



441 G St. N.W.
Washington, DC 20548

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

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 fiscal year 2021, CDMRP included

¹Extramural 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.

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 selected five programs to represent a mix of sizes (number and dollar amount of

²CDMRP 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.

³166 Cong. Rec. H8258 (daily ed. Dec. 21, 2020).

⁴Congress 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.

⁵An 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.

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

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

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

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

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

⁹Our 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).

¹⁰Although 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.

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 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

¹¹DOD 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.

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

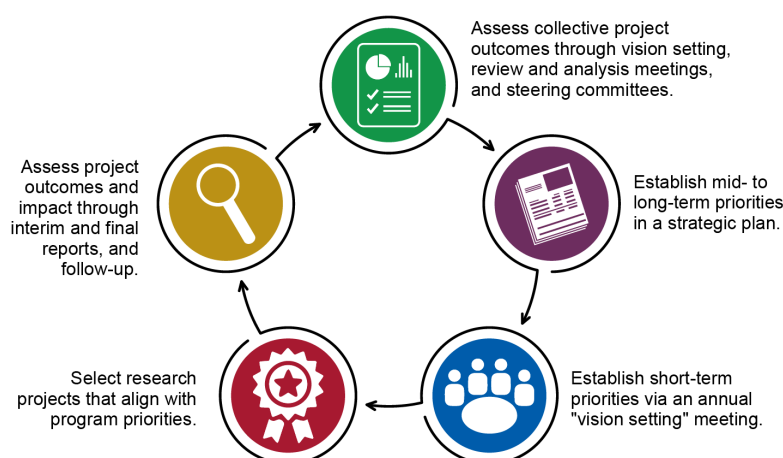
¹³GAO, *2012 Annual Report: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue*, [GAO-12-342SP](#) (Washington, D.C.: Feb. 28, 2012).

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

¹⁴Prior 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.

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 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

¹⁶[GAO-14-704G](#).

¹⁷[GAO-06-15](#).

¹⁸While 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](#)).

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 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>.

¹⁹[GAO-12-342SP](#).

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.

A handwritten signature in black ink, appearing to read 'Elizabeth A. Field', with a stylized, flowing script.

Elizabeth A. Field
Director, Defense Capabilities and Management

Enclosure – 1



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

Briefing for Congressional Committees

November 2021

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Overview

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Introduction

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.
- Of that amount, about \$1.5 billion funded DOD's Congressionally Directed Medical Research Programs (CDMRP), including 36 research program areas such as cancers, alcohol and substance abuse disorders, and spinal cord injury.
- 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.

CDMRP Selection Process for Research Projects

Through a competitive annual selection process, DOD awards CDMRP funds for the performance of research projects by:

- extramural researchers, who are affiliated with universities, academic medical centers, and other research institutes, generally through grants, cooperative agreements, and contracts; and
- intramural researchers who generally perform their work in-house through DOD's research and development organizations (e.g., U.S. Army Medical Research Institute of Infectious Diseases, Naval Medical Research Center) through fund transfers and accompanying agreements.



Introduction (cont.)

CDMRP Selection Process for Research Projects (cont.)

The CDMRP Program Office coordinates the review and selection of new projects to award, and manages the selected projects.¹ 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.

- In 2021, the Program Office was comprised of 191 staff members—two military officers, 56 civilian DOD employees, and 133 contractors. The staff manage the research programs and related support activities (e.g., public affairs and information technology). They also support DOD’s “core” medical research outside CDMRP.²
- A typical CDMRP award amount 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.
- 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.

¹The U.S. Army Medical Research and Development Command oversees and provides administrative support to the CDMRP Program Office.

²DOD develops an annual budget for “core” medical research that is aligned with department missions within topical research areas, including: military infectious diseases; medical simulation and information sciences; military operational medicine; combat casualty care; radiation health effects; and clinical and rehabilitative medicine.



Introduction (cont.)

