



Report to the Ranking Member,
Committee on Veterans' Affairs, House
of Representatives

July 2020

VA RESEARCH

Opportunities Exist to Strengthen Partnerships and Guide Decision- Making with Nonprofits and Academic Affiliates

GAO Highlights

Highlights of [GAO-20-570](#), a report to the Ranking Member, Committee on Veterans' Affairs, House of Representatives

Why GAO Did This Study

VA research, which has contributed to many medical advances, may be funded by VA's appropriation or extramurally by other federal agencies and nonfederal sources. To access extramural funding, investigators at VA medical centers usually work with an NPC or academic affiliate partner to submit a grant proposal. Once a grant is awarded, medical centers' partners administer the grant by distributing funding, fulfilling reporting requirements, and performing other administrative activities.

GAO was asked to review VA's extramural research. This report examines, among other objectives, (1) how much VA spent on extramural research in fiscal year 2019 and (2) the efforts VA has made to support medical centers' partnerships for extramural research.

GAO analyzed VA policies, documents, and data. It also conducted site visits and interviewed officials from VA's Central Office and from a nongeneralizable sample of VA medical centers, NPCs, and academic affiliates, which GAO selected to represent variation in geographic location and funding.

What GAO Recommends

GAO recommends that VA (1) provide more information to VA medical centers on strengthening research relationships with academic affiliates and (2) develop decision tools to help VA medical centers determine whether NPCs or academic affiliates should administer extramural grants. VA agreed with GAO's recommendations.

View [GAO-20-570](#). For more information, contact John Neumann at (202) 512-6888 or neumannj@gao.gov.

July 2020

VA RESEARCH

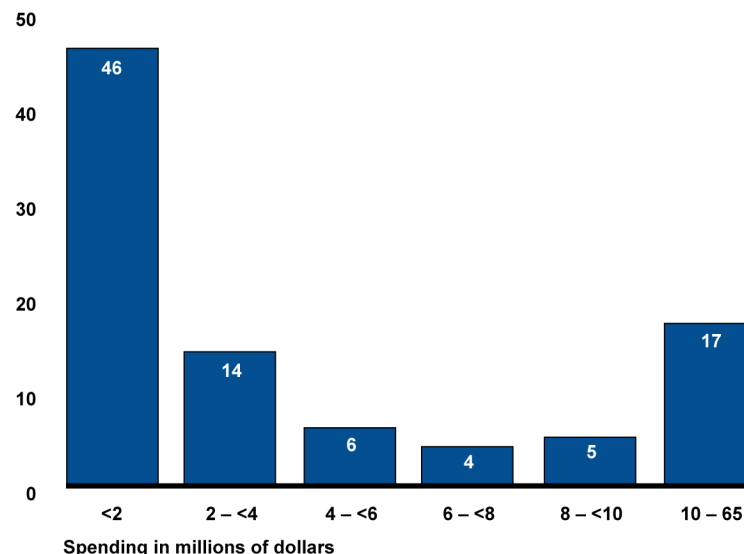
Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and Academic Affiliates

What GAO Found

The Department of Veterans Affairs' (VA) extramural research spending totaled about \$510 million in fiscal year 2019—nearly half of the \$1.1 billion in total spending on VA research. Of the \$510 million, federal sources, such as National Institutes of Health, funded \$382 million (75 percent), and nonfederal sources, including private entities, academic institutions, state and local governments, and foundations, funded \$128 million (25 percent). Spending at the 92 VA medical centers that conducted extramural research in fiscal year 2019 ranged from less than \$2 million to more than \$10 million (see figure). VA medical centers' nonprofit research and education corporations (NPC) and academic affiliate partners administered the grants that accounted for 91 percent of the spending.

Figure: Extramural Research Spending by VA Medical Centers that Conducted Extramural Research in Fiscal Year 2019

Number of VA Medical Centers



Source: GAO analysis of Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) data. | GAO 20-570

VA has made efforts to promote and support VA medical centers' partnerships with academic affiliates—for example, by coordinating a mentoring program for local VA research officials—and considers effective affiliations as an enhancement to research. However, VA's Central Office officials have not provided examples of successful practices for strengthening research partnerships with academic affiliates. Having such practices would promote collaborative opportunities for VA medical centers with academic affiliates, particularly for medical centers that have poor communication with affiliates. Additionally, VA's Central Office has provided general guidance but not specific tools to VA medical centers for determining when an NPC or an academic affiliate should administer a project's extramural funds. Having specific decision-making tools could help medical centers make more informed decisions to provide optimal support for the research.

Contents

Letter	1
Background	5
Extramural Funding Sources Accounted for Nearly Half of All Reported Spending on VA-Approved Research in Fiscal Year 2019	7
NPCs and Academic Affiliates Use Indirect Cost Reimbursements to Cover Costs of Supporting Research on Veterans' Health Issues, and Many Support Research in Additional Ways	15
VA Has Promoted Extramural Partnerships but Has Not Provided Key Information and Tools	19
VA's Central Office and VA Medical Centers Oversee Differing Aspects of Extramural Research	28
Conclusions	33
Recommendation for Executive Action	34
Agency Comments	35
Appendix I	36
Department of Veterans Affairs Comments	36
Appendix II	38
GAO Contact and Staff Acknowledgments	38
Tables	
Table 1: Median Amounts of Reported Extramural Research Spending at 92 VA Medical Centers in Fiscal Year 2019, by Type of Administering Entity	14
Table 2: Characteristics of VA Nonprofit Research and Education Corporations (NPCs) and Academic Affiliates and Their Potential Advantages and Disadvantages for Facilitating VA's Extramural Research	22
Figures	
Figure 1: Intramural and Extramural VA-Reported Research Spending in Fiscal Years (FY) 2017-2019	9
Figure 2: Federal and Nonfederal Sources of the Reported Extramural Research Spending for VA-Approved Research in Fiscal Year 2019	10

Figure 3: Funding Sources for VA’s \$1.1 Billion in Reported Research Spending in Fiscal Year 2019 and Administering Entities for Non-VA Funding	11
Figure 4: Reported Extramural Research Spending by VA Medical Centers in Fiscal Year 2019	13
Figure 5: Examples of Shared Equipment Purchased or Maintained by Nonprofit Research and Education Corporations (NPC) and Academic Affiliates	18
Figure 6: Generalized Process for VA Investigators to Submit Proposals for and Conduct Extramural Research Projects with Support from NPC and Academic Affiliate Partners	23
Figure 7: Examples of Local Memoranda of Understanding Used to Document Investigators’ Time Allocation	32
Figure 8: Example of Laboratory Space and Equipment Shared between a VA Medical Center Research Office and Its Academic Affiliate	33

Abbreviations

ACOS/R&D	Associate Chief of Staff for Research and Development
CRADO	Chief Research and Development Officer
DOD	Department of Defense
FY	fiscal year
IRB	Institutional Review Board
NCI	National Cancer Institute
NIH	National Institutes of Health
NPC	Nonprofit Research and Education Corporations
NPOB	Nonprofit Program Oversight Board
NPPO	Nonprofit Program Office
OAA	Office of Academic Affiliations
OIG	Office of Inspector General
OMB	Office of Management and Budget
ORD	Office of Research and Development
RDIS	Research and Development Information System
VA	Department of Veterans Affairs
VERA	Veterans' Equitable Resource Allocation
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Networks

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July 29, 2020

The Honorable Phil Roe, MD
Ranking Member
Committee on Veterans' Affairs
House of Representatives

Dear Dr. Roe:

For more than 90 years, the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) has managed or sponsored research that has led to health care breakthroughs and improved the lives of veterans and the public. According to VA, it has been instrumental in medical advancements such as therapies for tuberculosis following World War II, the implantable cardiac pacemaker, the first successful liver transplants, and the first powered ankle-foot prosthesis.

Much of the research takes place at VA medical centers under the direction of VA principal investigators, including clinicians who split their time between seeing patients and conducting research. According to VA officials, the investigators develop proposals for research projects and apply for funding through one of two routes:

1. Through proposals to VA under its research appropriation. In fiscal year 2019, VA's research appropriation totaled \$779 million. Through its appropriation, VA funded numerous studies, as well as career development awards and research centers and programs that focus on specific research areas, such as limb loss and spinal cord injury.¹ VA refers to research funded under its appropriation as intramural research.²
2. Through grant proposals to other federal agencies, such as National Institutes of Health (NIH) and the Department of Defense (DOD), and to nonfederal sources, such as state governments, nonprofit organizations, and private companies sponsoring clinical trials. VA

¹GAO, *VA Health Care: Efforts to Prioritize and Translate Research into Clinical Practice*, [GAO-20-211](#) (Washington, D.C.: Jan. 23, 2020).

²38 U.S.C. § 7303. VA also supports its intramural research program through other VA appropriations and reimbursements.

refers to research funded by these other sources as extramural research.³

Investigators generally have two options for submitting grant proposals for extramural research, according to VA officials. The investigator may submit a proposal through a nonprofit research and education corporation (NPC)—private, state-incorporated nonprofit entities initially authorized by the Veterans’ Benefits and Services Act of 1988 to provide a flexible funding mechanism for conducting research and education at VA medical centers.⁴ In fiscal year 2019, 80 NPCs were in operation. If the VA investigator has a dual appointment at an academic affiliate—such as a U.S. medical school or teaching hospital—that collaborates with a VA medical center on research, the second option is to submit a proposal through the academic affiliate. As of April 2018, the majority of VA physicians had dual appointments at academic affiliates.⁵

With the help of an NPC, academic affiliate, or both, VA investigators develop budgets for their extramural research projects and submit them as part of their grant proposals, according to VA officials. The budgets generally include costs that can be directly attributed to specific projects, such as research staff salaries, materials such as tissue samples, and supplies such as laboratory equipment. Additionally, the budgets cover the indirect costs of research, such as administrative staff salaries, capital improvements to research facilities, and other costs that cannot be easily associated with specific research projects.

Once the investigator’s grant is awarded, the prime grant awardee—either the NPC or the academic affiliate—administers the research project grant for the investigator. The prime awardee is responsible for distributing funds in accordance with the terms of the grant, such as for the budgeted cost of equipment, supplies, and personnel, and fulfilling all reporting requirements. The other entity—whether the NPC or the

³The funds received from federal and nonfederal sources through grants, cooperative agreements, and other funding awarded to VA principal investigators are referred to by VA as extramural research funds. In this report, we refer to all such awards as grants. VA refers to the expenditure of these funds as extramural research spending.

