January 31, 2022

The Honorable Jon Tester
Chair
The Honorable Richard Shelby
Ranking Member
Subcommittee on Defense
Committee on Appropriations
United States Senate

The Honorable Betty McCollum
Chair
The Honorable Ken Calvert
Ranking Member
Subcommittee on Defense
Committee on Appropriations
House of Representatives

Biomedical Research: Observations on DOD's Management of Congressionally Directed Medical Research Programs

Accessible Version

The Department of Defense (DOD) is among the United States' largest federal sponsors of biomedical research, which contributes to discoveries of new drugs, vaccines, medical devices, and other approaches for preventing, diagnosing, and treating diseases, conditions, and injuries. For fiscal year 2021, Congress appropriated nearly $2.4 billion for the Defense Health Program for research, development, test and evaluation, which includes biomedical research. The National Institutes of Health (NIH) and the Department of Veterans Affairs (VA) are other significant federal sponsors of biomedical research, with appropriations of nearly $43 billion and $2.1 billion, respectively, for fiscal year 2021 research and development.

About $1.5 billion of DOD's fiscal year 2021 appropriations funded Congressionally Directed Medical Research Programs (CDMRP). Through a competitive annual selection process, CDMRP awards funds to extramural and intramural researchers for projects with a specific focus on advancements in military medicine, as well as on public health benefits.[1] CDMRP has grown since its initial appropriation of $210 million in 1992 (about $367 million in fiscal year 2021 dollars) to fund a breast cancer research program. For

[1]Extramural researchers are affiliated with universities, academic medical centers, and other research institutes. They receive grants, cooperative agreements, and contracts from DOD to perform research. Intramural researchers generally perform their research in DOD laboratories and clinics.

fiscal year 2021, CDMRP included 36 research programs, including programs related to cancers, alcohol and substance abuse disorders, and spinal cord injury, among others.[2]

The Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2021 includes a provision for us to conduct a comprehensive review of DOD's CDMRP.[3] This report provides information on CDMRP's (1) execution of its annual appropriations; (2) efforts to prioritize and assess biomedical research programs and investments; and (3) coordination of biomedical research with NIH and VA. We briefed committee staff on the results of our work in November 2021. This report formally transmits the briefing slides (see enclosure I).

To address our first objective, for research programs included in the CDMRP appropriations from fiscal years 2015 through 2019, we reviewed congressionally designated amounts and reprogrammings to the Small Business Innovation Research and Small Business Technology Transfer programs, as identified in DOD's annual CDMRP reports.[4] We analyzed DOD data on obligations and disbursements as of September 30, 2021, as identified in status-of-funds reports from the General Funds Execution and Budget System and in appropriation status reports by the Defense Finance and Accounting Service.[5] We compared the congressionally designated amounts and reprogrammings to identify available amounts and compared available amounts with obligations and disbursements data to identify unexpended funds, including unobligated amounts and unliquidated obligations.[6] We assessed the reliability of DOD's data by interviewing responsible officials, comparing data from two sources (i.e., status-of-funds reports and appropriation status reports), and checking for errors and omissions. We found these data sufficiently reliable for our purpose of describing trends in budget execution.

To address our second objective, we interviewed CDMRP officials to understand what information they use for planning and assessing programs, and how they use it. We selected a nongeneralizable sample of programs and projects funded from fiscal years 2018 through 2020 to review how DOD has planned programs, awarded projects, and monitored progress in recent years. We

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[2]CDMRP research programs are distinct from DOD's "core" medical research areas, which are aligned with department missions. DOD develops an annual budget for its core research, which includes six topical portfolios: military infectious diseases; medical simulation and information sciences; military operational medicine; combat casualty care; radiation health effects; and clinical and rehabilitative medicine.

[3]166 Cong. Rec. H8258 (daily ed. Dec. 21, 2020).

[4]Congress generally specifies—in conference reports or explanatory statements accompanying appropriation acts— the amount designated for each research program that makes up the CDMRP, according to DOD officials. Reprogramming is the realignment of funds within an appropriation account. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are codified at 15 U.S.C. § 638. Each federal agency with an extramural budget for research or research and development in excess of a certain threshold must participate in the SBIR/STTR programs and obligate a minimum percentage of their extramural budgets required by statute for each fiscal year for awards to small business concerns under the SBIR/STTR programs.