Other Federal Entities Conducting Biomedical Research

- The National Institutes of Health (NIH), under the Department of Health and Human Services, is the largest biomedical research sponsor in the world, investing nearly \$43 billion for extramural and intramural research in fiscal year 2021.
- The Department of Veterans Affairs (VA) is another significant federal sponsor of biomedical research and development, with an intramural research budget of approximately \$2.1 billion for fiscal year 2021.³
- CDMRP, NIH, and VA sponsor research in a number of shared areas, such as chronic pain management, burns, and vision. CDMRP's specific focus is advancements in military medicine, as well as on public health benefits.

³This amount includes enacted appropriations, reimbursements, and grants from private and federal agencies. VA researchers may be awarded grants from DOD, NIH, and CDC.



Introduction (cont.)

Prior Evaluations of CDMRP

The National Academies of Sciences, Engineering, and Medicine have reviewed the 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. DOD first implemented this recommendation for its fiscal year 2018 programs. The National Academies also reported that DOD had implemented a number of its previous recommendations from reports in 1993 and 1997, including:
 - establishment of a two-tiered review process for scientific merit and for program relevance,
 - provision of summary statements and peer reviews to applicants,
 - communication to the scientific community about the role of consumer reviewers, and
 - inclusion of programmatic evaluation criteria in program announcements.⁴

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.⁵ We recommended that they improve information sharing and their abilities to identify possible duplication, which they have since implemented, as described later in this briefing.

⁴The National Academies of Sciences, Engineering, and Medicine, *Evaluation of the Congressionally Directed Medical Research Programs Review Process* (Washington, D.C.: 2016).

⁵GAO, *2012 Annual Report: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue*, GAO-12-342SP (Washington, D.C.: Feb. 28, 2012).



Source of Work and Objectives

The Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2021, includes a provision for us to conduct a comprehensive review of DOD's CDMRP.⁶

To that end, this briefing provides our observations on the following three objectives:

1. To what extent does DOD execute its annual appropriations for CDMRP?
2. How does DOD prioritize and assess its biomedical research programs and investments?
3. To what extent does DOD coordinate biomedical research with NIH and VA?

⁶166 Cong. Rec. H8258 (daily ed. Dec. 21, 2020).



Scope and Methodology

To address our first objective, for research programs included in the CDMRP appropriations from fiscal years 2015 through 2019, we compared DOD data on obligations, disbursements, and reprogrammings with congressionally designated amounts to identify any unexpended amounts. We assessed the reliability of DOD's data by interviewing responsible officials, comparing data from two source databases, and checking for errors and omissions. We found these data sufficiently reliable for our purpose of describing trends in budget execution during the period of our review.

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 in fiscal years 2018 through 2020 to review how DOD plans programs, selects projects to award, and monitors progress, and to identify examples of prioritization and assessment steps. We 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, resulting in a mix of award amounts, types, and funding years.

For the selected programs, we reviewed strategic plans, progress reports and planning documents, and outcome data. We searched for evidence of DOD's efforts to identify priorities, gaps, challenges, and outcomes, and to consider program changes, and compared them 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

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

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



Scope and Methodology (cont.)

For selected projects, we reviewed progress reports, impact statements, abstracts, and information on outcomes. We identified linkages between program priorities and project aims.

For our third objective, we interviewed CDMRP, NIH, and VA officials about their collaboration efforts for programs and projects and to identify examples of partnerships. We compared CDMRP's processes with relevant leading practices for collaboration, which are identified in our prior work.⁹ We also reviewed CDMRP reports and memorandums of understanding with NIH on data sharing and research partnership. We collected abstracts for the 25 research projects selected for objective two, and all abstracts for projects that NIH and VA funded in 2018 through 2020. In our analysis, 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 similarity measure.