⁴Veterans’ Benefits and Services Act of 1988, Pub. L. No. 100–322, § 204(a), 102 Stat. 487, 510 (codified as amended at 38 U.S.C. §§ 7361-7366).

⁵GAO, *Veterans Affairs Research: Actions Needed to Help Better Identify Agency Inventions*, [GAO-18-325](#) (Washington, D.C.: Apr. 25, 2018).

academic affiliate—can receive a sub-award from the prime awardee for work conducted using the other entity’s space, resources, or equipment.

You asked us to review several aspects of VA’s research program. This report focuses on VA’s extramural research and examines (1) how much VA medical centers reported spending on extramural research in fiscal year 2019, (2) how VA’s NPC and academic affiliate partners use indirect cost reimbursements to support VA research, (3) the efforts VA has made to support medical centers’ partnerships for extramural research, and (4) how VA tracks and oversees extramural research.

To address these objectives, we reviewed relevant statutes as well as VA policies, reports, and other documents about the agency’s extramural research efforts. We conducted site visits to a nongeneralizable selection of six VA medical centers and their associated NPCs and academic affiliates located in San Francisco, California; Palo Alto, California; Kansas City, Missouri; Syracuse, New York; Charleston, South Carolina; and San Antonio, Texas. The information we obtained cannot be generalized across all such entities, but provided context and insights into the operating environments of VA medical centers, NPCs, and academic affiliates. We selected sites to ensure variation with respect to geographic location and the level and sources of sites’ extramural research funding. In addition to our site visits, we interviewed officials from two VA medical centers in Bay Pines, Florida, and Fargo, North Dakota, that engage in extramural research and only work with either an NPC or academic affiliate, but not both. We also interviewed a VA medical center in Madison, Wisconsin, that had recently begun work with an NPC after previously only working with an academic affiliate. We also interviewed officials from four NPCs in Sacramento, California; Chicago, Illinois; and East Orange, New Jersey to learn more about the successes and challenges of small and medium sized NPCs (we spoke with two NPCs in Chicago). In our site visits and interviews, we conducted a series of semistructured interviews addressing each of our objectives, including grant funding levels for extramural research, use of indirect cost reimbursements, the relationships between VA medical centers and their NPC and academic affiliate partners, and VA oversight of extramural research. During site visits, we toured facilities at VA medical centers, academic affiliates, or both that were used to conduct VA extramural research. In addition, we conducted a series of semistructured interviews with VA investigators about their extramural research and their views on the questions we discussed with other VA medical center, NPC, and academic affiliate officials. When discussing the views of officials from VA medical centers, NPCs, and academic affiliates, we grouped them into

the following categories: “one,” “some” (more than one and fewer than half), and “many” (half or more).

Additionally, to address our objectives, we interviewed officials from VA’s Central Office, including the Office of Research and Development (ORD), which administers the department’s intramural research program and plays an oversight role for extramural research, and the Office of Academic Affiliations (OAA), which oversees all of the department’s educational affiliation agreements. To obtain additional perspectives on VA’s extramural research, we interviewed officials from groups that represent NPCs and academic affiliates, including the National Association of Veterans Research and Education Foundations, which is the membership association for NPCs, and the Association of American Medical Colleges, which is the membership association for medical education institutions.

In addition to the steps described above, to examine how much VA spent on extramural research in fiscal year 2019, we analyzed data from VA’s Research and Development Information System (RDIS) on extramural research projects. To provide additional context for fiscal year 2019 spending on extramural research projects, we obtained and analyzed similar data for fiscal years 2016 through 2018. We assessed the reliability of the data we collected by performing manual testing for missing data and obvious data entry errors. We also traced a subset of spending totals to source documents provided to us from three sites we visited to determine whether that fiscal year 2019 spending data reported in RDIS matched the data provided to us by the medical centers. We found no discrepancies. Additionally, we reviewed agency documentation related to reporting procedures, and conducted interviews with knowledgeable agency officials. In particular, we discussed the data sources and methods used to report the data. We determined that the data were sufficiently reliable for reporting the spending level for extramural research, federal and nonfederal sources of funding, the amount of extramural spending administered by NPCs and academic affiliates, and how spending on extramural research is distributed among VA medical centers.

To examine how VA’s NPC and academic affiliate partners use indirect cost reimbursements to support VA research, we reviewed the Office of Management and Budget’s (OMB) *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance) and examples from our nongeneralizable selection of NPCs

and academic affiliates that describe how indirect cost reimbursements are used to support research efforts.⁶

To examine the efforts VA has made to support medical centers' partnerships for extramural research, we reviewed national and local strategic plans, research policies, and other documents that describe VA's overall research goals and efforts. Further, we interviewed officials from VA's office of the Undersecretary for Discovery, Education and Affiliate Networks, which includes ORD and OAA. The information and communication component of internal control was significant to this analysis, along with the related principle that management should internally communicate the necessary quality information to achieve objectives. We assessed coordination between ORD and OAA and the information they may provide to VA medical centers on developing relationships with partners to strengthen research programs. Related to this coordination, we assessed the agency's information provided to VA medical centers on whether an academic affiliate or NPC should administer extramural research grants.

To determine how VA tracks and oversees extramural research, we analyzed VA documentation on national and local oversight activities, including national and local policies that govern VA's oversight activities, and interviewed officials from VA's Central Office, including the Nonprofit Program Office (NPPO), which oversees NPC operations.

We conducted this performance audit from July 2019 to July 2020 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

According to VA officials, their investigators conduct VA research, including extramural research, at VA medical centers or affiliated academic institutions in accordance with policies set by ORD. A VA investigator is any individual with a VA appointment, with or without compensation, who conducts Research and Development Committee-

⁶2 C.F.R. pt. 200.

approved research on VA time.⁷ A qualified VA investigator who directs a research study or program is known as a principal investigator. All VA investigators must meet research training requirements and are required to ensure the ethical and scientific merits of the research, welfare of VA research subjects, and integrity of research data. Investigators who are dually appointed to an academic affiliate also maintain memoranda of understanding that specify for each appointment the title and responsibilities of the appointment, distribution of compensation, and the percentage of his or her effort that is available for research.

ORD defines the roles and responsibilities of essential VA medical center research personnel. Specifically:

- **Medical center director.** The director is responsible for all aspects of the local research program including ensuring that research has been approved by the medical center's Research and Development Committee and is conducted in compliance with all applicable regulations and policies.⁸
- **ACOS/R&D.** The medical center director may appoint an ACOS/R&D (Associate Chief of Staff for Research and Development)—or a research coordinator at medical centers with smaller research programs—to administer the day-to-day activities of the research program, which includes maintaining documentation of all approved research protocols and ensuring that all research personnel hold an official VA appointment. The ACOS/R&D is expected to be a physician—unless VA's Chief Research and Development Officer (CRADO) has granted an exception—and to maintain his or her own research activities.
- **Administrative officer.** The administrative officer is responsible for the business operations of the medical center's research program, including reporting required fiscal and research project information and tracking program activities such as Research and Development Committee actions, written research agreements, and documentation of all required training for research personnel.

⁷An investigator can be appointed to the VA as a Without Compensation employee. This is an official VA appointment that allows the individual to conduct or support VA research for a defined period without receiving any salary or benefits from the VA.

⁸A Research and Development Committee at each VA medical center engaged in research oversees the maintenance of VA's research program standards and ensures that VA research is scientifically valid and complies with regulatory and ethical standards.

Extramural research funds are primarily administered by two types of entities: nonprofit research and education corporations (NPC) and academic affiliates.

- **NPCs.** According to VA officials, VA medical centers partnered with 80 NPCs—state-incorporated nonprofits established to facilitate the conduct of research and education at VA medical centers—in 2019. According to officials from a national membership association of NPCs, research, rather than education, is the primary focus for most NPCs. Certain VA medical center officials are statutorily required to serve on the NPC’s board as directors; at VA medical centers with research programs, this includes the ACOS/R&D.⁹ Some NPCs support more than one VA medical center. For example, an NPC in Hines, Illinois, supports VA medical centers in Chicago, Illinois, and Madison, Wisconsin.
- **Academic affiliates.** In 2019, VA medical centers had educational affiliation agreements with 127 accredited medical schools, including osteopathic medical schools. Such agreements allow medical students to complete their residency requirements at a VA medical center. According to officials from OAA, an academic institution that has entered into an educational affiliation agreement with a VA medical center is eligible to also enter into an agreement allowing it to administer extramural research funds for VA research projects. The officials said fewer than 100 academic affiliates currently maintain active research relationships with VA.

Extramural Funding Sources Accounted for Nearly Half of All Reported Spending on VA-Approved Research in Fiscal Year 2019

In fiscal year 2019, federal and nonfederal extramural funding sources accounted for almost half (46 percent) of the total reported spending on VA-approved research. VA medical centers’ extramural research spending varied widely, with those centers that partnered with both NPCs and academic affiliates reporting the highest median spending.