[5]An obligation is incurred when an agency places an order, signs a contract, awards a grant, purchases a service, or takes other actions that require the government to make payments to the public or from one government account to another. An obligation is liquidated, or disbursed, when payment is made.

[6]An unobligated amount is the portion of obligational authority that has not yet been obligated. Unliquidated obligations represent the amount of outstanding obligations.

selected five programs to represent a mix of sizes (number and dollar amount of awards), subjects, and extramural and intramural researchers.[7] We randomly selected five projects within each selected program and year, resulting in a mix of award amounts, types, and funding years. Although our observations on the selected programs and projects are not generalizable, they provided illustrative examples.

For the selected programs, we reviewed strategic plans, annual progress reports and planning documents, and research outcome information. We reviewed DOD's efforts to identify priorities, gaps, challenges, and outcomes and to consider program changes for the fiscal year. We compared these processes with federal internal control standards that call for using quality information to achieve objectives, defining clear objectives and risk tolerances, and designing control activities to achieve objectives and respond to risks.[8] For selected projects, we reviewed progress reports, impact statements, abstracts, and information on outcomes. We identified linkages between program priorities and project aims. We also interviewed CDMRP officials to understand how they used this information for program planning and assessments.

For our third objective, we interviewed officials from CDMRP, NIH, and VA to understand their collaboration efforts for programs and projects and to identify examples of partnerships. We compared CDMRP's processes with leading practices for collaboration, as identified in our prior work.[9] We also reviewed CDMRP reports and memorandums of understanding with NIH on data sharing and research partnership.
We compared abstracts for the 25 CDMRP research projects selected for our second objective with research abstracts for NIH- and VA-funded projects to help determine whether overlap or duplication existed between them and what coordination had taken place between CDMRP and NIH or VA. To do so, we obtained abstracts from the CDMRP website for each of the 25 selected projects. We then identified all NIH and VA projects funded from 2018 through 2020 based on information from the NIH Query View Report system, which NIH officials provided. Using the website https://federalreporter.nih.gov, we obtained all abstracts for the NIH- and VA-funded projects identified by NIH officials from Query View Report.[10]

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[7]Our five selected research programs included Breast Cancer, Duchenne Muscular Dystrophy, Hearing Restoration, Military Burn, and Autism.

[8]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

[9]Our prior work established eight leading practices to help enhance and sustain collaboration among federal agencies: define and articulate a common outcome; establish mutually reinforcing or joint strategies; identify and address needs by leveraging resources; agree on roles and responsibilities; establish compatible policies, procedures, and other means to operate across agency boundaries; develop mechanisms to monitor, evaluate, and report on results; reinforce agency accountability for collaborative efforts through agency plans and reports; and reinforce individual accountability for collaborative efforts through performance management systems. We assessed CDMRP against all but the last practice because performance management was outside the scope of our review. GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

[10]Although project information, including abstracts, was available through Query View Report, we obtained the abstracts ourselves because of the considerable time that NIH officials would have needed to manually download the information for us from the Query View Report system.

We used analytic software to compare CDMRP abstracts with those of NIH and VA by identifying similarities in key words, including synonyms and sentences, and generated our own measure of similarity between text from the abstracts. We manually reviewed abstracts with the largest degree of similarity, based on our measure, to determine whether possible overlap or duplication existed among the sample. Subject matter experts from CDMRP reviewed the results of our analysis and explained actions they took for any potentially overlapping or duplicative projects.

We conducted this performance audit from March 2021 to January 2022 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The CDMRP Program Office is a subordinate organization to the U.S. Army Medical Research and Development Command. The Program Office coordinates the review and selection of new projects to award, and manages the selected projects. At recent appropriation levels, the Program Office has overseen the selection of about 1,000 new projects per year, and managed about 4,000 to 5,000 active projects at a time, according to CDMRP officials.[11] A typical CDMRP award ranges from less than $100,000 for a project with a new research focus to several million dollars for a clinical trial in a mature research area. The performance period for a single project generally ranges from 1 to 5 years, depending on the project methodology and agreement terms set with CDMRP and USAMRDC.