We manually reviewed abstracts with the largest degree of similarity based on our measure to determine whether they exhibited possible overlap or duplication. CDMRP Program Office officials reviewed our analysis, explained to us how projects were similar and different, and described follow-up actions they took for any overlapping or duplicative projects. We provided a draft of this briefing to DOD for review and incorporated technical comments from the department as appropriate.

⁹Our 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).



Objective 1: DOD Obligated Nearly All of Its CDMRP Appropriations

For programs in fiscal years 2015 through 2019, based on DOD data, we found that the department obligated nearly all of its approximately \$4.46 billion in available CDMRP appropriations, with only about 1.3 percent (\$59.252 million) left unobligated for the period (see table 1 for data by fiscal year).

Table 1. Congressionally Directed Medical Research Programs (CDMRP) Designated and Available Amounts, Obligations, Disbursements, and Unexpended Funds for Fiscal Years 2015 through 2019 Appropriations, as of September 30, 2021
(dollars in thousands)

Fiscal year	Number of programs	Designated amount ^a	Available amount ^b	Disbursed obligations	Obligations	Unexpended funds			Unexpended rate (percent)
						Unobligated amount ^c	Unliquidated obligations	Total unexpended	
2019	33	1,054,821	1,020,856	280,421	1,015,745	5,112	735,323	740,435	72.5
2018	30	978,754	947,444	462,224	939,140	8,304	476,916	485,220	51.2
2017	30	898,294	869,631	619,428	858,994	10,638	239,566	250,203	28.8
2016	28	836,969	836,969	707,807	820,795	16,173	112,988	129,162	15.4
2015	26	786,936	786,936	767,911	767,911	19,025	0	19,025	2.4
Grand total	147	4,555,755	4,461,837	2,837,792	4,402,585	59,252	1,564,794	1,624,045	36.4

Source: GAO analysis of CDMRP annual reports; budget execution data from the General Funds Execution and Budget System and from appropriation status reports by the Defense Finance and Accounting Service. | GAO-22-105107

Notes: Research, Development, Test and Evaluation funds, including CDMRP funds, are typically available for 2 fiscal years. Shading represents amounts still available, within 5 years of expiration of the appropriation, for limited purposes such as adjusting and liquidating obligations properly chargeable to the fiscal year account. The general appropriation requirements applicable to the period of availability, account closure, and account cancellation can be found at 31 U.S.C. § 1551-1558.

^aThe amounts in the column include the fiscal year end proceeds of the Stamp Out Breast Cancer Act, as reported in the CDMRP annual reports for the Breast Cancer Semipostal Research Program.

^bAmounts available include the congressional designations less reprogrammings for the Small Business Innovation Research and Small Business Technology Transfer programs for fiscal years 2017 through 2019.

^cUnobligated amounts include (1) amounts not obligated during the appropriation's period of availability and (2) obligations subsequently deobligated.

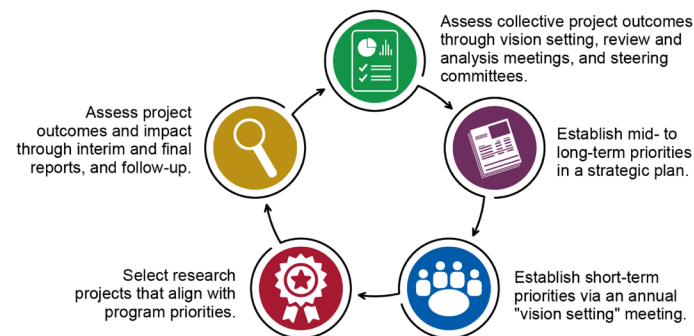
According to DOD officials, the predictability of CDMRP funding levels and the annual investment strategy for each program help them execute nearly 100 percent of their program budgets. They stated that amounts deobligated after funds expire are generally attributed to project awards that are withdrawn and terminated, or to remaining award funds that are deducted when projects end.