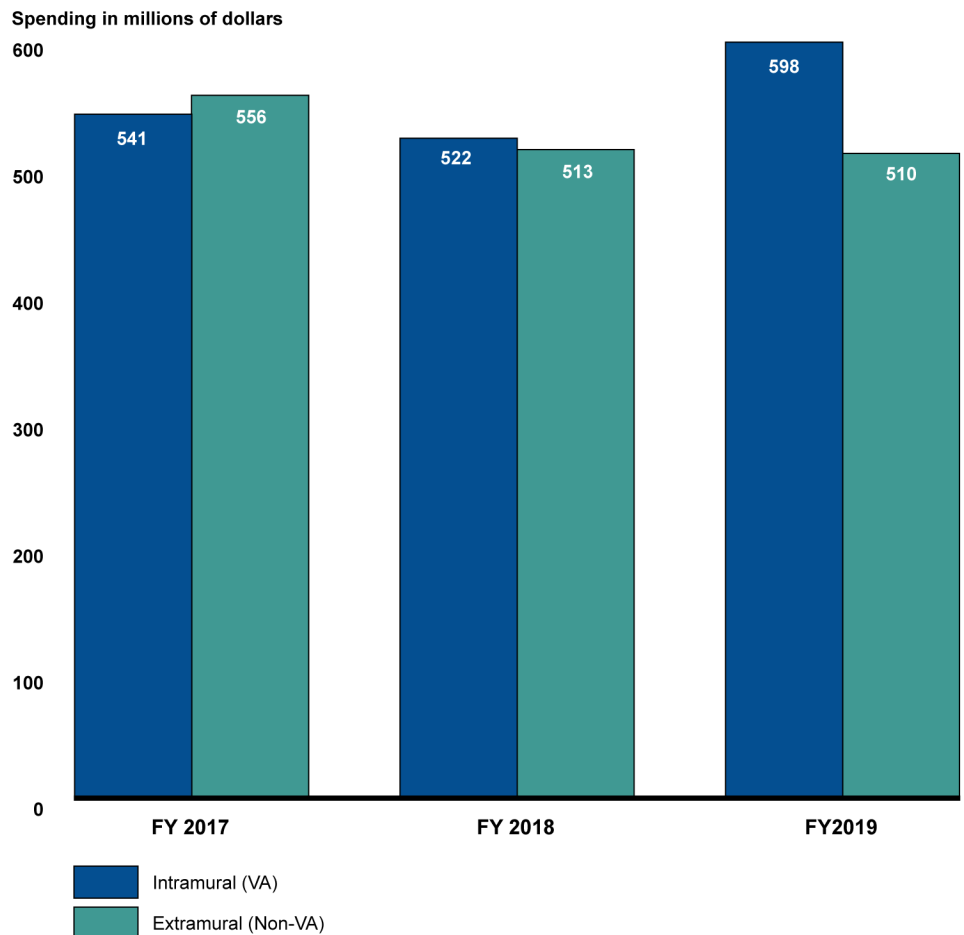
⁹38 U.S.C. § 7363.

Extramural Funding from a Variety of Sources Added About \$510 Million to VA's Reported Spending on Research in Fiscal Year 2019

According to data from VA's Research and Development Information System (RDIS), in fiscal year 2019, extramural research funding totaled \$509.7 million, which accounted for 46 percent of the approximately \$1.1 billion total reported spending on VA research. Expenditures for intramural research funded by VA research appropriations totaled \$598.2 million, which accounted for the other 54 percent of the total spending.¹⁰ The amount of extramural and intramural spending has varied over the last 3 years (fig. 1).

¹⁰An expenditure is "the actual spending of money; an outlay." GAO, *A Glossary of Terms Used in the Federal Budget Process*, [GAO-05-734SP](#) (Washington, D.C.: Sept. 2005), p. 48.

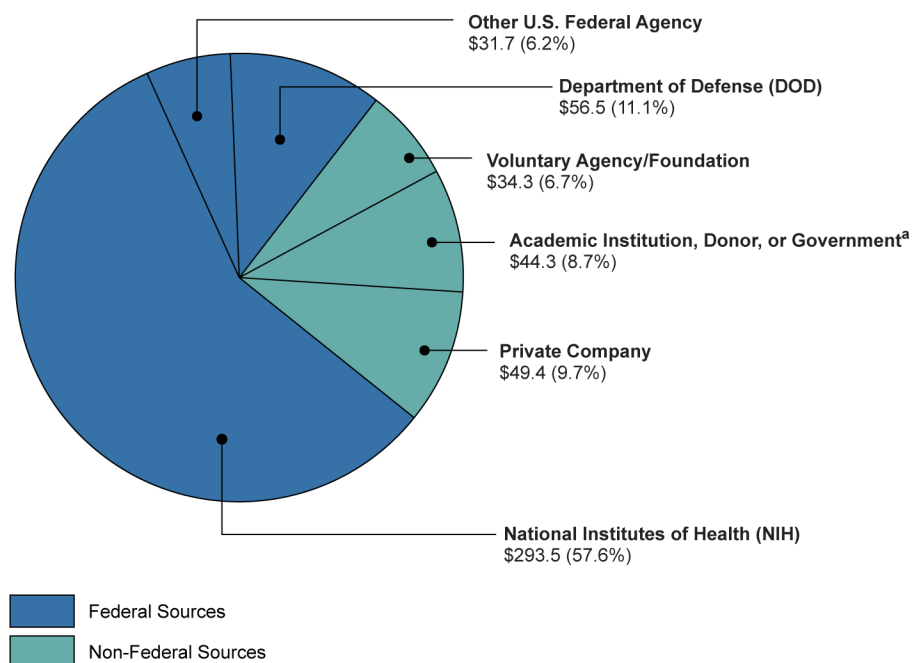
Figure 1: Intramural and Extramural VA-Reported Research Spending in Fiscal Years (FY) 2017-2019



Source: GAO analysis of Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) data. | GAO-20-570

A variety of federal and nonfederal extramural sources funded the \$509.7 million in extramural research spending reported in fiscal year 2019. Of this amount, federal sources funded \$381.6 million (approximately 75 percent) and nonfederal sources funded \$128.1 million (approximately 25 percent) (fig. 2).

Figure 2: Federal and Nonfederal Sources of the Reported Extramural Research Spending for VA-Approved Research in Fiscal Year 2019
(Spending in millions of dollars)



Source: GAO analysis of Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) data. | GAO 20-570

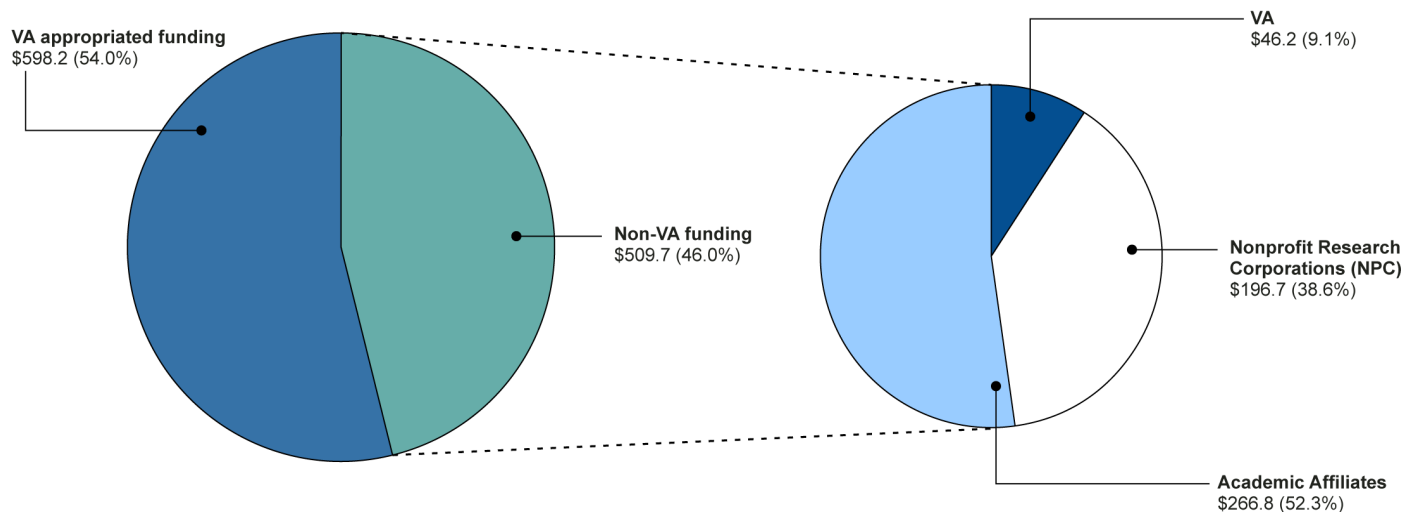
^aGovernment includes state and local government.

The federal and nonfederal sources of funding included a range of organizations and funding levels.

- Federal sources.** The National Institutes of Health (NIH) provided \$293.5 million (57.6 percent of federal and nonfederal extramural funding), while the Department of Defense (DOD) provided \$56.5 million (11.1 percent), and other U.S. federal agencies, including the Centers for Disease Control and Prevention (CDC) and the U.S. Public Health Service, provided \$31.7 million (6.2 percent).
- Nonfederal sources.** Private companies, including pharmaceutical and biotechnology companies conducting clinical trials, provided \$49.4 million (9.7 percent of all federal and nonfederal extramural funding). Academic institutions, private donors, and state and local governments provided \$44.3 million (8.7 percent), and voluntary agencies or foundations, including the American Heart Association and the American Cancer Society, provided \$34.3 million (6.7 percent).

According to VA's RDIS data, NPC and academic affiliate partners enabled access to and administered the grants for 91 percent of the \$509.7 million in spending for VA's extramural research in fiscal year 2019.¹¹ Specifically, NPCs administered the grants for \$196.7 million (38.6 percent), and academic affiliates administered the grants for \$266.8 million (52.3 percent) of the reported spending. VA administered the remaining \$46.2 million (9.1 percent) which came through other funding mechanisms. According to VA officials, such mechanisms may include donated funds and funds from VA that do not come from its research appropriation—for example if the VA Office of Rural Health funds a project specific to its mission (fig. 3).