Both the National Academies of Sciences, Engineering, and Medicine and we have reviewed CDMRP in recent years and made several recommendations to improve its performance. In 2016, the National Academies recommended, among other things, that DOD create a strategic plan for each research program.[12] DOD first implemented this recommendation for its fiscal year 2018 programs. In February 2012, we found that the databases used by NIH, DOD, and VA to check for duplication in health research did not always provide comprehensive information needed during the funding decision process.[13] We recommended that they improve information sharing and their abilities to identify possible duplication, which they have since implemented, as described later in this

[11]DOD has 2 years in which to obligate CDMRP funds from each annual appropriation, and another 5 years in which to disburse, or liquidate, those obligated funds.

[12]The National Academies of Sciences, Engineering, and Medicine, *Evaluation of the Congressionally Directed Medical Research Programs Review Process* (Washington, D.C.: 2016).

[13]GAO, *2012 Annual Report: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue*, GAO-12-342SP (Washington, D.C.: Feb. 28, 2012).

report and in enclosure I.

DOD Obligated Almost All CDMRP Appropriations

For fiscal years 2015 through 2019, based on data from DOD, we found that DOD obligated nearly 100 percent of its approximately $4.46 billion in available CDMRP appropriations, with only about 1.3 percent ($59.252 million) left unobligated for the period, as of September 30, 2021. CDMRP's unobligated funds include (1) amounts not obligated during the 2-year period of availability for each appropriation year, and (2) obligations subsequently deobligated. According to DOD officials, the predictability of CDMRP funding levels and the annual investment strategy for each program help them execute nearly 100 percent of their program budgets. They stated that unobligated amounts are generally attributed to deobligated funds from withdrawn and terminated awards or unused funds that are deducted when projects end.

DOD Uses a Process to Prioritize and Assess Biomedical Research Investments

DOD uses a cyclical, routine process to prioritize and assess biomedical research investments from CDMRP appropriations (see figure 1). This process applies to program planning and project selections within each program.

Figure 1: Department of Defense Cyclical, Routine Process for Prioritizing and Assessing Investments through CDMRP

Source: GAO analysis of Congressionally Directed Medical Research Programs (CDMRP) documents. | GAO-22-105107

Each year following receipt of CDMRP appropriations, DOD convenes panels of experts (i.e., "programmatic panels" of scientists, clinicians, other federal and nonfederal funding organizations, and consumers) to help program staff to agree on a research strategy

and priorities for the mid- and long-term and the upcoming year.[14] We found that this priority-setting process is consistent with federal internal control standards that call for management to define objectives clearly, define risk tolerances, and design control activities to achieve objectives and respond to risks.[15]

The programmatic panels—one per research program—set short-term priorities for yearly application announcements through an annual process known as "vision setting." The panels also review research applications and recommend ones to award on the basis of their alignment with program priorities and their expected impact, according to DOD officials. In our analysis of documentation for 25 selected projects and the strategic plan and vision setting document for the respective research program, we found that each applicant clearly stated the relationship between the proposed project and one or more program priorities.

CDMRP staff continuously assess progress through project management activities and periodically analyze the contributions that projects have made to research programs, efforts which we found are consistent with federal internal control standards that call for management to use quality information to achieve an agency's objectives.[16] For example, CDMRP program officials stated that they use researchers' statements of work as a project management tool to measure progress. In addition, science officers use researchers' interim and final reports to verify and record accomplishments, products, and outcomes. CDMRP staff assess collective project outcomes through cyclical program management and planning activities. For example, staff participate in annual "review and analysis" meetings, in which senior leaders from DOD, NIH, VA, and others discuss strategic plans, focus areas, and program outcomes.

DOD, National Institutes of Health, and Veterans Affairs Coordinate Research Programs

DOD officials coordinate with NIH and VA counterparts on CDMRP-funded research programs throughout their cyclical program and project management process (summarized above in figure 1). This coordination occurs through a number of mechanisms, including programmatic panels, senior leader portfolio review meetings, and topical committees or partnerships. We found that these

[14]Prior to a programmatic panel meeting for new research programs and then periodically thereafter, DOD also convenes a meeting of stakeholders to discuss the research landscape and gaps, and make recommendations to inform the panel's "vision setting" meeting.