Objective 2: DOD Prioritizes and Assesses Biomedical Research Investments through Program and Project Management

DOD uses a cyclical, routine process to prioritize and assess medical research investments from CDMRP appropriations (see figure 1). This process applies to program planning and project selections within each program. According to DOD officials, applying the process helps them maximize research outcomes and ensure that investments are aligned with program goals and the CDMRP vision, which is to transform health care for servicemembers and the American public.

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



Objective 2: DOD Prioritizes and Assesses Biomedical Research Investments through Program and Project Management (cont.)

Prioritizing Research Investments

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 for the upcoming year.¹⁰ We found that these priority-setting processes are 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.¹¹

- **Establishing mid- to long-term program management priorities.** Each programmatic panel—one per research program—provides key inputs to CDMRP staff to establish mid- and long-term priorities in a strategic plan for each program. The strategic plan:
 - outlines broad priorities, or “strategic goals,” based on current science, the global research landscape, and the greatest potential patient impact (e.g., prevention of breast cancer);
 - defines an investment strategy to facilitate the accomplishment of the priorities; and
 - is reviewed annually, updated as needed, and made available on the CDMRP website.

¹⁰Prior 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.

¹¹GAO-14-704G.



Objective 2: DOD Prioritizes and Assesses Biomedical Research Investments through Program and Project Management (cont.)

- **Establishing short-term program management priorities.** Concurrent with efforts to provide inputs on the strategic plan, each programmatic panel sets short-term priorities for yearly application announcements. This process, called “vision setting,” includes reviewing and updating specific priorities or focus areas. For example, in our review of documents for the Fiscal Year 2020 Hearing Restoration Research Program, we found that the panel had revised the previous year’s priorities and added one new priority—diagnosis of hearing injuries in austere or remote environments—to align the program with current science and warfighter needs.

Through vision setting, the panels also:

- consider the available budgetary resources for research for that fiscal year;
- produce an investment strategy to allocate resources among awards to be offered, including the number, types, and dollar amounts; and
- inform the broad agency announcements or program announcements that solicit research proposals for awards that will be made available that year.



Objective 2: DOD Prioritizes and Assesses Biomedical Research Investments through Program and Project Management (cont.)

- **Aligning selected research projects with program priorities.** Programmatic panels 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.¹²
 - Applicants are generally asked to describe how their proposed project would address at least one of the program's research priorities and how the results may impact servicemembers, veterans, and the general public.
 - In our analysis of documentation for 25 selected awards, including the impact statement for each 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. For example, a fiscal year 2020 autism project proposed a telehealth intervention method to improve children's social-communication development, which aligned with the program's priority to improve access to services.

¹²Programmatic panel review is the second step in a two-tier review process. The first step is scientific peer review, in which reviewers evaluate the scientific and technical merits of the proposal against the criteria in the broad agency announcement or program announcement. The programmatic panel review of projects occurs later in the year than the vision setting meeting, although it involves the same members.



Objective 2: DOD Prioritizes and Assesses Biomedical Research Investments through Program and Project Management (cont.)

Assessing Research Investments

Following its selection of research projects to fund each year, CDMRP staff continuously assess their progress through project management activities, and periodically analyze the collective contributions of projects to their respective programs. We found that these assessment efforts are consistent with federal internal control standards, which state that management should use quality information to achieve an agency's objectives.¹³

- **Continuous assessment of project outcomes and impact through project management.** Program officials stated that they use researchers' statements of work as a project management tool to measure progress. Other elements of their project management and reviews include:
 - *Collecting interim and final reports.* CDMRP requires researchers to submit progress reports and documentation on accomplishments, products and outcomes (e.g., publications, computer programs or software, patents or licensures, clinical care, potential therapeutics, drugs, reagents), which science officers record and track. Officials stated that project success is measured against program goals and potential benefit to servicemembers, veterans, and the general public.
 - *Conducting post-award follow up.* DOD officials stated that they conduct follow-up efforts to track outcomes on projects of highest priority after their completion, and the CDMRP Program Office has formed a working group to facilitate these efforts.