Figure 3: Funding Sources for VA's \$1.1 Billion in Reported Research Spending in Fiscal Year 2019 and Administering Entities for Non-VA Funding
(Spending in millions of dollars)



Source: GAO analysis of Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) data. | GAO 20-570

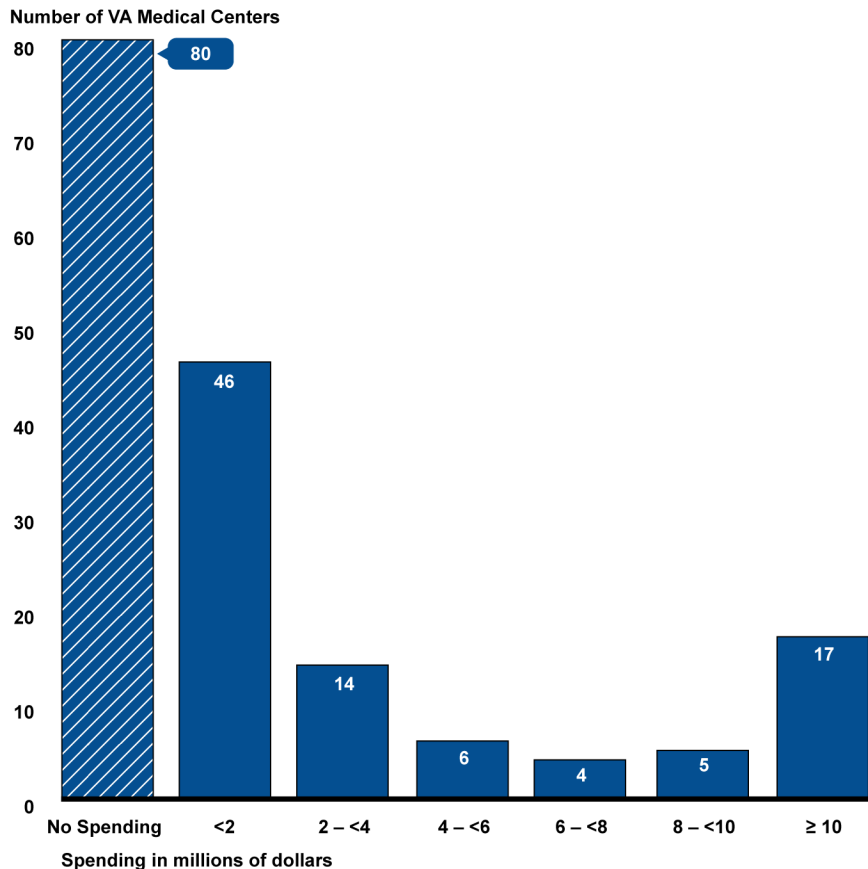
Note: Sources of non-VA funding include federal agencies (e.g., the National Institutes of Health (NIH) and Department of Defense (DOD)) and nonfederal sources (e.g., private companies, private foundations, academic institutions, and state agencies). VA administered funds include funds from sources such as VA direct grants and reimbursements from other federal agencies.

¹¹VA investigators can apply for funding through research proposals to non-VA federal agencies, nonfederal sources, such as nonprofit organizations, and private companies sponsoring clinical trials. Investigators may submit these proposals through VA's NPC and academic affiliate partners.

VA Medical Centers Varied in Reported Levels of Extramural Research Spending

According to VA's RDIS data, VA medical centers' spending on extramural research varied widely. Of the 172 medical centers, 92 (53.5 percent) reported spending funds on extramural research in fiscal year 2019 (fig. 4). The other 80 medical centers (46.5 percent) reported no spending on extramural research. One official told us it is difficult to attract researchers to medical centers that are small, have few laboratory facilities, and are in remote locations. Of the 92 VA medical centers that participated in extramural research, 46 medical centers (50 percent) reported spending less than \$2 million and 17 (18.5 percent) reported spending more than \$10 million. Reported extramural spending ranged from a low of \$5,358—at a medical center that partnered with an NPC and reported extramural expenditures for two projects—to a high of nearly \$65 million at the San Francisco, California, medical center. In San Francisco, investigators attributed the success of their extramural funding to collaborative relationships with partners that enabled access to resources.

Figure 4: Reported Extramural Research Spending by VA Medical Centers in Fiscal Year 2019



Source: GAO analysis of Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) data. | GAO 20-570

Nearly all (90 of 92) medical centers that reported spending on extramural research in fiscal year 2019 partnered with an NPC, an academic affiliate, or both to administer non-VA funds.¹² VA medical centers that partnered with both NPCs and academic affiliates to access extramural research funding reported higher median spending than other medical centers. In particular, 60 of the 92 medical centers partnered with both types of entities, and this category of medical center reported the highest median spending, at \$4.3 million (table 1). Twenty-six medical centers partnered with only an NPC, while four medical centers partnered with only an

¹²Of the two medical centers that did not partner with an NPC or an academic affiliate, one administered extramural research funds through VA, and the other administered its funds through VA and an entity not specified in the extramural spending data.

academic affiliate, and these categories of medical center reported lower median spending on extramural research—\$607,585 and \$125,016, respectively. Some medical center officials we spoke with said opportunities to work with both types of entities would strengthen extramural research programs. We spoke with officials from one medical center that had recently started working with an NPC after having previously partnered only with its academic affiliate, and they said the new partnership had opened up extramural funding options for investigators who did not hold dual appointments at the affiliate. In contrast, officials at a medical center that only worked with an NPC for research said that the physical distance between the medical center and the educational affiliate was a factor impeding its ability to foster research collaboration with the affiliate.

Table 1: Median Amounts of Reported Extramural Research Spending at 92 VA Medical Centers in Fiscal Year 2019, by Type of Administering Entity

Dollars in millions

Administering entities partnering with VA medical centers	Number of VA medical centers	Median extramural spending in fiscal year 2019
Both a nonprofit research and education corporation (NPC) and academic affiliate	60	\$4.3
Only an NPC	26	\$0.6
Only an academic affiliate	4	\$0.1
None	2	\$0.2

Source: GAO analysis of Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) data | GAO 20-570

Note: Other administering entities include VA, through direct grants and reimbursements from other federal agencies.

NPCs and Academic Affiliates Use Indirect Cost Reimbursements to Cover Costs of Supporting Research on Veterans' Health Issues, and Many Support Research in Additional Ways

NPCs and academic affiliates use indirect cost reimbursements to cover the administrative and, where applicable, facilities costs associated with supporting VA research that cannot be readily assigned to specific research projects such as accounting services, personnel, and operations and maintenance expenses.¹³ Some NPCs and academic affiliates support VA research in additional ways, depending on the flexibility of funding sources and the ability to accumulate residual funds.

NPCs and Academic Affiliates Use Indirect Cost Reimbursements to Cover Administrative and Facilities Costs that Support Research

NPCs and academic affiliates collect indirect cost reimbursements to recover administrative and facilities costs they have incurred in support of research activities, which cannot be specifically identified with a particular contract, grant, or award. NPC and academic affiliate officials we spoke with said that VA investigators often see indirect costs as a drain on their budgets for conducting research but that these costs cover critical support functions that enable research to take place. For example:

- **Indirect cost reimbursements collected by NPCs.** NPC executive directors that we spoke with told us that the administrative costs associated with supporting VA extramural research include salaries for executive directors and support staff, including those responsible for budgeting and human resources.
- **Indirect cost reimbursements collected by academic affiliates.** According to academic affiliate officials we spoke with, administrative costs typically include support for the salaries of staff managing the research. Additionally, when research is conducted in university facilities, academic affiliates incur costs for maintaining university laboratories and core facilities, library systems, and animal facilities.

NPC and academic affiliates' indirect costs differ depending on their size and facilities. Most NPCs are relatively small organizations of between

¹³ 2 C.F.R. § 200.56 defines indirect costs as "those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved." Indirect costs are distinct from direct costs, which can be identified with specific contracts, grants, or awards. For example, direct costs include the purchase of specialized equipment or software and investigators' salaries for time spent working on a specific research project.

one and a couple hundred employees, according to 2018 VA data. According to National Association of Veterans Research and Education Foundations officials, they typically do not incur facilities costs the way that academic affiliates might. NPCs generally administer extramural research projects being conducted in VA facilities, and few have their own research facility space. In contrast, academic affiliates that participate in VA research include large research universities with extensive staff and facilities. Additionally, when academic affiliates administer extramural research projects in their own space, they incur both administrative and facilities costs. As a result, affiliates tend to incur higher indirect costs than NPCs, according to officials from the Association of American Medical Colleges.

Federal funding sources, such as the National Institutes of Health (NIH) and Department of Defense (DOD), pay indirect cost reimbursements for administrative and facilities costs in accordance with OMB's Uniform Guidance. The Uniform Guidance defines administrative costs as general administration and general expenses such as a director's office, accounting services, personnel, and all other types of expenditures not listed specifically under one of the subcategories of facilities costs.¹⁴ The Uniform Guidance defines facilities costs as depreciation on buildings, equipment and capital improvement, interest on debt associated with certain buildings, and operations and maintenance expenses.

NPCs and academic affiliates collect indirect cost reimbursements from federal funding sources as a percentage of a research project's direct costs, known as an indirect cost rate. NPCs and academic affiliates establish their indirect cost rates for federal awards through negotiations with their assigned cognizant agencies for indirect costs.¹⁵ Because academic affiliates generally incur higher indirect costs than NPCs, they also are able to generally establish higher indirect cost reimbursement rates, according to officials from the National Association of Veterans Research and Education Foundations and the Association of American Medical Colleges. When nonfederal funding sources pay indirect cost reimbursements, rules may vary. For example, state governments may follow federal guidelines and establish a rate for administrative and facilities costs, but some private entities such as nonprofits and

¹⁴2 C.F.R. § 200.414 defines facilities and administrative costs for federal grants.

¹⁵Cognizant agency for indirect costs means the federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all federal agencies. 2 C.F.R. § 200.19.

companies may pay a lump-sum for a broad range of overhead costs, according to NPC officials.

Indirect costs may factor into decision-making about whether dually appointed investigators will apply for certain grants through an NPC or an academic affiliate. For example, an executive director told us that they cannot administer certain nonfederal grants that reimburse indirect costs at a rate that is lower than the minimum amount needed to cover the NPC's operations. Therefore, at this location, the academic affiliate will usually administer these grants because, as a larger institution, it is better equipped to absorb the unreimbursed administrative costs.

Some NPCs and Academic Affiliates Support VA Research in Additional Ways

NPC and academic affiliate officials told us that they were able to cover certain additional research costs from indirect cost reimbursements, but that their ability to do so depended on the entity's capability to (1) pay up front for research supports that are allowable as indirect costs, in anticipation of receiving later reimbursements, and (2) use unspent funds from nonfederal funding, including clinical trials. Specifically:

- At some of the sites we visited, NPCs and academic affiliates provided investigators with seed and bridge funding. Seed funding, also known as pilot funding, allows investigators to conduct the initial research necessary to complete grant applications that have a high likelihood of being selected for funding. Bridge funding covers investigators' salaries for a limited time after their grant funding has expired, which allows the VA medical center to retain the investigators while they apply for future grants and provides continuity of scientific research efforts. In addition, an NPC or academic affiliate may provide investigators with greater decision-making authority for using funds for purposes that qualify as indirect costs under federal rules, and they may have greater flexibility for the use of funds from nonfederal sources. For example, an executive director of one NPC we visited said that, when the NPC administers grant awards, it provides investigators with 8 percent of the award amount for research-related costs, including the costs of publishing or attending scientific conferences.
- An academic affiliate that we visited operated a grant application critique and consulting program to provide feedback on investigators' draft grant applications. The investigators were able to use the program to receive help with applications from a consultant, whether the investigators planned to submit their applications through the NPC, academic affiliate, or VA for intramural funding.