[15]GAO-14-704G. Each programmatic panel, through its priority-setting process, identifies specific research objectives that inform the respective program's investment strategy. An investment strategy defines award types and maximum dollar amounts to be offered. In turn, the investment strategy informs the solicitation of applications, including requirements that researchers must meet and document.

[16]GAO-14-704G.

coordination activities, and others described below, are consistent with leading practices for collaboration, such as establishing mutually reinforcing or joint strategies and leveraging resources.[17]

For program planning purposes during annual vision setting, programmatic panels discuss research sponsored by other organizations and help ensure CDMRP investments are complementary. The panels generally include officials from NIH, VA, or both, among other organizations. These discussions, according to DOD officials, help prevent research duplication. Likewise, we found that coordination with NIH and VA during CDMRP's project selection, management, and data sharing helps better manage fragmentation and prevent, identify, and mitigate unneeded duplication and overlap.[18] For example, programmatic and peer reviewers from other organizations provide information about related research sponsored outside DOD as they review project applications. If CDMRP recommends funding for a project application being considered by another federal organization, scientific and contracting staff coordinate with their federal counterparts. To prevent the same project from being funded by more than one federal organization, CDMRP staff may work to separate the scopes and tasks of proposed work between the organizations or agree on which organization will fully fund the entire project and which will withdraw funding.

To augment its interagency coordination and help identify unnecessary research overlap and duplication, CDMRP has collaborated since 2012 with NIH to develop data sharing capabilities on research applications, application status, and related information, including VA data. Specifically, in 2012, CDMRP and NIH began taking steps to implement an electronic interface between their respective research administration systems. These efforts were in response to a recommendation in our February 2012 report, in which we found that DOD, NIH, and VA could improve the sharing of information on health research to avoid the potential for unnecessary duplication.[19] CDMRP's full implementation of the NIH Query View Report system for data sharing began in fiscal year 2019, when program staff first used it to review applications and identify potential overlap or duplication with NIH and VA research. Query View Report provides CDMRP staff with access to all NIH and VA grants and researcher data from 1970 to the present.

According to DOD officials, using shared data from Query View Report helped them identify overlap and duplication, which led them to take mitigation steps and avoid cost for the federal government. In our comparison of abstracts for 25 selected CDMRP projects with abstracts for NIH and VA projects funded during the same period (2018 through 2020), we found that some projects were similar in topic and methods. Only two of the projects (one from CDMRP and one from NIH) contained verifiable overlap, which program managers had previously identified and addressed. In this instance, CDMRP and NIH officials coordinated to confirm the level of duplication. CDMRP requested that the researcher's academic institution address the overlap, which they achieved by removing a

[17]GAO-06-15.

[18]While researchers may apply for funding for the same research from more than one organization, DOD prohibits them from accepting funding from more than one source. DOD defines "unnecessary duplication" as research funding that is not necessary to corroborate or replicate prior research results for scientific purpose—a definition based on our February 2012 report (GAO-12-342SP).

[19]GAO-12-342SP.

major task from the CDMRP project proposal and reducing the scope of work. DOD and the researcher reduced the project's budget commensurate with the scope reduction. Through these and other coordination activities that are consistent with leading practices for collaboration, CDMRP avoids and mitigates overlap and duplication of biomedical research efforts across DOD, NIH, and VA.

Agency Comments

We provided a draft of this report to DOD for review and comment. In response, DOD indicated that it agrees with the overall findings presented in this report and officials also provided technical comments. We have included those technical comments as appropriate.

We are sending copies of this report to the appropriate congressional committees, and to the Secretary of Defense and the Commanding General, U.S. Army Medical Research and Development Command. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact Elizabeth Field at (202) 512-2775 or FieldE1@gao.gov. Contact points for our Offices of Congressional Relations and Office of Public Affairs may be found on the last page of this report. Other key contributors to this report included Lori Atkinson (Assistant Director), Melissa Blanco (Analyst-in-Charge), Lilia Chaidez, Alexandra Gonzalez, Samuel Portnow, Patricia Powell, Breana Stevens, and Cheryl Weissman.

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Enclosure – 1

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