¹³GAO-14-704G.



Objective 2: DOD Prioritizes and Assesses Biomedical Research Investments through Program and Project Management (cont.)

- **Assessment of collective project outcomes through cyclical program management and planning.**
 - *Review and analysis meetings.* To execute oversight responsibilities for DOD medical research and development, the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency lead an annual “review and analysis” meeting for each of four CDMRP portfolios.¹⁴ At the meetings, senior leaders from DOD and stakeholders from NIH, VA, and others discuss strategic plans, focus areas, and program outcomes.
 - *CDMRP Program Evaluation Steering Committee.* On a monthly basis, the steering committee reviews the status of ongoing evaluation projects, ensures the projects remain consistent with intent and are progressing toward completion, and identifies and prioritizes new evaluation projects to assess CDMRP programs and processes.
 - *Vision setting.* CDMRP shares information about individual projects and their contributions to the broader portfolio with the programmatic panel at the start of each fiscal year, according to Program Office officials. Officials stated that they and programmatic panel members use the information to identify any changes needed to refine their priorities for the following year.

¹⁴For the purpose of these meetings, DOD groups individual research programs from CDMRP into four related categories, or portfolios: Peer Reviewed Medical Research Programs, Injury Prevention and Rehabilitation Programs, Cancer Programs, and Neurological Programs. DOD also convenes the same type of annual meeting for its non-CDMRP medical research programs.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap

For fiscal year 2021, NIH, VA, or both sponsored research that aligned with 35 of CDMRP's 36 programs, as shown in figure 2 below.

Figure 2: Fiscal Year 2021 Congressionally Directed Medical Research Programs of the Department of Defense, and Areas of Shared Research Sponsorship with the National Institutes of Health (NIH) and the Department of Veterans Affairs (VA)

Congressionally Directed Medical Research Programs Research Area	National Institutes of Health	Veterans Affairs	Congressionally Directed Medical Research Programs Research Area	National Institutes of Health	Veterans Affairs
Alcohol and substance abuse disorders	✓	✓	Neurofibromatosis	✓	
Amyotrophic Lateral Sclerosis	✓	✓	Neurotoxin exposure treatment Parkinson's	✓	✓
Autism	✓		Orthotics and prosthetics outcomes	✓	✓
Bone marrow failure	✓		Ovarian cancer	✓	✓
Breast cancer	✓	✓	Pancreatic cancer	✓	✓
Chronic pain management	✓	✓	Peer reviewed Alzheimer's	✓	✓
Combat readiness medical research	✓	✓	Peer reviewed cancer	✓	✓
Duchenne muscular dystrophy	✓		Peer reviewed medical	✓	✓
Epilepsy	✓	✓	Peer reviewed orthopaedic	✓	✓
Gulf War illness	✓	✓	Prostate cancer	✓	✓
Hearing restoration	✓	✓	Rare cancers	✓	✓
Joint warfighter medical			Reconstructive transplant	✓	✓
Kidney cancer	✓	✓	Scleroderma	✓	✓
Lung cancer	✓	✓	Spinal cord injury	✓	✓
Lupus	✓		Tick-borne disease	✓	
Melanoma	✓	✓	Traumatic brain injury and psychological health	✓	✓
Military burn	✓	✓	Tuberous sclerosis	✓	
Multiple sclerosis	✓	✓	Vision	✓	✓

Source: GAO analysis of Congressionally Directed Medical Research Programs (CDMRP) program and project documents, and interviews with CDMRP, NIH, and VA officials. | GAO-22-105107