- An NPC we visited employed grants specialists to alert investigators to funding opportunities, and to train and work with investigators throughout the application process.
- An academic affiliate we visited provided investigators with access to its computer network through a local area network that the affiliate set up in the VA's research building. Similarly, an NPC we visited provided investigators with computer hardware, such as laptops, and software to support their VA research.
- At some of the sites we visited, NPCs and academic affiliates paid for maintenance of, and staff to oversee, core research facilities and allowed multiple investigators to share one or more pieces of specialized equipment in the core facilities (fig. 5).

Figure 5: Examples of Shared Equipment Purchased or Maintained by Nonprofit Research and Education Corporations (NPC) and Academic Affiliates



Source: GAO. | GAO-20-570

Some NPC officials we spoke with said they were able to accumulate residual funds from nonfederal funding because the rules for spending such funds are more flexible than for indirect cost reimbursements provided by federal funding sources. Nonfederal funding from sources such as state governments and private entities do not always require that unspent funds be returned at the end of a research project, and some allow for flexible uses. For example, some NPC executive directors we spoke with described how they allow investigators to use unspent funds from industry-funded clinical trials (which may be disbursed via general purpose accounts) to pilot new research, purchase general equipment for their laboratories, and perform other functions in support of research. While federal grants allow for certain discretionary uses of funds under the Uniform Guidance's definition of indirect costs, officials we spoke with said there were fewer restrictions related to residual funding from nonfederal awards.¹⁶

Some NPC executive directors described challenges to building up enough financial capacity to provide support to VA investigators beyond the NPC's basic administrative functions because indirect costs are paid later through reimbursements rather than up front, which makes the availability of these funds unpredictable. In addition, NPC executive directors we spoke with told us that numerous factors influence the amounts of residual funding left at the end of a project and that many of these factors are outside of their control. For example, residual funds at the end of a research project could be lower than expected if fewer patients than anticipated enroll in a particular study.

VA Has Promoted Extramural Partnerships but Has Not Provided Key Information and Tools

VA engages in efforts nationally and locally to promote extramural research partnerships with NPCs, academic affiliates, and other organizations. While VA's Central Office has made efforts to support VA medical centers' local partnerships with academic affiliates, it has not provided information on strengthening those partnerships. In addition, VA's Central Office has provided general guidance but not specific tools to assist VA medical centers in deciding whether NPCs or academic affiliates should administer extramural research grants.

¹⁶2 C.F.R. § 200.414.

VA Promotes National and Local Partnerships to Facilitate Extramural Research in Support of VA Goals for Veterans' Health

VA's Central Office and VA medical centers engage in efforts at the national and local levels, respectively, to promote partnerships with NPCs, academic affiliates, and other organizations. In doing so, VA's Central Office and VA medical centers facilitate VA investigators' access to extramural research opportunities that support VA goals by advancing veterans' health, expanding veterans' access to clinical trials, and attracting top physicians. Specifically:

- **Advancing veterans' health.** Extramural research fosters scientific discovery across a broad range of topic areas that inform clinical care for veterans. While VA identifies priority research areas for its intramural funding, extramural funding opportunities can serve to augment the research portfolio, especially on topics that may be outside of those priority research areas, according to VA officials. For example, we met VA investigators conducting research in cardiology—which addresses veterans' health needs but is not one of VA's cross-cutting clinical priorities—and basic science, which provides a foundation for additional research that directly contributes to veterans' health.
- **Expanding veterans' access to clinical trials.** NPCs enable VA investigators to access extramural research funding from sponsoring entities to conduct trials at VA medical centers. As a result of expanded access to extramural funding, veterans enrolled in these trials are able to receive cutting-edge care—for example, experimental cancer treatments—that is not yet widely available.
- **Attracting and retaining top investigators.** According to some VA medical center officials and dually appointed investigators we spoke with, investigators are attracted by the opportunity to conduct research involving veterans and by the range of funding opportunities available when working with VA medical centers. Officials also said that attracting and retaining top investigators improves (1) the quality of care veterans receive, because physicians conducting research are knowledgeable of the latest health care advances, and (2) the clinical learning environment for VA's educational mission, because investigators are able to instruct trainees on the latest advances.

In support of VA goals, VA's Central Office enters into national partnerships with funding organizations to facilitate VA investigators' access to extramural funding opportunities. For example, VA has partnered with the Prostate Cancer Foundation (PCF) to increase research funding and expand veterans' access to clinical trials for prostate cancer, which more than 16,000 veterans are diagnosed with each year. VA has also partnered with the National Cancer Institute (NCI)

to create a program in 2018 to facilitate the enrollment of veterans into NCI-funded clinical trials. The 3-year program is designed to establish a consortium of VA medical centers that will successfully participate in NCI trials and build capacity to participate in NCI trials long-term, which may enable more veterans to gain easier access to promising new cancer treatments.

VA develops formal agreements with its national partners to establish the responsibilities of each entity. For example, the VHA, through the VA ORD, entered into an interagency agreement with NCI for jointly managing the clinical trials program. By establishing this kind of agreement, VA facilitates access to extramural funding for participating VA medical centers.

Locally, VA medical centers partner with NPCs and academic affiliates to enable VA investigators to apply for extramural funding for research that benefits veterans. For example, at one site we visited, the VA medical center partnered with its NPC to gain access to Department of Defense (DOD) funding for a study comparing risks and benefits of medications used to treat post-traumatic stress disorder. At another site we visited, the VA medical center partnered with its academic affiliate to gain access to NIH funding for a study applying neuroimaging to identify risk for Alzheimer's disease.

NPC and academic affiliate officials described to us that they perform similar grant-administering functions, such as preparing proposals and assessing the space, resources, and equipment that extramural projects will require, but each may provide potential advantages to VA medical centers (see table 2).

Table 2: Characteristics of VA Nonprofit Research and Education Corporations (NPCs) and Academic Affiliates and Their Potential Advantages and Disadvantages for Facilitating VA's Extramural Research

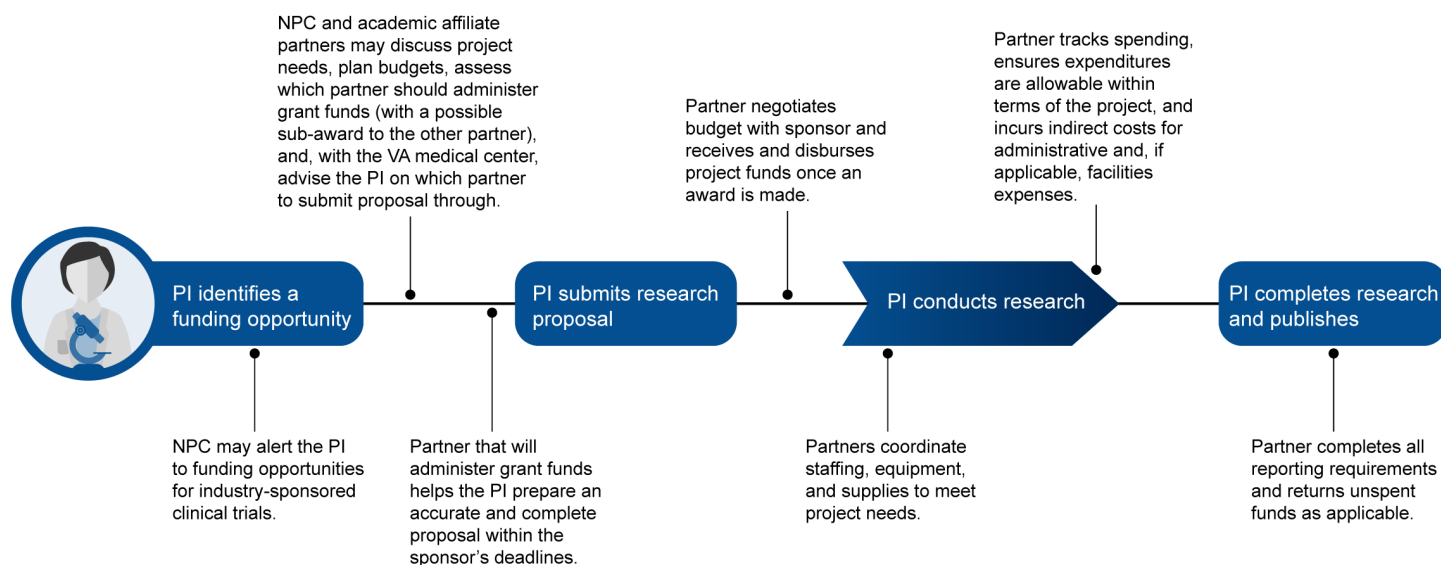
Characteristic	NPCs	Academic affiliates
Mission	Veteran-focused research and education mission.	Broad research and education mission that may include research relevant to veterans.
Eligibility of VA Investigators to access funding	All VA investigators are eligible.	VA investigators <i>with dual appointments</i> at an academic affiliate are eligible.
Potential advantages for facilitating VA extramural research	May involve fewer administrative barriers, as NPCs are often small organizations that are co-located within the VA medical center they support. NPC and VA medical center staff are often in frequent contact and are familiar with each other's missions and policies. As a result, they may work efficiently with one another.	May provide access to labs, libraries, staff, and equipment beyond what is available to investigators at VA medical centers. May have greater capacity for administering large grants. May provide salary support when administering NIH grants, which allows investigators to work on a project beyond VA's 40-hour work week at no additional cost to VA.
Potential disadvantages for facilitating VA extramural research	May lack capacity for administering large grants.	May not have staff dedicated specifically to helping VA investigators.

