific systems and supports CDMRP's current business process, the Grants.gov dataset, and web services.

In fiscal year (FY) 2014, the ASD(HA) issued guidance to the DHA, which directed the Joint Program Committee (JPC) Chairs to plan for improved data sharing using the NIH's Federal RePORTER and eRA. In response to this guidance, the JPC Chairs would work on the best course of action to move their program's individual proposal research data based on the successful implementation of the CDMRP's pilot project.

From March 2013 to July 2014, USAMRMC and NIH established a memorandum of agreement; completed the setup of a CDMRP instance of NIH (QVR) tool; created a test database composed of 50 grant applications; mapped relevant data elements to the database; loaded test proposal data; and evaluated for issues and completeness. In addition, with the launch of Federal RePORTER, CDMRP was able to provide a static data load of its award data from 2008-2012 to be housed along with NIH, VA, National Science Foundation, and other agencies in this new system (http://federalreporter.nih.gov/). Finally, a cost estimate for establishing a web service for real-time streaming of CDMRP data to NIH Federal RePORTER was completed and CDMRP received approval to establish a secure connection between the USAMRMC.mil network center and the NIH.gov network.

In process tasks for the pilot project include, but are not limited to, gap analysis for proposal data and establishing the .mil-to -.gov secure connection to enable use of the QVR. Web service establishment and testing is underway as the final step prior to implementation of ongoing data transfers to NIH for use in the QVR and Federal RePORTER. From October 2014 to February 2015, CDMRP worked to resolve connectivity issues in preparation for the phase 1 web services testing. Pending the approval of a memorandum of agreement between NIH and the DHA, phase 2 of the pilot, which includes loading prospective FY 2015 proposal data will begin in the third quarter of FY 2015. The pilot is scheduled to end by FY 2016.

5. IMPEDIMENTS AND CHALLENGES TO IMPLEMENTATION

Impediments and challenges for the DoD to using Federal RePORTER are as follows:

- Implementation of the use of the Federal RePORTER. The QVR and the eRA systems require business process re-engineering to obtain DBC. Beginning with an approved problem statement, this multi-step process can take more than a year. DBC must be obtained for Federal RePORTER, QVR, and eRA before obligating funds.
- DHP research funds cannot be used for procurement or sustainment of an IT system.

- Funds for procurement and sustainment must be programmed before a DBC can be provided.
- Operations and maintenance sustainment funding would be required from each component that uses DHP RDT&E funds. The final cost will be determined during the Fit Gap Analysis scheduled for the third and fourth quarters of FY 2015.
- The DoD uses a combination of very specific electronic applications across each Service and each organization within a Service.
 - The Fit Gap Analysis for each of the Services will identify the system and process changes required to determine the needs of each Service and prepare for subsequent phases of implementation. Implementation of Federal RePORTER, QVR, and eRA requires buy-in by each component to standardize data outputs and justify discontinuing their current systems.
- Use of Federal RePORTER, QVR, and eRA requires the DoD to develop interagency business rules for access rights.

6. Conclusion

The pilot program continues to move forward as the above mentioned challenges are addressed. The DHA has initiated the DBC process and is working with NIH to create a plan for the Fit Gap analysis. The DoD is committed to increasing access to medical research information and continually improving the coordination of research programs across agencies.