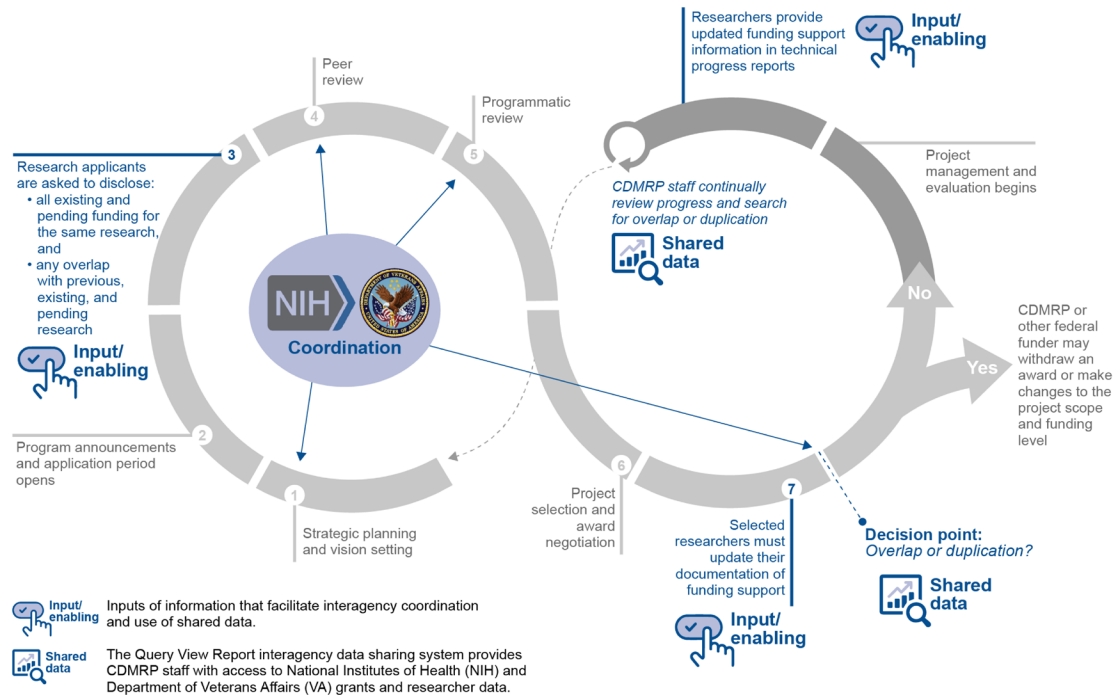
Note: Although only four of the CDMRP research programs for fiscal year 2021 include the term "peer reviewed" in the program name, DOD applies a peer-review process to assess research applications for all programs.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

Based on our review of program documents and interviews with officials, we found that DOD officials coordinate with NIH and VA counterparts on CDMRP-funded research programs throughout the program and project management cycle (see figure 3).

Figure 3. CDMRP Coordination with the National Institutes of Health and the Department of Veterans Affairs



Source: GAO analysis of Congressionally Directed Medical Research Programs (CDMRP) annual reports, and interviews with CDMRP officials. | GAO-22-105107



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

DOD coordinates with NIH, VA, and other research sponsors for program planning purposes through a number of mechanisms, including its programmatic panels, senior leader portfolio review meetings, and topical committees or partnerships. We found that these coordination activities, and others described below, are consistent with leading practices for collaboration, such as establishing mutually reinforcing or joint strategies, and leveraging resources.¹⁵

- **Programmatic panels.** As previously discussed, on a yearly basis for each CDMRP-funded research program, DOD convenes a programmatic panel of experts, generally including NIH and VA officials for shared research topics, to strategize and plan its investment priorities.
 - At these meetings, panel members discuss the research landscape, including research being sponsored by other federal agencies and nonfederal organizations. These discussions, according to DOD officials, help prevent research duplication.
 - According to DOD officials, in addition to programmatic panel membership, NIH and VA experts, among others, may be invited to attend panel meetings to present research, inform priority areas, and help identify gaps in funded research.
 - A goal of the panels' planning meetings, according to DOD officials, is to ensure that CDMRP investments complement those of NIH, VA, and others. For example, DOD directs the breast cancer program toward new research, while NIH's National Cancer Institute focuses the majority of its funds on the support of continuing awards.