Source: GAO analysis of documents and interviews with officials from Department of Veterans Affairs (VA), Nonprofit Research and Education Corporations (NPC), and academic affiliates. | GAO-20-570

Officials told us that before a grant has been awarded, VA medical centers' partners may facilitate extramural research by helping to prepare investigators' research proposals and coordinating project needs (see fig 6). In doing so, partners may jointly assess where the work will take place and the equipment the project will require, and, with VA medical center officials, advise the investigator on which entity to submit the grant application through. The partners also discuss whether the NPC or academic affiliate, as the grant-administering entity, will issue a portion of the awarded funding to the other entity as a sub-award, and they may work jointly to prepare budgets for the project.

Once a grant is awarded, entities often work together to coordinate staffing and supplies, according to officials. A research project may require the services of a specialist employed by the other entity. In this case, the specialist can perform work on the project under a temporary assignment to another entity through a joint personnel agreement or, in the case of one site we visited, through a memorandum of understanding. For example, VA officials told us the NPC may temporarily pay all or part of the salary of a university-employed lab technician for time spent working on an NPC-administered VA research project. According to officials at one site, NPCs and affiliates may also maintain, or develop as needed, agreements and memoranda of understanding for the reimbursement of supplies.

Figure 6: Generalized Process for VA Investigators to Submit Proposals for and Conduct Extramural Research Projects with Support from NPC and Academic Affiliate Partners



PI = Principal investigator

Partners = Nonprofit Research and Education Corporations (NPC) and Academic Affiliates

Source: GAO analysis of documents and information provided by officials from the Department of Veterans Affairs (VA), Nonprofit Research and Educations Corporations (NPC) and academic affiliates. | GAO 20-570

VA's Central Office Has Made Efforts to Support but Has Not Provided Information to Strengthen VA Medical Centers' Partnerships with Academic Affiliates

According to its handbook on relationships with academic affiliates, VA strongly promotes a policy of cooperation and professional interaction with educational institutions and considers effective affiliations with those institutions as an enhancement to VA patient care, education, and research. Similarly, in May 2018, the head of VA's OAA and ORD stated in testimony before the House Committee on Veterans' Affairs that the continued vitality of VA research depends upon a broad array of partnerships, including its partnerships with academic affiliates.

Related to this, VA Central Office officials told us that research relationship-building with academic affiliates is the responsibility of VA medical centers at the local level, and that the role of the Central Office is to support VA medical centers. Within VA, however, the two offices that are responsible for affiliate relationships and research—OAA and ORD—generally focus on differing aspects of the affiliate relationship, and officials from both offices told us that they coordinate infrequently. Specifically, OAA defines policies and procedures for VA medical centers on establishing and maintaining *educational* relationships with academic affiliates, but not on developing *research* relationships, and ORD focuses

primarily on *intramural* research and officials said ORD has not provided guidance to VA medical centers on relationship-building with extramural research partners. ORD officials told us that they do not regularly address issues related to extramural research relationships because management of extramural research is considered to be the responsibility of VA medical centers.

At the local level, the support provided by the Central Office to VA medical centers has taken various forms with varying degrees of success. For example, when Central Office officials have visited sites, they have participated in meetings with the academic affiliate at the request of local research officials to help build the affiliate relationship and discuss issues such as bringing in more dually appointed investigators to strengthen the local research program. Additionally, Central Office officials said they have supported relationships by coordinating a mentoring program to pair new Associate Chiefs of Staff for Research and Development (ACOS/R&D) with more experienced chiefs who can share knowledge about successful relationship-building practices. Central Office officials also told us they have begun to look at how to provide leadership training to ACOS/R&D officials that would include training on interactions with academic affiliates.

Some VA medical center officials we spoke with had developed affiliate relationships that have strengthened their extramural research programs. In our visits to sites that have strong relationships, VA medical center and academic affiliate officials provided examples of how their relationships strengthened extramural research. For example:

- At one site, the academic affiliate transferred the administration of certain grants to the newly established NPC, which provided a financial basis for the NPC to help expand the VA's research program.
- At two sites, academic affiliates allowed NPC-administered grants to count toward dually appointed investigators' promotion and tenure at the university, which officials said resulted in more support for VA research and less pressure on investigators.
- VA medical center officials at one site had a shared purchasing agreement, in which the center's academic affiliate agreed to pay ongoing maintenance costs for several pieces of VA-purchased lab equipment. Officials believed that the added equipment will result in investigators being able to submit stronger future research grant applications that will be more likely to receive funding.

In contrast, other VA medical center officials told us that poor communication with their academic affiliates hindered their extramural research. For example, at two sites, officials told us their academic affiliates regularly failed to communicate with them about investigators' grant proposals for VA research, resulting in NPCs missing opportunities to administer sub-awards. At one VA medical center, officials hoping to expand the extramural research program were unable to name the research contacts at their academic affiliate and said that a stronger affiliate relationship would bolster their efforts to attract new investigators to work at the medical center.

Some officials, including at sites where communication was poor, said they could benefit from information on how to build or strengthen research relationships with their academic affiliates. Related to this, VA Central Office officials told us that relationships with academic affiliates are essential to VA's ability to foster research. However, according to officials, neither of the key components within VA's Central office—OAA or ORD—currently provides information to VA medical centers on building stronger extramural research relationships. Providing such information would be consistent with the role of the Central Office to support VA medical centers in their relationship-building efforts. Drawing from these offices' expertise and from lessons learned by VA medical centers that have developed collaborative research relationships with academic affiliates, OAA and ORD could provide examples of successful practices for cultivating those relationships. As described in *Standards for Internal Control in the Federal Government*, management should communicate quality information internally to achieve objectives.¹⁷ With more information and support from VA's Central Office, VA medical centers facing challenges in their relationships with academic affiliates may be better able to support investigators' research and promote collaborative opportunities with academic affiliates, such as recruiting top physician-investigators into the VA health care system.

¹⁷GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

VA's Central Office Has Provided General Guidance but Not Specific Tools for Medical Center Decisions on Extramural Grant Administration

VA's Central Office has provided general guidance to VA medical centers for working with academic affiliates to determine on a case-by-case basis which entity—the NPC or the affiliate—will administer extramural research grants. According to meeting discussion notes provided to us by VA, the guiding principle is that the decision should be based on which entity can best support the research. Related to this principle, the Central Office has instructed medical centers to administer extramural funds for research being conducted at their centers through the NPC when possible. According to Central Office officials, in the past they have shared successful practices with medical centers during trainings and monthly field office calls, which included practices for working with affiliates to administer grants.

However, some VA medical centers face challenges in formalizing agreements with their academic affiliate to guide decisions on which partner should administer grants. Consistent with a study on extramural research that VA commissioned in 2018, many of the VA medical centers we visited or spoke with that partnered with both an NPC and an academic affiliate for research (five of seven) did not have formal written grant administration agreements with their affiliates.¹⁸ Based on interviews with officials, we found that it is difficult for some VA medical centers to develop formal written agreements with academic affiliates due to challenges and concerns with developing applicable criteria, retaining flexibility, and maintaining positive affiliate relationships. Specifically:

- **Challenges developing criteria that can apply to all research projects.** For example, one of the criteria used to guide the decision at the two sites we visited that had formal written agreements, the NPC administers the grant if the preponderance of the work is conducted at the VA. Officials at one of these sites told us it is not always clear where the preponderance of work lies, and that this needs to be resolved through discussions.
- **Concerns about maintaining flexibility in a formal written agreement.** For example, an agreement can specify alternative arrangements in cases such as when one entity is unable to cover its indirect costs or provide specialized support. One NPC executive director told us she worried that with a written agreement it would become more difficult to make flexible choices.

¹⁸Westat, *Study on Veterans Affairs (VA) Extramural Funding* (Rockville, Md.: Final Report Submitted to US Department of Veterans Affairs Office of Research and Development, 2018).

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- **Challenges maintaining positive affiliate relationships when formalizing agreements.** For example, at one site, officials told us they expected the affiliate would resist a formal agreement out of concern that it would not administer as many grants as a result. The officials were concerned that raising the issue could upset the relationship, which could harm the extramural research program.

As a result of challenges like these, many medical centers—including five of the seven we interviewed on the subject—rely on informal processes to decide which entity should administer grants. At one of these medical centers, officials meet with their NPC and affiliate partners to discuss each research proposal and decide case-by-case how best to support the research. At other medical centers, however, officials do not have regular discussions with partners. At one site we visited, officials said NIH grants always defaulted to the affiliate regardless of which entity was best equipped to support individual research projects.

Further, we found that differences among VA medical centers may make it difficult to apply successful practices that VA's Central Office has shared. Central Office officials said they would like to discuss with medical centers how to apply successful practices to their local context. However, the Office has not provided specific tools that could help medical centers make grant administration decisions consistently at both medical centers that work with well-resourced NPCs as well as those that work with small NPCs with fewer resources. One medical center we visited had developed its own decision tool, and another was considering developing its own tool to help decide which entity should administer extramural funding. Officials who were considering developing a tool said it was difficult to identify the range of factors and conditions they should consider and that knowing more about how other VA medical centers make grant administration decisions could help inform their efforts to develop a site-specific decision-making tool.

To support efforts at the local level to improve the process of making decisions about grant administration, VA's Central Office would be well positioned to facilitate the collection of input from the field. The Central Office would also be well positioned to provide more information to medical centers to help them address certain challenges. For example, the office could provide information to help medical centers develop and apply specific criteria for grant administration decisions that maintain positive affiliate relationships and that are based on the goal of providing best support for the research. As described in *Standards for Internal Control in the Federal Government*, management should communicate

quality information internally to achieve objectives. With better information from VA's Central Office, VA medical centers could develop clearer local criteria for making more informed decisions on which entity—NPCs or academic affiliates—should administer extramural funding based on providing optimal support for the research without disrupting essential affiliate relationships.

VA's Central Office and VA Medical Centers Oversee Differing Aspects of Extramural Research

VA's Central Office and VA medical center research offices have clearly defined roles for overseeing differing aspects of extramural research. VA's Central Office has broad oversight of VA medical centers' research offices and NPCs. Medical center research offices have oversight of their centers' individual projects, investigators, and resources through their Research and Development Committees.

VA's Central Office Oversees VA Medical Center Research Offices and NPCs

VA's Central Office provides broad oversight of VA medical centers research offices' and NPCs' operations. Within VA's Central Office, ORD is responsible for establishing the policies that govern VA research and oversight of VA medical centers' research programs.

VHA Directive 1200.02 describes the responsibilities of medical center directors, ACOS/R&D, administrative officers, and investigators for conducting research business operations. An ORD official told us that they also hold regular, monthly calls with research officials at VA medical centers to share information on policies and procedures. Officials, including the ACOS/R&Ds and administrative officers, at most of the VA medical centers we visited told us that they communicated regularly with ORD through the monthly calls and through additional emails and calls as issues arose, and that ORD visits and communication were generally helpful.

VA's Nonprofit Program Office (NPPO), the Chief Financial Officer, and Nonprofit Program Oversight Board (NPOB) each have responsibilities in overseeing NPCs. Officials from the NPPO visit each NPC at least every 3 years for audits. During these audits, they are to ensure compliance with applicable laws, regulations, and VA policies, including those in VHA Handbook 1200.17, which describes procedures and instructions for NPCs on operations including financial management and oversight. Specifically, NPCs are required to develop written policies detailing internal controls and to maintain a conflict of interest policy with which all Directors, officers, and employees must comply. Further, NPCs must also document financial records and submit an annual report to NPPO.

detailing revenues and expenditures, which the NPPO uses to prepare an annual report to Congress. NPPO also is to share its information with the VA Chief Financial Officer, who is responsible for providing additional financial oversight of NPCs by reviewing NPPO activities and, as applicable, the results of independent audits that NPCs with annual revenues above \$100,000 must obtain. According to NPPO officials, NPPO refers all instances of fraud or serious waste to the VA Office of Inspector General (OIG), which can conduct audits on broad issues affecting multiple NPCs or on issues or allegations affecting a single NPC. For example, VA's OIG found in 2008 that NPCs did not have adequate controls to manage funds or guard against conflicts of interest.¹⁹ VA's OIG found in 2019 that the VA health care system in Boston allowed a pattern of inappropriate payments to its NPCs due to failure to review and follow VA policy on invoices related to Intergovernmental Personnel Act agreements.²⁰

The NPOB is responsible for ensuring NPC activities are consistent with VA policy and interests. It also makes recommendations to the VA regarding VA policy on NPCs. For example, VA officials told us they are currently considering whether to implement a policy for NPCs that have annual revenues in excess of \$4 million per year to employ a financial officer who is a trained accountant. The NPOB also takes steps to ensure VA research is compliant with the policies and regulations set by funding sources. For example, the NPOB told us that VA officials worked with NIH to ensure that investigators on NIH-funded grants who were conducting all of their research at an affiliate's location were appropriately documenting their time.

**Local VA Medical Center
Research Offices Oversee
Research Projects,
Investigators, and
Resources**

Each VA medical center that participates in research is required to have a research office which oversees extramural research projects, the investigators working on the projects (including how they account for their

¹⁹Department of Veterans Affairs, Office of Inspector General, *Audit of Veterans Health Administration's Oversight of Nonprofit Research and Education Corporations*, 07-00564-121 (Washington, D.C.: May 5, 2008).

²⁰Department of Veterans Affairs, Office of Inspector General, *Veterans Health Administration: Financial Controls and Payments Related to VA-Affiliated Nonprofit Corporations: Boston VA Research Institute*, 18-00711-211 (Washington, D.C.: Dec. 2, 2019).

time), and VA resources used to implement the projects.²¹ VA's Central Office requires each medical center conducting research to have a Research and Development Committee that approves each research project, tracks progress, documents investigators' time allocation, and monitors the use of VA resources, such as space and equipment. These committees are to perform these functions for all extramural research projects involving use of VA investigators' time or the medical centers' resources, regardless of whether the research takes place at the medical center or the academic affiliate.

All nine VA medical center research offices we spoke with had a Research and Development Committee that reviewed and approved each extramural research proposal at various points in the process, including before each proposal was submitted to ensure it was an appropriate use of VA's resources. The Research and Development Committee at all nine VA medical centers we spoke with also regularly reviewed research progress as work progressed, as required by VA's Handbook 1200.01, which provides procedures for governing Research and Development Committees.

Although academic affiliates have their own policies for reviewing and approving institutional research, affiliate Institutional Review Boards (IRB) must have a memorandum of understanding or authorization agreement with its affiliated VA medical center if it is providing IRB services for VA research. The purpose of the memorandum or agreement is to ensure that VA and the affiliate will have access to all relevant records and mutually acceptable policies for monitoring human subjects research. The affiliate IRB is required to follow all VA regulations when reviewing VA research, and all affiliate-administered research must receive approval from the VA medical center's Research and Development Committee.

Further, VA medical centers, NPCs, and academic affiliates must ensure compliance with policies set by their respective funding entities. For example, NIH requires the entity administering grant funding—which can be either an NPC or academic affiliate or both—to file periodic reports that demonstrate project compliance. For VA research, the administering entity—either the NPC or academic affiliate or both—is responsible for

²¹VA's oversight practices for intramural research projects are similar to or the same as its practices for extramural research projects. In this report, we focus on its practices for extramural research projects.

ensuring that required project updates are completed, according to VA officials.

Local VA medical center research staff are to enter project funding information, project abstracts, and progress reports into VA's Research and Development Information System (RDIS). This VA database, which includes all extramural and intramural research projects nationwide, allows local research officials and Central Office officials to track each research project. RDIS data also plays an important role in determining the amount of Veterans' Equitable Resource Allocation (VERA) funding dollars that may be allocated to each VA medical center. VA's Office of Finance uses the total amount of extramural spending—in combination with information on which entity administers the extramural funding (NPC or academic affiliate) and the funding source (whether the research is funded by NIH, an industry partner, or another source)—to calculate the amount of VERA funding for research, which is then allocated among VA medical centers.

Some of the research offices we spoke with also used local databases to track research. For example, research offices at two of the VA medical centers that are among those with the largest research programs told us that they developed a local version of RDIS which contains additional information about local research projects. Examples of additional information include details on decisions about which entity—the NPC or academic affiliate—would administer the research funding and the factors on which those decisions were based and potential conflicts of interest.

VA officials told us they use memoranda of understanding to document investigators' time allocation across their various research projects and other responsibilities, such as clinical and administrative time. The memoranda for dually appointed investigators outline time commitments both to the VA medical center and the university and may specify allocation of time to both research and non-research responsibilities (fig. 7). According to VA officials, the number of hours that dually appointed investigators spend on their VA research, clinical time, and other duties varies. Some investigators spend just a few hours while others spend up to 40 hours per week on their VA responsibilities. For the VA, the memoranda are important to ensuring that the investigators allocate the agreed-to amount of time to conducting VA research and essential patient-care responsibilities.

VA officials also told us they update investigators' memoranda at the start of a new research project or for each significant change to the

investigator's responsibilities or distribution of effort. In addition, investigators are required to review and certify that their time was appropriately allocated across their various work activities at least annually. Investigators' allocation of time for research and other duties, such as clinical and administrative time, is also recorded in VA's labor mapping database.

Figure 7: Examples of Local Memoranda of Understanding Used to Document Investigators' Time Allocation

JOINT APPOINTMENT MEMORANDUM OF UNDERSTANDING (MOU)

NAME: _____
DATE: _____

The following schedule represents the distribution of total responsibilities representing 100% effort for [Name].

	VA		[University]	
Official Title:				
Appointment:	Eights Hours			
	% OF VA EFFORT	% OF TOTAL EFFORT	% OF [UNIVERSITY] EFFORT	% OF TOTAL EFFORT
Research				
Other				
Total				

By signing this MOU, parties represent that there is no possibility of dual compensation or conflict of interest for work being performed by the named investigator and that there are no outstanding issues that would prevent investigator from completing his/her assigned responsibilities at the VA or [University].

ACOS for ResearchInvestigator

Chief of StaffDepartment of Medicine

[UNIVERSITY]/VAMC MEMORANDUM OF UNDERSTANDING

This form describes the total professional responsibilities mutually arranged by the [University] and the Veterans Administration Medical Center (VAMC). For purposes of this Memorandum of Understanding (MOU), the combination of administration, clinical, research, and teaching activities at both [University] and the VAMC comprises 100% of the total professional responsibilities (TPR) as described below. This MOU serves to verify there is no dual compensation for the same work, nor is there an actual or apparent conflict of commitment regarding such work.

Section A: Faculty Information

1. Date: _____
2. Name of Faculty Member: _____
3. Title of VAMC Appointment: _____
4. VAMC Service: Research
5. Title of [University] Appointment: _____
6. [University] Department: _____

Section B: Allocation of Professional Activities

PROFESSIONAL ACTIVITY	VAMC					[UNIVERSITY]			TOTALS	
	EIGHTHS	HOURS	F.T.E.	VAMC effort	TPR	F.T.E.	[UNIVERSITY] effort	TPR	F.T.E.	TPR
Administration	0	0	0.000	#DIV0!	#DIV0!	0.000	#DIV0!	#DIV0!	0.000	#DIV0!
Clinical	0	0	0.000	#DIV0!	#DIV0!	0.000	#DIV0!	#DIV0!	0.000	#DIV0!
Research	0	0	0.000	#DIV0!	#DIV0!	0.000	#DIV0!	#DIV0!	0.000	#DIV0!
Teaching	0	0	0.000	#DIV0!	#DIV0!	0.000	#DIV0!	#DIV0!	0.000	#DIV0!
TOTAL	0	0	0.000	#DIV0!	#DIV0!	0.000	#DIV0!	#DIV0!	0.000	#DIV0!