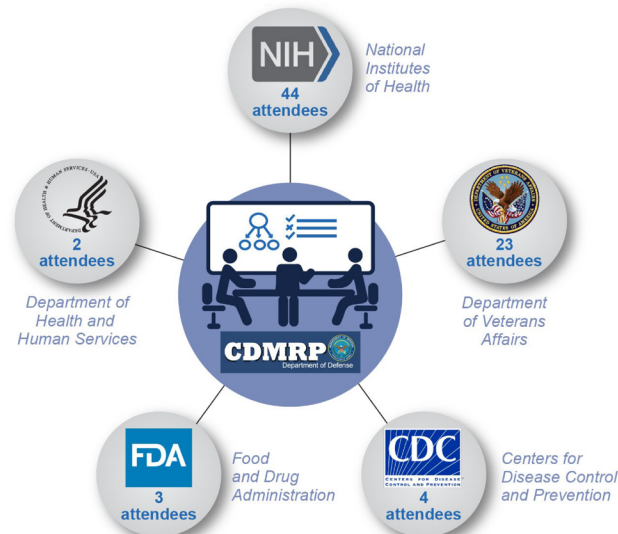
¹⁵GAO-06-15.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

- According to a CDMRP briefing document on its fiscal year 2021 programs, the programmatic panels for its 36 programs included 76 participants from other federal research sponsors, including NIH, others from the Department of Health and Human Services, and VA (see figure 4).

Figure 4. Fiscal Year 2021 Participation in CDMRP Programmatic Panels from Other Federal Biomedical Research Sponsors



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



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

- **Senior leader portfolio review meetings.** Once a year for each of four broad portfolios, according to DOD officials, the Defense Health Agency convenes a “review and analysis” meeting with the Office of the Assistant Secretary of Defense for Health Affairs to evaluate CDMRP’s ongoing programs and receive input from experts from NIH, VA, and other stakeholders.
- **Topical research partnerships and joint funding initiatives.** DOD participates in collaborative partnerships that augment its programmatic planning within selected research areas. For example:
 - *Cancer.* CDMRP is a founding partner of the International Cancer Research Partnership, an alliance of cancer research organizations that facilitates the coordination of research and funding through a shared system of coding project data.
 - *Vision.* The Vision Research Collaborative between CDMRP and NIH’s National Eye Institute is a joint initiative in which the two organizations have partnered to provide NIH funding opportunities for CDMRP applicants who were not selected for funding but whose research addresses critical gaps in the research landscape.
 - *Pain Management.* DOD, including CDMRP, has partnered with NIH and VA to fund individual projects and support a grant program focused on developing, implementing, and testing research on nondrug approaches for pain management and related conditions in military and veterans health care settings.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

Project Selection Approach and Management

Through its project selection approach and management, CDMRP coordinates with NIH and VA to better manage fragmentation and prevent, identify, and mitigate unneeded duplication and overlap.¹⁶

- Coordination with NIH and VA helps ensure the completeness and accuracy of information that research applicants provide DOD regarding pending and existing support from other organizations, including other federal research sponsors.
- CDMRP's programmatic and peer review panels—which generally include members from NIH, VA, and other research sponsors as appropriate—help uncover any potential research overlap or duplication as they review project applications to make selections.
 - According to DOD officials, the programmatic and peer review panel members from other federal funding organizations provide valuable information about related research being sponsored by their own organizations.
 - These reviewers advise the CDMRP Program Office on whether proposed research has already been published or is the subject of an application to another organization, thereby helping identify and address potential duplication that the applicant did not disclose.

¹⁶While 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).