Section C: Authorization

Typed or Printed Name: _____Signature: _____

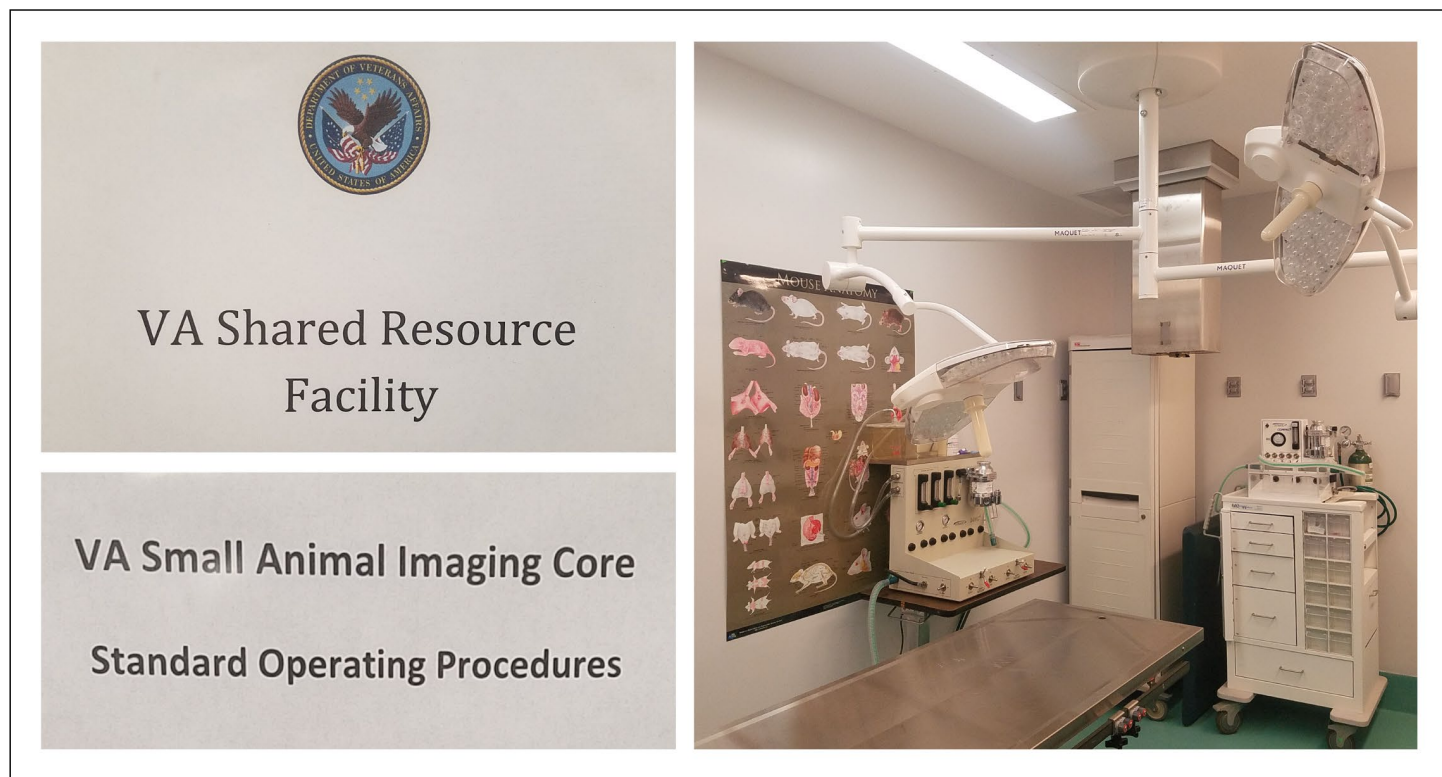
1. Faculty Member: _____
2. Department Chair: _____
3. VA ACOS-Research: _____
4. VA Chief of Staff: _____
5. [University] Institutional Official: _____

Source: GAO representation of VA documents. | GAO-20-570

At some of the sites we visited, the VA medical center shared resources such as space and equipment with its academic affiliate, which helps to justify the expense of purchasing and maintaining expensive equipment, according to NPC officials. One VA medical center we visited also worked with its NPC to establish core laboratories—shared spaces with

equipment that may be used by investigators for a small fee. Officials from these sites told us they had written agreements that defined how the institutions share space and equipment and outlined which entity was responsible for ongoing equipment maintenance. One facility employed a shared facilities manager who managed the VA-affiliate agreements on ownership and maintenance, and ensured fair usage of shared equipment. We also found that sites clearly documented property ownership through equipment labels or office signage (fig 8).

Figure 8: Example of Laboratory Space and Equipment Shared between a VA Medical Center Research Office and Its Academic Affiliate



Source: GAO. | GAO-20-570

Conclusions

Extramural research at VA medical centers plays an important role in advancing veterans' health, expanding veterans' access to clinical trials, and attracting top physicians. VA's Central Office supports extramural research in various ways, including by supporting medical centers' partnerships with NPCs and academic affiliates. Because VA medical centers rely on partnerships with NPCs and academic affiliates to administer grant funds for extramural research, the strength of

relationships with partners is critical to the success of local research programs. However, some VA medical centers are hindered by poor communication with affiliates, and OAA and ORD—the offices within VA’s Central Office that are responsible for affiliate relationships and research—have not provided information to VA medical centers on how to build or strengthen research relationships with their academic affiliates. This information could include practices from VA medical centers that had successfully cultivated these relationships. By leveraging its expertise to provide more information to VA medical centers on strengthening relationships with academic affiliates, VA’s Central Office can, in turn, better enable VA medical centers to support investigators’ research and promote collaborative opportunities with academic affiliates.

Some VA medical centers also face challenges in formalizing agreements with their academic affiliate to guide decisions on whether an NPC or affiliate should administer extramural research grants. According to VA’s Central Office, such decisions should be based on which entity can best support the research, with extramural funds for research being administered by NPCs when possible. However, the VA’s Central Office has not developed specific tools based on input from the field that could help medical centers make such decisions consistently, taking into account local factors such as the size of the NPC. With specific tools to assist VA medical centers in making grant administration decisions, VA medical centers experiencing challenges in formalizing agreements with academic affiliates will be better equipped to ensure grants are administered by the entity most capable of providing optimal support. As a result, VA investigators will be better positioned to conduct their research with more effective administrative support systems and be better positioned to devote attention to advancing veterans’ health.

Recommendation for Executive Action

We are making the following two recommendations to VA:

The Under Secretary for Health should ensure VA’s key offices, such as OAA and ORD, provide VA medical centers with examples of successful practices for strengthening research relationships with academic affiliates and that such information reflects the lessons learned from VA medical centers that have successfully cultivated these relationships.

(Recommendation 1)

The Under Secretary for Health should ensure ORD, in consultation with the field, develops tools, such as a decision tree and successful practices, to help local VA medical center officials decide which entity—NPCs or

academic affiliates—should administer extramural funding based on providing optimal support for the research. (Recommendation 2)

Agency Comments

We provided a draft of this report to the Department of Veterans Affairs for review and comment. In written comments reproduced in appendix I, VA concurred with our recommendations and stated it would address them by establishing a working group comprised of representatives from VA's Office of Academic Affiliations, Office of Research and Development, VA Medical Centers, NPCs, and academic affiliates. To address our recommendation on providing VA medical centers with successful practices for strengthening research relationships with academic affiliates, VA stated that the working group will identify best practices for establishing, maintaining, and growing relationships among partners, and will share its recommendations with the broader VA research community. In addition, VA stated that it would also charge the working group with addressing our recommendation on developing tools to help local VA medical center officials decide which entity—NPCs or academic affiliates—should administer extramural funding. VA stated it has a target completion date of December 31, 2020.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Veterans Affairs, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6888 or neumannj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

Sincerely yours,



John Neumann
Managing Director, Science, Technology Assessment, and Analytics

Appendix I: Department of Veterans Affairs Comments



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON

July 13, 2020

Mr. John Neumann
Managing Director
Science, Technology Assessment
and Analytics
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Neumann:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office (GAO) draft report: ***VA RESEARCH: Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and Academic Affiliates*** (GAO-20-570).

The enclosure contains the actions to be taken to address the draft report recommendations. VA appreciates the opportunity to comment on your draft report.

Sincerely,

A handwritten signature in blue ink that reads "Brooks D. Tucker".

Brooks D. Tucker
Acting Chief of Staff

Enclosure

Enclosure

The Department of Veterans Affairs (VA) Comments to the
Government Accountability Office (GAO) Draft Report
***VA RESEARCH: Opportunities Exist to Strengthen Partnerships and Guide
Decision-Making with Nonprofits and Academic Affiliates***
(GAO-20-570)

Recommendation 1: The Under Secretary for Health should ensure its key offices, such as OAA and ORD, provide VA medical centers with examples of successful practices for strengthening research relationships with academic affiliates and that such information reflect the lessons learned from VA medical centers that have successfully cultivated these relationships.

VA Comment: Concur. The Veterans Health Administration's Assistant Under Secretary for Health, Discovery, Education and Affiliate Networks will establish a working group with representatives from the Office of Academic Affiliations (OAA), Office of Research and Development (ORD), field representatives from VA Medical Centers (VAMC), VA Nonprofits and Academic Institutions. During an April 2019 meeting with Non-Profit Corporations (NPC), VA field research offices and academic affiliate representatives provided insights into likely participants for such a "best practices" workgroup. Based on the available data from the GAO report and prior meetings with the field, a key feature of the workgroup's goal will be to recognize that there can be multiple successful solutions to establishing and maintaining mutually beneficial partnerships among NPCs, VA and academic affiliates. The objectives of the working group will be to:

1. Review field practices and identify a "menu" of best practices, along with core "ingredients" that lead to the development of those best practices.
2. Host a webinar that presents the initial recommendations of the workgroup and allows time for discussion, questions and input from the broader VA research community, including NPCs, VA field research offices and academic partners.
3. Develop and disseminate to the field a white paper on best practices for establishing, maintaining, and growing relationships among all partners.

Target Completion Date: December 31, 2020.

Recommendation 2: The Under Secretary for Health should ensure ORD, in consultation with the field, develops tools, such as a decision tree and successful practices, to help local VA medical center officials decide which entity—NPCs or academic affiliates—should administer extramural funding based on providing optimal support for the research.

VA Comment: Concur. The working group established in Recommendation 1 will, as part of its overall charge, utilize a similar process to develop tools, such as a decision tree and successful practices to assist local VAMCs and academic affiliates in the determination process of Federal award submissions.

Target Completion Date: December 31, 2020.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact:

John Neumann at (202) 512-6888 or neumannj@gao.gov

Staff

Acknowledgments:

In addition to the named contact above, Joseph Cook (Assistant Director), Sarah Harvey (Analyst-In-Charge), Nora Adkins, Louise Fickel, Anika McMillon, Miranda Richard, and Michael Walton made key contributions to this report.

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