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

- If CDMRP recommends selection and funding for a project being considered by another federal organization, scientific and contracting staff will coordinate with other federal counterparts, based in part on information from the applicant's disclosure of current, pending, and existing support (see figure 3 above).
- As discussed in more detail later in this briefing, courses of action that the CDMRP staff may take to prevent the same project from being funded by more than one federal organization include separating the scopes and tasks of proposed work between the organizations, or agreeing on which organization will fully fund the entire project and which will withdraw funding.
- After a project begins, researchers provide updated funding support information in technical progress reports. CDMRP staff use this information, along with internal and external award databases (including shared databases with NIH and VA, as discussed below), to continually monitor for overlap or duplication.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

Data Sharing

To augment its interagency coordination aimed at identifying unnecessary research overlap and duplication, DOD has collaborated since 2012 with NIH to develop data sharing capabilities, including VA data, on research applications they receive, along with application status and related information.

- In February 2012, we found that DOD, NIH, and VA could improve the sharing of information on health research to avoid the potential for unnecessary duplication.
- In response to our February 2012 report, DOD and NIH began taking steps to implement an electronic interface between their respective research administration systems that would allow staff to search and view detailed research application and award information.
 - From 2012 through 2014, the agencies conducted a feasibility study.
 - From 2015 through 2018, CDMRP and NIH piloted use of the NIH Query View Report system for sharing data.
 - Full implementation of the system began in fiscal year 2019, when CDMRP program staff first used it in the process of reviewing applications prior to awards, identifying any potential similarities or duplication with NIH and VA research.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

- Data sharing using Query View Report provides CDMRP staff with access to all NIH and VA grants and researcher data from 1970 to the present. CDMRP data are available in the system for fiscal year 2019 to the present. DOD officials stated that they do not have plans to enter data from prior years because the resources needed would exceed potential benefits, and CDMRP award data from all years are publicly available at federalreporter.nih.gov and cdmrp.army.mil.
- According to DOD officials, Query View Report, due to its ability to generate a research “match score,” has led to the identification of overlap and duplication in research projects that applicants did not fully disclose. These discoveries enabled mitigation steps between agencies, and in some instances led to cost avoidance for the federal government. For example:
 - A researcher applied to NIH for funding of a project that appeared identical to one with funding underway from CDMRP without mentioning the CDMRP award on the “Previous, Current, and Pending Support” document submitted during award negotiations. As a result, NIH did not fund a duplicative award, but the CDMRP Program Office allowed the project to continue.
 - A researcher who applied to CDMRP for project funding listed a pending NIH grant but stated that there was no overlap between the two proposed projects. The CDMRP Program Office determined that there was 100 percent overlap with one of the aims of the NIH application and discussed the overlapping applications with NIH. As a result, the CDMRP Program Office withdrew its award and used the \$169,494 to fund another application.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

- In our review of NIH and VA data from the Query View Report system, we compared abstracts for 25 selected CDMRP projects with abstracts for all NIH and VA projects funded during the same period (2018 through 2020). While some NIH and VA projects appeared to show similarity, only two of the projects (one from CDMRP and one from NIH) contained verifiable overlap, which we determined had been previously identified and addressed by program managers. Specifically:
 - CDMRP program officials had identified a fiscal year 2019 breast cancer research application that appeared to be partially duplicative of an NIH award from the same year.
 - CDMRP and NIH officials responsible for award negotiation for the respective projects coordinated during negotiation to confirm the level of duplication.
 - As a result of the coordination, DOD requested that the researcher's academic institution address the overlap, which was achieved by removing a major task from the CDMRP project proposal, thereby reducing the scope of work.
 - DOD and the researcher also reduced the project's budget to be consistent with the scope reduction.



Objective 3: DOD Coordinates with NIH and VA for Research Program Planning and Project Selection, and Leverages Shared Data to Identify Overlap (cont.)

- DOD officials stated that they have identified lessons learned from their implementation of the Query View Report system, and they are working with NIH to make improvements. According to the officials, examples of those improvements underway include:
 - automating data transfers and proactive error resolution;
 - increasing the sensitivity of “match scores” for identification of research project duplication; and
 - establishing standard operating procedures for interagency communication and resolution when overlap is identified.

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